Potential for an improved pesticide regulatory system in Mexico

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Abstract

Hazards arising from an increase in the use of pesticides in Mexico have stimulated the development of a complex pesticide regulatory system, comprising inter-institutional participation of four governmental Secretariats. However, because this arrangement has not been reformed, despite several analytical reviews, since its creation almost 20 years ago and evidence of environmental and health damage by pesticides has continued to increase there is concern about its effectiveness.

This thesis focuses on the proposal to improve the regulatory system for pesticides in Mexico. The regulation is covered by a patchwork of laws which are not integrated into a single structure. The analysis of the current system showed few gaps in the legal framework but its implementation and enforcement have been slow and difficult. The narrow achievement of the objectives of the Inter-Secretarial Commission for the Control of the Processing and Use of Pesticides, Fertilizers and Toxic Substances (CICOPLAFEST), as a coordinating body of the regulation of pesticides and other hazardous substances, also denotes clear organisational and administrative limitations.

Considering the political, administrative and economic context of Mexico and the main objectives of pesticide stakeholders, the leadership of the Health Secretariat (SSA) on pesticide control through the concentration of the main regulatory activities in the Federal Commission for the Protection against Health Risks (COFEPRIS), the creation of an exclusive law for pesticides and the presence of a reformed CICOPLAFEST were found to be the way to improve the regulatory system most appropriately within the range of objectives identified and defined.

This work supports the view that legislation is the short-term solution to the range of pesticide problems; hence the new law would provide strong foundations and clarity to the regulation of pesticides. It is also considered that institutional factors can have a decisive influence to promote an intensive use of pesticides; thus it is expected that the leadership of SSA would provide a balance in the public policies as the current subsidy to pesticides is a clear incongruence with policies on protection of human health and the environment. Along with these strategies other initiatives are supported, such as the strengthening of training and education, closer contact with the scientific community, encouragement of the use of less toxic pesticides, among others, which would constitute the long term solution to pesticide problems. A set of indicators is also proposed to measure the adequacy or inadequacy of this proposal, which would provide the basis for a continue improvement.

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List of abbreviations

AMIFAC	Asociación Mexicana de la Industria Fitosanitaria A.C. (Mexican Association of the Pesticide Industry)
CEC	Commission for Environmental Cooperation
CICOPLAFEST	Comisión Intersecretarial para el Control del Proceso y Uso de Plaguicidas, Fertilizantes y Sustancias Toxicas (Inter-Secretarial Commission for the Control of the Processing and Use of Pesticides, Fertilizers and Toxic Substances)
COFEMER	Comisión Federal de Mejora Regulatoria (Federal Regulatory Improvement Commission)
COFEPRIS	Comisión Federal para la Protección contra Riesgos Sanitarios (Federal Commission for the Prevention of Health Risks)
DDT	Dichlorodiphenyltrichloroethane
DEFRA	Department for Environment, Food and Rural Affairs
DOF	Diario Oficial de la Federación (Official Gazette)
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FEPA	Food and Environment Protection Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HSE	Health and Safety Executive
INAP	Instituto Nacional de Administración Publica (National Institute of Public Management)
IPM	Integrated Pest Management
LFSV	Ley Federal de Sanidad Vegetal (Federal Plant Health Law)
LGEEPA	Ley General del Equilibrio Ecológico y Protección al Ambiente (General Law for Ecological Balance and Environmental Protection)
LGS	Ley General de Salud (General Health Law)
MRLs	Maximum Residue Levels
NAFTA	North America Free Trade Agreement
NOM	Norma Oficial Mexicana (Mexican Official Standard)
OECD	Organisation for Economic Cooperation and Development
OPP	Office of Pesticide Programs
PAHO	Pan American Health Organisation
PCPA	Canadian New Pest Control Products Act

PIC	Prior Informed Consent
PLAFEST	Plaguicidas, Fertilizantes y Sustancias Toxicas (Pesticdes, Fertilisers and Toxic Substances)
PMRA	Canadian Pest Management Regulatory Agency
POPs	Persistent Organic Pollutants
PSD	Pesticides Safety Directorate
SAGARPA	Secretaria de Agricultura Ganadería, Desarrollo Rural, Pesca y Alimentación (Secretariat of Agriculture Livestock Rural Affairs Fishery and Food
SCT	Secretaria de Comunicaciones y Transporte (Secretariat of Communications and Transport)
SE	Economy Secretariat
SEMARNAT	Secretaria de Medio Ambiente y Recursos Naturales (Secretary for the Environment and Natural Resources)
SINAVE	Sistema Nacional de Vigilancia Epidemiológica (Epidemiological Surveillance Programme)
SSA	Secretaria de Salud (Health Secretariat)
STPS	Secretaria del Trabajo y Previsión Social (Labour Secretariat)
TWG	Technical Working Group on Pesticides
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
WHO	World Health Organisation

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Chapter I Introduction

1.1 Overview on pesticide use

Worldwide pesticide use has sharply increased over the past 50 years; the market grew from US$9.2 million dollars in 1939 to US$30,725 million dollars in 2004 (CropLife International, 2006). However, at present the pesticide market in industrialised countries is effectively saturated[1] (Mazlan, 2005) and its growth has decreased in recent years, while in Latin America the market still shows considerable growth. The growth rate of the pesticide market for this region between 1993-2002 was 73% while for Western Europe it was -23% (CropLife International, 2004). During the years 2003/04 the growth for Latin America was 41.9% and for Europe 19.2%.

North America has constituted the biggest market of agrochemicals in the World. In 1996, its agrochemical market accounted for US$8,856 million, where the USA contributed 87%, Canada 9% and Mexico 4% (PAHO, 2002).

[1] The decline of the pesticide market has been attributed to inflation and currency exchange, adverse weather conditions and also an increase in usage of genetically modified (GM) such as products herbicide tolerant and insect resistant crops (Mazlan, 2005).

The estimated value of the Mexican market for pesticides in 1996 was US$530 million, which increased 8.1% in 1997 to US$573 million (Rios, 1998). In 1995, the Secretary for Environment and Natural Resources (SEMARNAT) reported a national production of 70,000 tonnes (including active ingredients and formulated product) and in the same year, Tansey (1995) reported the great reliance of Mexico on pesticide imports, which placed the country as the second largest pesticide importer in Latin America.

According to the database of pesticide factories of the Secretariat of Agriculture Livestock Rural Affairs Fishery and Food (SAGARPA) (SAGARPA, 2004c) there are 290 pesticide factories registered in the country, mainly for importing companies belonging to multinational pesticide corporations, hence the national production is very limited.

1.2 Pesticide safety control

In the beginning, the pesticide regulatory objective was controlling adulteration and fraud by pesticide producers, distributors and retailers (Johnson and Ware, 1992). However, due to the growing dependence on pesticide use and greater knowledge about its negative effects on human health and the environment, the regulation objective then evolved to minimising such health [2] and environmental [3] risks [4]. Methods of pesticide safety control are predominantly legal and administrative arrangements [5]. At present, the majority of governments have set up a process of registration or approval to authorise the use, manufacture, sale and import of pesticides in their countries, which is supported by a

[2] Acute effects associated with high occupational exposure to pesticides include chemical burns of the eye, skin damage, neurological effects and liver effects. Chronic exposures are suspected of leading to reproductive problems and an increased risk of developing cancer, delayed neurological and psychological effects, and effects on immune function.
[3] Due to the ability of pesticides to spread in the environment and their degree of persistence they have affected non-target organisms and the wider environment.
[4] The introduction of pesticide licensing prior to marketing under the 1947 FIFRA regulations in USA was the beginning of the modern regulatory period of pesticides (Johnson and Ware, 1992).
[5] These include both measures relating specifically to pesticides and non-specific measures, such as legislation concerning pollution of land and water, which cover activities involving pesticides, either explicitly or implicitly, along with other activities (Gilbert, 1987).

process of compliance and enforcement and by programmes to encourage the use of less toxic products and the use of Integrated Pest Management (IPM) Systems in the agriculture sector.

International organisations have developed international conventions and agreements such as the UN Rotterdam Convention on Prior Informed Consent (PIC) (UNEP/FAO, 1998) and the Stockholm Convention on Persistent Organic Pollutants (POPs) (UNEP, 2001) to regulate the trade of pesticides and establish timetables to phase out highly toxic products as appropriate. Other international organisations such as the North America Free Trade Agreement (NAFTA) and the Organisation for Economic Cooperation and Development (OECD) have aimed to harmonise the requirements and criteria for evaluation for pesticide approvals among countries in order to share the burden for registration and streamline pesticide trade.

This overall trend has been assimilated by Mexico; however, because priorities between developed and developing countries are not similar (and this trend has mainly been marked by developed countries) its advance has been slow. Mexico began to regulate pesticides with a preventive focus on human health and environmental protection in the 1980's. In 1984, the General Health Law was created (SSA, 1984), which establishes the main statements to regulate all steps included in the life cycle of pesticides. In 1988, the General Law of Ecological Balance and Environmental Protection was published (SEMARNAT, 1996), which confers power to the Secretariat of the Environment to share the responsibility with the Secretary of Health in the regulation of pesticides by protecting the environment from the pollution caused by hazardous material, products and residues.

Additionally, the SAGARPA published in 1994 the Plant Health Law (SAGARPA, 1994), which provides power to regulate the efficiency of agricultural pesticides and their application in the field. The Labour Law created in 1970 (STPS, 1970) also provides power to the

Labour Secretary for its participation in pesticide regulation since it aims to promote safety in the workplace.

Due to the number of laws and Secretariats involved in the regulation of pesticides and other hazardous products an Inter-Secretarial Commission for the Control of the Processing and Use of Pesticides, Fertilizers and Toxic Substances (CICLOPLAFEST) was created in 1987 (DOF,1987). The aim of the Commission is to coordinate all the issues related to pesticide regulation, so it works as a coordinating body to prevent over regulation and conflicts between legal instruments, and to promote a more efficient use of the administrative, economic and human resources provided from each Secretariat.

However, the performance of the CICOPLAFEST has been very limited. The six years report (1994-2000) of the Commission published in 2001 (CICOPLAFEST, 2001) showed the very little advance in the development and strengthening of the legal framework and that its main interest was in the administrative process to authorise the use of pesticides in the country without updating its procedures of evaluation to create higher standards of protection. Additionally, because of the various responsibilities the commission members have in their respective fields of work, problems of attendance at the commission meetings are common, while activities beyond the scheduled meetings can hardly be carried out.

Three studies focused on the analysis of CICOPLAFEST's performance and on proposals to restructure it have been carried out (Quantica, 1998; COFEMER, 2001; INAP, 2002); however no recommendations derived from them have been adopted yet, thus the CICOPAFEST remains unreformed.

So, it seems a the regulatory system for pesticides is in place; however there are a few gaps in the legal framework, many difficulties in its implementation and insufficient monitoring and control of the pesticide market. Additionally, the administrative organisation to address this

problem seems to be ineffective. The following chapter will provide a documentation of these faults.

1.3 Overview on pesticide effects on the population and the environment

The externalities[6] caused by pesticide use in Mexico have not been quantified; hence there is a deep unknown about their negative effects. The Health Secretariat reported 2,508 cases of poisoning in Mexico in 2003 (SSA, 2006); however, it stresses the possible under-registration of cases, which is estimated at 80%. There have been three mass acute poisonings by pesticides. In Baja California State, during the 1960s a very severe poisoning occurred, with 559 persons affected. Sixteen of them, the majority of whom were children, died. The poisoning was caused by the ingestion of bread that was manufactured with contaminated flour that had become contaminated by parathion during transport (Valdez, 2000).

The second accident occurred in Cordoba in the state of Veracruz in 1991, when an explosion and fire in the factory Agricultura Nacional de Veracruz S.A. (ANAVERSA) caused the acute poisoning of 300 people by the release of gases produced by the combustion of pesticides such as methyl parathion, malathion and paraquat, amongst others. No casualties were reported during the accident only people feeling sick; however, up to 1999, 272 people in the community have suffered death by cancer, and fetus malformations have also been reported, which have been attributed to the poisoning suffered eighth years earlier (AMACUP, 2002). The third accident happened in the state of Salamanca, at Guanajuato City in 2000, in which a tank containing malathion exploded in a factory owned by Tekchem. The explosion generated a toxic cloud that poisoned approximately 6,000 people, although only 800 needed medical attention due to sickness and 50,000 people had to be evacuated, no deaths were reported (AMACUP, 2002).

[6] Externalities can be defined as inherent negative side effects of a process or activity.

Scientific studies have also reported the presence of pesticide residues in water resources and edible organisms. Additionally, the illegal use and sale of pesticides is a constant complaint of authorities, sellers and farmers.

The government is aware of this situation and makes an effort to improve the situation. In 2001, it started a national project called Train-the-Trainers in which, until 2004, 361 people had been trained to present a curriculum on the prevention of risks and safe use of pesticide. A new procedure to register pesticides was published in 2005, which solved some irregularities in the process and updated the requirements for the evaluation. In the period 1995 to 2001, 480 registrations of formulated products and 100 registrations of active ingredients were issued on average every year. 75% of the active ingredients and formulated products registered were agricultural pesticides and according to the type of pest that they control, 44% were insecticides, 18% were herbicides and fungicides and 12% were mixtures (COFEPRIS ,2001).

In spite of these activities, the lack of an integrated policy on pesticides and of a lead agency that provides formality and compliance, the advance is slow and isolated, with deficiencies in providing adequate protection to human health and the environment from pesticide use. Additionally, the international agreements and conventions that Mexico has signed demand a strategic plan to achieve the commitments and optimise resources.

1.4 Aim and thesis structure

So by several criteria there is a clear cause for concern about the effectiveness of pesticide regulation in Mexico. Therefore, the aim of this work is to clearly define the nature of the problems associated with pesticides in Mexico, to propose restructuring and improvements

to the pesticide control arrangement in Mexico and to demonstrate the likely congruence of this proposal with broader government administrative criteria.

To achieve this aim, the following activities are carried out pursuing this structure:

Chapter I Introduction. An overview on the use of pesticides in the world and in Mexico is presented along with a brief description of the international and national trends on pesticide safety control and problems associated with it in the country. This provides the context to justify the aim of this work, which is set out in the Chapter, as well as the structure of the thesis and its outputs.

Chapter II -Regulation of pesticides in Mexico –achievements and deficiencies– A critical analysis of the shortcomings of the regulation of pesticides is carried out, which firstly includes the description and breakdown of the legal framework by determining the powers of each Secretariat, which highlight the regulatory gaps and problems of implementation and enforcement. Secondly, an analysis of the achievements and limitations of the CICOPLAFEST is presented.

Chapter III - Effects on human health, the environment, society and the economy by pesticide use in Mexico - A compilation of verifiable and circumstantial evidence of social, health and environmental damage in Mexico by pesticide use is presented along with an estimation of the economic loss due to food safety rejections at the Mexico-USA border because of pesticide residues.

Chapter IV – International trends in pesticide regulation – To take advantage of the international experience in the regulation of these products for the proposal of alternatives for improvement, a review of the systems of regulation for pesticides in the United States, Canada, the United Kingdom and international organisations such as NAFTA, European

Union and OECD is conducted. An outline of the international trends in pesticide regulation is presented.

Chapter V -Proposals to improve the regulatory system for pesticides- It includes the proposal of alternatives to restructure the system for pesticide regulation in the country and the selection of the most viable option through a qualitative assessment in which dimensions that have a direct impact on the viability of the proposals are defined and their impact analysed. The assessment also includes the definition of the objectives of parties involved and how they could be achieved through the several alternatives.

Chapter VI – Potential proposal to improve the regulatory system for pesticides – The structure and mechanism of implementation of the proposal selected are described, including the legal and administrative modifications implied, and a policy analysis to improve the overall system is presented.

Chapter VII – Proposal for a set of indicators to evaluate the national pesticide policy– A set of indicators is proposed to evaluate the performance of the regulatory system and the effectiveness/efficiency of its strategies.

Chapter VIII – Final discussion and conclusion – A final discussion and conclusion on the findings of the study are presented, as well as the limitations of the work and recommendations for further studies.

1.5 Outputs of the research

- Definition of the shortcomings of the regulatory system for pesticides in Mexico.

- Proposal of a qualitative assessment for the selection of the most viable alternative to reform the pesticide regulation system.
- A potential proposal to improve the regulatory system.
- A set of indicators to evaluate the performance of the regulatory system.
- Recommendations for further data and analysis related to potential improvements in pesticide regulation in Mexico.

Chapter II Regulation of pesticides in Mexico –achievements and deficiencies-

In this chapter the regulatory framework for pesticides is described by highlighting the statements in the laws and regulations that confer specific powers to the governmental Secretariats to exercise control on these products. The performance of the Inter-Secretarial Commission for the Control of the Processing and Use of Pesticides, Fertilizers and Toxic Substances (CICLOPLAFEST) is also analysed because of its role as the coordinating body for all activities related to pesticides, fertilisers and toxic substances. The analysis is based on its main activities: process of registration and authorisation for the import of pesticides, participation in international agreements, and the current status of the National Programme against Risks by Pesticide Use.

2.1 Legal framework

The juridical framework for Mexico's regulatory process of chemical substances starts with the Political Constitution of the Mexican United States. It grants the power to the President and Congress[7] to promulgate laws. The laws provide the framework for regulations, which in

[7] The legislative power of Mexico is granted to the Congress, divided into two parliamentary chambers: Chamber of Deputies and Senate.

turn provide the framework for the Official Mexican Standards[8] (Normas Oficiales Mexicanas (NOMs)).

Under this framework, chemical substances are grouped into three categories: 1) pesticides; 2) fertilizers; and 3) toxic substances. All are governed by six regulatory Secretariats:

- Health Secretariat (SSA)
- Secretariat of the Environment and Natural Resources (SEMARNAT)
- Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA)
- Economy Secretariat (SE) (previously Commerce and Industrial Development)
- Secretariat of Communications and Transport (SCT)
- Labour Secretariat (STPS)

Table 2.1 shows the laws and regulations that provide powers to the Secretariats aforementioned to regulate pesticides. As can be seen in the table every step of the life cycle of pesticide is controlled by different laws and regulations and thus by different Secretariats, which is understandable because of the varied forms of impact that pesticide use has on the economy, health and the environment in the country. In the next sections the laws and regulations, and specifically the statements related to pesticides, are described.

[8] Official Mexican Standards (NOMs) are technical regulations that establish requirements, procedures and specifications of compulsory observance in their field of application. There also are voluntary standards called as Mexican Standards (Normas Mexicanas abbreviated to NMX). The standards follow a fixed coding system that consists of at least the following four elements: 1) whether the standard is mandatory (NOM) or voluntary (NMX); 2) a three-digit sequential number; 3) a code for the topic or issuing agency. These include Ecology (ECOL), Natural Resources - excluding fish & seafood (RECNAT), Fish (PESC), and Commercial Information (SCFI), Health Secretariat (SSA), Labour Secretariat (STPS), Phytosanitary (FITO), and Zoosanitary (ZOO); and 4) a year, which is generally, but not always, the year it was issued as a proposal. For example: NOM-018-STPS-2000.

Table 2.1 Laws and regulations that confer powers to the Secretariats to govern every step in the life cycle of pesticides. activities included in the cycle of life of pesticides.

ACTIVITY	SECRETARIATS					
	Health Secretariat	**Secretariat of the Environment and Natural Resources**	**Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food**	**Labour Secretariat**	**Secretariat of Communications and Transport**	**Economy Secretariat**
MANUFACTURE (INCLUDE PACKING, LABELING AND STORAGE)	LGS and its regulation on Sanitary Control of Activities, Establishments, Products and Services	LGEEPA	LFSV and LFSA	LFT		
REGISTRATION	LGS and its regulation on sanitary control of activities, establishments, products and services and the regulation on registrations, authorisations for import and export and certification of export for pesticides, fertilisers and hazardous substances and materials	LGEEPA and its regulation on registrations, authorisations for import and export and certification of export for pesticides, fertilisers and hazardous substances and materials	LFSV and LFSA and the regulation on registrations, authorisations for import and export and certification of export for pesticides, fertilisers and hazardous substances and materials			
TRANSPORT	LGS and its regulation on Sanitary Control of Activities, Establishments, Products and Services	LGEEPA		LFT	Regulation on Transportation of Hazardous Material and Wastes on Road	
SALE	LGS and its regulation on Sanitary Control of Activities, Establishments, Products and Services		LFSV and LFSA			
USE	LGS and its regulation on Sanitary Control of Activities, Establishments, Products and Services	LGEEPA	LFSV and LFSA	LFT		
IMPORT AND EXPORT	LGS and its regulations on sanitary control of activities, establishments, products and services and on registrations, authorisations for import and export and certification of export for pesticides, fertilisers and hazardous substances and materials	LGEEPA and its regulation on the registrations, authorisations for import and export and certification of export for pesticides, fertilisers and hazardous substances and materials	LFSV and LFSA			LCE
FINAL DISPOSAL	LGS and its regulation on Sanitary Control of Activities, Establishments, Products and Services	LGEEPA				

LGS: General Health Law; LGEEPA: General Law for Ecological Balance and Environmental Protection; LFSV: Federal Plant Health Law and LFSA: The Federal Animal Health Law; LFT: Federal Labour Law.

2.1.1 General Health Law and its regulations

The General Health Law (SSA, 1984) (LGS)[9] and its regulation on the Sanitary Control of Activities, Establishments, Products and Services[10] (Hereinafter Sanitary Control Regulation) (SSA, 1988), and the Regulation on Registrations, Authorisations for Import and Export and Certification of Export for Pesticides, Fertilisers and Hazardous Substances and Materials (hereinafter Regulation on registration and authorisation) (SEMARNAT, 2004) are the most important pieces of legislation in Mexico governing pesticides, which concede the primary power to regulate pesticides to the Health Secretariat (SSA). Table 2.2 presents the duties and responsibilities of SSA granted by these regulations, whose implementation and enforcement are accomplished by the Federal Commission for the Prevention of Health Risks (COFEPRIS) created in 2001, which is a subordinated body of SSA.

As can be seen in Table 2.2, SSA has the power to apply a sanitary control to all steps in the life cycle of pesticides. In order to exert its powers it has developed different instruments mainly to regulate manufacturers, sellers and distributors with a preventive focus, as they are focused on assuring that the facilities in which pesticides are manufactured or formulated are safety (by a Sanitary Licence[11]), that pesticides to be sold do not represent an unacceptable risk for human health (by a Registration and Import Authorisation Procedure[12] and two

[9] LGS has its foundation in Art. 4 of the Political Constitution of the Mexican United States, which states the right that every person has to the protection of the health. In this sense, LGS establish the basis and ways for having access to the health services and the concurrence of the Federation and States on the subject of health (SSA, 1984). This law was published in 1984 and amended in 1987, 1991, 1997, 2000, 2001, 2003, 2004, 2005 and 2006.

[10] Health Control Regulation establishes specific sanitary statements for regulating and controlling activities, enterprises, products and services in order to keep the health of the population and avoiding sanitary risks. Published in 1988 (SSA, 1988). At present, it has not been modified to include the amendments made to LGS since then.

[11] There are three types of license: type A, which is focused on the enterprises that provide urban services of fumigation; type B, is specifically for enterprises that manufacture toxic or harmful substances, and type C is for enterprises that manufacture, formulate, mix or pack pesticides and fertilizers. The information requested in the sanitary licence includes general and technical information. The general information consists of data from proprietor and data and description of activities of the enterprise. Technical information consists of the layout of the installations, programme of health, training and diffusion for the workers that handle such substances, programme of security, list of control equipment for contaminants and fire prevention, and special constructions (such as alarms of leak detection or sprinkling systems). Particularly, for toxic substances it is necessary to present the security sheet of each substance and for pesticides their register number and a detailed description of process including the treatment and/or final disposal of hazardous residues. With regard to the license type A it is also necessary to designate the type of pesticides and the pests that will be controlled. In addition, the people interested in the application of pesticides must complete an examination in order to check their knowledge in the area, as well as a medical examination.

[12] The procedure is described in the next section on CICOPLAFEST.

Official Standards on labelling[13]), and that pesticides are handled following appropriate safety measures to avoid accidents (by a Notification of Beginning of Activities for Sellers[14] and Applicators[15]) (Table 2.6).

However, the effectiveness of these instruments is highly dependent on an efficient programme of enforcement and compliance, which seems to have clear limitations in the country. The inspections to verify the compliance of pesticide regulations are included in a programme of verification of manufacturers, distributors and sellers of toxic substances by the COFEPRIS. The verifications are carried out by following a priority programme of compulsory inspections to those who received a sanitary licence, following a specific programme for a particular sector or in response to a public denunciation on illegal behaviour of factories or companies. Due to data on the number of establishments currently under verification by SSA was not available; an estimation was obtained using data reported by the National Institute of Statistics, Geography and Informatics (INEGI), calculating 460,384 establishments[16]. According to Castañeda (Pers. Commun. 2004) there are around 77 inspectors in the country[17], which carry out between 3 and 7 inspections per day. So, between 780 and 1820 inspections are carried per year and taking in account the total number of establishments estimated around 0.2% and 0.4% of the businesses are verified per year.

As an example of the deficiencies in the enforcement and compliance of these instruments, the use of six pesticides banned in the United States and exported to Mexico was reported in

[13] The two Official Standards are: NOM-045-SSA1-1993, which establishes the information, general characteristics, format and size of the labels for pesticides of agricultural, forestry, livestock, gardening, urban and industrial use. It was published in the Official Gazette in October 20, 1995 (DOF, 20/09/1995), and NOM-046-SSA1-1993, which defines the information, general characteristics, format and size of the labels for pesticides of domestic use. It was published in the Official Gazette in October 13, 1995. (DOF, 13/09/1995).

[14] The notification of functioning requests information related to location of the enterprise, date operations commence, description of the process and products generated. This requirement does not need a resolution, because it is only a notification and the enterprise declares under protestation that its functioning complies with all the obligations appointed by laws.

[15] The notification of functioning includes only general information of the enterprise and of the person in charge.

[16] This total amount was estimated considering the sectors that according to the General Health Law are subject to a verification: 5,988 industrial establishments, whose activities are denominated as highly pollutant by the SEMARNAT (INEGI, 2006); 264,459 services (including only preparation of food and drinks); 86,997 sellers (including only those of big scale), and 102,940 health service and social assistant units (INEGI, 2004). More detailed description on the estimation is presented in the Annex D.1.

[17] Two inspectors for each State and seven for the Federal District.

an article of the American University published in 2000[18], considering that Art. 160 of the Sanitary Control Regulation states that the authorisation of import will be rejected when the use and consumption of the products to import have been forbidden in the country of origin. Also, Gomez et al. (2000) reported the use of Aldrin, Dieldrin and Endrin by floriculturists in the State of Morelos, Mexico, even though their use was forbidden in Mexico since 1991, due to the extreme danger to human health. Additionally, this author reported the use of DDT and Lindane because their application, in 2002, was not allowed for agricultural uses[19]. Because of the limited number of inspections and the lack of publication of their results, it is unknown if these illegal uses occur frequently or are isolated events.

Another weak aspect of the regulation of the manufacture, application, sale and distribution of pesticides by SSA is the lack of definition of technical standards that limit direct and indirect exposure to these products in order to protect the health of users and general public, and the methodologies that guide users, sellers, manufacturers and distributors to comply efficiently with the regulations. In this respect, SSA has made little advance focusing its efforts on the authorisation of Maximum Residue Levels (MRLs) on food, which are proposed by the pesticide industry in order to apply for the registration of its products[20]. SSA does a dietary risk assessment to evaluate if the pesticide residues present in food represent a risk for the population[21]. However, there is not a technical standard that present the guidelines to establish a MRL or an adaptation to include the dietetic regime of the Mexican population as it used dietetic regime who applies to all Latin America. Previously, there was

[18] When pesticides produced by United States manufactures are not approved by the United States Environmental Protection Agency (USEPA), US manufacturers allegedly often export them to developing countries because the restrictions on pesticide use are poorly implemented (American University, 2000).

[19] Currently, the use of both pesticides is forbidden in Mexico.

[20] SSA has also published four general standards to regulate the use of some hazardous substances: 1) NOM-047-SSA1-1993, which establish the maximum biological limits of organic solvents in work place; 2) NOM-056-SSA1-1993, which establish the sanitary requirements of equipment for personal protection; 3) NOM-053-SSA1-1993, which establish the sanitary measures for the production and use of methanol and, 4) NOM-076-SSA1-1993, which establish the sanitary requirements for the production and use of ethanol.

[21] Establishment of a MRL in the country: Pesticide industry proposes a MRL for the combination crop/pesticide that wishes to register, in general, the industry proposes a MRL already established by the Codex Alimentarius or by the USEPA. COFEPRIS does a dietetic analysis based on information from FAO/WHO Codex Alimentarius Commission for Latin America and if the theoretical value obtained from using the MRL proposed is less or equal to the Acceptable Daily Intake (ADI) COFEPRIS accepts the MRL and publishes it in the Official Catalogue for Pesticides. According to an official of COFEPRIS very rarely a MRL proposed overcome the ADI, and if it is the case COFEPRIS does a more sophisticated study. The use of Codex MRL and EPA tolerances presents great advantages as they are based on toxicological assessments of the pesticide and its residue, and the review of data are obtained from supervised trials and supervised uses including those reflecting national good agricultural practices.

an Official Mexican Standard NOM-050-FITO-1995 enacted by SAGARPA, which was cancelled to concede the duty to the SSA due to implications on health protection that it represents.

So, guidelines for the establishment of MRLs along with limits of pesticide residues in drinking water and the definition of exposure limits for workers that manage or use pesticides are missing in the regulation of SSA. Additionally, the definition of sanitary criteria for the formulation, bottling, packing and storage of pesticides are also necessary as well as the updating of the Health Regulation in order to include the amendments made to LGS after its publication in 1988.

The lack of scientific evidence in the country about the effects of pesticides on the population and its magnitude are in part responsible for the lack of technical standards as policy makers show reluctance to regulate issues when there is no sound information that backs them.

With regard to the transportation and final disposal of pesticides there is not a specific instrument to control them, which represents a gap in the regulatory system. Because these responsibilities are shared among different Secretariats (Table 2.1 and 2.6) there could be some confusion of duties among the Secretariats since they could assume that other Secretariats are responsible or have greater responsibility on the issue. The registration and authorisation for import pesticides are other tasks of the SSA, which will be discussed in the next section related to the performance of the Inter-Secretarial Commission for the Process and Use of Pesticides, Fertilisers and Toxic Substances (CICOPLAFEST).

2.1.2 The General Law of Ecological Balance and Environmental Protection

The General Law of Ecological Balance and Environmental Protection (LGGEPA, by its abbreviation in Spanish) (SEMARNAT, 1996) is the main law on environmental issues and is based in Articles 4 and 27 of the Political Constitution of the Mexican United States.

Table 2.2 Responsibilities of SSA conceded by the General Health Law and regulations for the control of pesticides.

ACTIVITY	ARTICLES			DESCRIPTION
	LGS	Sanitary Control Regulation	Registrations and authorisations regulation	
General	194, 278, 279 and 280	1214 and 1221		They provide authority to apply sanitary control procedures[1] to the use, process, import, export, application and final disposal of pesticides, fertilizers and harmful substances. Particularly, Art. 279 of LGS states that the SSA, in coordination with the corresponding Secretariats[2], must establish the conditions that have to be fulfilled in the manufacture, formulation, bottling, packing, labelling, storage, transportation, commercialisation and application of PLAFEST through the creation of Mexican Official Standards (NOMs). This article also stipulates that in order to protect human health the opinion of SSA will prevail over all other Secretariats[3]. They also concede responsibility to define that substances will be under sanitary control and classifying them according to their risk[4].
Manufacture	198, 214 368, 373[5], 375 and 380	129, 62, 88, 139, 146 and 188		Enterprises dedicated to the manufacture and application of pesticides, fertilizers and toxic substances must obtain a sanitary authorization from SSA called sanitary licence. Vehicles that transport toxic substances must also obtain it. Authorisations have not limited by time but can be revoked. A sanitary permit[6] is requested to the enterprises that manage toxic or harmful substances and wish to modify their installations, when this implies new systems of security. Enterprises that also process and apply toxic substances must obtain it.
	279			Art. 279 Section II of LGS states that the SSA has to authorize the composition of pesticides and fertilizers and the production of persistent and bioaccumulative pesticides.
		1219 and 1220		SSA, in coordination with SEMARNAT, has the responsibility for determining and publishing maximum limits of exposure to toxic substances for workers and the public.
Registration	376	167	3	Pesticides, fertilizers and toxic substances have to be registered by SSA
Labelling	210 and 281	1222, 1223, 1270, 1277 and 1279		All packed products have to show labels in agreement with the regulations and NOMs published by the authorities. The reuse of containers is forbidden.

[1] Sanitary control is understood to be the set of actions of training, education, sampling, verification or application of security measures and fines that SSA exerts with the participation of producers, sellers and consumers in agreement with NOMs and other regulations.
[2] Such as SEMARNAT, SAGARPA and SCT, which also have the responsibility of regulating PLAFEST.
[3] Idem 10
[4] It is adequate to mention that currently these lists have not yet been published.
[5] In order to meet Art. 373, SSA developed a format and defined the information required for supplying a sanitary licence. There are three types of license: type A, which is focused on the enterprises that provide urban services of fumigation; type B, is specifically for enterprises that manufacture toxic or harmful substances, and type C is for enterprises that manufacture, formulate, mix or pack pesticides and fertilizers.
[6] The information requested in the permit consists of general information on the enterprise, description of the modifications, layout of the installations, programme of security, list of control equipment of contaminants and fire prevention, and list of special constructions (such as alarms of leak detection or sprinkling systems). This requirement has the key SSA-05-006 (SSA, 2003).

Table 2.2 Responsibilities of SSA conceded by the General Health Law and regulations for the control of pesticides (continuation).

ACTIVITY	ARTICLES			DESCRIPTION
	LGS	Sanitary Control Regulation	Registrations and authorisations regulation	
Storage, commercialisation and distribution	194, 204 and 279	1235 and 1234		In order to regulate the enterprises that store, sell and distribute PLAFEST, the SSA requires that these enterprises notify the authorities about their functioning or operations in a specific format denominated notification of functioning[7]. The transportation of PLAFEST with food, medicine or with other product related to human use and/or consumption is prohibited. It also prohibits their transportation in inappropriate packaging and the final disposal of empty containers in sites without a sanitary licence. SSA, in coordination with SEMARNAT, must authorise the temporary storage of substances and products, while these do not constitute a risk to human health. People that apply pesticides must notify their activities to SSA supplying a Notification of person in charge for pesticides[8].
Application	198	1228		SSA must supervise the application of products, which by their toxicological characteristics affect human health. This should be done in agreement with the NOMs that SSA publishes on the subject.
Final disposal	194			In order to minimize the risks to human health, SSA can promote with the corresponding authorities, to restrict the location of enterprises dedicated to the process or final disposal of toxic substances.
Import	298	160	3	A sanitary authorisation for the import of pesticides, fertilizers and toxic substances is necessary when they constitute a risk to human health. Hence, SSA has to determine which substances require authorisation. In the case of persistent and bioaccumulative pesticides, SSA will only give authorisation for their import when they do not constitute a health risk and when their substitution is not possible. Once the authorization has been released, SSA has the responsibility of checking and controlling the activities in which these are involved. The authorisation can be rejected when the use and consumption of the products to import have been forbidden in the country of origin[9].
Export			3	SSA has the power to issue authorisations for export of pesticides, fertilisers and toxic substances.

[7] The *notification of functioning* request information related to location of the enterprise, date operations commence, description of the process and products generated. This requirement does not need a resolution, because it is only a notification and the enterprise declares under protestation that its functioning complies with all the obligations appointed by laws. This requirement has the key SSA-05-001 (SSA, 2003).
[8] The *notification of functioning* includes only general information of the enterprise and of the person in charge. Its key is SSA-05-014 (SSA, 2003).
[9] Art. 160 also states that authorization of import will be rejected by recommendation of specialised international organisations.

LGGEPA provides authority to the Secretariat of the Environment and Natural Resources (SEMARNAT, by its abbreviation in Spanish) for regulating all matters related to hazardous material and residues in the environment (Art. 150[22]). Table 2.3 presents the articles that define its responsibilities.

LGEEPA provides a potential power to SEMARNAT to have an active participation in the regulation of pesticides related to their manufacture, registration, transportation, use, import, export and final disposal. However, SEMARNAT has developed few instruments to exercise its control; hence its participation in pesticide regulation is very limited.

SEMARNAT regulates chemical industries that release atmospheric pollutants due to their industrial processes through a Licence for Working, which has a preventive focus as it requires the description of the industrial processes, facilities and the equipment to control the pollutant emissions.

The Secretariat is also participating in the process of registration of pesticides providing an opinion to SSA regard to the convenience to register a pesticide considering its environmental impact and in the process to authorise pesticide import stated in its Regulation on Registrations, Authorisations of Import and Export and Certification of Export for Pesticides, Fertilisers and Hazardous Substances enacted in 2004 (SEMARNAT, 2004). More information on these activities is described in the section of CICOPLAFEST due to the role that this Commission played at the beginning of the process.

In 2003, SEMARNAT also passed another law: the General Law for the Prevention and Integral Management of Residues (SEMARNAT, 2003a), which provides relevant points for the management and final disposal of hazardous residues. Article 28 establishes the joint responsibility of manufacturers, importers, exporters, distributors of products that after being

[22] In addition, Chapter II Section VI of the LGGEPA stipulates that corresponding to the Federation the regulation of activities considered as highly risky, as well as the generation, handling and final disposal of hazardous material and residues. As a complement, Art. 120 establishes that in order to avoid water pollution federal regulations apply to the application of pesticides, fertilizers and toxic substances.

used become hazardous residues, for defining and carrying out a residues management programme. Article 31 states that pesticides and their containers will be subject to this programme[23], which aims to minimise the generation of residues, value their properties for a possible reuse and select the most suitable technology and procedure for its recollection, temporal storage, transportation and if it is the case for their treatment and final disposal. Article 55 also appoints SEMARNAT to publish the regulations and standards that establish the adequate procedure to manage and treat the residues.

At present, there is a programme called Campo Limpio managed by the pesticide industry association called AMIFAC, whose objective is to promote the washing of empty pesticide canisters and their final disposal. This programme is derived from an agreement between SEMARNAT and the AMIFAC in 1996. After ten years of work the advances of this programme have been limited as there are only three States participating with nine sites for the collection and temporary disposal of washed canisters. AMIFAC highlighted the importance of the enactment of the General Law for the Prevention and Integral Management of Residues to encourage a more active participation among the users, manufacturers and government as it noticed that the lack of legal or economic incentives have undermined the advance of this programme[24].

SEMARNAT has also published the Regulation on Hazardous Residues (SEMARNAT, 1988) and Official Standards for the final disposal of hazardous residues; however, there is not any statement that defines a specific measure to exercise a control on pesticides[25].

[23] According to this law specific residues will be subject to a Management Plan, which aim to prevent the generation of residues, value their properties for a possible reuse or select the most suitable technology for their treatment and final disposal.

[24] From 1997 to 2004 (until March) 702.5 tonnes of canisters have been collected, however, there is no information about the total amount generated of residues to compare and quantify the advances.

[25] These standards are: NOM-052-SEMARNAT-1993, establishes the characteristics and a list of the hazardous residues (under this NOM water waste, dust, sewage and residues from process of elaboration of pesticides are considered as hazardous residues); NOM-053-SEMARNAT-1993, establishes the procedures to identify a hazardous residue; NOM-054-SEMARNAT-1993, establishes the procedure to identify the incompatibility between two or more residues; NOM-055-SEMARNAT-1993, NOM-056-SEMARNAT-1993, NOM-057-SEMARNAT-1993 and NOM-058-SEMARNAT-1993 establish the requirements for the final disposal of residues and establish the requirements for the design and construction of complementary building work of the sites of final disposal.

Table 2.3 Duties of the SEMARNAT on pesticide control conceded by the LGEEPA.

ARTICLE	DESCRIPTION
143	*Pesticides and fertilizers and* ***other hazardous material*** *will be regulated by the NOMs that release, in agreement with their competence, SEMARNAT, Economy Secretariat (SE),* Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food *(SAGARPA) and Health Secretariat (SSA)*[26]. In addition, the Regulations derived from this law, which will establish the control within this framework of coordination[27], must enforce activities related to hazardous material and residues, including final disposal of residues, empty containers and packaging. It also includes preventative measures and procedures to avoid environment pollution.
111bis	Enterprises that manufacture fertilizers[28] and pesticides must obtain a license for working[29] provided by SEMARNAT since they are considered as stationary sources[30] releasing air contaminants.
144 and 153	In accordance with this law and other legal regulations, SEMARNAT in coordination with SSA, SAGARPA and SE will participate in the determination of tax restrictions related to import and export of hazardous material. Import of pesticides and fertilisers banned in the country of origin is prohibited.
134	The use of pesticides, fertilizers and toxic substances must be compatible with the ecological balance of soil ecosystem. So, this article sets the basis for the cleaning and remediation of contaminated soils for their reuse.
135	Requirements to prevent and control land pollution have to be considered in the authorizations for the manufacture, import, use and other activities related to pesticides, fertilizers and toxic substances.

So, the environmental legal framework for the regulation of pesticides is poorly implemented in spite of the powers provided to SEMARNAT by the laws aforementioned. The lack of technical standards and legal instruments that define the rules to control pesticides makes it difficult to assure an adequate protection to the environment by pesticide use.

[26] So, in spite of the fact that LGGEPA does not define pesticides, they are considered as hazardous materials, hence they are under its jurisdiction.
[27] That implies in agreement with SSA, SE and SAGARPA.
[28] Only when the process includes chemical or biological reactions.
[29] License of working requires both general and technical information. The general information includes data of the enterprise such as lay out of the installations, number of workers and shifts, and localization. The technical information includes the identification of the contaminants to release according to industrial process and an estimation of the emissions, type of fuel to use, information about pollution control equipment and measures to prevent the contamination. If the enterprises generate hazardous residues, it is necessary to inform their quantities and final disposal. The annual report (COA) requires the same information, but updated and a direct or indirect measuring of the annual pollutant emissions.
[30] Stationary source is defined as those enterprises localised in a specific area that due to their industrial process generate and release contaminants to the environment.

2.1.3 The Federal Plant Health Law

The Federal Plant Health Law[31] (Ley Federal de Sanidad Vegetal) (LSV)) (SAGARPA, 1994) grants SAGARPA authority to develop phytosanitary standards relating to the production, manufacture, movement and commercialisation of vegetables, vegetable products or materials used in their production. So, SAGARPA has an important influence in the regulation of pesticides with regard to their effectiveness and appropriate use in the fields to keep a steady behaviour in agricultural production level. The duties designated by this law to the SAGARPA with respect to pesticides are shown in Table 2.4.

Table 2.4 Powers of the SAGARPA to regulate pesticides conceded by the LFSV.

ARTICLE	DESCRIPTION
Art. 7	It is responsibility of SAGARPA establishes the maximum limits of pesticide residues on crops.
Art. 10	According to its powers, SAGARPA will support the Health Secretary and the Secretariat of Social Development to ensure full compliance of the regulations in relation to pesticides and fertilizers.
Art. 38	SAGARPA must establish the procedures to certify and evaluate the biological effectiveness, application, use and management of pesticides and fertilizers in the field and publish the respective NOMs.
Art. 39	Pesticides and fertilizers must be registered by the corresponding Secretariat and one of the requirements for the registration will be to provide a study of biological effectiveness, which will be evaluated by SAGARPA. Subsequently, SAGARPA must provide an opinion about the appropriateness of registering the product to the Secretariat in charge of the registration.
Art. 42	SAGARPA must define what type of pesticides must be applied by specialised people and supervise their application.
Art. 13, 19 and Art. 48 and Art. 40	The approbation of national mechanisms of standardisation and the certification of laboratories and third party units to carry out pesticide studies are a responsibility of SAGARPA.
Art. 44	People interested in providing or developing phytosanitary activities must present a notification of beginning of activities, so authorities can be aware of their activities and compliance with present regulations can be corroborated.

So, one of the main responsibilities of SAGARPA is to pass judgment about the biological effectiveness of pesticides and provide a technical opinion to SSA on whether to register or

[31] LSV uses the terms agricultural inputs and vegetal nutrition input to make reference to pesticides and fertilizers, respectively. According to this law agricultural input is defined as any substance or mixture of these used in the control of pest such as pesticides, biological control agents or resistant plants to pests. Vegetal nutrition input is defined as any substance or mixture of these useful for the nutrition and development of the plants.

not pesticides, considering their effectiveness. SAGARPA published the Official Mexican Standard NOM-032-FITO-1995, which establishes the data requirements and the protocol to follow to carry out the biological effectiveness studies[32]. Based on this standard SAGARPA has authorised researchers that present the knowledge and expertise required to accomplish these studies; however, there is not a test to corroborate their expertise and a laboratory or research centre in which the analysis can be carried out using calibrated equipment and an standardised methodology, in other words there are no certified laboratories or third parties even though this standard states the need to certify them. So, this activity needs additional instruments to assure its effectiveness.

Another responsibility of SAGARPA is the authorisation of pesticide applicators, thus it has published three standards focused on the Notification of Beginning of Activities for persons interested in applying phytosanitary treatments (NOM-022-FITO-1995[33]), in commercializing (NOM-033-FITO-1995[34]) and manufacturing and importing agricultural pesticides (NOM-034-FITO-1995[35]).

The Notification of Beginning of Activities for persons interested in applying phytosanitary treatments allows the Secretariat to assure the ability of applicators and integrate a directory of those having the power to verify the compliance of their duties. However, technical guidelines to instruct applicators on the adequate use and handling of pesticides are missing as well as a core examination on their capabilities. Currently, SAGARPA is holding

[32] Currently this standard has been updated to streamline the procedure to issue the judgment on biological effectiveness.
[33] NOM-022-FITO-1995 indicates the kind of information that people interested in applying phytosanitary treatments have to present such as to prove their knowledge and experience in the area and legal data of the enterprise. This standard also specifies the type of material and equipment requirements for the application of methyl bromide and aluminium phosphate and for the treatment of aspersion and atomization of insecticides and disinfectants.
[34] NOM-033-FITO-1995 stipulates that the people interested in commercialising agricultural pesticides have to notify to SAGARPA the beginning of activities including general information such as type of pesticide to commercialise, experience and knowledge of the people in the area. In addition, this standard specifies that pesticides authorized by Inter-Secretarial Commission for the Procedure and Use of Pesticides, Fertilizers and Toxic Substances (CICOPLAFEST) can only be commercialised and that the enterprises will be responsible of generating a registration of these and their providers, as well as, to register those pesticides whose efficiency is low or nil. Finally, this NOM stipulates that the enterprise has to proportionate training to its workers.
[35] NOM-034-FITO-1995. In this standard the notification of beginning of activities has basically the objective of creating a directory of the enterprises dedicated to the manufacture and import of agricultural pesticides, since the information required is general and not demand additional activities to those established by CICOPLAFEST.

presentations on the proper use and management of pesticides in aerial application[36]. At present, the Secretariat has provided 21 talks addressing to 531 pilots (Negrete, 2004 Pers. Commun.).

In order to support the compliance of NOM-033-FITO-1995 and train sellers on safety measures to reduce risks by pesticide handling, SAGARPA has been imparting courses in different cities of the country since 2002. At present, 15 courses have been provided with the participation of SSA, training to 806 sellers (including owners and workers).

As part of the field work carried out in Mexico, a questionnaire was applied to 54 sellers of pesticides that attended one of these courses held in La Piedad, Michoacan City in February 2004 (before they took the course). The objective of this questionnaire was to determine their level of knowledge on the regulation established by SAGARPA and to know their perception about it[37]. The questionnaire is presented in Annex D.2.

The results show that, in general, sellers had an acceptable knowledge on the regulation on sale of pesticide established by SAGARPA, and they consider it as easy to understand and necessary. They also need to have sufficient knowledge to provide an adequate advice to farmers with regard to the selection of pesticides stressing their interest and the importance of these trainings[38]. However, these results can not be extrapolated to the country since the sample is not representative. Finally, in the survey and during the course the sellers stressed their dissatisfaction with the authorities due to their limited attention and prosecution of provisional sellers, who appear when there is greater demand for pesticides that fail to

[36] These courses called *Security in low and agricultural flights* (SEVRA, by its abbreviation in Spanish) are organised by the Direccion General de Aeronautica Civil (DGAC) (General Office of Civil Aeronautic) in order to provide a re-licensing to commercial and agricultural pilots.

[37] 90% of the attendants were agronomist or with a similar profession.

[38] The results show that 20% of the attendants have an excellent knowledge of the regulation, 40% a sufficient knowledge, 26% a poor knowledge and 11% reported do not have any information about it (this scale was defined previously in the questionnaire: excellent means a complete knowledge of the regulation; sufficient makes reference to the necessary knowledge to comply with it; poor that there is a knowledge about the existence of the regulation but its content was unknown. 60% of the people considered that the Notification of Beginning of Activities is important, as well as the verifications carried out by the Secretariat. 67% judge the Notification as an application easy to fill, 15% very easy, 11% complex. Because farmers are used to asking sellers about effectiveness of pesticides, sellers play an important role in the selection and use of pesticides. According to the survey 54% of farmers often ask for advice and 33% always ask; 48% of sellers considered themselves to have sufficient knowledge to advise farmers and 28% excellent knowledge. 94% of the attendants stressed the importance and necessity of these courses to update the information on the regulation and assessment of risks.

comply with the minimal conditions of security, since they are used to selling pesticides by kilos or litres in houses or small shops. SAGARPA recognised this problem and accepted that it does not have a strategy to solve the problem yet. So, the enforcement is failing in this activity.

The standard NOM-034-FITO-1995 also requires a Notification of Beginning of Activities, which has basically the objective of creating a directory of the enterprises dedicated to the manufacture and import of agricultural pesticides and the authority to confirm such information by SAGARPA. The pesticide industry has called for the Federal Regulatory Improvement Commission (COFEMER) to cancel this standard as they consider it as repetitive and useless, since SSA also requests the same information, which is understandable. So, this standard needs a revision in order to include a coordinated mechanism that allows SSA and SAGARPA to share information and avoid overregulation. SAGARPA also needs to modify the LFSV in order to officially concede the powers to SSA for the establishment of the Maximum Residue Levels (MRLs). Previously, it was mentioned that SAGARPA cancelled the standard NOM-050-FITO-1995, which made reference to the protocol to follow for the establishment of the MRLs.

The verification of the compliance of the MRLs by the authority can be useful to corroborate an appropriate use of pesticides by farmers. Based on the information published by the Food and Drug Administration (FDA) of the United States in 2003, SAGARPA determined that 37% of the rejections of agricultural products at the border with the United States are caused by the violation of the limits of pesticides allowed in the food, which reflects a misuse of pesticides in the field. As support to the exporters SAGARPA created the Programa Nacional de Monitoreo de Residuos de Plaguicidas (National Monitoring of Pesticide Residues) in 2002 in order to identify the problems and advise the exporters how to avoid rejections. In 2003, 277 samples of diverse products were analysed; the results show that 43 samples presented residues of pesticides not authorised for the product, and only 2 samples exceeded the allowed limits of permitted products. So, these results clearly show a

deficiency in the compliance of the regulations highlighting the need for a permanent training to farmers on the adequate use of pesticides. This also entails to ask if national products present the same problem.

Another problem with the use of pesticides in the fields makes reference to the excessive use of pesticides or the preparation of mixtures of pesticides "cocktails" to improve the control of pests, which have generated presence of residues do not allowed in the crops and pest resistance to pesticides.

SAGARPA is participating in the courses *Train the Trainer* for the correct use of pesticide organised by the National Programme, which will be mentioned in the section for CICOPLAFEST.

2.1.4 The Federal Labour Law

The Federal Labour Law (Ley Federal del Trabajo y Seguridad en el Trabajo) (hereinafter Labour Law) (STPS, 1970) and the General Regulation Regarding Safety and Hygiene in the Workplace (Reglamento General de Seguridad e Higiene en el Trabajo) (STPS, 1997) (hereinafter Work Safety Regulation) provide protection standards for individuals working in areas where chemical substances are an integral part of the business operations or could pose occupational health risks. So, the Labour Secretariat (STPS, by its abbreviation in Spanish) together with the SSA have jurisdiction to enforcement standards for worker's protection. Table 2.5 presents the responsibilities of STPS related to pesticide regulation.

Based on its powers, STPS has published four NOMs: 1) NOM-003-STPS-1999, which establishes the conditions of security and hygiene in the use, transportation and storage of pesticides and fertilizers; 2) NOM-005-STPS-1998, that establishes the conditions of security and hygiene in workplaces where hazardous chemical substances are handled, transported

and stored; 3) NOM-010-STPS-1999[39], which establishes the conditions of security in workplaces where chemical substances that can cause contamination in the workplace are managed, transported, processed or stored,, and 4) NOM-018-STPS-2000 [40], that establishes a system for the identification and communication of risks from hazardous chemical substances in a workplace.

Table 2.5 Powers of the STPS to regulate pesticides conceded by the Labour Law and Work Safety Regulation.

ARTICLE		DESCRIPTION
LAW	REGULATION	
4, 132 , 134, 511 and 512		The principles of security and hygiene established by the Labour Law include the adoption of measures to avoid exceeding the maximum limits of release of contaminants and the development of legal regulations for controlling and checking their adherence
	54-75 and 101	Handling, transportation and storage of hazardous material and substances[41] should be carried out by trained personnel following security measures established in the Programme of Security and Hygiene, in order to prevent or avoid damage to worker health and the workplace This is in accordance with the standards published on the subject.
	84	Enterprises have the responsibility for establishing a Programme of Security and Hygiene that improves the security conditions in the workplace and reduces the exposure to pollutants of workers, particularly by pesticides and fertilizers. This is in accordance with the standards developed on the subject.

Basically, two weaknesses are found in the regulation of hazardous substances and materials by STPS. One of these is the system of verification, since there is not a constant programme for checking that the security measures have been implemented and the standards fulfilled. The second point is the lack of coordination with other Secretariats to develop joint regulations and provide training to workers in direct contact with pesticides,

[39] NOM-010-STPS-1999 includes the maximum limits of exposure to hazardous chemical substances in the workplace.
[40] NOM-018-STPS-2000 includes the information that must be included in a security data sheet.
[41] Work Safety Regulation defines hazardous material or substances as those substances or material that by their physical or chemical properties can be inflammable, explosive, toxic, reactive, radioactive, corrosive or biologically dangerous; hence they can cause damage to worker health or workplace.

since this Secretariat independently developed training material to train farmers respect to the appropriate use of pesticides considering that there is a National Programme made up by SAGARPA, SSA and SEMARNAT already working in the subject.

2.1.5 Regulation for the Land Transport of Hazardous Materials and Wastes

The Regulation for the Land Transport of Hazardous Materials and Wastes 1993 (Reglamento para el Transporte Terrestre de Materiales y Residuos Peligrosos) (hereinafter Waste Transportation Regulation) (SEMARNAT, 1993) provides a separate legal regime governing the transport of hazardous materials and waste, including chemical substances. The administration and enforcement of the Waste Transportation Regulation falls under the jurisdiction of the Secretariat of Communications and Transport (SCT). The Waste Transportation Regulation establishes the security conditions for transporting hazardous material and wastes, which include requirements of labelling and packing and the characteristic of the vehicles used for transporting them.

Presently, 28 NOMs have been derived from this regulation, which establish the characteristics that the containers and vehicles used for the transport of hazardous substances and material must have. These characteristics include design, labelling and safety measures for security and cleaning. Additionally, the standards stipulate the conditions in which hazardous substances and material must be packed, loaded, transported and unloaded (the conditions of transport include the compatibility of transported materials and their quantities). The NOMs are presented in Annex A.

However, the problem with the regulations on transportation of hazardous material and waste is their enforcement and compliance, since there is a high number of accidents related to the transportation of these materials. The National Centre for the Prevention of Disasters (CENAPRED) reported 3,039 accidents on vehicles transporting chemical substances in the period 1996-2000 (CENAPRED, 2006). The limited number of inspectors is one of the main

reasons for the deficiencies in the enforcement and compliance. According to the Office for the Supervision of Federal Transportation of SCT, there are 700 inspectors in the country, which are not sufficient to verify the broad number of enterprises involved in public transportation, tourism, freight services, breakdown help, central bus stations, airports, service of recollection and transportation of hazardous material and other transportation services.

Currently, the Commission for Transportation and Storage (COTRA), which is directed by the pesticide industry association called AMIFAC is holding courses to train distributors on the safety storage and transportation of pesticides. In the period 2003-2005, 25 courses were held in collaboration with the SSA and SAGARPA, training to 1,578 participants, which were distributors, wholesalers and local officials (AMIFAC, 2003, 2004 and 2005). However, at the moment there is not any information that indicates the effectiveness of these courses and their impact in the reduction of number of accidents in these activities.

2.1.6 Discussion and conclusions

The enactment of the laws of health (LGS) and environment (LGEEPA) in 1984 and 1988, respectively, marked the beginning of the regulation of pesticides with a preventive focus on human health and environmental protection. After that, the publication of the Federal Animal and Plant Health Laws complemented the regulation including the agricultural aspect in 1993 and 1994.

An integrated regulation started with the creation of the Inter-Secretarial Commission for the Control of the Processing and Use of Pesticides, Fertilizers and Toxic Substances (CICLOPLAFEST) and the publication of an integrated procedure to issue registrations and authorisations for import and export in 1987 and 1988, respectively. More information on this Commission is presented in the next subchapter.

So, after the analysis of the laws regulating pesticides it seems that the basis of their regulatory framework is in place, since the laws provide enough power to the Secretariats to regulate all the aspects on pesticides. There are also administrative processes running such as the registration process, import and export authorisations and a notification process for sellers and professional applicators. There is an Inter-Secretarial Commission (CICOPLAFEST), whose aim is to coordinate pesticide regulation among the Secretariats with powers to participate in and a Federal Commission (COFEPRIS) to prevent health risks. However, the regulation of pesticides in the country presents several deficiencies. While the legal framework is in place, there are still gaps that need to be fulfilled such as the lack of legal power of the authorities to request the compulsory report of sales from the pesticide industry, the compulsory creation of database and publication of information on pesticides. But the main deficiencies are found in the implementation of the regulations and in their enforcement and compliance. Figure 2.1 shows the causes and effects of an ineffective regulatory system for pesticides.

In 2000, the Federal Regulatory Improvement Commission (COFEMER), in its document *Causes for which CICOPLAFEST has not worked properly* (COFEMER, 2000) carried out an evaluation on the legal framework for pesticides, fertilisers and toxic substances. Its main findings were the lack of coordination for the creation and reformation of legal instruments related to these substances and products, since there is a conflict among the different regulations, beginning with the criteria and connotations used for defining them, for the overlapping that exists among legal instruments, and for the gaps in the implementation of the regulatory framework stressing the limited number of technical standards enacted, which have been mainly created to solve emergent problems.

Reiterating the findings of the COFEMER, the different connotations and criteria to define a pesticide, used in the regulations enacted by the Secretariats, lack of uniformity[42], even

[42]The General Health Law defines pesticide as substance or mixture of substances that are used for controlling pests, included vectors that transmit human and animal diseases and species that cause damage or interfere with forestry, agricultural and livestock production, as well as, the substances that dry or promote the premature drop of the leaves. In comparison, the Federal Plant Health Law defines pesticide as a phytosanitary material that prevents,

though they are not contradictory in some cases they are more extensive than others, which can create different interpretations or juridical uncertainty for the recipient of these regulations.

Table 2.6 supports the assertions of COFEMER with regard to the overlapping of regulations as manufacture of pesticides is regulated by four different instruments that have different approaches but most of the technical information required is similar[43] and there is not any report about sharing information or carrying on joint work to check on adherence, which represents the main weakness of the regulation of this activity. Another point in relation to this activity is the lack of legal power of the authorities to demand the report of sales by the pesticide industry, which currently is very hermetic to provide this information

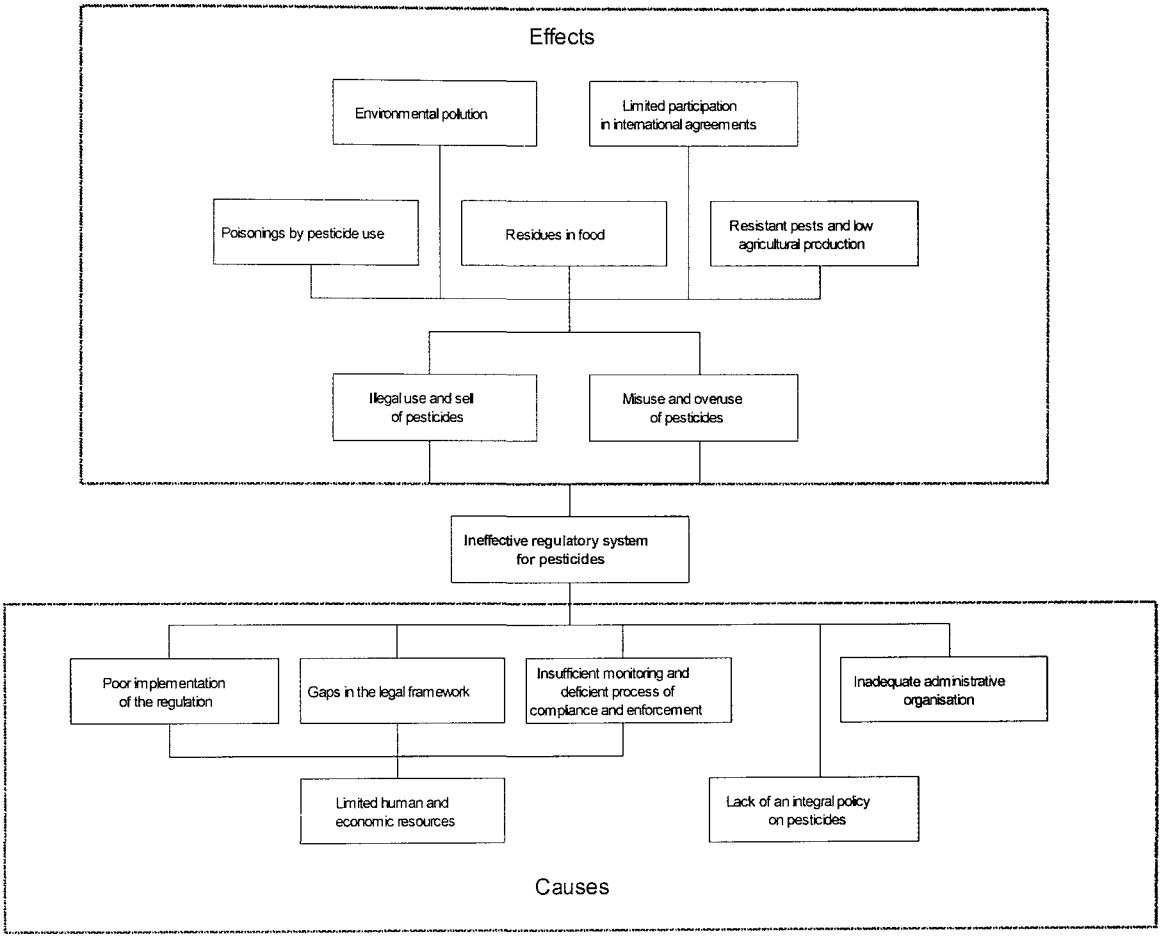
The same situation of overregulation is presented in the sale of pesticides with a Notification of Beginning of Activities required independently by SAGARPA and SSA. Since these notifications do not require an official resolution and the main objective is to create a registration of pesticide sellers one of the notifications could be cancelled and the records could be shared avoiding overregulation and concentrating efforts on the compliance and enforcement.

The cover of the regulation of transportation of pesticides seems to be sufficient to control this activity mainly by the standards published by SCT; however, the lack of diffusion and training on the subject and the deficiencies of the authorities for their compliance and enforcement are the weakness of this aspect.

repels combats or destroys the harmful biological organisms of plants, such as: insecticides, fungicides, herbicides, etc. In some cases these substances are called by different names. e.g. material for vegetal nutrition instead of fertilizer.

[43] The similarities are found on general data requirements of the enterprise, description of the manufacturing process and of the installations, description of pollution prevention equipment and the security measures implemented by the enterprise, which reflect excessive regulation of this activity, since the enterprises that wish to manufacture pesticides or fertilizers must comply with these compulsory requirements. The Sanitary Licence is focused on the prevention of accidents and minimisation of risks by assuring that the facilities are in compliance with the safety measures to protect health workers. The Working Licence is focused on the prevention and control of atmospheric pollutants; the Notification of Beginning of Activities is centred on the quality of the products and finally the standard NOM-003-STPS-1999 states safety measures to handle pesticides and other hazardous substances aiming to protect health workers.

Figure 2.1 Causes and effects of an ineffective regulatory system for pesticides.



According to the new regulation enacted by the SEMARNAT ((SEMARNAT, 2004), the registration of pesticides is now an exclusive activity of SSA receiving technical support from the SAGARPA and SEMARNAT. With regard to import authorisation, this is independently provided by SEMARNAT and SSA, hence SAGARPA will have to modify the requirement of a Notification of Activities for pesticide importers as this is out of its control. Comments on the background, information and effectiveness of these two activities are provided in the section for CICOPLAFEST.

The use of PLAFEST is regulated by four instruments (Table 2.6), basically, the license and notifications are focused on the creation of a register of applicators and assure that they have the knowledge and experience to carry out the applications; however, technical guidelines to instruct applicators on the adequate use and handling of pesticides are missing

as well as a core examination of their capabilities. Additionally, the notifications seem to be repetitive as the information required is mainly focused on general data on the enterprises that apply pesticides, aiming to generate a database of them. With regard to the official standard NOM-003-STPS-1999, its effectiveness is undermined due to the lack of diffusion and training on its content. Currently there is a national programme to train people on the proper use of pesticides organised by CICOPLAFEST, in which is also participating STPS; however, STPS developed another training material with the support of a Spanish agency, which shows lack of coordination and low priority to work jointly.

Final disposal is an activity that remains without any instrument of regulation that implements the powers of the SSA and SEMARNAT, representing a clear gap in the regulatory system and an inadequate protection to the environment. The Programme *Campo Limpio* coordinated by AMIFAC highlighted the need of an economic and legal instrument that encourage the participation of the sectors involved in this programme, since after 10 years from its creation their participation has been very limited.

After an analysis of the main amendments to the laws described previously, it seems that after the enactment of these laws, where general statements for the regulation of pesticides were established, there is not a clear trend or continuity in the regulation of hazardous substances including pesticides as the amendments have covered diverse topics, which have not been of relevance to pesticide regulation. Additionally, the lack of technical standards that limit the exposure to pesticides, the guidelines and methodologies that support pesticide registrants, the lack of instrument to regulate the final disposal shows the limited implementation of the regulations, even in spite of the creation of CICOPLAFEST and COFEPRIS and the study of the COFEMER, which criticised severely the performance of the CICOPLAFEST.

Without doubt the enactment of the regulation to issue registrations and import authorisations for pesticides, fertilisers and toxic substances by SEMARNAT in 2004

represented an important advance for the prevention of risks by pesticide use; however, there are still many deficiencies in the regulation of pesticides that need to be solved.

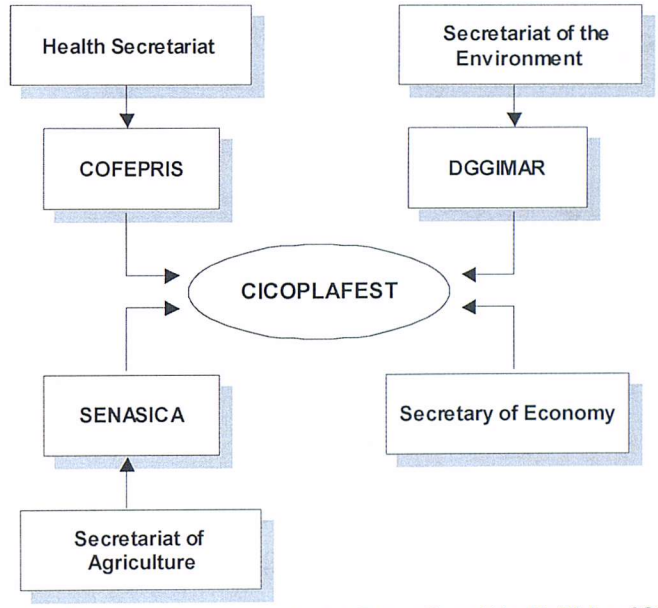
Table 2.6 Legal instruments developed for the regulation of pesticides

ACTIVITY	LAW					
	GENERAL HEALTH LAW	GENERAL LAW OF ECOLOGICAL BALANCE AND ENVIRONMENTAL PROTECTION	FEDERAL PLANT HEALTH LAW AND THE FEDERAL ANIMAL HEALTH LAW	FEDERAL LABOUR LAW	REGULATION FOR THE LAND TRANSPORT OF HAZARDOUS MATERIAL AND WASTES	EXTERIOR COMMERCE LAW
MANUFACTURE (INCLUDE PACKING, LABELING AND STORAGE)	Sanitary license, NOM-045-SSA1-1993 and NOM-046-SSA1-1993	License for working	Notification of beginning of activities (NOM-034-FITO-1995)	NOM-003-STPS-1999; NOM-005-STPS-1998; NOM-010-STPS-1999 and NOM-018-STPS-2000		
REGISTRATION	Registration of pesticides	Technical participation in the registration process.	NOM-032-FITO-1995			
TRANSPORT	Sanitary license			NOM-003-STPS-1999 and NOM-010-STPS-1999	NOM-002-SCT2-1994; NOM-021-SCT2-1994; NOM-003-SCT-2000; NOM-023-SCT2-1994; NOM-004-SCT-2000; NOM-024-SCT2-1994; NOM-005-SCT-2000; NOM-006-SCT2-2000; NOM-007-SCT2-1994; NOM-010-SCT2-1994; NOM-011-SCT2-1994; NOM-017-SCT2-1995; NOM-043-SCT2-1995; NOM-018-SCT2-1994; NOM-045-SCT2-1995; NOM-019-SCT2-2004; NOM-020-SCT2-1995 and NOM-043-SCT-2003.	
SALE	Notification of functioning		Notification of beginning of activities (NOM-033-FITO-1995)			
USE	Sanitary license and notification of functioning		Notification of beginning of activities (NOM-022-FITO-1995)	NOM-003-STPS-1999		
IMPORT AND EXPORT	Import and export authorization	Import and export authorization	Notification of beginning of activities (NOM-034-FITO-1995)			Provide technical opinions to CICOPLAFEST through an agreement
FINAL DISPOSAL						

2.2 Inter-Secretarial Commission for the Control of the Processing and Use of Pesticides, Fertilizers and Toxic Substances.

Due to the number of laws and Secretariats that regulate hazardous substances, an Inter-Secretarial Commission for the Control of the Processing and Use of Pesticides, Fertilizers and Toxic Substances (CICLOPLAFEST) was created in 1987 (DOF, 1987) made up of representatives from SSA, SEMARNAT, SAGARPA and SE (previously Commerce and Industrial Development)[44]. (Figure 2.2).

Figure 2.2 Secretariats involved in pesticide regulation.



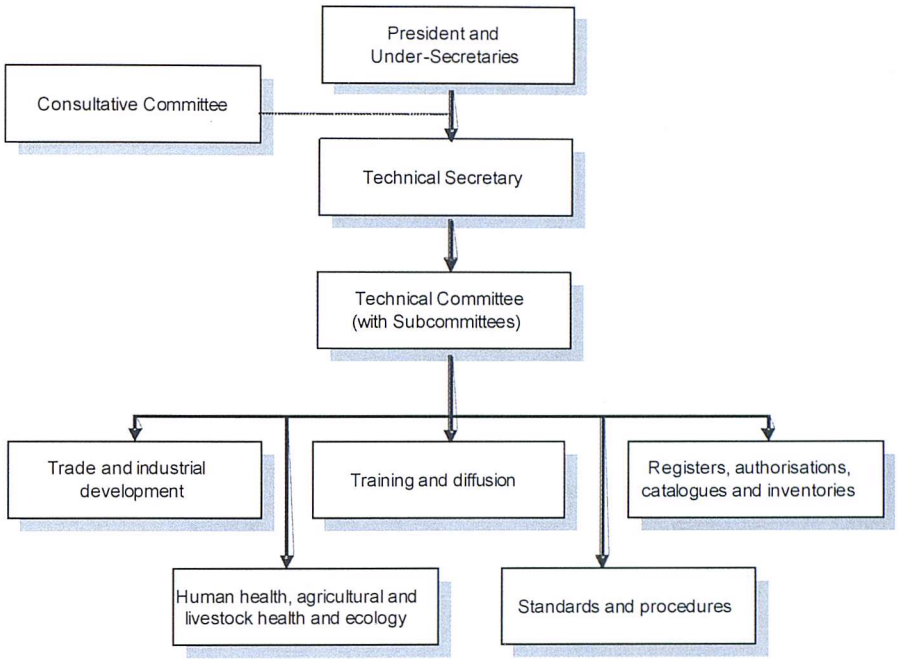
Note: COFEPRIS: Federal Commission for the Prevention of Health Risks of SSA; DGGIMAR: General Office for the Integrated Management of Hazardous Materials and Activities of SEMARNAT; SENASICA: National Service of Safety Food of SAGARPA.

The aim of the Commission is to coordinate the policy of regulation of pesticides, fertilisers and toxic substances defined among the Secretariats involved and to promote jointly research projects and training to users and general public, so overregulation and

[44] The Secretariats of Communications and Transport (Secretaría de Comunicaciones y Transportes (SCT)) and Labour (Secretaria del Trabajo y Prevision Social (STPS)) participate in some activities of the Commission as guests due to their influence in the regulation of hazardous substances.

contradictions could be avoided and a better use of the resources can be carried out. Its official organisation is presented in Figure 2.3.

Figure 2.3 Structure of the CICOPLAFEST.



Based on its Internal Regulation published in the Official Gazette (DOF, 1988).

According to the decree of creation (DOF, 1987), the President is the leader and representative of the Commission[45] and in co-ordination with the Under-secretaries must organise, co-ordinate, uphold and enforce the activities of the Commission. The Technical Secretary must provide administrative support to the President, Under-secretaries and Subcommittees. The Technical Committee must analyse the opinions of the subcommittees and carry out the relevant technical recommendations to the President and Under-secretaries.

The Subcommittees are in charge of the technical work by evaluating registration applications and providing import authorisations, defining operative process of regulation, technical standards and economic instruments to encourage industry participation and

[45] The Presidency must be taken in turns among the Under-secretaries.

training personnel, users and general public on the adequate management of pesticides, fertilisers and toxic substances.

The Consultative Committee must analyse the opinions from the industrial sector related to the regulation of PLAFEST, and streamline the communication process among the participating Secretaries. The different groups should have periodical meetings to discuss the issues of mutual concern organised and hold by each Secretary following a rotary programme. It is important to highlight that the Commission lacks legal power hence it is unable to legally enforce the compliance of its objectives and thus is dependent on the commitment and willingness of the Secretariats involved.

2.2.1 Performance of the Commission -achievements and deficiencies-

After fourteen years of functioning, the Commission published its first report of activities called Six Year Report 1995-2000 (CICOPLAFEST, 2001). According to this report, in this period its activities were mainly focused on the issue of registrations for pesticides and fertilisers and the authorisation for their import. The participation in international fora to define the involvement of Mexico in treaties, the updating of the classification and taxation of imported goods and the beginning of the discussions on the modernisation of the Commission were other activities attended by it. However, CICOPLAFEST recognised the minor advance achieved in the development of the regulatory framework and infrastructure, the limited activities in the enforcement and compliance of the regulations and its minimum advance in the compliance of its international commitments.

Before the publication of this report CICOPLAFEST was aware of the deficiencies of its organisation, since the frequency and participation of its members in the meetings were decreasing. At that point only the Technical Committee and the Subcommittees of Registers, Authorisations, Catalogues and Inventories and Training and Diffusion were working, even thought with some struggles, being the Technical Committee the main forum of discussion to

define the work of the Commission. So, the lack of leadership by the President and Under-Secretaries, a Technical Secretary and a Consultative Committee, undermined the formality and plurality of the Commission.

In 1998, as a first initiative to reform the Commission, the SSA requested a private consultancy called Quantica C.V. to carry out a diagnostic of the situation of the Commission and propose alternatives to improve it. According to a personal communication with officials of the SSA as this study was not published, Quantica identified organisational problems with inadequate mechanisms to make decisions and the lack of a leader responsible of the performance of the Commission and suggested the disintegration of the CICOPLAFEST and the creation of an independent organisation with enough legal power and independence. However, after some discussions among the members there was not any concrete action to solve the problem.

There were two other studies that analysed the performance of the Commission. One was carried out by the COFEMER in 2000, which was already mentioned in the section of Legal Framework, who qualified the regulation proposed by CICOPLAFEST as an inefficient and ineffective regulation on paper. The second study was done by an academic institute called Instituto Nacional de Administracion Publica (National Institute of Public Management; INAP) in 2002 (INAP, 2002) whose main finding agreed with the unsatisfactory performance of the CICOPLAFEST due to the lack of congruency and harmony in its policies and the lack of a work plan, mission, vision, strategic objectives and continuity in its activities. It defined its organisation as virtual since its personnel were commissioned with sporadic participations.

In order to evaluate the current performance of the CICOPLAFEST after these studies, in the following sections the main activities of the Commission are described along with their achievements and limitations so far.

2.2.1.1 Registration process

The first integral procedure to register pesticides, fertilisers and toxic substances was enacted in 1988 (CICOPLAFEST, 1988) in order to authorise their use, sale and import in the country. The procedure was jointly defined by the CICOPLAFEST in which administrative data, the efficacy and the possible adverse effects of the use of pesticides are evaluated in order to assurance that pesticides, fertilisers and substances registered do not represent an unacceptable risk for the population[46]. This instrument helped to harmonise the procedure of registration as Secretariats used to issue the registrations independently. However, this procedure became outdated by the creation of the Federal Animal and Plant Health Laws (LFSV and LFSA, as appropriate) in 1993, and the subsequent amendments carried out to the General Law of Ecological Balance and Environmental Protection (LGEEPA) and the General Health Law (LGS), and to the creation of new regulatory instruments such as the Sanitary License by the SSA. Additionally, the type and number of studies required in this procedure were considered obsolete taking into account the advance in methodologies and techniques to identify more accurately risks by pesticide use and assure higher protection to the population and the environment.

In response to this situation CICOPLAFEST was eventually modifying the procedure including more specific requirements and scientific studies, making reference to the new regulatory instruments and alternative routes to issue the registrations[47]. Following this

[46] The official procedure establishes two different types of requirements depending on if or not pesticide has been included previously in a Catalogue Official. If a pesticide has been included, the requirements are basically focused on administrative information, such as: form of registration, updated certificate of use in the origin country, letter from the provider, label draft, description of bottle or pack and a fee for the registration. There is a point of confusion in this part because when PLAFEST are registered by the first time they are included in the Official Catalogue, so, it is feasible that these requirements makes reference to changes in the register previously conceded, for instance, to change the commercial name of product or name of the owner or to introduce new uses for the pesticide, since these kind of modifications are not foreseen in the process. If a pesticide is not included in the catalogue the data requirements are centred on the same administrative information and additional technical information. The type of technical information depends on if the products are formulated product (pesticides) or active ingredients. In general, the information requested is focused on: physic-chemical properties, toxicological and environmental studies (including the behaviour of residual pesticides in the environment) and security measures by the use of these products. According to this Regulation the applications of agricultural and forest pesticides and fertilizers must be received by the Agriculture Secretariat and the rest by the Health Secretariat. The Subcommittee of Registers, Authorisations, Catalogues and Inventories must check the applications and attached information and give its opinion after 15 days of receiving the requests, the total time of answer is of 30 days. The register is provided indefinitely, that is, it has a undefined validity.

[47] The modified procedure centred the data requirements on the active ingredient and established some variations if the active ingredient corresponds to a formulated or technical pesticide a new route to issue applications that only implied administrative changes. The proposal of a Maximum Residue Limit of agricultural pesticides and other variations depending on the use of the pesticides were also included, although the time of response from the authorities was excluded. The data requested in this version shows more similarity with those requested by the European Community or those recommended to the members of the Organisation for Economic Cooperation and

scheme CICOPLAFEST is reported to have issued, in the period of 1995 to 2001, 480 registrations of formulated products and 100 registrations of active ingredients on average every year (Figure 2.4a). 75% of the active ingredients and formulated products registered were agricultural pesticides (Figure 2.4b) and according to the type of pest that they control, 44% were insecticides, 18% were herbicides and fungicides and 12% were mixtures (Figure 2.4c).

However, this modified procedure lacked legal support since its publication was not official being only presented in the website of SSA, which generated multiple complains from the pesticide industry and inclusive some companies took legal action against SSA for requiring information without legal foundations.

Additionally, COFEMER warned the confusion that existed among the Secretariats to provide the registration of pesticides since all Secretariats were providing technical opinions without having legal power to do it (COFEMER, 2000). It was mentioned that SAGARPA can provide a technical opinion on the biological effectiveness of the pesticides and SEMARNAT could have a great incidence in the decision; but it has not defined the legal instrument to exert its power.

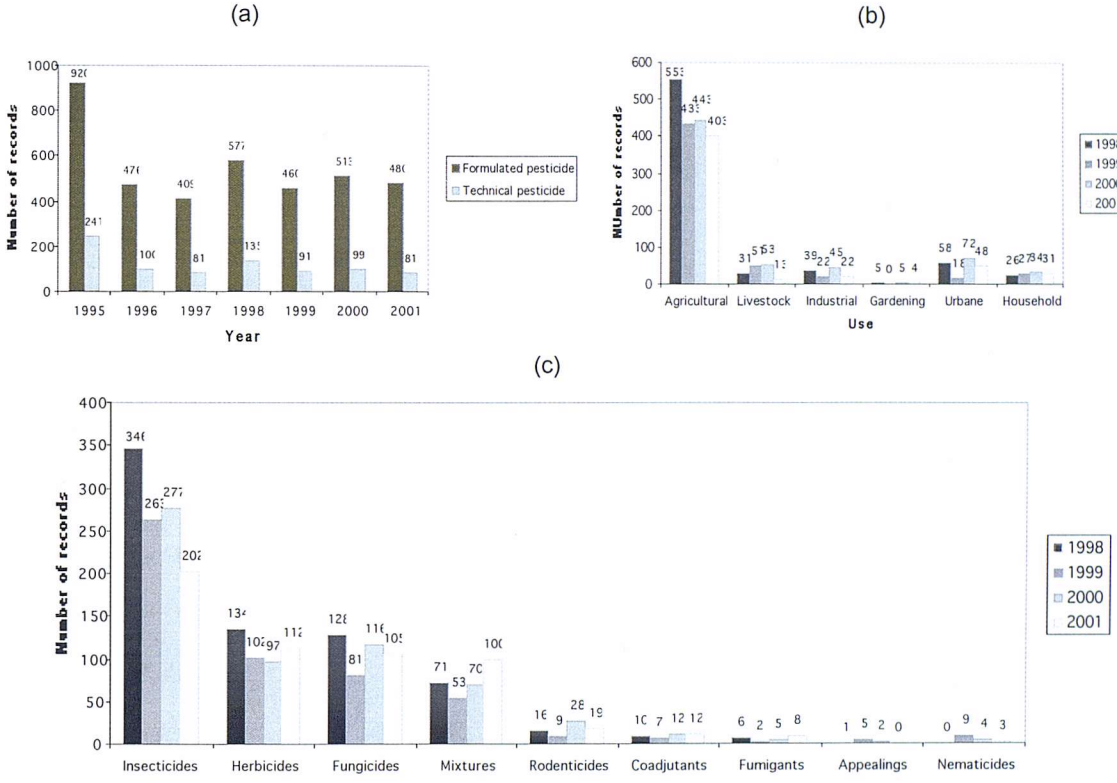
It was not until 2004 that a new procedure was officially enacted to issue registrations, authorisations of import and export and certification of export for pesticides, fertilisers and hazardous substances, which required the active participation of COFEMER as a coordinator body since the Secretariats could not reach an agreement on its content easily after almost five years of discussions. This new procedure distinguishes two tiers to process the applications: the administrative and the technical level, which facilitates the procedure to manage and issue applications[48]. The data requirements were established taking into

Development (OECD). Nevertheless, the procedure offers scarce information to the users, since it did not specify the methodologies that must be used to carry out the studies required, and the standards that must be achieved, as well as, the specific format of data to be submitted.

[48] The administrative level processes the applications that do not require technical revision (e.g. change of owner, address or name of the enterprise) and the technical level evaluates the applications for the registration of new

account the type of pesticide (e.g. chemical, biopesticide) promoting the use of less toxic products by stricter studies for more hazardous pesticides, which is also supported by the fees of registration as they are established according to the toxicity of the products being higher for extremely toxic pesticides[49].

Figure 2.4 (a) Registers of active ingredients and formulated products (pesticides) between 1995 and 2001. (b) Type of pesticides registered according to its use. (c) Pesticides registered according to their function. Source: COFEPRIS (2001).



In order to avoid the confusion presented in the previous procedure among the Secretariats to provide the registrations, this regulation clearly establishes that SSA has the exclusive power to register pesticides limiting to SAGARPA and SEMARNAT to provide a technical opinion on the biological effectiveness and environmental impact respectively, and the

substances, new products or changes to existing products. Additionally, the rules establish that the required studies must follow a recognised international methodology such as those established by CODEX or the OECD.

[49] There are some disagreements between members of the CICOPLAFEST with regard to fees based on the toxicity of the pesticides, since they only consider the effects to human health without taking in account the environmental effects of pesticides.

shared responsibility to authorise pesticide import between SSA and SEMARNAT through two different instruments.

This registration procedure relies heavily on experience from other countries to support the decision whether or not to register a pesticide in Mexico. The certificate of use in the original country as a compulsory requirement to apply for a registration; the use of international methodologies to carry out the scientific studies; the acceptation of Maximum Residue Levels (MRLs) considering the information provided by the CODEX Alimentarius and the Environmental Protection Agency of the US (USEPA)[50], which helps to eliminate trade irritants, are examples of this reliance.

Additionally, considering the global process of harmonisation on data requirement and criteria of evaluation, Mexico accepts registration applications carried out following the formats and methodologies proposed by the OECD and also applications prepared for the USEPA.

Without doubt this procedure represents a relevant advance in the regulation of pesticides recognising its effectiveness as a mechanism that enables the authorities to exercise control over quality, use levels, claims, labelling, packaging and advertising and thus to ensure that the these do not represent an unacceptable risk for the population. However, there are still weak points that limit its effectiveness and hence diminish its preventive effects. Firstly, there is very limited information, material and training to the pesticide industry on data requirement that support and improve the quality of the information that they provide and hence help to

[50] The proposal of a MRL is a compulsory requirement in the new regulation. So, the pesticide industry suggests a MRL for the combination crop/pesticide that it wishes to register, in general, the industry proposes a MRL already established by the Codex Alimentarius or by the USEPA. COFEPRIS does a dietetic analysis based on information from FAO/WHO Codex Alimentarius Commission for Latin America and if the theoretical value obtained from using the MRL proposed is less or equal to the Acceptable Daily Intake (ADI) COFEPRIS accepts the MRL and publishes it in the Official Catalogue for Pesticides. According to an official of COFEPRIS very rarely a MRL proposed overcome the ADI, and if it is the case COFEPRIS does a more sophisticated study. The use of Codex MRL and EPA tolerances presents great advantages as they are based on toxicological assessments of the pesticide and its residue, and the review of data are obtained from supervised trials and supervised uses including those reflecting national good agricultural practices. There is not an official and technical standard that guide and specify the establishment of a MRL as the official standard (NOM-050-FITO-1995) created by the SAGARPA was cancelled in 2004 in order to concede all the powers to the SSA; however at present SSA has not published any official information on the subject.

ensure its reliability. The procedure states that the scientific studies must be carry out following a recognised international methodology; however, there are no laboratories certified to elaborate such studies, so they have to be carry out in other countries.

The procedure does not include adaptations or inclusions to these methodologies in order to protect vulnerable groups in the country or for endemic or in danger species. This is, in part, a consequence of the limited communication between government and the scientific sector which has hold back the definition of limits of pesticide exposure to users and general public in order to protect their health.

The lack of a scientific advisory committee in the evaluation of the applications is another limitation of the procedure as evaluators lack advice to identify pesticides that could represent higher risks for their use in the country or to support their decisions with sound scientific information.

Finally, as COFEMER mentioned there is not a verification process that permits the authorities to ensure that: 1) pesticides that are being sold in the country have been registered; 2) registered pesticides fulfil with the requirements authorised at the moment of the registration, and 3) pesticides are being used according to the recommendations of the manufacturers. So, a post-registration verification is still missing.

2.2.1.2 Authorisation for import of pesticides

The first agreement that establishes the classification and codification of goods whose importation is subject to regulation on the part of the Secretariats that comprise the CICOPLAFEST was published in 1996[51], followed by the enactment of the procedure to obtain such import authorisation in the same year (DOF, 1996). Similar to the process of registration, the need to modify the procedure to adjust it to the new regulations and to

[51] This agreement has been amended in 1998, 2000, 2001, 2002 and 2005, in order to introduce the new international harmonised nomenclature of goods for import and export and update the tariffs (DOF, 2005).

obtain more precise data in the submissions drove the CICOPLAFEST to carry out modifications. However, the lack of leadership and formality in their activities meant that such reforms were made without an official publication hence CICOPLAFEST fell in an illegality of functions, which was exacerbated by the misunderstanding of the Secretariats to participate in the process of authorisation without having legal power to do it. The problem was solved with the publication of the regulation on the registrations, authorisations for import and export and certification of export for pesticides, fertilisers and hazardous substances and materials published by the SEMARNAT in 2004.

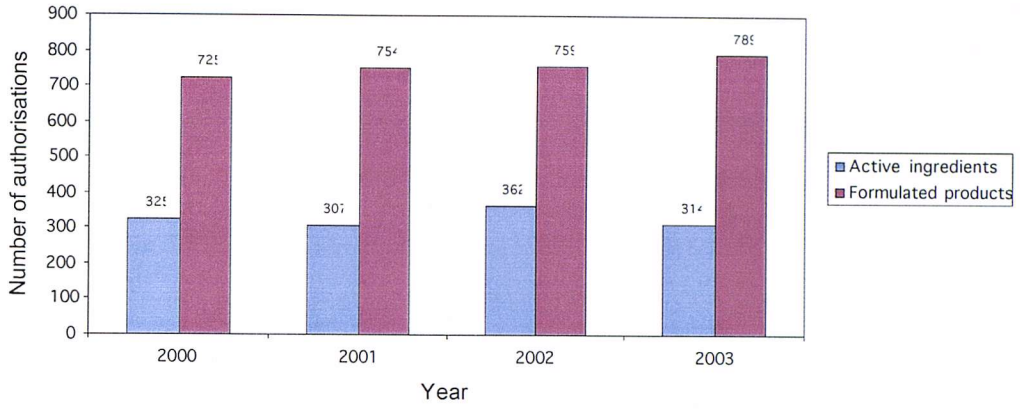
The new procedure reinvokes the legal exclusivity of SEMARNAT and SSA to provide import authorisations stating the need to request one first authorisation to SSA followed by another request of authorisation to the SEMARNAT linking the two procedures in a way that it is not possible to obtain the authorisation of SEMARNAT without having the authorisation by SSA[52] (Rocha, 2005 Pers. Commun.). COFEMER supports the elaboration of this process mentioning that because the urgent need to solve the illegal activities of the CICOPLAFEST was not possible to unify the import authorisation process as it implies deep legal changes in the health and environmental laws which is highly time consuming.

According to Cortinas (2000), approximately 70% of the total of applications received by CICOPLAFEST is related to import authorisations, which is understandable considering that only 7% of the agrochemical companies established in Mexico manufacture pesticides, hence active ingredients and formulated products are mainly imported.

Over the period 2000-2003, CICOPLAFEST conducted, on average, 327 authorisations to import active ingredients and 757 authorisations for formulated products per year (Figure 2.5).

[52] The information required by SSA is the number of sanitary license of the industry, number of registration of the pesticide, the form of authorisation of import and the payment of a fee. More specific information is required for the import of experimental samples of pesticides for research purposes; for those pesticides regulated by the Vienna Convention; for an authorisation of temporal import of products that after a industrial transformation will be exported, and for permits of authorisation requested by agricultural associations. For its part, SEMARNAT requests a copy of the permit of authorisation provided by SSA, an insurance policy, a fee payment and a programme that presents the safety measures to follow in case that a emergent situation be presented.

Figure 2.5 Authorisations of import of active ingredients and formulated products conducted by CICOPLAFEST between 2000 and 2003. Source: SAGARPA (2004b).



The volumes of authorised imports of active ingredients and formulated products over the same period are showed in Figure 2.6. In spite of the fact that the companies import less volume of pesticides than the quantities authorised, the data presented in the figure provide a close approximation of the final imported volumes. The trend of active ingredient import seems to be flat, maybe due to the limited data, and for formulated products the import seems to show a modest rise. As can be seen in the figure, formulated products are mainly imported into the country.

Figure 2.6 Import of pesticides and active ingredients between 2000 and 2003. Source: SAGARPA (2004b).

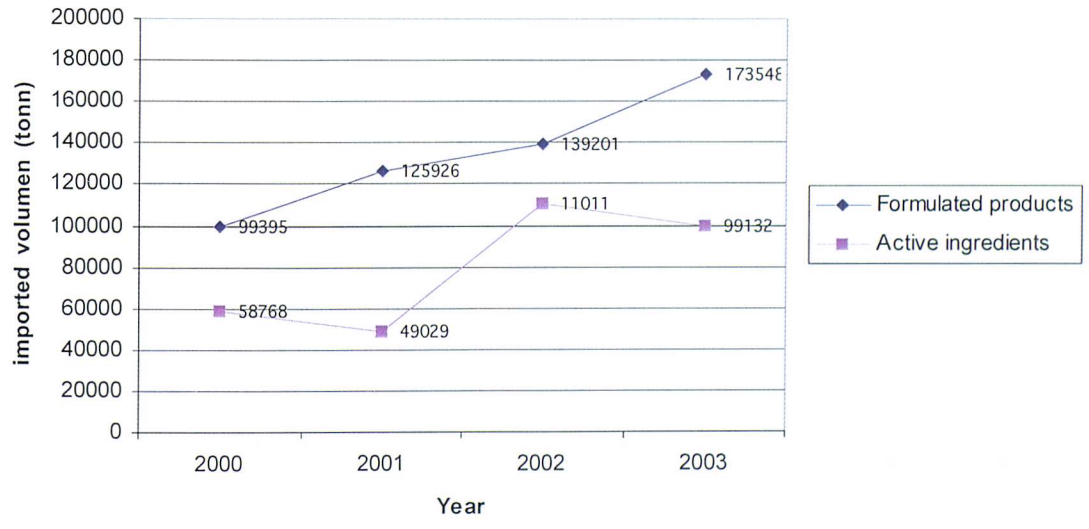


Table 2.7 shows the main active ingredients imported, which constitute about 70% of the total volume of imports. According to the toxicological classification of pesticides of the World Health Organisation Atrazine, Chlorothalonil, Diuron, Glyphosate are unlike to present damage; Ametryne and Chlorpyrifos-ethyl are slightly hazardous; 2-4 D, Endosulfan and Paraquat are moderately hazardous and Carbofuran is highly hazardous. Methyl bromide and Chloropicrin are between extremely and moderately hazardous[53]. 2,4-D, Ametryne, Atrazine, Diuron, Glyphosate and Paraquat are herbicides; Endosulfan, Chlorpyrifos-ethyl and Carbofuran are insecticides; Methyl bromide and Chlorpicrin are fumigants, and Chlorothalonil is an insecticide. Their use is therefore mainly in agriculture.

Table 2.7 Main active ingredients imported between 2000 and 2003 (tonnes).

Active ingredient	Year			
	2000	2001	2002	2003
2,4-D	2311	2488	3188	2288
Ametryne	3110	2700	15076	6900
Atrazine	1500	2750	2630	1640
Methyl bromide	12138	1800	2000	164
Carbofuran	1325	1435	2110	1375
Chloropicrin	2000	2000	2000	2000
Chlorothalonil	2775	1112	3172	1808
Chlorpyrifos-ethyl	4614	1704	4860	4280
Diuron	1208	772	1110	3630
Endosulfan	2333	2063	1842	2302
Glyphosate	2302	2610	6155	8684
Paraquat	5264	7209	47371	45953

The main formulated products imported between 2000 and 2003 are shown in Table 2.8. These products represent about 65% of the total formulated products imported. The active ingredients aforementioned are also imported as formulated products, though Cymoxanil (bactericide), Mancozeb (fungicide), Terbufos (insecticide) and Metham sodium (fumigant) are mainly imported as formulated product[54].

[53] Methyl bromide and Chlorpicrin are fumigants, which produce vapours (gases) that are toxic when absorbed or inhaled. Therefore, the evaluation of acute inhalation is the main criterion to determine their hazard (the classification of the WHO is therefore not suitable for these compounds since its main criteria are dermal and oral exposure). For Chlorpicrin two acute inhalation studies in rats indicated LC50 values of 0.178 and 11.9 mg/L. For Methyl Bromide studies on rats indicated a LC50 (15 minutes) of 21 000 mg/m3.

[54] It is important to highlight that the level of hazard of formulated products depends on their formulation, hence it is not possible to classify them.

Table 2.9 presents the main countries exporting active ingredients to Mexico between 2000 and 2003. The United States of America (USA) is the main exporter with 33% of the total volume and it is followed by Israel, 12%; United Kingdom, 10%; Guatemala, 9%; Panama and Brazil, 7%, and Switzerland 5%.

Table 2.8 Main formulated products imported between 2000 and 2003 (tonnes).

Pesticide	Year			
	2000	2001	2002	2003
2,4-D	2702	2925	3108	1590
Atrazine	4698	6020	16554	9490
Methyl bromure	9564	8200	10363	13163
Carbofuran	880	4138	4113	7791
Chlorothalonil	9168	3807	6251	17051
Chlorpyrifos-ethyl	1213	2115	1863	2043
Cymoxanil and Mancozeb	1579	1658	1579	1579
Diuron	2416	4104	3342	3150
Glyphosate	6407	7841	5762	18286
Paraquat	4404	1936	11394	12690
Mancozeb	12936	24752	17541	18055
Metham sodium	1460	3559	6062	8183
Terbufos	8100	3900	2100	2100

With respect to formulated products the USA is also the main exporter, with 41% of the total volume, followed by Colombia, 9%; Israel, 8%; Guatemala, 6%, and Brazil, 5% (Table 2.10).

Table 2.9 Main exporting countries as sources of active ingredients in Mexico between 2000 and 2003 (tonnes).

Country	Year			
	2000	2001	2002	2003
The United States of America	23484	15455	33097	29368
United Kingdom	4349	2696	14556	15074
Guatemala	2669	2606	13268	13524
Brazil	1257	1805	11392	11362
Israel	8179	7019	11829	7446
India	4346	5369	4957	4798
Switzerland	2833	3618	6342	2934

In contrast to industrialised countries whose pesticide market has decreased in recent years, the Latin America market still shows considerable growth and Mexico is an example of this

trend considering the upward trend in its imports. According to Tansey et al. (1995) Mexico was place as the second largest pesticide importer in Latin America. As in other Latin American countries, the US is the main source, highlighting the similarity of products used in the US and Mexico. Among the main imported formulated products 8 were also used by the US in 2001 (Donaldson et al, 2004).

Table 2.10 Main exporting countries as sources of formulated products in Mexico between 2000 and 2003 (tonnes).

Country	Year			
	2000	2001	2002	2003
The United States of America	34821	54864	62230	71733
Colombia	7039	15578	11294	17777
Israel	7490	9385	11869	12738
Guatemala	8934	5263	7611	12581
Brazil	5146	4881	4751	10010
Panama	4259	1840	4563	9532
England	3553	3274	5368	6152
South Africa	2565	3923	2075	2055
France	2943	4938	5440	4935
Switzerland	1915	2340	6604	4078

2.2.1.3 International participation

Due to the process of globalisation, international agreements have become an important tool to manage related issues among countries. Pesticides have been an issue subject to these agreements, principally for two reasons: to protect human health and the environment from their negative effects, and to improve the efficiency of their trade and goods in which pesticides are used. So, CICOPLAFEST has constituted the discussion forum to define the participation of Mexico in these agreements, which are described in the next subsections along with their current status and achievements so far.

- Basel Convention

The Basel Convention set up a framework for controlling the movement of hazardous wastes across international frontiers, along with the development of criteria for their environmentally

sound management. Hence a control system, based on prior written notification, was also put into place. As a work plan for the decade 2000-2010, the Convention will centre its efforts in the full implementation and enforcement of treaty commitments and the minimisation of hazardous waste generation.

The Convention was adopted in 1989 by the Conference of Plenipotentiaries. Mexico signed it in 1989 and ratified it in 1991.

- Convention of Rotterdam

In order to promote shared responsibility and cooperative efforts in the international trade of certain hazardous chemicals and contribute to their environmentally use, governments of 73 countries adopted the Convention of Rotterdam in 1998 and until September of 2006 110 have ratified it, accepted it or accessed it (UNEP/FAO, 1998)[55].

The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure[56], hence the export of a chemical covered by the Convention can only take place with the prior informed consent of the importing Party. At present, Annex III of the text of the Convention lists a total of 39 chemicals among these 24 are pesticides[57], 11 industrial chemicals[58] and 4 severely hazardous pesticide formulations[59] (UNEP/FAO, 1998). The Convention entered into force in 2004.

[55] The Convention provides Parties with information and tools to support decisions on importing hazardous chemicals. If a country agrees to import chemicals, the Convention promotes their safe use through labelling standards, technical assistance, and other forms of support.
[56] The Prior Informed Consent (PIC) procedure was built on the existing voluntary PIC procedure, operated by UNEP and FAO since 1989 and takes into account experience gained during the implementation of the voluntary procedure (as set out in the London Guidelines for the Exchange of Information on Chemicals in International Trade and the FAO International Code of Conduct on the Distribution and Use of Pesticides).
[57] These pesticides are 2,4,5-T; Binapacryl; Chlordane; Chlordimeform; Chlorobenzilate; DDT; 1,2-dibromoethane (EDB); Ethylene dichloride; Ethylene oxide; HCH (mixed isomers); Heptachlor; Lindane; Toxaphene; Aldrin; Captafol; Dieldrin; Dinoseb and Dinoseb salts; Fluoroacetamide; Hexachlorobenzene; Monocrotophos; Parathion; Pentachlorophenol; Methamidophos; Phosphamidon and Methyl-parathion. The last 12 pesticides are considered to be highly and extremely hazardous.
[58] These chemicals are Crocidolite; Actinolite; Anthophyllite; Amosite; Tremolite; Polybrominated biphenyls (PBB); Polychlorinated biphenyls (PCB); Polychlorinated terphenyls (PCT); Tetraethyl lead; Tetramethyl lead and Tris (2,3-dibromopropyl) phosphate.
[59] Dinitro-ortho-cresol (DNOC); Mercury compounds; dustable powder formulations containing a combination of benomyl, carbofuran and thiram and Phosphamidon.

A member of the CICOPLAFEST participated in the Inter-governmental Negotiating Committee for the definition of the text of the Convention. However, Mexico did not sign the agreement in 1998, since the Economic Secretariat (SE) rejected adoption because, in its opinion, Art. XI of the text of the Convention, which establishes some restrictions on export to importing countries, violates Art. XX of the General Agreements on Tariffs and Trade (GATT), which establishes general exemptions to restrict the trade of goods (Lopez Olvera, 2003 Pers. Commun.). However, SSA, SEMARNAT, and SAGARPA reconsidered the discussion for the adherence in 2001 with the result that SE changed its position and finally agreed to the accession, arguing that the restrictions to the export of hazardous chemicals established by the PIC had a minimal impact on Mexican trade, since Mexico does not trade in the chemicals covered by the Convention or their trade had been previously restricted in the country. So, Mexico joined the Convention in May 2005.

Currently, according to the Pesticide Catalogue (SSA, 2005), the use of five pesticides regulated by the Convention has been prohibited by CICOPLAFEST (2,4,5-T; Aldrin; Dieldrin; Dinoseb and Acetate of phenyl mercury) and three have restricted use (DDT, Lindane and Pentachlorophenol); however, Captafol, Monocrotophos, Methamidophos and Methyl-Parathion, also regulated by the Convention, with the last three considered as severely hazardous, are commonly used in Mexico, while the rest are not traded in Mexico

So, Mexico now needs to update its regulations to include the responsibilities specified in this Convention to authorise the import and export of these substances and establish an efficient mechanisms of compliance and enforcement to avoid their illegal trade.

- Montreal Protocol

The Montreal Protocol on substances that deplete the ozone layer is an international agreement designed to protect the stratospheric ozone layer[60] (UNEP, 2004). The Montreal Protocol stipulates that the production and consumption of compounds that deplete ozone in the stratosphere such as chlorofluorocarbons (CFCs), halons, methyl bromide, carbon tetrachloride, and methyl chloroform are to be phased out. The Protocol was adopted in 1987 and came into force in 1989; Mexico adopted it and ratified it in 1988.

As part of the commitments acquired by Mexico, it must reduce the consumption of methyl bromide[61] and eventually eliminate its use. Specifically, the commitment was not to exceed the mean level of use between 1996 and 1998 in 2002, and reduce by 20% its use in 2005 and by 2015 eliminate its use (SEMARNAT, 2002).

In Mexico, there is no production or export of methyl bromide, so it is therefore imported. Basically, the level of consumption is equal to the imported amounts less the amounts used for quarantine and pre-shipment, which, according to the Protocol, are not significant. Mexico began to report the levels of consumption in 1991, which is a compulsory activity for the Parties. Figure 2.7 shows the amounts of methyl bromide imported and used between 1991 and 2002.

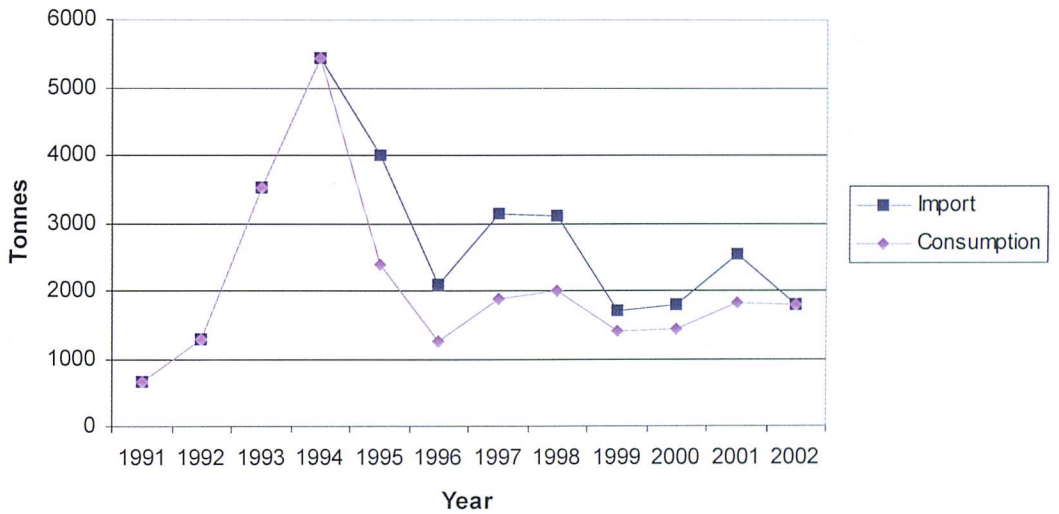
In general, both the import and consumption of methyl bromide show an upward trend between 1991 and 1994, rising to a peak in 1994 with a consumption and import of 5,421 tonnes. From this point until 1996 there was a sharp decrease from 5,421 tonnes to 2,084 for import and to 1,250 tonnes for consumption. After this point imports have fluctuated with a slight downward trend and consumption has varied only slightly. In fact, the mean level of consumption between 1996 and 1998, which is 1713.5 tonnes/year was exceeded only by 3.8% in 2002; however, according to the Protocol, Mexico may exceed the limit by up to ten

[60] Intergovernmental actions for an international agreement to phase out ozone depleting substances started in 1985 with the adoption of the Vienna Convention for the Protection of the Ozone Layer. The Vienna Convention encourages intergovernmental cooperation on research, systematic observation of the ozone layer, monitoring of CFC production, and the exchange of information. Afterwards, the Montreal Protocol was adopted in 1987 and came into force on 1989. The Protocol has been amended in 1990, 1992, 1997 and 1999 (UNEP, 2004).
[61] Methyl bromide is a fumigant used widely in agriculture.

per cent of its calculated level of consumption in order to satisfy its basic domestic needs. At present, this first achievement has not been reported officially

SEMARNAT, which is the Secretariat in charge of the implementation of the Protocol in the country, has designed courses and training to farmers to have a more efficient use of this pesticide (Sanchez, 2004 Pers. Commun). However, according to Gonzalez (Pers. Commun. 2004) the primary reason for the decrease in the import and consumption of Methyl bromide is because of its high price and the awareness of the farmers about its future prohibition of use.

Figure 2.7 Consumption and import of methyl bromide between 1991 and 2002.
Source: SEMARNAT, 2002.



In general, Mexico has had an exemplary performance as a Party of the Protocol, achieving the levels of reduction of production and use of the substances regulated in early stages[62]. In fact, in the 21st Open-Ended Working Group Meeting of the Protocol carried out in 2001, Mexico presented its disapproval because its projects received discriminatory treatment,

[62] Mexico has had important achievements in the reduction of CFC, their use decreased in 80% in 2000; while the use of halon 1301 and Carbon Tetrachloride was completely eliminated. SEMARNAT is the Secretariat responsible of the implementation of the Protocol in the country.

since the Council of the Convention considers Mexico as a non-priority country due to the early achievement of its commitments.

In 2004, Mexico achieved a consensus among the Secretariats involved and the Legislative Congress to ratify an amendment of this Protocol called Amendment of Montreal.

- Stockholm Convention

The Stockholm Convention is a global treaty to protect human health and the environment from persistent organic pollutants (POPs) (UNEP, 2001)[63, 64]. In implementing the Convention, Governments take measures to eliminate or reduce the release of POPs into the environment, beginning with a list of 12 POPs, which includes nine highly dangerous pesticides (DDT, Aldrin, Dieldrin, Endrin, Chlordane, Heptachlor, Hexachlorobenzene, Mirex and Toxaphene), Polychlorinated biphenyls and Dioxins and Furans.

Through a consensus reached by the Secretariats that comprise the CICOPLAFEST and the Secretariat of Public Credit (SHCP), Mexico signed and adopted the text of the Convention in 2001 and ratified it in 2003. This agreement was included in the Mexican legislation as a legal binding instrument.

The Convention was adopted in 2001 and came into force in May 2004 and in accordance with its Art. 7, Mexico, like all country Parties, must develop a national plan for the implementation of its obligations and transmit the implementation plan to the Conference of the Parties within two years. At present, Secretariats involved in the CICOPLAFEST, non-governmental organisations (NGOs) and industry are participating in the elaboration of the plan, which, due to the use of the pesticides included in the Convention being already

[63] The Stockholm Convention derived from the United Nations Environment Programme (UNEP) negotiations that began in Montreal in 1998 to discuss about an international agreement to minimize emissions and releases of persistent organic pollutants. However, UNEP's Governing Council called for an international assessment of 12 POPs recognised as priorities (Decision 18/32) since 1995.
[64] POPs are chemical that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of living organisms and are toxic to humans and wildlife.

forbidden, restricted or not authorised to be used in the country[65], should include a mechanism to enforce the compliance of the regulations in order to avoid any illegal production, import or use of these products, define a programme for the elimination of stocks still present in the country such as DDT, and establish an environmental monitoring to identify areas contaminated by these products (Gomez, 2004 Pers. Commun.).

Part of the advance in the control of these substances derived from the participation of Mexico in the North America Regional Action Plans of the Commission for Environmental Cooperation (CEC)[66] of the NAFTA, which, based on the list of 12 substances proposed by UNEP, addressed the reduction and elimination of use of DDT, Chlordane and Mercury.

In the 1980's CICOPLAFEST had restricted the use of DDT in the agriculture and its use was only authorised for control of disease vectors. Nevertheless, in the 1990s the application of DDT in residential areas decreased from 1,264 tonnes used in 1991 to 477 tonnes applied in 1997 (Figure 2.8) due to the alternative use of other pesticides called pyrethroids, which are less toxic and not persistent. In 1997, Mexico started its participation in the Regional Action Plan for DDT and compromised in a decision to eliminate its use in 2002. This goal was achieved two years earlier than planned (CEC, 2003)[67].

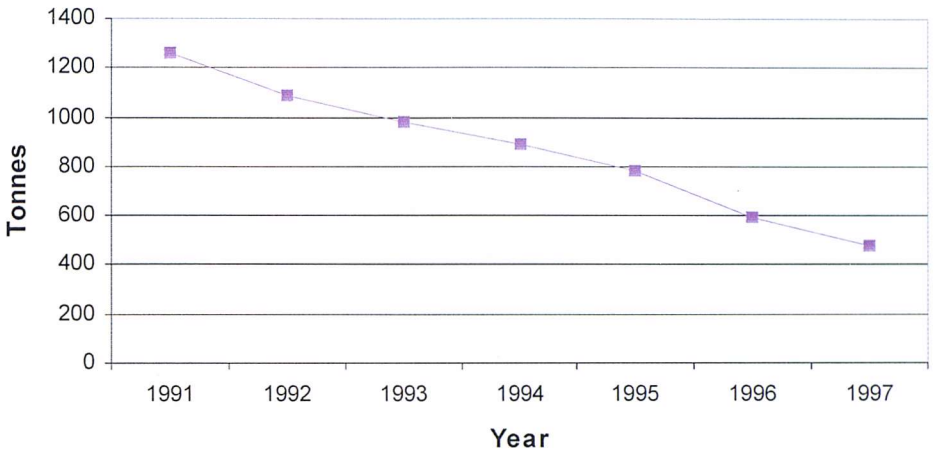
With regard to Chlordane, CICOPLAFEST restricted its use in 1988. From 1992 until 1996 the only authorised use was in "urban use" for the control of termites in installations, structures, and wood construction. From 1990 to 1996, a total of 212.8 tonnes of technical product were imported from the US (CEC, 1997); however, in 1997 Mexico prohibited its import and in 1998 stopped its use through the prohibition of its registration and the use of alternative chemicals (Moody, 2003).

[65] The use, import, manufacture and sale of Aldrin, Dieldrin, Endrin, Chlordane and Mirex is forbidden in the country; the use of DDT is restricted and the use, sale, manufacture and import of Heptachlor, Hexachlorobenzene and Toxaphene is not authorised.

[66] The Commission for Environmental Cooperation (CEC) was created to implement the environmental side agreement to NAFTA in 1994. CEC's working group on the Sound Management of Chemicals (SMOC) has taken action on a regional basis to reduce the use of and reliance on two pesticides: DDT and Chlordane. These were identified as priority persistent and toxic substances for joint attention due to their potential risks (EPA, 2001).

[67] The strategy of elimination consisted in the identification of the areas infected with malaria, the treatment to infected people with a unique dose of chloroquin, elimination of rearing of mosquitoes and the use of pyrethroids as a pesticide which is less toxic and non persistent (CEC, 2003).

Figure 2.8 Applications of DDT in residences to control disease vectors.
Source: SSA (2002b)



So, Mexico has had positive advances and experiences in the control of POPs, in fact, it took the lead among the countries of Latin America in the elimination of use of DDT. Thus, the development and the implementation of the national plan represent an advantageous opportunity to obtain economic resources and continue advancing in the control of these substances.

- NAFTA Technical Working Group on Pesticides

In the framework of the North American Free Trade Agreement (NAFTA) signed by the United States of America, Canada and Mexico in 1994[68], the NAFTA Technical Working Group (TWG) on Pesticides was created in 1996. The goal of the NAFTA TWG is to eliminate barriers to trade of pesticide by developing a coordinated pesticide regulatory system to address trade irritants, building national regulatory/scientific capacity, sharing the review burden, and coordinating scientific and regulatory decisions on pesticides (EPA, 2001). NAFTA TWG partners include the Canadian Pest Management Regulatory Agency (PMRA), CICOPLAFEST and the Office of Pesticide Programs (OPP) of the United States Environmental Protection Agency (USEPA).

[68] The North American Free Trade Agreement (NAFTA) was created for eliminating barriers to the trade in, and to facilitate the cross border movement of, goods and services between the three countries.

On a project-by-project basis NAFTA TWG addresses four subject areas: 1) Joint review of pesticides, 2) Food residues, 3) Risk reduction and 4) Regulatory capacity building.[69].

CICOPLAFEST has had a discretional participation in activities related to the process of harmonisation of data requirements for the registration of pesticides, establishment of MRLs[70] and toxicological evaluation of some new molecules in the area for joint review. At present, the Commission has not implemented any harmonised process in the national regulation and joint reviews and work sharing are only taking place on a routine basis between USEPA and PMRA.

The process of harmonisation between NAFTA Partners has showed great advances between Canada and the US[71], which is logical considering the existing similarities between their regulatory processes, infrastructure, economic and human resources and also the time that they have invested in harmonisation[72]. For its part, Mexico is trying to modify its legal framework by updating and strengthening its regulatory process of pesticides, however, it will take a long time to reach a harmonised process, since the differences in infrastructure, economic and human resources and the years of experience represent another difficult barrier to overcome.

[69] The conceptual framework for the work of NAFTA TWG is included in the document entitled The North American Initiative for Pesticides published in 1998 (NAFTA-TWG, 1998a).
[70] In Procedures for the Identification and Resolution of NAFTA Pesticide Trade Irritants (NAFTA-TWG, 1998b) and in the Guidance for the Establishment of Tolerances/MRLs for Imported Commodities. CICOPLAFEST also provided mapping information to complete the North American residue zone maps, which are based on scientifically defined common crop zones not affected by political borders. In 1997, a workshop was held in Mexico on the "Regulation of Agrochemical Products", which provided information about the procedures and requirements needed to establish pesticide MRLs/tolerances in food in the U.S., Canada and internationally (Codex Alimentarius). This workshop was a joint effort of the PMRA, EPA, CICOPLAFEST, the American Crop Protection Association (ACPA) and the Asociación Mexicana de la Industria Fitosanitaria (AMIFAC).
[71] Canada and the US have completed joint and work share reviews of numerous pesticides, guidance and protocols for submitting pesticide applications electronically and have begun to develop a joint Integrated Pest Management (IPM) strategy to priority crops such as canola and cranberry and a joint pesticide applicator core examination. Additionally, they are jointly working with the Organisation for Economic Cooperation and Development (OECD) in order to expand the process of harmonisation; in fact, they accept the common review format or monograph established by the OECD for the registration of pesticides.
[72] Canada and the US signed a trade agreement (CUSTA: Canada-United States Trade Agreement) in 1988, which directed the two countries to work toward equivalency of pesticide standards and regulatory processes.

In the framework of NAFTA-TWG, CICOPLAFEST has also participated in the Interregional Research Project Number 4 (IR-4), which is a government- and university-sponsored programme that develops the data necessary to support registration of pesticides for use on minor crops[73]. However, the performance of the Commission in IR-4 has also been limited due to the difficulties of reaching a consensus for the selection of joint projects, since the combinations of pesticide/crop proposed by Mexico have not been considered as a priority by the partners, as well as by the lack of economic resources to sponsor the projects.

As another complementary activity in NAFTA-TWG, Mexico and the United States have also implemented the U.S./Mexico Pesticide Information Exchange Program (USMPIE)[74], [75], which provided the technical basis and resources to establish a training program in Mexico on the safe and proper use of pesticides, reduction of human exposure to pesticides, and strengthen coverage of pesticide risk education efforts. The advances on this programme are discussed in the next subsection.

2.2.1.4 National Programme against Risks by Pesticide Use

Farm workers that migrate from Mexico to the US and seasonal workers who may live in these two countries at different times of the year constitute a high percentage of the agricultural labour force in both countries[76]. Recognising this trend and that those who work with or around pesticides such as farm owners/operators, pesticide handlers/applicators, farm workers and their families, represent the population at highest risk from pesticide

[73] Examples of minor use pesticide registrations include many pesticide uses on fruit and vegetable crops, and uses on commercially grown flowers, ornamentals, trees, and turf grass. IR-4 is beginning to play a major role in helping North American minor-use growers to access effective pest control tools (EPA, 2001). Mexico participated for the first time in the annual workshop organised by the U.S. Department of Agriculture Interregional 4 (IR-4) in 1998 and in the next year, it proposed a residue trials for one commodity, Imidacloprid/papaya with the US.

[74] The U.S./Mexico Pesticide Information Exchange Program (USMPIE) is funded by grants from the U.S. Environmental Protection Agency (U.S. EPA), Regions 6 and 9, and is administered by the Texas Department of Agriculture.

[75] Closer linkages have also been established with the Environmental Health Working Group (EHWG) which coordinates environmental health projects along the U.S.-Mexico border under the Border XXI program. The TWG Secretariat participated in the Annual Planning meeting of the EHWG (October 1999) to exchange information on regional pesticide activities. Lastly, Canada, Mexico and the U.S. continue to work together on specific pesticides of concern through the activities of the Commission for Environmental Cooperation (CEC).

[76] According to the data published by the US Department of Labour about 57% of the migrant farm workers in the US come from Mexico (NAFTA-TWG, 2002).

exposure, Mexico and the US aim to coordinate their regulatory and educational pesticide programmes. Mexico and the US started a project called *Pesticide Safety for Agricultural Workers* under the NAFTA-TWG in 2001. In order to cover the objectives of this project and also provide the basis for a national campaign that gives continuity to the activities initiated, Mexico created the "National Programme against Risks by Pesticide Use" in 2001[77].

The Programme is supported by a work group made up of the SSA, SEMARNAT, STPS, SAGARPA, the State Committee of Vegetal Health of Guanajuato (Comite Estatal de Sanidad Vegetal: CESAVEG) and the pesticide industry association called AMIFAC[78].The scope of this Programme is focused on the creation of networks of trainers specialised in the proper use and management of pesticides that reproduce the information to agricultural workers ("Train the trainer" course) [79,80,81] , and of doctors, technicians, health care assistants trained in the diagnostic, treatment and registration of poisonings by pesticides. It also includes the development of material such as booklets or guides that support the communication of risks. Table 2.11 presents the number of courses, workshops and talks imparted in different States of the country as well as the number of people trained between 2002 and July 2006.

It was mentioned in the Subchapter on the Legal Framework for Pesticides that SAGARPA is also offering courses to pesticide sellers focused on the safety management of pesticides

[77] Although this should not be formally called a National Programme because this has not been derived from the National Plan of Development, which is created at the beginning of each new government in order to establish the national programmes that will be implemented during the governmental six-year period.
[78] USEPA and the University of California at Davis participated initially by providing technical assistance and economic resources to the Programme; however they are no longer collaborators and the economic resources are provided by each Secretariat and organisation participating in the Programme.
[79] According to the Guide for trainers of agricultural workers developed by the work group, there are two levels of courses that can be imparted: 1 and 2. Level 1 consists in a talk addressed to agricultural workers and their families about general information of pesticides (common definitions, ways of exposure), symptoms of poisoning, first aids and how request medical assistance. Level 2 includes the information from the Level 1 and a description of the pesticide labels, proper management of pesticides, their environmental impact and final disposal of containers.
[80] So that the attendees of this course should train other people, a careful selection of the participants is demanded, which must meet the requirements established in the Programme. Additionally, a pre-evaluation and post-evaluation must be applied to them and their personal data will be included in a directory to make up the network of trainers (Enriquez, 1994 Pers. Commun.).
[81] Each trainer is supported with training material elaborated by the work group, which include a Folder for trainers and a flip chart for presentations on field. Another material that has been developed to support the Programme includes: 1) Booklets about What you should know about pesticides, Guide against the risks caused by the pesticide use, Protection against the risks caused by pesticide use and Safe management of pesticides; 2) Colouring book Basic guidelines for the safe use of pesticides; 3) Posters Steps to diminish heat effects on agricultural workers and NOM-003 (official standard published by the Labour Secretariat about proper use of agricultural pesticides).

and on their regulation, and courses addressed to commercial and agricultural pilots, as complementary part of this Programme[82].

So, the National Programme against Risks by Pesticide Use constitutes an essential non regulatory mechanism in the overall regulatory system to prevent risks by pesticide use in the country, hence its creation constitutes an important advance in the protection of the health of the population. Additionally, its establishment has provided an important forum for coordinating efforts among the Secretariats to provide educational and technical training on the adequate use and management of pesticides to people who work with or around pesticides.

However, some deficiencies are perceived in this programme. The lack of an official recognition and publication of this programme and a leader responsible for it, as well as the lack of clearly defined objectives and a work plan that appoints the strategies to achieve them in the middle- and long-term put at risk its effectiveness and continuity. In this respect, in spite of the fact that people have been trained and networks of trainers are being set up there is not an objective indicator that evaluates the effectiveness of the programme, correlating, for instance, the impact of the courses with the number of cases of poisoning reported in the country. It is also important to highlight that at the moment there is not an official publication of the objectives, activities and results of this programme, thus the results presented in this section were obtained from internal reports of the Secretariats.

The participation of Mexico in the main international agreements regulating hazardous substances and particularly pesticides, demonstrates the concern of the country to protect human health and the environment by their use, having a satisfactory advance in the control of use of methyl bromide, DDT and chlordane so far. However, now that PIC and POPs conventions came in force and the constant commitments emerging by the Basilea

[82] These courses called *Security in low and agricultural flights* (SEVRA, by its abbreviation in Spanish) are organised by the Direccion General de Aeronautica Civil (DGAC) (General Office of Civil Aeronautic) in order to provide a re-licensing to commercial and agricultural pilots.

Convention and NAFTA, an adequate coordination and optimisation of resources represent a challenge for the CICOPLAFEST, as these agreements manage dangerous pesticides in common (PIC regulates 7 pesticides included in the Stockholm Convention) and some of the agreements provide economic resources (such as Stockholm Convention). So, the Secretariats involved need to plan carefully their actions, trying to ensure that the various agreements complement each other, and for that, CICOPLAFEST needs to overcome the deficiencies in its organisation and provide adequate support for the establishment of an efficient mechanism of communication and exchange information process among them, so that policies, infrastructure and regulatory capacities can be defined and implemented jointly.

2.2.1.5 Other activities

As mentioned in the last subchapter on Legal Framework that the development of legal instruments and implementation of the regulations has been very limited even though the encouragement, coordination and strengthening of the regulatory framework for pesticides are some of the main tasks of the CICOPLAFEST and many Articles in the laws make reference to the creation or definition of criteria for the implementation of the statements through a regulation or official standards. After 19 years from the creation of the CICOPLAFEST, 28 official standards have been published on pesticides, which do not include mechanisms of coordination among the Secretariats. 64% of them were elaborated by the SCT and therefore related to transportation of hazardous substances. The most relevant regulatory instrument created in the framework of the Commission was the Regulation on registrations, authorisations for import and export and certification of export for pesticides, fertilisers and hazardous substances and materials, whose development has to be coordinated by the COFEMER as the Secretariats struggled to reach a consensus on its content among them.

The CICOPLAFEST has periodically updated the agreement that establishes the classification and codification of goods whose importation is subject to regulation on the part of the Secretariats that comprise the CICOPLAFEST[83].

Table 2.11 Courses, talks and workshops provided in the country derived from the National Programme against Risks by Pesticide Use between 2002 -2006*.

		Course Train -the-Trainer on Safe Use of Pesticides direct to:		Workshops on the Diagnosis, Treatment and Registration of Poison ings by Pesticides direct to:						Talks on Safety Use of Pesticides direct to:	
		Officials, Industry, Teachers and NGO 's		Health Care Assistants		Technicians		Doctors		Agricultural workers	
State	Year (s)	Number of workshops	People trained	Number of workshops	People trained	Number of workshops	People trained	Number of workshops	People trained	Number of workshops	People trained
Baja California	2004			2	60	2	200			2	100
Baja California Sur	2006	1	35	1	32						
Chiapas	2004							10	443	42	880
Chihuahua	2003									2	27
Coahuila	2002							5	97	5	673
Durango	2004			1	102	1	14			1	20
Guanajuato	2002					9	126			18	332
Guerrero	2005	1	20	1	8					5	82
Hidalgo	2004			13	447	8	141	4	99	53	1131
Jalisco	2003	1	30								
Michoac án	2003 / 2005	1	28			3	91			44	1184
Morelos	2004-2006	1	30								
Nayarit	2002/2005	3	82	1	20			2	201	20	350
Oacaxa	2006	1	30	1	38						
Puebla	2002/2004					1	120	2	300	3	96
San Luis Potosi	2005	1	22	1	18	2	59				
Sinaloa	2002/2005	3	125			15	284	2	171	9	307
Sonora	2002/2005	2	54					1	29	15	1181
Tamaulipas	2003/2004	1	20								
Veracruz	2003/2005	1	20	4	78					5	129
Zacatecas	2006	1	35	1	32						
Total		**18**	**531**	**25**	**803**	**41**	**1035**	**26**	**1340**	**224**	**6492**

Source: COFEPRIS (2006) *Until July 2006.

[83] This agreement has been amended in 1998, 2000, 2001, 2002 and 2005, and the amendments have been centred on the introduction of new international harmonised nomenclature of goods for import and export and the updating of tariffs (DOF, 2005).

2.2.2 Discussion and conclusion

After the first report of the activities of the CICOPLAFEST and the three studies that evaluated its performance, there have not been any reforms to improve its situation; hence some important deficiencies still prevail: the limited advance in the implementation and development of the regulatory framework and infrastructure, the deficient enforcement and compliance of the regulations, and the lack of coordination among Secretariats, which operate independently from each other and the resources are scarce. The lack of leadership by the President and Under-Secretaries, which has slowed down the decision-making process as members that attend the meetings have no sufficient power to make decisions, was mentioned in Quantica's study. The Technical Secretary and the Consultative Committee have still not been appointed, in fact, at present, the situation is more critical as the only group that keeps periodical meetings is the Technical Committee. As INAP's study mentioned, a work plan, mission, vision, strategic objectives and continuity in its activities are still missing.

However, one of the major irregularities of the regulation was solved with the enactment of the regulation on registration and authorisation for import and export (SEMARNAT, 2004), and important achievements have been reached in the international context with the accession to the Rotterdam Protocol and the prohibition of use of DDT and lindane and the reduction of use of methyl bromide.

So, it is clear that the organisation of the CICOPLAFEST is failing, that the lack of exclusivity of the members dealing with the Commission's responsibilities, the limited interest from high executives, the lack of economic resources and legal power to enforce its objectives, and the difficulties to reach consensus among the Secretariats involved have diminished its success.

Nevertheless, these problems may be common in countries that lack a principal law that directs pesticide control. For instance, according to a study carried out by Agne (1996), Costa Rica presents similar difficulties in the implementation of the laws mainly because of the large number of institutions involved in the legislation, which leads to interinstitutional friction and neglect of duties, because it is sometimes assumed that other institutions handle the issue. The enforcement is also difficult due to the high costs of monitoring and the independent work of the government agencies that impedes to optimise resources.

In spite of these problems of organisation, the permanent interaction among institutions involved directly or indirectly in pesticide control plays a decisive role in the regulation of pesticides because the impact that they have in the economy, health population and the environment, as well as, to define a congruent national pesticide policy, which should also be in harmony with the international commitments and concerns generated around pesticide use.

So, the CICOPLAFEST needs to be imminently reformed in order to be the key for the development of all embracing, developed and efficient pesticide legislation in Mexico, which should cover the national and international demands for development growth along with adequate protection to human population and the environment.

Chapter III Effects of pesticide use on human health, the environment, society and economy in Mexico

Pesticide use has brought numerous benefits for human beings, their role in protecting public health is broad and varied since they are used to control insects and rodents that vector disease, allergen-producing weeds and as disinfectants in hospitals and homes. Pesticides also have a key role in increasing agricultural production thereby maximizing profits, slowing the spread of exotic pest populations, and in producing high quality grain and forage for livestock. In urban areas, pesticides help to preserve buildings by controlling termites, carpenter ants and other structural insects, and to maintain recreational areas and improve roadside visibility by controlling weeds. However, the excessive and unsafe use of pesticides have also brought negative effects on human health and the environment. The publication of Rachel Carson's Silent Spring in 1962 exposed the hazards of DDT and initiated awareness and encouraged study of the negative side effects of pesticide use. This chapter presents information on these side effects and their impact on society and the economy of Mexico. Even though there are few studies to determine such impacts, the available information gives cause for concern about the effectiveness of the protection of the population and the environment in Mexico.

3.1 Effects on human health

Acute poisoning from pesticides is a widespread health problem, with an estimated global number of cases of 1–3 million/year (WHO, 2003a). The World Health Organisation (WHO) reported that mortality rates can vary from 1 to 9% of cases presented for treatment, depending on the availability of antidotes and the quality of medical services (WHO, 2003a). Many of these deaths occur in agricultural areas of developing countries, where a lack of hygiene, information and adequate controls has created unsafe working conditions, and in factories where pesticides are manufactured or formulated with inadequate respect for safety requirements (IPCS, 1993)[84].

Acute effects associated with high occupational exposure to pesticides include chemical burns of the eye, skin damage, neurological effects and liver effects. Chronic exposures are suspected of leading to reproductive problems and an increased risk of developing cancer, delayed neurological and psychological effects, and effects on immune function. Many cases of pesticide poisoning occur in children who gain access to opened pesticide packs kept in the home. Episodes of mass poisoning following the consumption of food contaminated with pesticide have also occurred and resulted in numerous deaths (WHO, 2003a).

In Latin America it is estimated that about 3% of exposed agricultural workers suffer from an episode of acute pesticide poisoning (APP) every year (PAHO, 2002)[85].

The incidence rate of APP in the Central American Isthmus is close to 20 cases per 100,000 population, with a progressively increasing risk for the period, from rates of 6.3 per 100,000 population in 1992 to 19.5 in the year 2000[86].

[84] Ostrosky and Gonsebatt (1996) mention that health effects from environmental toxicants may be a more serious problem in developing countries compared with developed countries because the problem is potentiated by other factor such as: a) the lack of or failure to enforce regulations; b) undernourishment of the lower economic and social classes that comprise the most exposed populations from industrial and agricultural activities, and c) parasitic infections that afflict a wide range of populations in both urban and rural areas.

[85] More than 50% of all pesticide poisonings occur in less industrialized countries, though the quantity of pesticides used is less (PAHO, 2002).

3.1.1 Pesticide poisoning in Mexico

In the First Diagnostic of Environmental and Occupational Health (SSA, 2002a) it is mentioned that the register of poisonings by toxic substances in Mexico is inadequate as information related to poisoning by pesticides is only available. Like in the rest of Latin America, poisoning by pesticide is the main problem of acute poisoning in the country.

The collection and recording of pesticide poisonings are carried out by the Epidemiological Surveillance Programme (SINAVE) of the Epidemiology General Direction (DGEPI) of SSA following the stipulations of the official standard NOM-017-SSA-1994 (DOF, 1999). According to this standard, the hospitals and health centres located around Mexico that belong to the National Health System must keep a record of the poisonings and send them to DGEPI. There are also toxicological centres that provide medical attention to attend poisonings by phone[87]; however, their records are not included in the SINAVE as the standard NOM-017-SSA-1994 has not been modified to allow the authorities to include these additional records (Rosales, 2006 Pers. Commun.).

Figure 3.1 shows the number of cases of poisonings by pesticides recorded by the SINAVE in 2004 and published in the Epidemiological Bulletin (SSA, 2006). According to the figure, Jalisco, Sinaloa and Nayarit are the States that reported more cases of pesticide poisonings in the country. However, SSA stressed that this might be caused by a system of registration of cases more efficient compared with the registration from other States, hence this does not constitute conclusive evidence of a larger problem of poisonings.

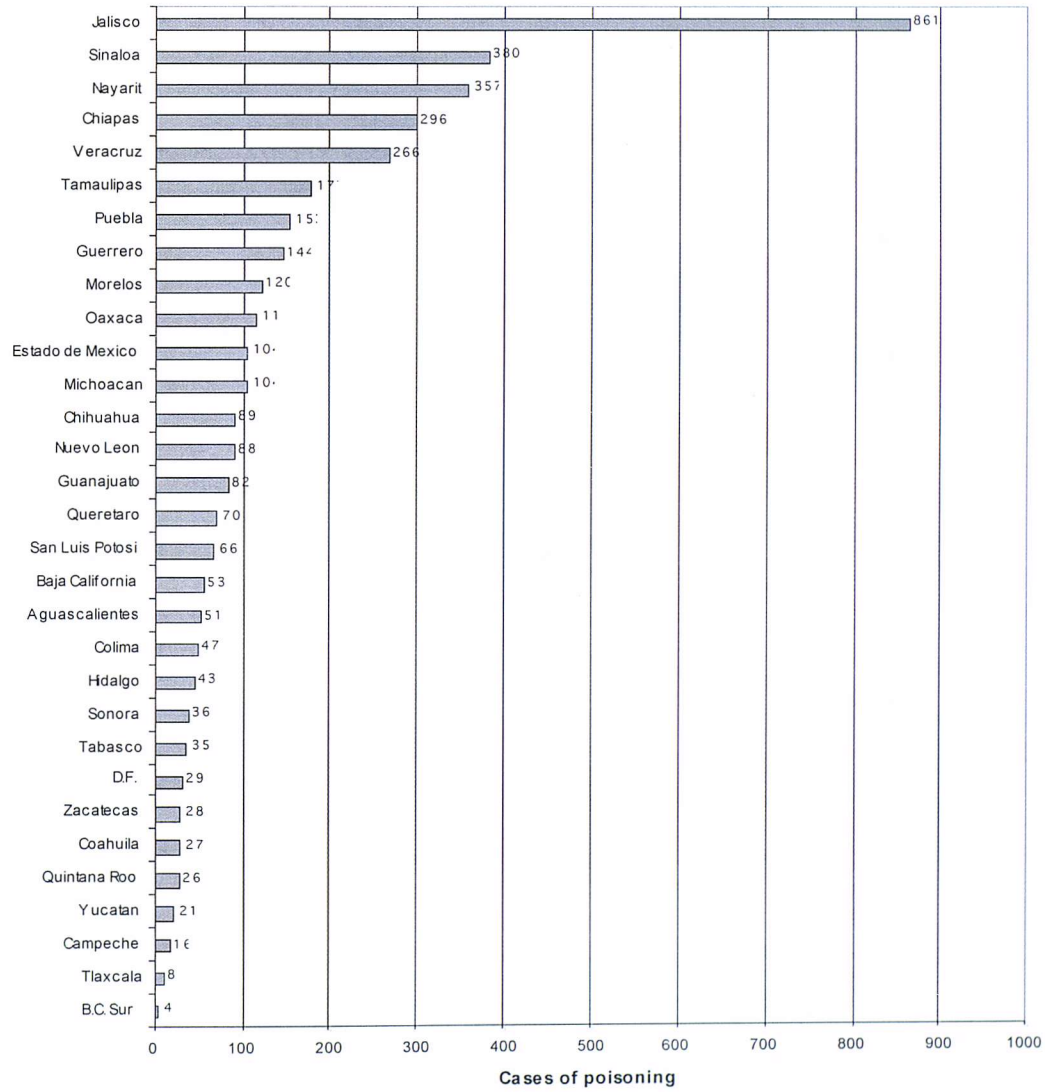
Figure 3.2 presents the total number of cases of poisoning reported between 1993 and 2004 in Mexico. In 1993, the registration of cases of poisonings began and in that year 1576

[86] The data obtained through the surveillance system show that the 12 pesticides responsible for the greatest number of APP are Paraquat, Aluminium Phosphide, Methyl-Parathion, Metamidophos, Monocrotophos, Chlorpyriphos, Terbufos, Ethoprop, Endosulfan, Carbofuran, Methomyl, and Aldicarb. It should be pointed out that these pesticides are of a high toxicity. According to the WHO toxicological classification of pesticides, these pesticides are considered extremely hazardous (level 1a) and highly hazardous (level 1b) (WHO, 2004c).

[87] In 2004, 21 Toxicological Centres were reported working in a national toxicological network (RETOMEX) in Mexico, some of them also provide outpatient service and have toxicological laboratories. The network is independent from the SSA and its funding comes from NGOs.

cases were reported. From 1993 until 1996 there was a steady increase, with the largest number of cases in 1996, at 7,032. Then, between 1996 and 1999 there was a gradual decrease in the reported cases. Between 1999 and 2000 the decrease was particularly sharp, falling by 5,642 to 2,887. By 2001 there were 2,532 reported cases; however, from 2002 to 2004 an upward trend is again observed, reporting an increase of 977 cases between 2002 and 2003 (2,802 cases in 2002 and 3,777 in 2003) and in 2004 3,898 cases were reported.

Figure 3.1 Number of cases of poisonings by pesticides in the States.
Source: SSA, 2006.

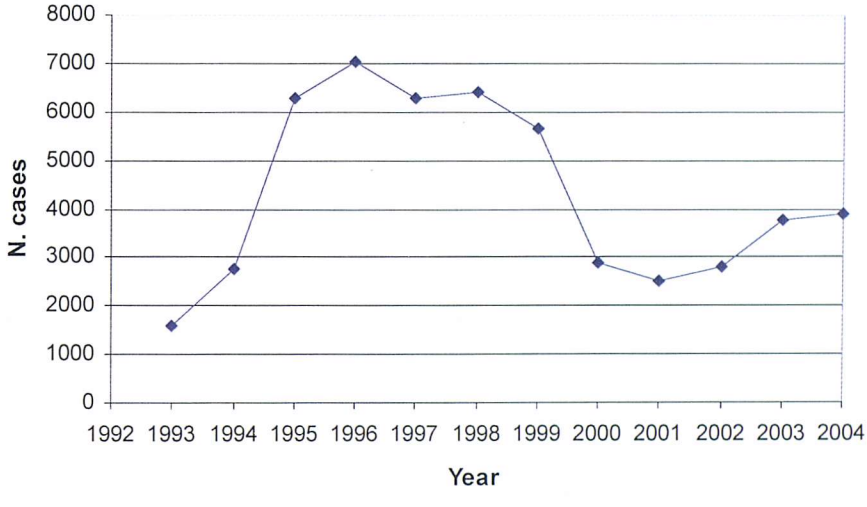


However, SSA recognizes that there are diverse factors that influence the likely under-registration of cases in the country (SSA, 2002b). These factors are:

- Difficulty accessing health services
- No inclusion of cases of poisoning attended by private medics
- Lack of information about the real population at risk
- Incapacity to diagnose accurately pesticide poisoning in rural communities
- Scarce training for the safe use of toxic substances in workplace

The lack of inclusion of poisonings attended by the toxicological centres in the SSA records also contributes to this under reporting of cases.

Figure 3.2 Number of cases of pesticide poisoning between 1993 and 2004.
Source: SSA 2006.

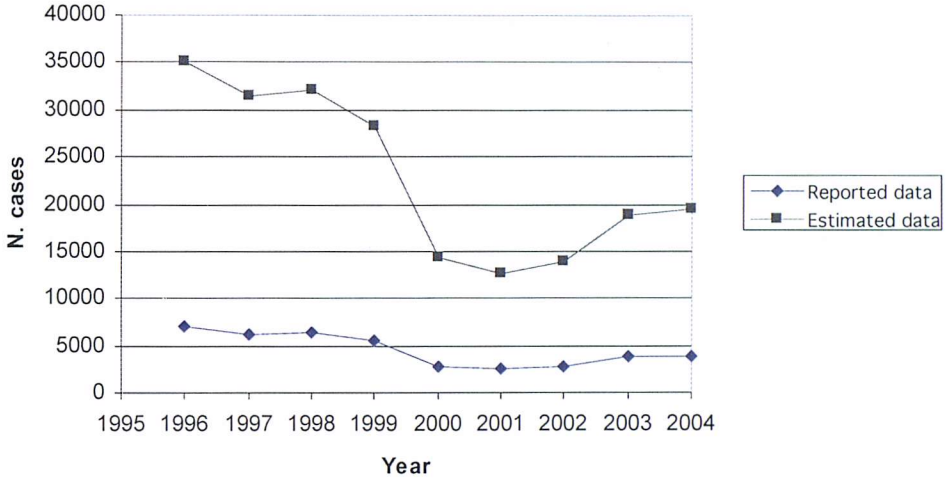


In a study carried out in the Mexican state of Chiapas it was found that there was underestimation of 80%, in other words, for each case reported four are not registered (Figure 3.3)[88].

[88] Through a project called PLAGSALUD, the Pan American Health Organization (PAHO) also reported that in the Central American Isthmus there is an under-registration between 80 and 99%, in other words, only between one and 20 of every 100 cases of APP are reported (PAHO, 2002; Fernandez et al, 2002). Belize presents the highest underestimation (99%) and El Salvador presents the "lowest" underestimation (80%). According to this project, the causes that promote the under-registration are similar to the causes mentioned for Mexico, which support the perception of under-registration in Mexico. These results were obtained through community surveys and administrative under-registration research (analysis of the information system that supports epidemiological surveillance in the health system) carried out in each of the seven countries that form the Central American Isthmus.

Apart from the poor reliability of the CITs, there are other possible factors that could contribute to the marked decrease of cases between 1998 and 2001. Between 1994 and 2003 there was a reduction in the agricultural area of crops with high dependence on pesticides. The agricultural land for cotton decreased by 87% between 1996 and 2002; beans, 14.5% and corn[89] 11.6% between 1994 and 2003, and tomatoes 17.6% between 1999 and 2002 (Figure 3.4). So, this could imply a reduction in the use of pesticides and hence less exposure to these products.

Figure 3.3 Underestimation of poisoning cases in the country.
Source: SSA 2002b.



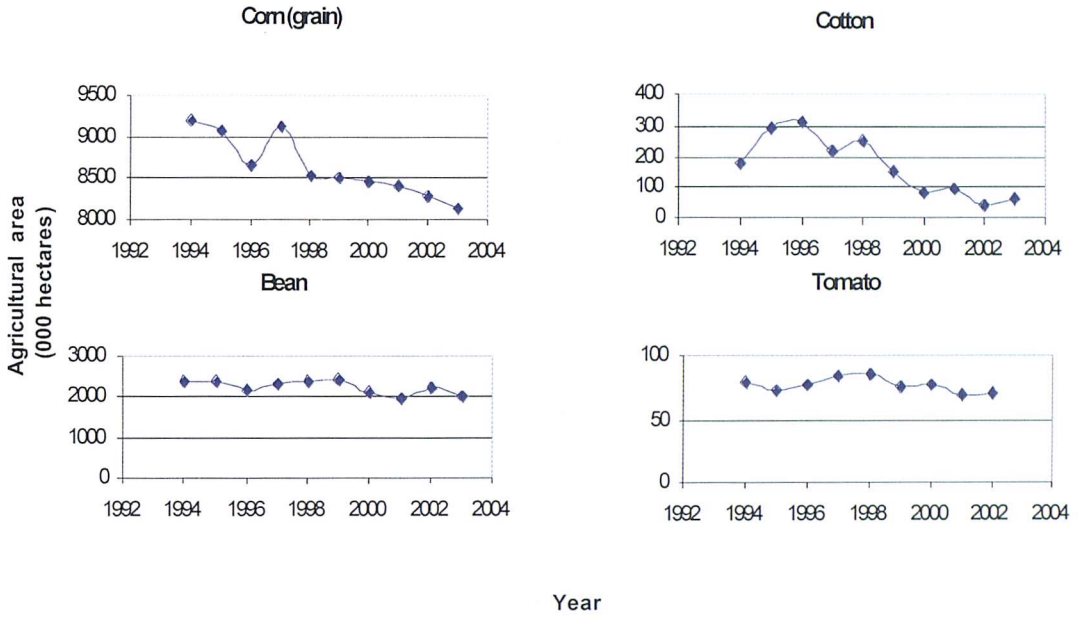
In general, agricultural production and trade in Mexico have suffered variations after the North America Free Trade Agreement (NAFTA) came into force in 1994. In accordance with the Department of Economy and Trade of the Chamber of Deputies of Mexico, between 1995 and 2000, Mexico increased its agricultural dependence on the world market, principally on basic grains such as corn, wheat and rice, and oilseeds[90].

[89] Maize is not highly dependent on pesticides but due to its extensive production in Mexico, the demand for pesticides is high.
[90] Between 1995 and 2000 agricultural imports grew more than agricultural exports. In 1995, agricultural exports were larger than imports by $939 million and in 2000, the agricultural trade balance presented a deficit of $2,465 million (Camara de Diputados, 2003).

So, the variations in the production of crops and in consequence the variations in the amounts and kinds of pesticides used could represent a minor risk of poisoning by pesticides, which should be reflected in the records of the SINAVE.

Additionally, the sharp decrease in the cases of poisoning reported in 2000 coincides with a reduction in the import of pesticides in the same year. According to the Bank of Mexico in

Figure 3.4 Agricultural area of crops with high demand of pesticides.



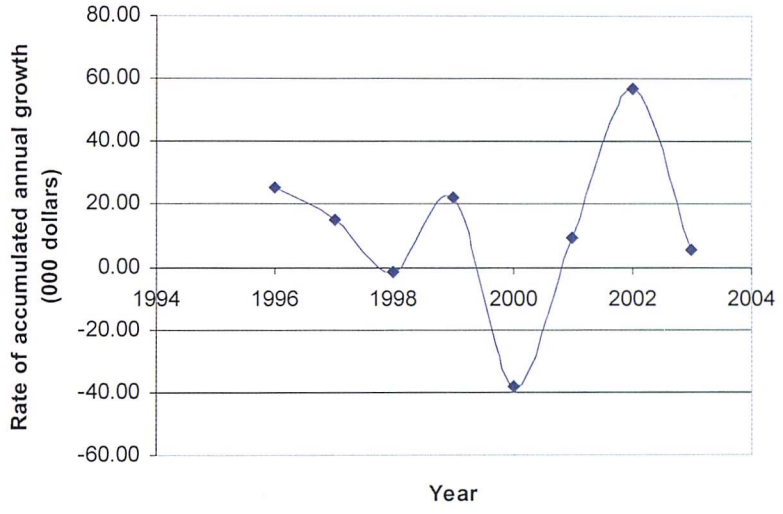
Source: Service of Statistical Information on Agriculture and Fisheries SIAP/SAGARPA (with records of SIACON).

December of 2000 the rate of accumulated annual growth of the import of pesticides was of –38.40 (Banco de Mexico, 2003) (Figure 3.5). The aforementioned could also infer less use of pesticides and consequently a reduction of poisonings in the year.

It is important to mention that the Mexican pesticide industry association called AMIFAC has provided training on safe use of pesticides to agricultural workers since 1997, and currently there is a National Programme that provides courses, talks and workshops to a wide sector of people including agricultural workers, doctors, governmental officials, students, technicians, etc, which started in 2002 (COFEPRIS, 2006). However, there is not an

indicator that measures their impact and therefore, at the moment, it is difficult to find a reliable association in the trend of the cases of pesticide poisonings and the number of people trained or number of courses provided.

Figure 3.5 Rate of accumulated annual growth in the import of pesticides between 1996 and 2003.



Source: Banco de México, 2003. Note: the rate of accumulated growth is the reported in December of each year.

3.1.2 Effects on Mexican population

With regard to the effects on the health of the Mexican population due to pesticide use there are limited studies. Guillette *et al.* (1998) determined the health effects on children exposed to pesticides in Sonora's Yaqui Valley, an agricultural area with an intense use of pesticides[91]. The results show that the Yaqui Valley children show functional differences compared with children rarely exposed to pesticides. They demonstrated decreases in stamina, gross and fine eye-hand coordination, 30-minute memory, and the ability to draw a person.

[91] According to the author, farmers spray their crops with pesticides as often as 45 times per crop cycle and farm families tend to use household bug sprays daily.

In women with agricultural exposures to pesticides, excesses for several types of cancer have been reported. In Mexico, exposure to organochlorine pesticides was detected as a risk factor for female breast cancer. A recent report related high levels of exposure to dichlorodiphenyldichloroethylene (DDE, a metabolite of DDT) with increased breast cancer risk in the country, particularly for postmenopausal women (Romieu *et al.* 2000 and London *et al.*, 2002). Additionally, Medina *et al.* (2002) found an association between exposure to pesticides and congenital malformation in pregnant women exposed to pesticides in Nayarit State, which was considered as a public health problem in the State and in other rural areas with similar exposure to pesticides.

The accidental exposure to orthodichlorobenzene vapours caused chromosomal changes in 26 people exposed; although the changes were definite, the alterations seemed to be reversible after several months (Zapata *et al.* 1982)

In 2000, Gomez *et al.* (2000) determined cytogenetic differences between floriculture workers in Morelos State exposed to pesticides and non-exposed people. Additional concern caused by this study was the reported use of pesticides prohibited since 1991 such as aldrin, dieldrin and endrin, and pesticides with restrictive use such as dichlorodiphenyltrichloroethane (DDT), BHC and Lindane.

As an initial part of a research programme for the assessment of health effects in children living in a malarious area of Chiapas sprayed with DDT, a group of researchers found higher levels of DDT and DDE in a community highly exposed to DDT compared with another less exposed and determined the environmental pathways of exposure (Herrera *et al.* 2005).

The findings from Recio *et al.* (2005) in a study carried out in agricultural workers in Durango State suggest that organophosphorus pesticide exposure disrupts the hypothalamic-pituitary endocrine function and also indicates that follicle-stimulating hormone (FSH) and luteinizing hormone (LH) are the hormones most affected.

The number of studies is still limited since there is little economic support to the research in this area and also due to the intrinsic difficulty to evaluate the effects of pesticides exposures. According to Guillette *et al.* (1998), the multitude of diverse social factors, including socioeconomic status, multiple facets of traditional customs and/or acculturation, dietary patterns and the exposure to other chemicals during lifetime are factors that affect the comparison of pesticide effects and their interpretation. The author mentions that frequently these factors are used to question, criticize, and even discount research findings involving the impact of pesticides, particularly on a child's growth and development.

So, the difficulties to determine the epidemiological effects resulting from pesticide exposure along with limited support to carry out such studies represent two main barriers to better knowledge on pesticide effects; however, the results of these studies should be a clear cause for concern about the effectiveness of the protection of the population provided by the authorities.

Finally, it is important to emphasize the progress in reducing DDT use in Mexico through improved malaria control. Through an integrated pest management programme that included community participation in the environmental management of mosquitoes, the use of bacilli and nematodes to control the insects, and improving the Health Secretariat's surveillance, diagnosis and treatment system Mexico stopped the use of DDT in 2000 and therefore eliminated the exposure to this persistent pesticide to the population. By developing and instituting a target–oriented strategy to replace DDT with effective alternatives, Mexico took bold yet prudent leadership in the face of malaria, a major disease in many tropical regions.

3.2 Environmental effects

Delineating the effects of pesticides in the environment[92] is complicated due to the great multitude of pesticide formulations that exist and their different effects on the species. The most hazardous pesticides include those that can be distinguished on the basis of either water or fat solubility. Water soluble compounds are easily transported out of the target area into groundwater and streams; fat soluble chemicals are readily absorbed in insects, fish, and other animals, often resulting in extended persistence in food chains (Scientific Committee on Problems of the Environment, 2003). In general, insecticides are the most toxic pesticides to the environment, followed by herbicides and fungicides[93]. Some of the most troublesome pesticides to the ecology are:

- insecticides: DDT, dieldrin, diazinon, parathion and aldicarb
- herbicides: 2-4-D, atrazine, paraquat, and glyphosate, and
- fungicides: benomyl, captan, mercury, copper, and pentachlorophenol.

Scientific studies have reported that pesticide use has resulted in acute and chronic ecological damage either by direct injury to non-target organisms (NTOs) such as birds and fish or by indirect effects such as modification of interspecies relationships. Pest resurgence has been observed following applications of select pesticides that reduce natural enemy

[92] Air can become contaminated during pesticide spraying operations. The evaporation of droplets during the spraying of emulsified formulations may result in the formation of tiny particles that can be carried great distances in air currents. Substantial quantities of agriculturally applied pesticides have been shown to become airborne during and after application operations (Egboka *et al.* 1989). Soil contamination can be generated by the direct application of pesticides on soil, which may lead to residues in plants grown in the soil or for spraying pesticides on crops. Egboka *et al.* (1989) mentions that as much as 50% of the pesticides sprayed on crops or used as herbicides misses its target and falls onto the soil surface. Persistence of pesticides in soil is a necessary condition for translocation from the soil to the plant. However, compounds that are similar in persistence in the soil may be absorbed into plant tissues in widely different amounts. Some pesticides, notably, organochlorines, may persist in soil for years, even though a large proportion evaporates[92]. Pesticides can move into groundwater influenced mainly by their adsorptive properties, although soil characteristics, environmental conditions, application techniques and agricultural practices also influence their migration. Superficial water can be contaminated for the direct application of pesticides to control disease vectors or aquatic weeds. In addition, it may be contaminated, for example, from discharges of surplus pesticide after spray operations, crops to be sprayed being planted right up to the water's edge, accidental spillage of pesticide formulations, runoff, leakage, erosion from treated soils and the fall-out of pesticides from polluted air (Egboka *et al.* 1989).

[93] Exceptions exist for certain herbicides which are highly toxic such as 2-4-D, and are far more hazardous to the environment than are insecticides.

populations and subsequently increase pest populations[94]. Some pesticides exert their effects on particular components of an ecosystem; for instance, some herbicides affect primary production in plants, and persistent organochlorine insecticides (such as DDT) bioaccumulate in higher trophic levels such as predators[95]. The major adverse effects of organochlorine pesticides have been manifested through effects on reproduction. Broad-spectrum organophosphate and carbamate insecticides with high acute toxicity to many species may acutely alter energy flow as well as other ecological parameters. Extensive mortality of canopy-dwelling song birds has been observed with applications of phosphamidon and to a lesser extent, with fenitrothion.

In Mexico, there are studies that report the presence of organochlorine pesticide residues in organisms and the environment. In 1995, Kuehl and Haebler (1995) reported the presence of organochlorine, organobromine, metal and selenium residues in bottlenose dolphins (*Tursiops truncatus*) collected during an unusual mortality event in the Gulf of Mexico in 1990.

Waliszewski *et al.* (1996 and 2003) reported the presence of persistent organochlorine pesticides in butter from Veracruz, Mexico, specifically lindane and DDT[96]. These pesticides have been used in Veracruz to combat malaria vectors, livestock ectoparasites and as seed dressings. However, subsequent studies carried out by the same author (Waliszewski, 2003) showed that organochlorine pesticide residual levels have diminished comparing the results found in 1994 and 2001. Since 1999, DDT has been replaced by pyrethroids, and lindane has a restricted use, which may explain their gradual diminution in the environment. The same trend was found in organochlorine pesticide levels in bovine muscle fat and kidney fat from cows living in the same area, measured in 1994 and 2003 (Waliszewski *et al.*, 2004).

[94] Soil biota have been observed to be affected in a complex manner; some species increase in numbers, while others are reduced by injury.
[95] In eastern Canadian forests, DDT caused fish mortality as a result of bioaccumulation through the food chain (Kerswill and Edwards, 1967). DDT has also caused eggshell thinning in several high trophic level avian species and sufficient impact on reproduction to result in population declines (Risebrough, 1986).
[96] According to Spencer *et al.* (1996), the organochlorine pesticide volatilization is considered to be a major process in removing them from treated areas through air currents, resulting in potential exposure to animals and humans through the air route. Bentabol and Jodral (1995) mention that organochlorine pesticides stored in the body are moved and excreted through milk with endogenous fat during lactation.

Albert and Armienta (1977) detected organochlorine residues (DDT, dieldrin, endrin, DDE and hexachlorocyclohexane (HCH)) in water samples from agricultural drainage system in Northwest Mexico. Rosales *et al.* (1985) detected high residue concentrations of DDT and heptachlor in sediments from two coastal lagoons in northwest Mexico. Several authors reported the presence of organochlorine pesticide residues (DDT, dieldrin, endrin, aldrin, heptachlor, endosulfan) in the Coasts of Gulf of Mexico and coast of Chiapas (Albert, 1996). Albert (1996) mentions a serious case of groundwater pollution in the Yucatan Peninsula due to that this is the only source of drinking water for the population. In the groundwater the presence of 2,4-D and 2,4,5-T was detected.

Organochlorine insecticide residues (DDT, DDE) in edible freshwater fish and crustaceans have been found in western Mexico, Veracruz and Baja California according to some studies carried out in the 1980s (Albert, 1996). In 1995, there were reports of the presence of heptachlor, endosulfan and aldrin in the fish *Lutjanus novemfasciatus* in Chiapas State (Vazquez, 1995). Albert (1996) also mentions the presence of organochlorine pesticides (DDT and its derivatives) in bivalves from the northwest Mexico and Gulf of Mexico.

The presence and effects of organochlorine and organophosphorus compounds have been documented on shrimps in the coastal ecosystems of Sinaloa. Reyes *et al.* (1999) and Carvalho *et al.* (2002) detected their presence in the region of Altata, Ensenada del Pabellon and Bahia de Santa Maria, which are among the greatest shrimp producing areas. Both studies warned of the potential ecological risk to these ecosystems due to the levels of some pesticide residues that were considered highly toxic for aquatic organisms. Carvalho *et al.* suggested that due to the concentrations of chlorpyrifos approaching acute toxic levels for shrimp, drainage from agricultural fields during high runoff may, on occasion, cause mass mortality of shrimp and fish. Reyes *et al.* highlighted the presence of forbidden pesticides in the country after the use of aldrin and endrin was prohibited in 1991. Additionally, these studies stressed the concern for the areas because the slow growth, diverse pathologies and

mortality in shrimp that have been reported in recent years, considering pesticides as one of the possible causes.

Galindo *et al.* (2002) determined a reduction in protein and DNA breaks or adducts in shrimp larvae from the California Gulf exposed to DDT, azinphosmethyl, permethrine, parathion, chlorpyrifos, malathion, endosulfan and carbaryl. Another study elaborated by Castro *et al.* (2005) determined the acute toxicity in white shrimp *(Litopenaeus vannamei)* postlarvae exposed to two chlorinated pesticides, DDT and endosulfan, under laboratory conditions, finding a low resistance to these pesticides as their growth rate decreased from 50 and 80%.

Effects of organochlorine pesticides, polychlorinated biphenyls (PCBs) and polynuclear aromatic hydrocarbons (PAHs) present in sediments obtained from Bahia de Chetumal, Mexico, was studied in Nile tilapia (*Oreochromis niloticus*). The results demonstrate that sediments from Bahia de Chetumal have the potential to cause histopathological, haematological and biochemical alterations in fish (Zapata et al, 2000).

The effect of the bioaccumulation of methyl parathion in several species of the freshwater community in Ignacio Ramirez dam was analysed by De la Vega (1997). This author found a significant concentration in reproductive tissues (plants)/unborn progeny (animals) which could affect egg viability and also an increase in enzymatic activity which could indicate liver damage.

In birds of prey located around the Gulf of Mexico and Chiapas, organochlorine pesticides, mainly DDT and DDE, have been detected, which has been related to eggshell thinning (Albert, 1996). Other studies evidenced the presence of these pesticides in wild ducks and other species of birds in Baja California, Sonora, Sinaloa and Lerma States.

Organochlorine compounds including dioxins, furans, biphenyls and p-p'-DDE were measured in house sparrows (*Passer domesticus*) and common ground doves (*Columbina*

passerine) from Baja California Sur finding higher DDT levels in the omnivorous species (Jimenez *et al.*, 2005).

In migratory birds between Mexico and Central America organochlorine pesticides have also been detected; however, it was not possible to differentiate how much and which of these residues found in these birds come from Mexico and which from other countries in the region. Fyfe *et al.* (1991) carried out studies on peregrine falcon prey and they found that one-third of the migrants from Mexico showed DDE levels, which has been considered a cause of adverse reproductive effects.

So, several studies show a clear evidence of the pollution of pesticides in organisms and the environment; however, few studies have evaluated their impact or followed their trend. Albert (1996) commented that the low priority assigned by the science and technology authorities for research on the health and environmental effects of these chemicals, contributes to the lack of scientific support for establishing legal regulations that control their use and protect adequately the environment.

It was also suggested that the low level of participation by the scientific community in decisions whether or not to authorise the use of pesticides in the country also impedes the identification of possible effects on sensitive areas or endemic species in the country. Finally, the detection of forbidden pesticides in the environment and organisms shows weakness in the enforcement and compliance of the regulations.

3.3 Social impact

The negative effects of pesticides have been of concern to Mexican society, however, their demands to the government and pesticide industry have been more active when mass poisoning and death by pesticides have happened or when economic losses in agricultural areas have been reported.

In Mexico, there have been three mass acute poisonings by pesticides. In Baja California State, during the 1960s a very severe poisoning occurred, with 559 persons affected. Sixteen of them, the majority of whom were children, died. The poisoning was caused by the ingestion of bread that was manufactured with contaminated flour that had become contaminated by parathion during transport (Valdez, 2000).

The second accident occurred in Cordoba in the state of Veracruz in 1991, when an explosion and fire in the company Agricultura Nacional de Veracruz S.A. (ANAVERSA) caused the acute poisoning of 300 people by the release of gases produced by the combustion of pesticides such as methyl parathion, malathion, paraquat, amongst others (AMACUP, 2002). Up to 1999, 272 people have suffered death by cancer, and fetus malformations have also been reported, which have been attributed to the poisoning suffered eighth years earlier. An association of sick and affected people from the ANAVERSA accident was formed by the community in order to demand specialised medical attention and more support from the government, which has been accused of weak actions against the owners of ANAVERSA[97] and criticised by its own deficiencies since this factory was working with the respective permits and authorisations of the Environmental and Health Secretariats, without complying with the minimal conditions of security for workers, community and the environment. After 10 years since the incident, the University of Veracruz along with NGO's and the association of sick and affected people from the ANAVERSA explosion organised a symposium on environmental health and vulnerability, in which was mentioned the high infant mortality rate and high number of immunodeficiency diseases in the region, which may be related to the accident. However, it stressed the importance to carry out more research in the area to determine clearly the effects of the incident on the population, mainly due to the dioxins generated during the combustion of the pesticides, and provide then the medical care required.

[97] Initially ANAVERSA was fined 238 thousand Mexican peso, which after factory's allegations it was reduced to 119 thousand Mexican pesos. At present, the factory was not been removed nor the area has been treated in order to avoid further pollution in the area.

The third accident happened in the state of Salamanca, Guanajuato City in 2000, in which a tank containing malathion exploded in a factory owned by Tekchem. The explosion generated a toxic cloud that poisoned approximately 6,000 people and 50,000 had to be evacuated, although only 800 needed medical attention. A committee of affected communities was formed, which also demanded medical attention and the closure of the company. The government considered that the closure was not necessary, hence it required the factory to pay a fine whose amount was not reported, and to update its programme of health and safety (AMACUP, 2002).

Numerous articles published in different newspapers have stressed the frequency of pesticide poisoning amongst indigenous workers, principally of the ethnic group known as *huicholes*[98] (AMACUP, 2002)

In 1993, Patricia Diaz Romo published a video called *Huicholes y Plaguicidas* (*Huicholes* and Pesticides), which shows evidence of the abuse and precarious situation to which the *huicholes* are subjected and the lack of information about the work and environmental exposure to these products and their chronic effects[99].

Cases of poisoning in the ethnic group *tarahumaras* have also been reported. In 2000, the Local Commission of Human Rights in the state of Chihuahua presented a formal complaint against the Attorney General's Office of Mexico (PGR by its abbreviation in Spanish) about the application of paraquat on illegal marihuana crops without the safety measures necessary to prevent impacts in the nearby *tarahumara* communities. The Commission mentioned that the herbicide was transported by the wind to the communities, poisoning up to 300 people and causing the death of a two year old child ((AMACUP, 2002).

[98] Every year the *huicholes* migrate from the Sierra Madre Occidental, their place of origin, to the agricultural areas of Ixtintla, Nayarit State to work in the tobacco crops. This migration is based in religious beliefs, but now due to the extreme poverty of the communities, the migration is more related to obtaining food and resources for the family.
[99] The video has been translated into 12 indigenous dialects and the National Indigenist Institute disseminates it.

Indigenous peoples from different communities in the state of Chiapas presented another complaint against fumigations carried out by the federal government (AMACUP, 2002). The indigenous people demanded the suspension of the Programme *MOSCAMED*[100], which was reactivated in 1995 by the government to control an outbreak of the Mediterranean fruit fly in 43 villages in Chiapas. The control established by the government consisted of aerial applications of malathion and the release of sterile male flies as biological control in the fields. According to an article published in the newspaper *La Jornada* the applications of malathion affected the production of coffee for 11,000 farmers in 116 villages, which were finally compensated economically by the government (AMACUP, 2002). According to comments from other reporters, the strategy of the applications of malathion was carried out to create a military cordon due to the presence of guerrillas in the zone; they supported their comments on the basis that the biological control was scarcely used, the aerial applications were carried out by the navy and that the outbreak was presented mainly in the area of the armed conflict.

The Valleys of Yaqui, Culiacan and San Quintin located in the states of Sonora, Sinaloa and Baja California, respectively, are characterised by their high agricultural production and also by their intensive use of pesticides. Different articles mentioned the migration of workers from different states of the country to these valleys, which 66% are women and children. The articles mainly highlighted their acute poisoning and the presence of pesticide residues in their blood and breast milk of women[101].

In 2005, the newspaper *El Universal* (21 May 2005) published reports of a serious problem of public health due to the acute pesticide poisoning suffered by agricultural workers in cane sugar fields in the state of Veracruz.

[100] The programme MOSCAMED began in 1977 to control the Mediterranean fruit fly through an integrated strategy that included a periodic review of the fruits permitted for import, elimination of the infested fruit, and cultural and biological controls. In 1982 the government declared that the pest had been controlled, keeping a biological control for sporadic outbreaks. However, the sanitary authorities detected an outbreak of this pest in indigenous villages of Chiapas in 1993.

[101] Newspapers: La Jornada 28 January and 27 March of 2000 and Reforma 25 May 2000.

In general, agricultural workers are the most sensitive group to suffer the negative effects of pesticides; the need of food and money for the sustainability of the family and the lack of education promote the acceptance of any job with minimal conditions of security. In Mexico, the population of agricultural workers is estimated at 3.4 million, 1.2 million of them are migratory workers and 28% are illiterate[102] Whole families generally participate in the agricultural work; it is estimated that the children provide a third of the income to the family (SEP, 2002).

Recognising the degree of marginalisation of agricultural workers, the Secretary of Social Development jointly with the Secretaries of Health, Labor, Public Education and other social organisations implemented the programme *Programa Intersectorial de Atencion a Jornaleros Agricolas* (Inter-sectorial Programme of Attention to Agricultural Workers). The objective of the programme is to improve the life and working conditions of agricultural workers in the country[103]. The programme has been implemented in the states of Guerrero, Oaxaca, Baja California, Sinaloa, Hidalgo and Nayarit.

In Mexico there is also representation of the Pesticide Action Network called Pesticide Action Network and Alternatives in Mexico (RAPAM), which has participated in diverse forums promoting the participation of the society in the regulation and use of pesticides.

In 2004, the Citizen Committee of Juchitepec, state of Mexico presented a complaint to the authorities against the factory Artivi, which is a pesticide formulator, due to the number of acute poisoning occurring in the population as a consequence of the release of residual water from the factory to the public drainage without any treatment. The Citizen Committee was supported by Greenpeace and RAPAM (*La Jornada,* 23 July 2004).

[102] This figure only includes workers that are older than 15 years.
[103] The Programme provides a part of the economic resources for the development of projects; producers and other sponsor organisations contribute with the rest of the resources.

3.4 Economic aspect

Pimentel and Lehman (1993) estimated that losses to pests would increase 10% in the United States if no pesticides were used at all; specific crop losses would range from zero to nearly 100%. In the United States of America $4.1 billion is spent each year in purchasing and applying roughly 500,000 tonnes of pesticides, which are estimated to save $16 billion in crops each year. Pimentel also mentioned that while a return of $4 for every $1 spent in direct costs (purchase and application of pesticides) may seem favourable, the indirect costs may diminish their benefits as he estimated the indirect costs of pesticide use at $8 billion per year in the US, which he believes may be an underestimate. Table 3.1 shows the estimates of the indirect costs of pesticide use determined by Pimentel and Lehman.

Table 3.1 Indirect costs by pesticide use in the United States (Pimentel and Lehman, 1993)

ACTIVITY	COSTS (MILLION DOLLARS /YEAR)
Public health impact due to pesticide poisoning and illnesses (includes costs of hospitalization, outpatient treatment, lost work time, treatment of pesticide-induced cancers and fatalities)	787
Deaths of domestic animals and contamination of meat, milk and eggs	30
Additional pesticide applications due to loss of natural enemies and increased crop losses	520
Additional pesticide applications due to pesticide resistance	1400
Honeybee and pollination losses	320
Crop losses due to the affectation of pesticides	942
Monitoring and cleaning groundwater	1800
Fishery losses	24
Birds losses	2100
Government regulations	200

In Latin America there are estimates of the economic burden of illness from pesticides poisonings for specific crops. In research carried out in a highland potato growing region in Ecuador during 1991-1992, Cole *et al.* (2000) determined that the public and social security health care direct costs were $9.85/case; private health costs were $8.33/case and lost time indirect costs were $8.33/agricultural worker. Each one of those costs was over five times

the daily agricultural wage, which was then about $1.50[104]. According to the authors these figures are comparable to those reported for Nicaragua with a mean treatment cost of $11.90/case, private costs of $10.36/case and wage losses estimated at $4.07/case[105]. In other countries, estimates have been made of combined costs. In Costa Rica, these expenses were between $75 and $100 per case in total costs to the health system, the enterprise, and the workers or small farmers involved (Cole *et al.*, 2000). These authors also made reference to a study developed in Yucatan State, Mexico by Alvarado *et al.* (1998) who used a different approach to estimate that poisoning cases cost the equivalent of 1.9% of the value of the gross agricultural product of the cultivated area.

The estimation of indirect costs is a complex task due to the great demand of information, the limitation of methodologies to quantify the impacts and the definition of a monetary value for a human life lost or for cancer illness, impacts on wild birds, invertebrates, microbes, food or groundwater; and in some cases, the difficulty to isolate the effects of pesticides exclusively. In this work, due to the extreme difficulty of getting information from the authorities and considering the scope of this work, the costs of the rejections of products at the border with the US due to pesticides are evaluated in the following section, further and deeper estimations exceed the scope of this research.

3.4.1 Rejections of food goods in the border USA-Mexico due to pesticide residues

The United States of America is the main trade partner of goods with Mexico, according to the Secretariat of Economy (SE, 2005) the value of exports to the US was $165,111 millions in 2004, which represented 87% of the total value of Mexican exports in the year[106]. In 2003,

[104] This information was associated with 50 poisoning cases reported during the period.
[105] The author recommended carrying out further costing of pesticide poisonings in other settings to provide appropriate information for decisions about pesticide use.
[106] The total value of the exports was $189,200 million.

the value of agricultural and livestock goods (including agricultural products, animal skin, leather, essential oils and cotton) for export was $7,183 millions (SAGARPA, 2004a)[107].

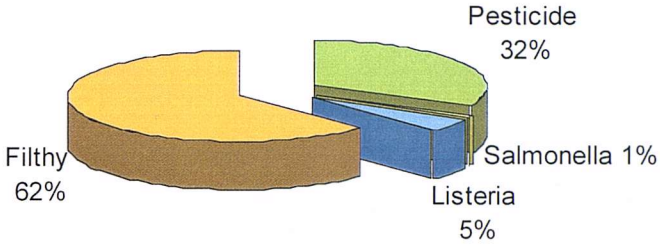
The import of agricultural food to the USA is regulated by the Federal Food, Drug, and Cosmetic (FDC) Act, which is designed to protect consumer health, safety, and economic interests. FDC is enforced by the Food and Drug Administration (FDA), which through an inspection process at the borders verifies that all imported products meet the same health and safety standards as domestic goods. If products fail to comply with the requirements of the Act, FDA has the authority to detain the product and inform the owner or consignee, with a *Notice of FDA Action* the nature of the violation. If the owner fails to submit evidence that the product is in compliance or fails to submit a plan to bring the product into compliance, FDA issues another *Notice of FDA Action* refusing admission to the product. The product then has to be exported or destroyed within 90 days. Import Rejects Reports (IRR) are published monthly for every country on FDA's website where the cause and date of the rejection is specified.

Using the IRR for Mexico, the Secretariat of Agriculture (SAGARPA) estimated that 32% of the rejections of fresh agricultural products at the Mexico-US border in 2004 are due to the violation of Maximum Residue Levels (MRLs) of pesticides (Figure 3.6); pesticide residue infringement in fact is the second cause of rejections of Mexican fresh products for export.

Of the countries that had rejections by FDA between June 2004 and May 2005, Mexico had the highest number of total rejections and the highest number of rejections due to pesticides (FDA, 2005) (Figure 3.7)[108].

[107] Mexico is the third main exporter of goods to USA. The value of the imports of USA from Mexico was $155, 843 million, which represented 10% of the total value of the imports. The main products imported from Mexico were electrical machinery, vehicles and parts, sound equipment, boilers, mineral fuel, oil, among others (USDOC, 2004).
[108] The main import partners of the USA and their contribution are: Canada 16.9%, China 15%, Mexico 10%, Japan 8.2% and Germany 5% (CIA, 2006).

Figure 3.6 Refusals of products in the border Mexico-US by FDA in 2004.
Source: SAGARPA (2005) using data from FDA.



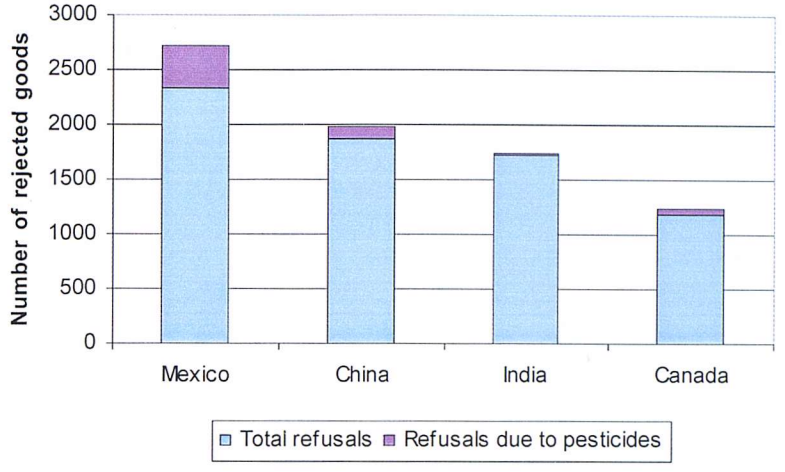
The economic impact of these rejections was evaluated using data provided from FDA, although they represent just an approximation and its use must be limited[109]. Figure 3.8 shows the economic loss due to the refusal of fresh and dry agricultural goods between 2000 and 2004, in this period the lowest loss was registered in 2000 with $630,000 and the highest loss was $1.9 million in 2002. The amounts rejected are presented in Figure 3.9 and the main products refused are shown in Table 3.2.

Considering that in 2002 the export of food goods was worth $6,345 million, the economic loss due to the rejection of products represented 0.03% in the year and compared with the total exports of the country in the same year[110], $160,763 million, its overall effect is negligible.

Even though the rejections do not represent a high impact on the economy of Mexico, it is clear that the data show clear evidence of the misuse of pesticides in Mexico, whose

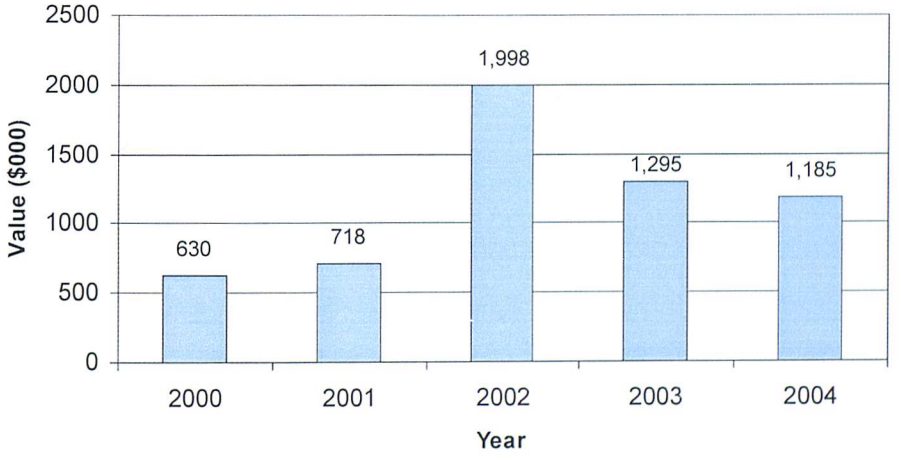
[109] The reliability of the data provided by FDA is limited as FDA tracks the amount of rejected goods by the line item count and not by mass, weight or volume, however it receives this information but it is not concerned with the units of measurement, so it is possible to find inconsistencies among the units, which entails the elimination of data.
[110] Manufacturing industry constituted 96% and the extractive industry 0.6% (BANXICO-INEGI-SAT-SE, 2005). In the same year the agricultural sector (including silviculture, fishery and livestock) represented 4.3% of the GDP

Figure 3.7 Rejections of goods for import to USA by main import partners between June 2004 and May 2005. Source: FDA (2005)



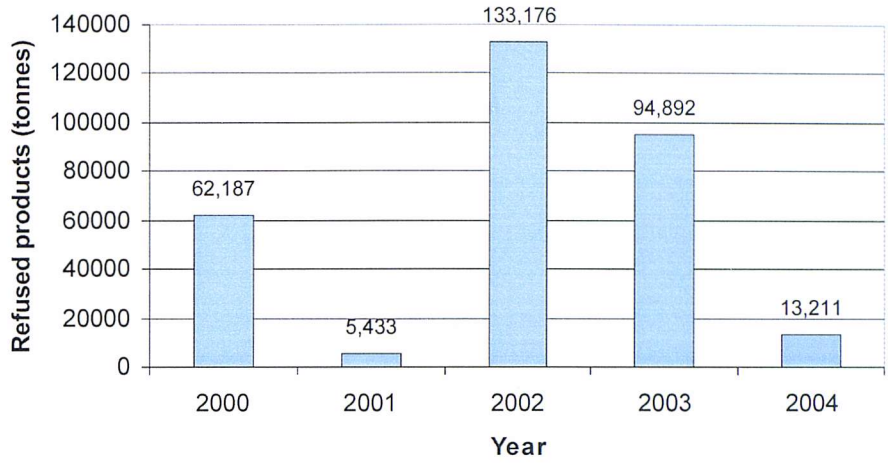
additional effects on human health and the environment would have an additional impact on the economy. Furthermore, the incidence of these violations undermines the perceived quality of Mexican products, which restricts a major pathway to export to other countries; it represents monetary losses for the importers and delays the process of imports as a more exhaustive inspection is required.

Figure 3.8 Economic losses due to the rejection of products at the US-Mexico border between 2000 and 2005.



(industrial sector represented 27.1%, trade, restaurants and hotels 19.8% and the rest of services 48.8%) (SE,

Figure 3.9 Amount of Mexican products refused (tonnes) at the border with the United States between 2000 and 2004.



It was not possible to obtain information on the number of shipments that are destroyed at the border and the number of shipments that are turned back to the owners, which would help to determine the amount of contaminated food that could be re-sold within Mexico.

As a response to the rejections registered in 2002, SAGARPA created the National Programme for Monitoring Pesticide Residues in the same year, which consists in the monitoring of fresh agricultural products that according to the reports of FDA present problems of pesticide residue. In 2003, 277 samples of the main products rejected were analysed showing that 43 samples had residues of non-authorised pesticides, for instance the use of monocrotophos for chillies or the use of acephate for tomatoes, uses not authorised according to the Catalogue of Pesticides (SSA, 2005). Two samples only exceeded the MRL allowed, in which tomatoes presented a high level of chlorpyrifos residue and chillies methamidophos residue.

Based on the results of the monitoring and in the IRR published by FDA, SAGARPA submits an informal contact with the growers advising them to improve their agricultural practices and avoid the rejections.

2005).

According to the rejections reported by the FDA there were 192 rejections by pesticides in 2003, 254 in 2004 and 320 in 2005, so the efforts of SAGARPA have not yet had the desired effect, which seems logical since the number of foodstuffs and pesticides used is great and only a limited number of samples are analysed. It is well known that due to the great number of pesticides and foodstuffs the monitoring programmes imply high costs and heavy workloads (PSD, 2005), so a rational and focussed programme of monitoring is required along with a permanent training and enforcement of the regulations and involvement of national export associations to support compliance.

Table 3.2 Products refused at the Mexico - United States border due to pesticides between 2000 and 2005.

	2000		2001		2002		2003		2004		2005 [1]	
	Value [3] (%)	Weight (%)	Value (%)	Weight (%)	Value (%)	Weight (%)	Value (%)	Weight (%)	Value (%)	Weight (%)	Value (%)	Weight (%)
Pepper, Hot [2]	31.27	13.33	26.35	84.00	12.95	0.45	6.65	0.20	28.64	90.30	20.58	23.45
Pepper, Sweet	4.04	0.06	7.34	4.10	8.95	0.45	-	-	3.05	0.26	6.87	3.17
Cucumbers	6.03	0.09	2.39	0.25	0.15	0.00	-	-	-	-	-	-
String beans	5.71	0.07	1.08	0.11	7.74	0.21	0.68	0.00	1.31	0.15	1.64	1.78
Strawberries	19.77	85.80	-	-	5.96	93.80	-	-	3.14	0.29	-	-
Spinach	7.40	0.18	0.12	0.01	-	-	-	-	-	-	0.81	0.64
Cauliflower	4.10	0.05	-	-	-	-	-	-	-	-	-	-
Blackberries	3.54	0.01	-	-	-	-	-	-	-	-	39.27	14.72
Swiss Chard	0.38	0.00	12.63	0.98	0.03	0.00	0.12	0.00	0.02	0.00	-	-
Celery	-	-	13.04	4.44	0.20	0.01	0.34	0.02	0.86	0.10	-	-
Leaf & Stem Vegetables	1.87	0.03	10.44	1.78	7.21	3.98	5.69	3.01	1.91	0.45	16.30	31.99
Papaya	0.11	0.00	11.29	1.74	2.90	0.07	5.58	92.22	9.83	1.85	1.36	1.04
Squash	2.03	0.06	6.84	0.93	37.61	0.75	76.10	4.45	31.38	4.14	-	-
Tomatoes	0.02	0.00	1.66	0.35	10.36	0.15	-	-	7.07	0.39	1.03	0.87
Scallions, Green Onions	2.37	0.04	2.83	0.42	0.60	0.01	-	-	4.56	0.48	-	-
Total	88.65	99.71	96.01	99.12	94.66	99.88	95.17	99.91	91.79	98.42	87.86	77.66

[1] Preliminary data from January to June 2005.

[2] Includes fresh and dry peppers.

[3] The value column presents the percentage of the total products rejected by value. For instance, 31.27% of the total products rejected by value was hot peppers in 2000 and the products in that column account for 88.65% of the value of all product rejected. The same explanation applies to the weight column.

In conclusion, it seems that the concern about the negative externalities of pesticide use is increasing and according to the figures derived from the different studies mentioned at the beginning of this section, their value may deserve to be included in the economic discussions interrelated with agricultural productivity and international trade in the country.

Cole *et al.* (2000) mention that the costs associated with human health may be particularly more relevant in developing countries where the major number of poisonings is registered.

3.5 Discussion and conclusions

Ecobichon (2001) highlighted the little effort in the determination of pesticides effects in developing countries, mainly on long-term adverse health effects in the agricultural workforce and local consumers. Albert (2000) mentioned that the limited research on pesticide effects in Mexico does not show any relationship with the amount and diversity of pesticides used since their introduction almost 40 years ago. Albert also states that the studies carried out to determine the effects of specific pesticides have not covered all the effects both in the environment and human health, neither the great variety of pesticides used in Mexico nor all the areas with an intensive use.

So, it is clear that there is a limited knowledge on pesticide effects in Mexico, possibly as a consequence of the little economic support to do research in this area and also due to the intrinsic difficulty to evaluate the effects of pesticide exposures. However, the findings cited in this chapter, such as the effects on children and women with agricultural exposures to pesticides (Romieu *et al.* 2000; London *et al.*, 2002; Medina *et al.* 2002; Guillete, 1998); the high number of pesticide poisonings; the three massive acute poisonings registered in the country, the potential ecological risk in the coastal ecosystems in Sinaloa State, due to high concentrations of organochlorine and organophosphorus compounds (Reyes *et al.* 1999; Carvalho *et al.* 2002); the high percentage of rejections of goods at the border USA-Mexico due to pesticide residues, the anecdotal and suggestive information on pesticide poisonings reported in the daily newspapers, mainly those involving indigenous groups and rural population, are evidence of the presence of pesticide effects, which represents a clear cause for concern about the effectiveness of the protection of the population and the environment in Mexico.

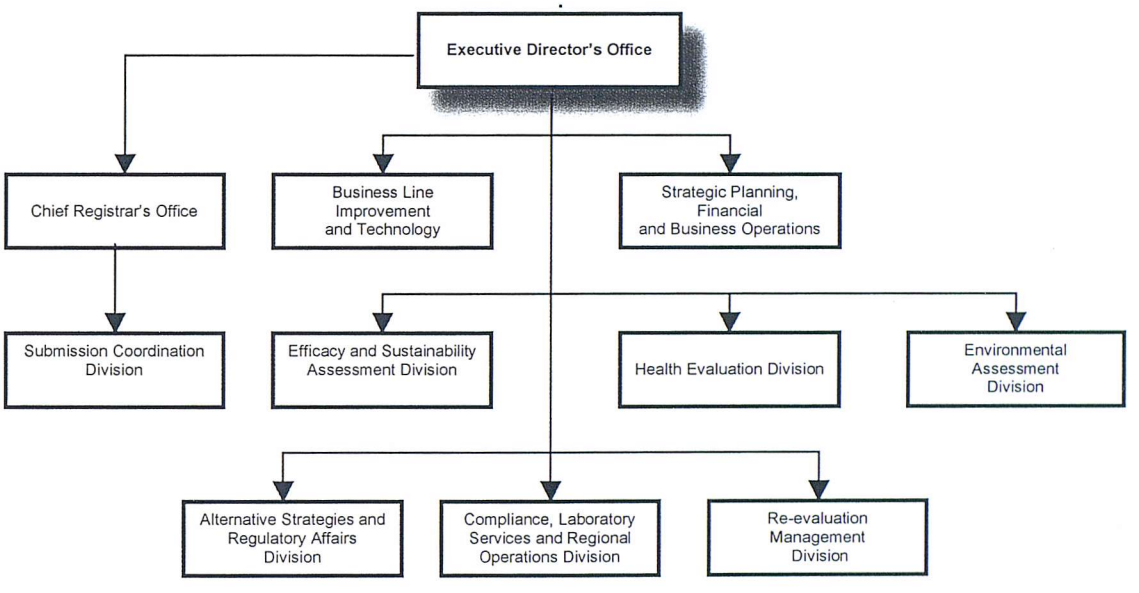
Chapter IV International trends in pesticide regulation

Governments in many countries are recognising the benefits of international cooperation in carrying out regulatory activities to protect the environment and health and also support growing trade among countries (PMRA, 2004). Thus a process of harmonisation of regulatory actions has been initiated, bringing responsibilities and repercussions to national levels. Mexico is an active international participant, being involved in a free trade zone with Canada and the USA (NAFTA), which constitute its main trade partners, also being a member of the OECD, GATT and participating in several international agreements related to pesticide safety and control. In this context, this chapter aims to describe the international trends in pesticide control by describing the regulatory systems for pesticides of Canada, USA, UK and EU along with the initiatives of international organisations related to pesticide safety and international trade in order to introduce or consider this trend in the proposal to improve the regulatory control system for pesticides in Mexico.

4.1 Canada

The Pest Management Regulatory Agency (PMRA) is responsible for regulating pesticides in Canada to prevent unacceptable risks to people and the environment from their use. PMRA was established in 1995 when the Minister of Agriculture and Agri-Food transferred the administration of the Pesticide Control Products Act to the Minister of Health. Figure 4.1 shows its organisation and Table 4.1 presents its advisory committees.

Figure 4.1 Organisation of the Canadian Pest Management Regulatory Agency (PMRA).
Source: PMRA (2005).



The Executive Director's Office: Oversees the operation of the PMRA and chairs the Agency Management Committee, comprising the directors of all divisions.

Minor Use Advisor: Liaises with grower organisations, provinces, and registrants, the Interregional Research Project Number 4 (IR-4) and Agriculture and Agri-Food Canada, and advises the PMRA on minor use issues, needs and developments.

Chief Registrar's Office: Manages registration, including minor use on science-based decisions, provides policy and strategic advice and participates in various advisory committees.

Submission Coordination Division: Manages and tracks submissions, manages databases and provides information services.

Business Line Improvement and Technology Development Division: Directs business line improvements projects, including electronic environment initiatives and provides information technology support.

Efficacy and Sustainability Assessment, Health and Environment Divisions: Provides expertise on the use of antimicrobials, fungicides, herbicides, insecticides and other pesticides, on health and environmental hazards, risk assessment and risk mitigation as appropriate.

Alternative Strategies and Regulatory Affairs Division: Develops policies, programs and projects related to sustainable pest management and coordinates national and international activities; it directs regulatory reforms and liaises with other departments. It is also in charge of a Continuous Learning Programme and the Access to Information.

Compliance, Laboratory Services and Regional Operations Division: Conducts national pesticide compliance inspections and investigations to enforce PCPA and provides expertise on the chemistry of pest control products and analytical testing.

Re-evaluation Management Division: Manages the re-registration programme and related issues.

Strategic Planning, Financial and Business Operations Division: Manages the financial, human resource and business operations.

4.1.1 Legal framework

The New Pest Control Products Act (PCPA), which received Royal Assent in 2002 and came in force in July 2006 (Department of Justice Canada, 2006), is the primary federal legislation to control the import, manufacture, sale and use of all pesticides, including insecticides, herbicides and fungicides, in Canada. This new act strengthens rigorous safeguards against the risks to people (with main emphasis on children and infants) and the environment. It also includes the evaluation of accumulative impacts by the use of pesticides and promotes the

access to more information and new opportunities for input into major pesticide registration decisions[111]. New regulations are being developed to give effect to key provisions of the new Act[112].

Table 4.1 Advisory Committees of PMRA.

ADVISORY COMMITTEES	FUNCTION
The Economic Management Advisory Committee (EMAC)	To advise the Executive Director of the PMRA on specific ways to improve efficiency and cost effectiveness in the regulation of pesticides, without compromising health or environmental protection or industry competitiveness.
Pest Management Advisory Council (PMAC)	To foster communication and dialogue among stakeholders and with PMRA, and provides advice to the Minister of Health on policies and issues relating to the federal pest management regulatory system. It is multi-stakeholder group.
Federal-Provincial-Territorial Committee on Pest Management and Pesticides	To strength the relationships between the different levels of government and seek harmonisation and also promote information exchange and mutual advice .
Policy Council	To provide a forum for the exchange of advice between federal departments and the PMRA on policies and programs related to pest management regulation, and also to coordinate the flow of information**.

*The Federal-Provincial-Territorial Committee on Pest Management and Pesticides comprises representatives designated by PMRA and representatives from territorial and provincial governments and other groups such as industry and users.
**The Policy Council is made up by the Executive Director of the PMRA and Assistant Deputy Ministers of the Federal Departments of Agriculture and Agri-Food, Environment, Fisheries and Oceans, Health, Industry, and Natural Resources.

The other federal statutes regulating pesticides are the Food and Drugs Act 1985 (Department of Justice Canada, 1985a), which provides power to PMRA to set the Maximum Residue Levels (MRLs) and the Pesticide Residue Compensation Act 1985 (Department of Justice Canada, 1985b) that provides compensation to farmers whose agricultural products are contaminated by pesticide residue even though they have used them in accordance with recommendations made by the department of agriculture and approved by the Minister.

The PCPA Act and Regulations currently do not have specific and detailed rules governing pesticide export. However, the PCPA Regulations have a significant impact on pesticide

[111] This new Act introduces similar modifications to the established by EPA in the Food Quality Protection Act in 1996.
[112] These include pesticide sales reporting, adverse effects reporting, providing material safety data sheets in workplaces, review panels for reconsideration of major registration decisions.

export, which provide the basis to establish the export guidelines[113]. The Fisheries Act 1985 (Department of Justice Canada, 1985c) and the Migratory Birds Convention Act 1994 (Department of Justice Canada, 1994) also provide for the protection of fisheries and migratory birds from substances that pose risks to them and may affect the use of pesticides.

Additionally, PMRA follows the Administrative Monetary Penalties Act 1995 (Department of Justice Canada, 1995) as an enforcement tool for the PCPA. The purpose of this Act is to establish, as an alternative to the existing penal system and as a supplement to existing enforcement measures, an administrative monetary penalty system for the enforcement of the agri-food Acts[114].

4.1.2 Registration of pesticides

Only pesticides that are registered for use under the PCPA may be imported into, or sold or used in Canada. During the registration process PMRA evaluates the safety, merit and value of pesticides[115]. The responsibilities, timelines and performance standards are outlined in Regulatory Proposal PRO-9601, *Management of Submissions Policy* (MOSP). PMRA manages five categories of applications for registration (Table 4.2). At the end of the evaluation process a Proposed Regulatory Decision Document (PRDD) is prepared with the resolution. There are also emergency registrations in case of a pest outbreak that can cause significant economic, environmental or health problems.

PMRA have participated in a number of NAFTA projects to harmonize data requirements for pesticide submissions, to develop common study protocols (test guidelines) and common

[113] All products manufactured for both export and Canadian use must be registered and labelled in Canada under provisions of the PCPA and Regulations. Any technical grade pesticide or manufacturing-use product imported into Canada for the formulation of an export product must be registered under the authority of Section 6 of the PCPA Regulations (PMRA, 1995).

[114] Provinces and territories regulate the sale, use and disposal of pesticides within their jurisdictions, and they may impose more stringent controls than those applied under PCPA, but they may no permit the use of products that are not registered under the Federal Act.

[115] The duration of registration is of 5 years with the possibility to renewal it.

formats (dossiers) including electronic approaches for submissions by registrants, to develop common formats including electronic approaches for the review of submissions (monographs), to share reviews, and to harmonize risk assessment/risk management procedures. So, currently their registration process is very similar[116] and joint reviews are being carried out.

There are approximately 550 pesticide active ingredients in more than 7000 products registered under the PCPA for use in Canada. During fiscal year 2003–2004, PMRA received 3042 submissions. Category A and B submissions accounted for about 19% of the total number. The number of submissions completed was 2949 and 86% (2534) submissions received a positive decision.

In the same period six new reduced-risk chemicals and two new biopesticide active ingredients were registered in (44% of new active ingredients registered were reduced-risk chemicals or biopesticides). Twenty-eight percent of new active ingredients were registered via the joint review process[117] and 302 minor crop uses were also registered. PMRA also received 39 emergency requests and granted 25 emergency registrations.

PMRA also maintains a close communication with other international organisations such as the Organisation for the Economic Cooperation and Development (OECD) and the European Commission to advance international cooperation (harmonization) in pesticide regulation[118].

[116] Although PMRA put more emphasis on the studies of efficacy than EPA.
[117] The PMRA and the USEPA worked closely with registrants to prepare three fully electronic submissions for submission in March 2004 as potential joint reviews.
[118] Currently, PMRA also requests that applications for registration of a major new use or new active ingredient include comprehensive data summaries that have been prepared according to the European Commission (EC) guidelines. Additionally, PMRA accepts submissions formatted according to the guidelines and criteria for industry for the preparation and presentation of dossiers implemented by the OECD. PMRA is also implementing Good Laboratory Practices (GLP) following the OECD principles of Good Laboratory Practice (PMRA, 2005).

Table 4.2 Categories of applications for registration.

CATEGORY	DEFINITION	AVERAGE TIMES TO REGISTRATION (DAYS)
A	This includes submissions of new active ingredients and formulated products (end-use products), or the inclusion of major new uses for products before registered and the establishment of MRLs.	1072*
B	Applications that require the evaluation by one or more science divisions due to changes in product chemistry, form of active ingredients, formulation and new combinations of active ingredients or due to changes of rates of application, timing, method, level of control among others.	419*
C	Include applications that do not require supporting data for new or amended registrations requiring minor label and/or formulation reviews.	185-225** (98)
D	This category of submissions includes applications for new or amended registrations representing special programs.	NA
E	Applications that include Research Permits for new active ingredients, new use of registered active ingredients, and notifications that are required for field research carried out in Canada.	NA

* Average times for the submissions that were registered in 2003-2004, which include PMRA time (average time for the PMRA to complete a verification step, a first screen, a preliminary review step, an evaluation step, the first decision and Proposed Regulatory Decision Document preparation, decision time after public consultation, and the first final-label review); Applicant time (average time for applicants to address deficiencies), Deficiency time (average time for the PMRA to examine information related to deficiencies in a submission) and Consultation time (average public consultation time).
**Time only corresponds to a review performance standard (The review time does not start until the submission enters the review stage, when the submission is considered complete and reviewable. . The number in brackets is the time for a priority Category C submission.
NA. No Available
Information taken from the Annual Report 2003-2004 of PMRA (PMRA, 2005).

4.1.3 Re-registration process

In 2001, PMRA published the Re-evaluation Programme under the Directive DIR2001-03, which has the objective to re-evaluate all products active registered on or before 1994. Of the 550 currently registered pesticide active ingredients and their end-use products on the market in Canada, 401 require re-evaluation. At present a total of 143 active ingredients have been addressed. In fiscal year 2003–2004, 84 active ingredients were re-evaluated, of which 54 were proposed for continuing registration with label modifications, 3 without label modifications, 23 were discontinued by the registrant and 4 were phased out as a result of

PMRA reviews (PMRA, 2005). The PMRA aims to complete re-evaluation within the same timeframe as the US EPA: 2008–2009.

4.1.4 Other activities

PMRA also sets Maximum Residue Levels (MRLs) under the Food and Drugs Act (FDA) in order to ensure that consumption of the residues that are likely to remain in or on the food when the pesticide is used according to label directions will not pose an unacceptable health risk. In 2003–2004, a total of 75 final MRLs were published in the Canada Gazette, Part II. The NAFTA TWG is finalizing an initiative to develop common guidance, including data requirements and policy and procedures for the establishment of pesticide tolerances/MRLs on commodities imported into NAFTA countries[119].

4.1.5 Sales of pesticides

PMRA does not ask pesticide companies to report their pesticide sales; however, recognising the importance that sales data have as a risk indicator and as a basis to define strategies and national policies, PMRA is working on The Pest Control Products Sales Information Reporting Regulations which will specify requirements for recording, retaining and reporting sales of pest control products under the new Act (PMRA, 2006).

The available information on pesticide use in Canada was reported in a document of Alberta Environment with information recompiled by the OECD in 1991 (Alberta Environment, 2001), where 41,684 tonnes of active ingredients were used in 1988 and an intensity of use of 0.9 kg ai/ha (Table 4.3). According to this data Canada uses less pesticide per hectare than most developed countries partly because of a shorter growing season (one crop per year), the type of crops grown, and generally less intensive agricultural practices. Also these

[119] The draft NAFTA document *NAFTA Guidance Document on Data Requirements for Tolerances on ImportedCommodities* was released for public comment in 2003 on the NAFTA pages of the PMRA and the USEPA websites.

characteristics explain the fact that Canada uses a high proportion of herbicides (78%) relative to insecticides (8%) and fungicides (7%) in contrast with other countries, which tend to use a higher proportion of insecticides and fungicides. The contribution to the GDP by the agricultural sector is of 2.2% (CIA, 2006).

Table 4.3 Agricultural pesticide use comparisons among countries (1988 and 1995). (Alberta Environment, 2001)

COUNTRY	1988 TOTAL USE (TONNES AI)	USE INTENSITY (KG AI/HA)	1995 TOTAL USE (TONNES AI)	USE INTENSITY (KG AI/HA)
Canada	41,684	0.9	N/A	--
The United States	341,669	1.8	349,266 (1997)	2.8
Germany	31,487 (West Germany)	4.2	25,551	2.2
France	85,386	4.4	84,006	4.6
UK	40,774	5.8	20,627	3.4
Netherlands	N/A	--	10,923	4.6
Italy	N/A	--	48,490	5.4
Japan	82,553	17.7	N/A	--

4.1.6 Health effects

The Quebec Poison Control Centre and the Quebec Ministry of Environment and Wildlife released statistics on pesticide poisoning in 1996. They reported 1,650 poisoning cases. 79.4% of the cases were in private homes, and 46.1% of the victims were children under age of five. 31% of these cases were due to oral ingestion, and 34.9% followed a pesticide application (Centre Anti-Poison du Quebec, 1997).

4.1.7 Environmental effects

Principally, the effects of pesticides in the wildlife in Canada have been investigated in birds[120]; however, there are relatively few well-documented cases of mass pesticide poisoning of birds. Between June 1986 and September 1988, at least five cases of poisoning of flocks of Canada Geese were recorded in southern Ontario caused by the insecticide Diazinon. Several thousands of Lapland Longspurs were poisoned with Carbofuran used to

[120] The first comprehensive institutional review of agrochemical use in the United States—otherwise known as the Mrak Commission—concluded that: "Much of the significant evidence on the worldwide effects of insecticides have been provided by birds" (Mrak, 1969).

control flea beetles in a canola field in 1984. Also Carbofuran was the cause of at least three cases of poisoning of Ring-billed and California gulls between 1984 and 1986 in the Canadian prairies (British Columbia, 2004).

Finally, the use of Phosphamidon (1963 to 1977) and Fenitrothion (1969 to 1997) to reduce the defoliation caused by spruce budworm was found to result in heavy mortality and massive reductions in the numbers of kinglets and several warbler species (British Columbia, 2004).

4.2 The United States of America

The Environmental Protection Agency (USEPA) is in charge of regulating pesticides in the United States through various programmes; its objective is to protect human health and the environment. The Office of Pesticide Programs (OPP) along with the Office of Prevention, Pesticides, and Toxic Substances (OPPTS) work with 10 Regional Offices and other EPA program offices on a wide range of pesticide issues and topics, such as evaluating potential new pesticides and uses; providing for special local needs and emergency situations; reviewing safety of older pesticides; registering pesticide producing establishments and enforcing pesticide requirements (EPA, 2005c).

The OPP is chiefly responsible for regulating pesticides. OPP is managed by an Office Director and includes nine divisions:

- **Antimicrobial Division:** In charge for all regulatory activities associated with antimicrobial pesticides, including product registrations, amendments, and re-registrations.
- **Biological and Economic Analysis Division:** Responsible for assessment of pesticide use and benefits; and operating analytical chemistry and antimicrobial testing laboratories
- **Biopesticides and Pollution Prevention Division:** Regulates biopesticides and the establishment of measures to reduce pesticide risks.

- **Environmental Fate and Effects Division:** Evaluates and validates environmental data submitted on pesticide properties and effects.
- **Field and External Affairs Division:** Responsible for program policies and regulations; legislation and Congressional interaction; regional, State and tribal coordination and assistance: international and field programs; and communication and outreach activities.
- **Health Effects Division:** In charge for reviewing and validating data on properties and effects of pesticides, as well as, characterizing and assessing exposure and risks to human and domestic animals.
- **Information Technology and Resources Management Division:** Responsible for information support; Public Docket; records computer support; Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 6(a)(2) issues; pesticide incident monitoring; the Web site; and the National Pesticide Information Centre and OPP budget and personnel.
- **Registration Division:** Responsible for product registrations, amendments, registrations, tolerances, experimental use permits, and emergency exemptions for all pesticides not assigned to BPPD or AD.
- **Special Review and Re-registration Division:** Responsible for Re-registration Eligibility Decisions (REDs), product reregistration; tolerance reassessment; and Special Reviews

Partnerships. The OPP has no formal advisory committees but instead has created many partnerships to support its work with states, tribes, universities, companies, non-profit organizations and community groups. Examples of these are the Consumer Labelling Initiative made up by EPA, the pesticide industry, environmental groups, and state and local governments, whose aim is to make labels for home and garden pesticides easier to read and understand. Another one is the Pesticide Environmental Stewardship Program (PESP), which is a voluntary program that forms partnerships with pesticide users to reduce the health and environmental risks associated with pesticide use and implement pollution prevention strategies (EPA, 2005c).

4.2.1 Legal framework

- The Federal Insecticide, Fungicide, and Rodenticide Act 1947 (FIFRA)[121] (Department of Justice USA, 2006a) and the Federal Food, Drug, and Cosmetic Act (FFDCA) (as amended 2003) (Department of Justice USA, 2006b).

EPA regulates the use of pesticides under the authority of two federal statutes: FIFRA and FFDCA. FIFRA provides the basis for regulation, sale, distribution and use of pesticides; it authorizes EPA to register pesticides before their manufacture, transport, and sale in order to prevent unreasonable adverse effects on the environment. Additionally, FIFRA provides the ability to regulate pesticide use through labelling, packaging, composition, and disposal. In 1988, FIFRA was amended to introduce the process of re-registration of pesticide products in order to ensure that all pesticide products in the market satisfy EPA's current criteria.

Pesticides residues on agricultural commodities are regulated by FIFRA and FFDCA. FIFRA forbids the use of a pesticide in a manner inconsistent with its label and denies registration of pesticides that may have unreasonable adverse effects to man or the environment. Thus FIFRA regulates pesticide residues by regulating pesticide use.

FFDCA authorizes EPA to set Maximum Residue Levels (MRLs) or tolerances for pesticides used in or on foods or animal feed, and also provides authority to exempt a pesticide from this requirement. FFDCA demands a reasonable certainty of no harm to human and principally infants and children for the establishment of MRLs[122]. Pesticide residues in foods are monitored and the tolerances enforced by Food and Drug Administration (FDA) for fruits

[121] States are authorized to regulate pesticides under FIFRA and under state pesticide laws. States may place more restrictive requirements on pesticides than USEPA. Pesticides must be registered both by EPA and the state before distribution.

[122] Before a registration can be granted for a food use pesticide, a MRL or MRL exemption must be in place and according to FFDCA benefits may be considered only in limited extreme circumstances for setting them.

and vegetables and seafood) and USDA for meat, milk, poultry, eggs, and aquacultural foods.

The Food Quality Protection Act of 1996 (FQPA) amended FIFRA and FFDCA, setting tougher safety standards for new and old pesticides and to make uniform requirements regarding processed and unprocessed foods. Specifically, FQPA states that for the establishment of MRLs the assessment must include aggregate exposures and consider cumulative effects and common mode of toxicity among related pesticides; the potential for endocrine disruption effects, and the incorporation of a safety factor that provide more protection to human and particularly to infants and children. FQPA also establishes a program to re-evaluate all tolerances that were in place as of August, 1996 within 10 years, the revision of every pesticide registration every 15 years, the creation of a programme for minor use and setting tolerances for use of pesticides under emergency exemptions (FIFRA Section 18).

In 2004, the Pesticide Registration Improvement Act (PRIA) was promulgated, establishing a registration service fee system for applications for specified pesticide registrations, amended registrations and associated MRLs actions. This Act establishes stricter time limits for completing actions for which fees are submitted (Lindsay, 2005).

- Worker Protection Standard 40.

The Worker Protection Standard (WPS) is a regulation issued in 1992 by EPA to protect agricultural workers from pesticide exposure. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It also contains requirements for training, decontamination, notification and emergency assistance, and specific instructions and

exceptions pertaining to the statements on label about personal protective equipment, notification of workers and restricted-entry intervals[123].

- Other regulations

In additional to FIFRA and FFDCA a number of other laws influence the use, storage and transport of pesticide products: Clean Water Act, Safe Drinking Water Act, Delaney clause of FFDCA, Endangered Species Act, and Superfund Amendment and Reauthorisation Act.

4.2.2 Registration of pesticides

Approximately 1,200 pesticide active ingredients are registered in the US with associated registrations for about 20,000 pesticide products. On average EPA registers 26 new pesticide ingredients per year (Lindsay, 2005). EPA manages four types of registration actions (Table 4.4).

Table 4.4 Type of registration actions of the Environmental Protection Agency.

TYPE	FUNCTION
Federal Registration Action	To register pesticides for use throughout the United States[124] (including imported pesticides)
Experimental Use Permits	To allow manufacturers to field test pesticides under development
Emergency Exemptions	To allow State and Federal Agencies to use unregistered pesticides if there is an emergency pest condition
State-Specific Registrations	To allow States register pesticides when there is a demonstrated special local need to use a new pesticide product or a federally-registered product for an additional use.

[123] A number of agricultural uses of pesticides are not covered by WPS such as the application of pesticides to pastures, rangelands, livestock, parks and home gardens. Applications of pesticides in government sponsored public pest control programs and research applications of unregistered pesticides are also not covered by WPS.
[124] States, Tribes and Territories can place further restrictions on pesticides for EPA-registered products used or sold within their own jurisdictions.

The OPPTS developed guidelines to indicate the type of studies required for the registration and how they have to be carried out. Optionally, the registrants can follow the templates created between OPP and the Canadian Pest Management Regulatory Agency (PMRA)[125,126]. The time for the revisions is variable and some can take several years, although for biopesticides and reduced-risk conventional pesticides the process is faster.

If a pesticide meets EPA's standards and it is intended for use on food EPA establishes a MRL, registers the pesticide and publishes a notice in the Federal Register (the official publication of the Executive Branch).

EPA continues registering chemical pesticides[127] and privileging reduced risk pesticides[128]. At the end of FY 2005 EPA had registered 143 reduced risk pesticides including alternatives for organophosphate pesticides and for methyl bromide. At the same time, new pesticide registrations have been carried out through joint review process with PMRA. At the end of 2004 EPA and PMRA had issued 53 registrations under the joint review process.

4.2.3 Re-registration

FIFRA was amended in 1988 to introduce the process of re-registration of pesticide products that had been initially registered prior to 1984. EPA's goal is to complete pesticide re-registration eligibility decisions by 2008 (food use by 2006) and, in parallel to reassess 9,721

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[125] These templates describe the layout and scope of information that should be contained within a study profile and can serve as guides for preparation of study documents. The templates have been in use by OPP and PMRA since 2002 for writing their data evaluation records of studies submitted and they have found that the use of these templates results in increased review quality, efficiency, and transparency.

[126] OPP is implementing electronic data submission and review tools to improve the efficiency and effectiveness of its regulatory processes.

[127] In 1989, EPA cancelled nearly 20,000 pesticide registrations, many of the cancellations represented a general cleaning out of obsolete registrations of which many had reported no production since 1985 (University of Minnesota, 1996).

[128] However, this policy of EPA, of replacing hazardous pesticides by much less dangerous alternatives, has been criticised because too little attention has been given to the economic impact in the country and in the world by the reduction of pesticide use. Studies carried out by the Agricultural and Food Policy Center of the Texas A&M University have shown the negative economic impact that the use reduction would cause. According to Knutson (1999), who summarises the findings of these studies, the production of some crops (such as apples, cotton, peanuts and tomatoes) would be seriously affected, and also an increase in the costs and prices would be inevitable. So, this author suggests that studies of the effects of eliminating broader groups of pesticides need to be undertaken by EPA, considering the economic impact and mainly food security.

MRLs by 2006. By the end of FY 2005, the agency had reassessed 80% o the 9,721 pesticide tolerance levels, including tolerances on foods most commonly eaten by children (EPA, 2005a).

According to Lindsay (2005) re-registration will be replaced by a process called registration review, which implies a re-evaluation of a pesticide's registration at least every fifteen years. This process will start in 2006.

4.2.4 Other activities

EPA also focuses its activities on the export of pesticides[129], registrations for minor use pesticides [130] and pesticide producing establishments, as well as to certify pesticide applicators. In 2003, applications for minor use pesticides accounted for nearly 70% of all registration decisions for new uses, and in the same year OPP and PMRA, through a NAFTA project, completed the development of a pesticide applicator core exam (EPA, 2005c).

4.2.5 Sales of pesticides

According to the report *Pesticide Industry Sales and Usage: 2000 and 2001 Market Estimates* (Donaldson et al, 2004) 67% of the pesticide expenditures in these years were in the agricultural sector; 14% in industry, commercial and government, and 19% home and garden. In particular, the agricultural sector has been very successful in the US economy in terms of productivity growth. The annual average increase in productivity from 1948 to 1994 was 1.94 percent. This reflects an annual growth in output of 1.88 percent per year and an

[129] An interesting point of this regulation is that pesticides produced solely for export are not required to be registered with EPA. This fact generates a problem called "circle of poison", which means that food products treated with exported pesticides not registered by EPA are imported back into the USA. This problem has generated numerous complaints by farmers since FDA allows the import of these products by establishing residue levels of these pesticides, despite the case that their use is forbidden in the country (Florida Farmers Suppliers Coalition, 1996).

[130] Minor use pesticides are those pesticides for which the total United States production for a crop is fewer than 300,000 acres. Minor uses also apply to pesticides uses which do not provide sufficient economic incentive for a registrant to support initial or continuing registrations.

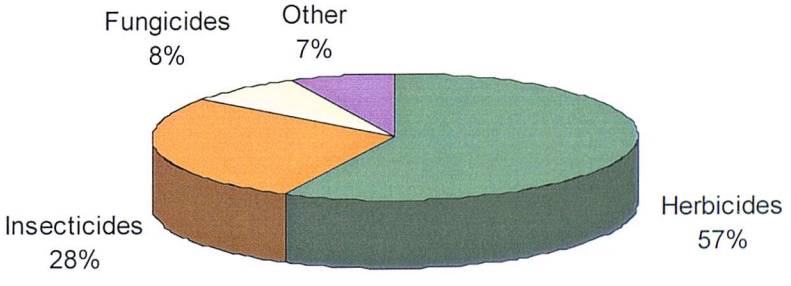
actual decline in agricultural inputs of 0.06 percent per year (Aheam *et al.*, 1998). Indeed, agriculture contributes 1.0% of GDP (CIA, 2006).

Donaldson *et al.* (2004) reported that the US pesticide market totalled more than $11 billion in 2000 and 2001, which accounted for approximately 33% of total world expenditures on pesticides (total world expenditures was approximately $32.5 billion in the same years)[131]. The percent of US pesticide expenditures by pesticide type are showed in the Figure 4.2.

Pesticide sales related to US production and consumption of pesticides comprised $9.3 billion for domestic production, $1.0 billion for imports, $1.6 billion for exports, and $8.7 billion for net supply at the producer level.

US pesticide active ingredient used in 2001 exceeded 540 000 tons. Figure 4.3 shows the amounts and percents of pesticides used by type[132]. The use of pesticides in 2001 accounted for more than 20% of total world pesticide amount used, which exceeded 2.25

Figure 4.2 Percent of US pesticide expenditures by pesticide type in 2001. Source: Donaldson *et al.* (2004)



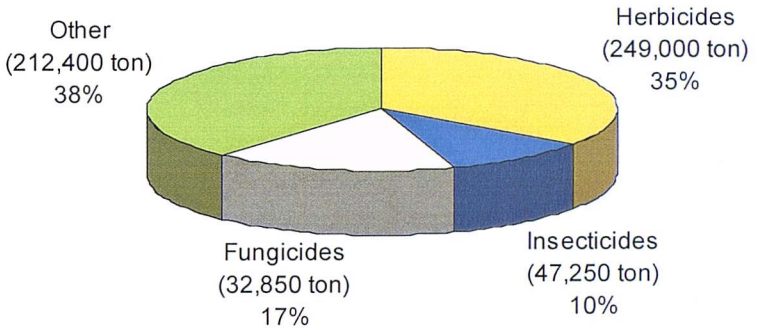
[131] US expenditures accounted for more than 40% of world expenditures on herbicides, 33% of world expenditures on insecticides, and more than 10% and 25% of world expenditures on fungicides and other pesticides, respectively (Donaldson *et al.* 2004)).

[132] Other includes nematicides, fumigants, rodenticides, molluscicides, aquatic and fish/bird pesticides, other miscellaneous conventional pesticides, plus other chemicals used as pesticides (e.g. sulfur and petroleum oil).

million ton in the same year, as well as, for more than 25% of world herbicide amount used, less than 10% of world insecticide amount used, and approximately 15% and 30% of world fungicides and other pesticide amount used, respectively.

Total pesticide amount used in the US approximated 2.25 million ton in 2001. This estimate included conventional pesticides, which represented 18% of the amount used, wood preservatives with 16%, specialty biocides 7%, other 6%[133], and chlorine/hypochlorites with 52%.

Figure 4.3 US pesticide active ingredient by pesticide type in 2001.
Source: Donaldson *et al.* (2004)



The most commonly used conventional pesticide active ingredients in the agricultural sector in 2001 were the following:

- Atrazine
- Glyphosate
- Metam Sodium
- Acetochlor
- Methyl Bromide
- 2,4-D
- Malathion
- Metolachlor
- Metolachlor-s
- Trifluralin
- Pendimethalin
- Dichloropropene
- Chlorothalonil
- Simazine
- Chloropicrin
- Copper hydroxide
- Chlorpyrifos
- Alachlor
- Propanil
- EPTC
- Dimethenamid
- Mancozeb
- Dicamba
- Sulfosate
- Ethephon

[133] Other includes other chemicals used as pesticides, e.g. sulphur and petroleum oil.

Glyphosate was the most used active ingredient in 2001 (between 38,250 ton and 40,500 ton), displacing atrazine, which had been the most used active ingredient in agriculture for a number of years. Fifteen of the top 25 active ingredients used are herbicides; three are fungicides; two are insecticides; four are fumigants; and one is a plant growth regulator.

The United States has a very important pesticide industry; there are 18 major basic producers, between 150 and 200 major national formulators and 250-350 major national distributors and establishments. It has 384, 092 commercial certified applicators (Donaldson *et al.*, 2004).

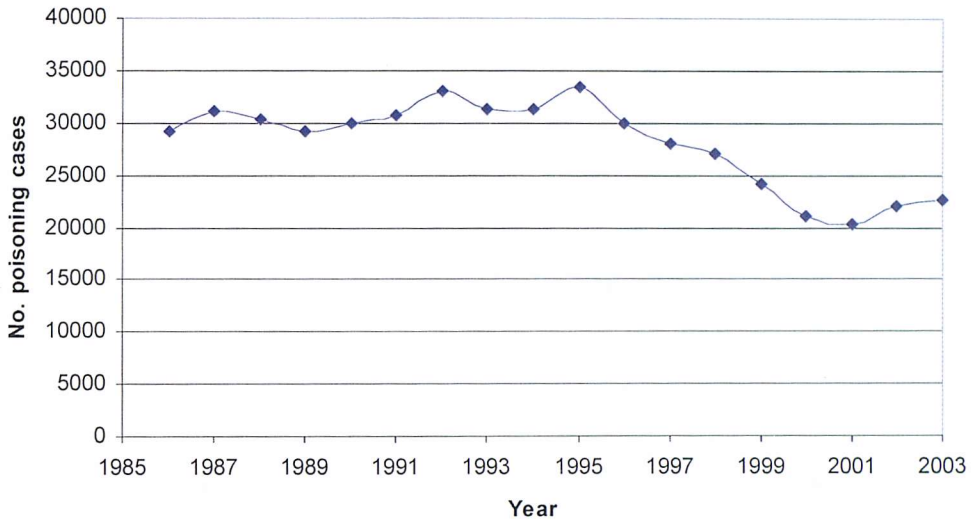
4.2.6 Health impact

According to data from the American Association of Poison Control Centers (AAPCC) reported by Watson *et al.* (2003) there were 97,677 cases of exposure to pesticides registered in 2003: 52.3% by insecticides, mainly by pyrethroid and organophosphate; rodenticides 20.1%, mainly with anticoagulant; repellents, mainly insect repellent with DEET; herbicides 9.6%, with glyphosate and chlorophenoxy as major compounds; fungicides 1.4%, along with wood preservatives; and finally fumigants with 0.5%, with sulfuryl fluoride the major compound. 41 deaths were reported caused principally by the organophosphate insecticides and the herbicide glyphosate. Langley (2002) reported that the main fraction of pesticide mortality in the United States is intentional poisonings, primarily suicides, which are decreasing more slowly than accidental poisonings.

According to Jeremy Blondell (personal communication), official of the Health Effects Division of OPP, since 1986-1988 to 2001-2003 there has been an overall 28% decline in estimated reported symptomatic exposures to pesticides reported in the United States (Figure 4.4). The single largest decline occurred for organophosphate insecticides which had accounted for 23% of all pesticide poisonings from 1986 to 1988, but more recently accounted for just 12% of all pesticide poisonings from 2001 to 2003; a decline of 65%. He

explains that much of this decline resulted from declining use brought about by cancellations, limitations in use, and more restrictive labelling imposed by the US Environmental Protection Agency.

Figure 4.4 Estimated numbers of symptomatic exposures for pesticides reported to the Toxic Exposure Surveillance System (TESS) of the American Association of Poison Control Centers (Blondell, 2004)[134].



4.2.7 Environmental effects

There have been reports of pesticide-related fish kills, some of them have been large, involving thousands of fishes, as well as frogs, turtles, mussels, water birds, and other wildlife. The official data on this subject were reported in the FY 2005 Annual Performance Plan (EPA, 2005b) where EPA reported the goal of reducing wildlife incidents and mortalities taking as baseline the reports of 1995, which accounted 80 reported bird incidents (involving 1150 estimated bird casualties) and 65 reported fish incidents (involving 632,000 estimated fish casualties) (EPA, 2005b).

[134] The data reported by AAPCC were adjusted according to changes in participation rates by Poison Centres and changes in US population.

4.3 The United Kingdom

At present there are two parallel systems of regulation of pesticides in UK. Under the first, the scientific evaluation of pesticides is carried out entirely at a national level and under the second a major part of the scientific evaluation is organised by the European Commission. The trend is that the second system gradually replaces the first one[135].

The regulation of pesticide in the United Kingdom is carried out by the Pesticides Safety Directorate (PSD), an agency of the Department for Environment, Food and Rural Affairs (DEFRA) created in 1993[136], and by the Biocides and Pesticides Assessment Unit (BPAU) of the Health and Safety Executive (HSE) (PSD, 2005). Specifically, PSD administers the regulation of agricultural, horticultural, forestry, food storage and home garden pesticides and BPAU deals with other non-agricultural pesticides such as rodenticides and biocides[137]. Due to the aims of this work, the main focus will be on the regulation of agricultural pesticide.

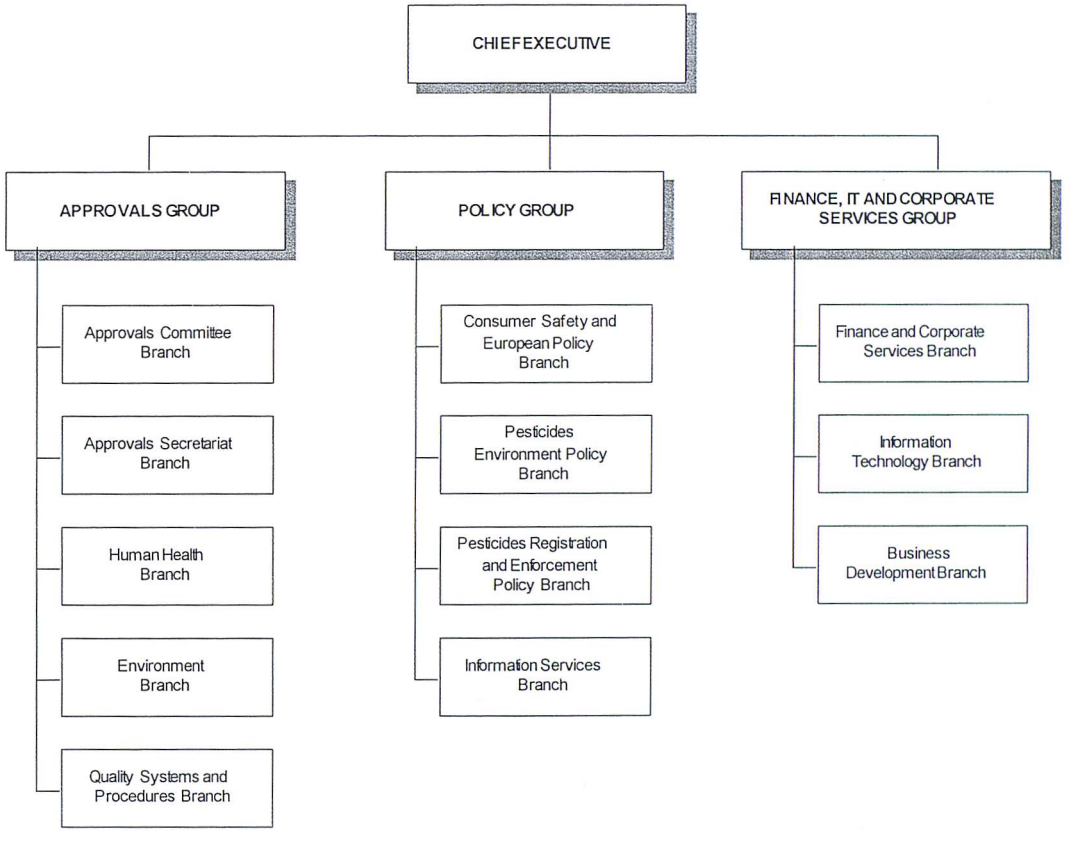
PSD's objectives are to ensure the safe use of pesticides for people and the environment; to reduce its negatives effects as a part of the move towards sustainable food and farming, and to harmonise pesticide regulation within Europe and provide a level playing field for crop protection.

PSD is headed by a Chief Executive, who is supported by a Management Board comprising three groups subdivided into a number of branches. The structure of PSD is presented in the Figure 4.5.

[135] The new plant protection products are increasingly being approved under the European system, and work has begun to review the many older pesticides that are on the market in individual Member States with the aim that eventually they too will be authorised in the same way. It will however, be some years before the process is complete, and in the meantime the national and European systems will continue to work in parallel (Advisory Committee on Pesticides, 2003).
[136] PSD was initially established as an Executive Agency of the Ministry of Agriculture, Fisheries and Food.
[137] Biocides include patio cleaners; masonry and wall washes to remove algae and mould, and surface wood treatments. BPAU also deals with ant, fly and wasp killers.

The approval group comprises of coordinating branches: **Approvals Committee and Secretariat**, which are responsible for the coordination of the evaluation and processing of applications for registration and UK/EU reviews, and specialist branches: **Human Health and Environment branches,** which encompasses the scientific evaluation of

Figure 4.5 Structure of Pesticide Safety Directorate (Source PSD, 2003a)



applications in health and environmental issues. **The Quality Systems and Procedures Branch** revises the quality systems within PSD and its procedures. **The Policy Group** encompasses the advice, development and implementation of UK pesticide policy (including enforcement) and associated national and European Legislation, as well as liaison with other Departments responsible for pesticide approvals and provision of information.

The Finance, IT and Corporate Services Group deals with financial affairs[138] such as liaison with industry on fees and charges issues, cost recovery and with parliamentary accounting and budgetary controls. In addition, it also is responsible of administrative issues such as marketing and publicity, contracts and development of databases.

The pesticide regulation system is supported by three independent committees, which are presented in the Table 4.5.

Table 4.5 Committees for the regulation of pesticides in the UK.

COMMITTEES	FUNCTION
Advisory Committee on Pesticides	To advise the Ministers on pesticide regulations, approval process of pesticide registration, the appropriate ways to control pests and to make information about pesticides available to the public. This is set up by Ministers under the Food and Environment Protection Act (FEPA). (Advisory Committee on Pesticides, 2003).
Pesticides Residues Committee	To carry out the monitoring of both produced and imported food for pesticide residues in order to back up the statutory approvals process for pesticides*.
Pesticide Resistance Action Groups	To produce advice on current pesticide resistance issues. These are informal UK-based groups consisting of experts from different organisations and groups** (PSD, 2003b).

* Some 4,000 food samples are analysed each year for a wide range of pesticides with the result that the number of individual pesticide/food combinations is around 100,000. (PSD, 2003a).

** Examples of these are: 1) Crop Protection Association (CPA) represents those companies engaged in manufacture, formulation and distribution of Crop Protection products for agriculture, forestry, horticulture, gardening, industrial, amenity and local authority uses in the UK. 2) Rothamsted Research (Previous Institute of Arable Crops Research) is a research Institute on agricultural issues. 3) ADAS is the UK's leading research based consultancy to rural and land-based industries. 4) NIAB is an independent organisation working in the fields of food, farming, environment and research. 5) Home-Grown Cereals authority provide a market information service; sponsor or undertake research work in home-grown cereals and oilseeds; undertake other non-trading initiatives aimed at improving the production and marketing of cereals. 6) British Potato Council is a company that produces potatoes, and 7) The Horticultural Development Council is a statutory body who administer the collection of an 'industry levy' to fund essential near-market research and development for the benefit of UK horticulture.

4.3.1 Legal Framework

The legal framework of the pesticide regulation in UK is based firstly in statutory powers contained within the **Food and Environment Protection Act 1985** (FEPA)[139,140], which

[138] PSD is required to recover the full economic costs of its operations through charges for the services that it provides.

[139] The constitutional law of the UK is regarded as consisting of statute law and case law. The statute laws are appointed by the Parliament in acts denominated Acts of Parliament. Case law are developed through decisions by judges necessary to decide cases brought before them.

[140] The Food and Environment Act can be consulted at http://www.legislation.hmso.gov.uk/

establishes as aims to protect the health of human beings, creatures and plants; to safeguard the environment; secure safe, efficient and humanness methods of controlling pests, and to make information about pesticides available to the public (HSE, 2003a).

In order to achieve these aims, the **Control of Pesticides Regulations 1986 (COPR)** (SI 1986/1510) (as amended) define those types of pesticides which are subject to control and those which are excluded; prescribe the approvals required before any pesticide may be sold, stored, supplied, used or advertised; and allow for general conditions on sale, supply, storage, advertisement, and use, including aerial application, of pesticides. These regulations were updated by the **Control of Pesticides (Amendment) Regulations 1997** (SI 1997/188)[141].

FEPA also empowers authorities to set Maximum Residue Levels (MRLs) for pesticides in food: to issue Codes of Practice; to charge fees; to recover certain expenses; to authorise enforcement officers and to require manufacturers and dealers of pesticides to supply information. Specifically, pesticide residue levels in food are controlled by the **Pesticides (Maximum Residue Levels [142] in Crops, Food and Feeding Stuffs) Regulations 1999** (as amended).

Additionally, in order to incorporate the European legislation into UK law, and to recognise the jurisdiction of the European Court of Justice in matters of EU law[143], the **Plant Protection Products Regulations 1995 (PPPR)** [144] were created. These regulations implement the Directive 91/414/EEC concerning the placing of plant protection products (mainly agricultural pesticides) on the market in the EC[145] and harmonise the arrangements

[141] Similar legislation exists in Northern Ireland and the majority of products approved for use in Great Britain are subsequently approved for use in Northern Ireland (HSE, 2003a).
[142] Maximum Residue Levels are defined as the maximum concentration of pesticide residue (expressed as milligrams of residue per kilogram of food/feeding stuff) likely to occur in or food and feeding stuffs after the use of pesticides according to Good Agricultural Practice.
[143] United Kingdom joined to the European Economic Community (now the European Union) in 1973 and since when it has been a requirement to incorporate the European legislation into UK law.
[144] The original document can be consulted at http://www.hmso.gov.uk/si/si1995/Uksi_19950887_en_1.htm#end Last visited 28 November 2003.
[145] Northern Ireland has similar legislation.

for the regulation of plant protection products within the EU, and provides for a ten years review programme for active substances on the market before July 1993[146].

COPR will continue until all existing EC active ingredients are reviewed and placed on a list known as Annex I of the Directive. PPPR will apply to new active ingredients coming into the UK market and existing EC reviewed active ingredients that obtain Annex I listing. (PSD, 2003c).

4.3.2 Registration of pesticides

The approval to register pesticides is granted by Ministers of five Departments: Environment, Food and Rural Affairs; Transport and Local Regions (for the Health and Safety Executive); Health; The Scottish Executive Environment and Rural Affairs, and the National Assembly of Wales and the Department of Agriculture and Rural Development in Northern Ireland. There are different levels of approval (Table 4.6)[147]:

Basically, there are four general procedures used to process different types of application (Figure 4.6). It is appropriate to mention that every Committee or advisor group provide only comments and recommendations about the applications and on their basis the Ministers take the final decision to approval or refusal the applications (with the exception of minor amendments to products previously approved). In 2002/03, 1443 applications were processed of which approximately 66% were administrative approvals and 1% approvals for new active substances.

4.3.3 Other activities

Another important part of the work of PSD is centred on the harmonisation process of the pesticide regulation within European Union. Additionally, it is in charge of developing policy

[146] At the moment this period has been extended until 2008. More details are provided in the subchapter 3.2 Pesticides Regulation at European Community.
[147] These levels apply to agricultural and non-agricultural pesticides regulated under the national system, and to plant protection products regulated under the European system.

initiatives to reduce the negative effects by pesticide use and the proposal of alternatives to replace it, as well as to increase the public awareness on safe use and regulation of pesticides.

Table 4.6. Types of approvals to register pesticides in the UK.

TYPE OF APPROVAL	DESCRIPTION	PROCESSING TIME (WEEKS)*
Experimental	It permits the evaluation of new pesticides on limited scale in order to generate scientific data to support their commercial use. It is given for a limited period and covers only storage, supply and use, but not sale or advertisement.	19
Provisional	It allows commercial use of a pesticide (i.e. including its sale) for a stipulated period whilst it is being evaluated under the European system by Member States, or whilst specific scientific data are being generated.	26-29
Full	It allows the use and sale of the pesticide evaluated since all the data requirements necessary to support its use have been met. It is provided for a period of 10 years or longer.	30-51
Emergency	It allows the sale, supply and limited and controlled use of an unapproved product just in the case that a an unforeseeable pest has risen that cannot be contained by other means. This is provided for a limited period of up to 120 days.	1

* Data are from the period 2002-2003 (PSD, 2005).

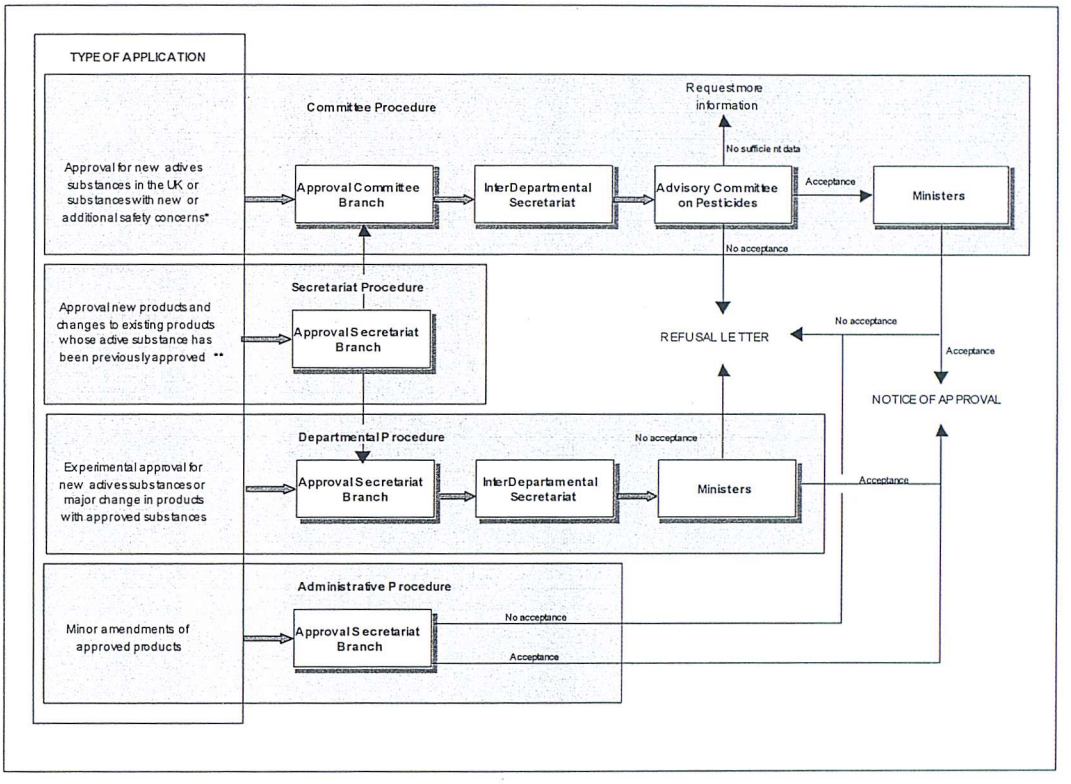
In conclusion, the UK is currently operating a parallel process for the registration of pesticides. In this way, the evaluations of active substances seeking Annex 1 listing with UK as rapporteur or provisional approval prior to Annex 1 listing are evaluated through Committee Procedure and the existing active substances continue being evaluated under the national regulatory process (Figure 4.6), the latter until the EC finished the re-evaluations of existing substances. However, the EC regimen will gradually replace the national ones.

4.3.4 Use of pesticides

According to the Department for Environment, Food and Rural Affairs (DEFRA) UK farming contributes £6.6 billion a year to the economy, uses around three quarters of this country's land area, and employs over half a million people (DEFRA, 2003). In 2005, this sector contributed with 1.1% to the GDP (CIA, 2006).

Agriculture in the UK is based mainly on cereals (wheat and barley are the main crops), which use less pesticides compared with fruits and vegetables. According to a report of Alberta Environment (2001), the use intensity[148] of pesticides in the UK, was of 3.4 kg ai/ha,

Figure 4.6 Procedures for processing of applications for approval.



* Include those substances seeking Annex 1 listing with UK as rapporteur or provisional approval prior to Annex 1 listing.
** The evaluation is undertaken by the Approval Secretariat Branch and, where appropriate, advice from departmental or committee experts is sought. The approval includes commercial approval (including parallel imports), experimental approval and extension of use (off-label) approval of substances also listed in Annex 1 of 91/414/EEC.

which is less than the intensity of use for Italy (5.4 kg ai/ha) or France (4.6 kg ai/ha), which are among the main producers of cereals in Europe.

The Crop Protection Association (2003) in the period 2000/01 reported that the areas treated with herbicides were 10,767,000 ha, specifically the area treated to cereals represented 76%, sugar beet 10% and 7% oilseed rape[149]. The area treated with fungicides was of

[148] Use intensity is determined by dividing total use of pesticide active ingredients by agricultural land area.
[149] The area treated is the number of hectares of crop grown multiplied by the number of times the relevant treatment was applied at full or reduced rate dose rates.

11,587,000 ha, cereals were the main crop treated with 80% of total area, followed by potatoes with 13% and oilseed rape with 5%. Table 4.7 summarises of areas grown and treated for the period 2000/01.

Table 4.7 Area planted and treated[1] with pesticides in UK 2000/2001 crop.
(Source: Crop Protection Association, 2003)

	CEREALS	POTATO	SUGAR BEET	OILSEED RIPE	PEAS	FIELD BEANS	LINSEED
AREA GROWN							
2000/2001	3,323	181	181	385	148	171	26
HERBICIDES							
Total[2]	8,137	338	1,046	736	279	200	31
Couch/stubble	488						
Grassweed and residual	3,598						
Broad-leaved weeds	4,051						
FUNGICIDES							
Total	9,216	1,461		557	146		207
Foliar sprays	8,977						
Seed treatments[3]	239						

[1] Hectares treated can exceed the hectares grown as some of the area is treated more than once.
[2] Includes clean up products
[3] For the control of mildew and broad-spectrum products

The sales of agricultural and horticultural pesticides represented £360.6 million in 2003 and 22,967 tonnes of active ingredients were sold during the same year, herbicides represented 63% of the sales with 14,408 tonnes sold and fungicides represented 18% with 4,109 tonnes (Crop Protection Association, 2004).

In this same year imports represented £249.3 million, with herbicides mainly imported, 52% of the total imports, and fungicides at 30%. Exports represented £258.7 million, with herbicides and insecticides the main exports with 62% and 14%, respectively (Table 4.8).

4.3.5 Effects to human health

In the Pesticide Incidents Report (HSE, 2005), the Field Operations Directorate (FDO) of the Health and Safety Executive (HSE) reported the number of incidents and complaints involving pesticides. During 2004/05, FDO investigated 150 reported pesticide incidents (Figure 4.7). Fifty complaints involved allegations of ill health, with the remaining 95

Table 4.8 Imports and exports of plant protection products in 2003 (1 Jan – 31 Dec).
Source: Crop Protection Association (2004).

IMPORTS	£ (000)
Herbicides	130,880
Fungicides	74,865
Insecticides	14,832
Seed treatment	16,822
Plant Growth Regulators	8,469
Others	3,448
TOTAL	249,316
EXPORTS	
Herbicides	160,432
Fungicides	37,131
Insecticides	56,537
Seed treatment	1,433
Plant Growth Regulators	261
Others	2,921
TOTAL	258,715

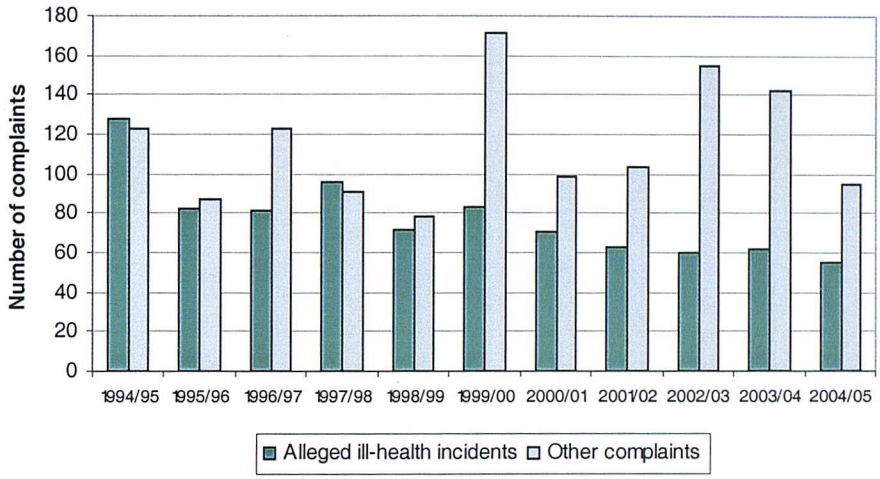
complaints involving other issues related to pesticides. The number of complaints alleging ill health is seven less than in 2003/04 and 18 lower than the average of the previous ten years.

With regard to the 55 alleged ill-health incidents reported, 52 involved members of the public (67 persons) and 3 (3 persons) involved employees/self-employed[150]. The ranking of severity designated for the incidents are: confirmed, likely, open assessment, and insufficient information. No incident has been confirmed, 5 were assessed as having a "likely" link to pesticide exposure. 15 were reported as pending, which may in due course be categorised

[150] Health and Safety Executive reported that the majority of people involved in reported incidents each year continue to be members of the public (HSE, 2003b).

as confirmed or likely. 3 incidents are in the category open assessment and for 25 incidents had no sufficient information. As can be seen in the Figure 4.7 the number of alleged ill-health incidents has fallen steadily since 1999/2000.

Figure 4.7 Number of alleged ill-health incidents and other complaints reported (by the Field Operations Directorate from 1994/05 to 2004/05. Source: HSD, 2003b.

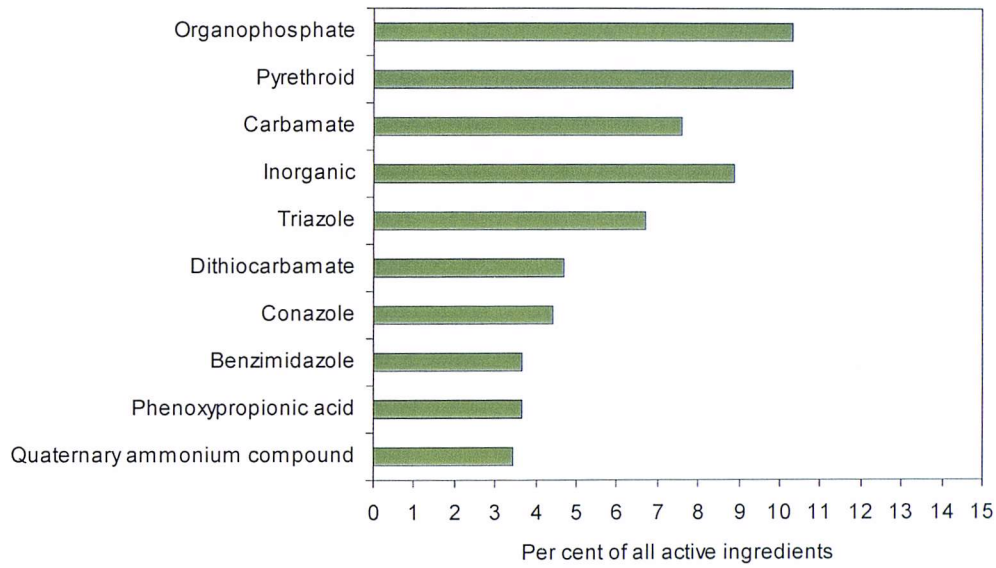


The most common pesticides involved in the incidents are herbicides, followed by insecticides and fungicides. Figure 4.8 shows the top ten chemical types involved in confirmed/likely incidents 1993/94-2002/03. Organophosphates and pyrethroids were the most commonly recorded pesticide types involved in poisonings over the period 1993/94-2002/03 and 2004/05. Indeed, these chemicals remain as the most commonly recorded active ingredients involved in incidents over the past ten years. However, FDO highlights that the relative importance of particular categories may simply reflect the fact that their usage is more widespread rather than indicating that they are more hazardous, and also mentions that a pesticide can have more than one active ingredient and non-active components, so it is difficult to determine which was responsible (HSE, 2005).

4.3.6 Effects to the Environment

With regard to environmental and other complaints during the period 2004/05 there were 95 incidents reported. This is a decrease of 47 (33%) over 2003/04 and compares with an average of 117 and a range of 78 to 171 in the previous ten years (1994/95-2003/04).

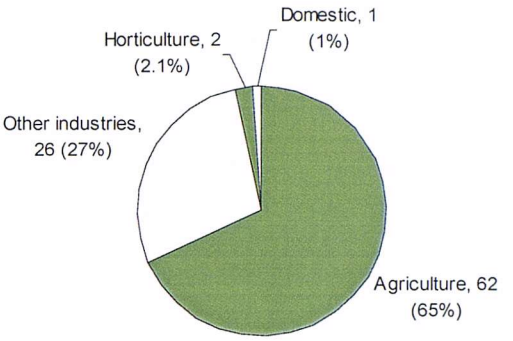
Figure 4.8 Top ten chemical types involved in confirmed/likely incidents 1993/94-2002/03.
Source: HSE, 2003b.



Note: Shows percentage of all active ingredients excluding not known.

The Figure 4.9 summarises the number of complaints in 2004/05 classified according to the industry sector in which the pesticides were used. Crop spraying was the main activity related to the complaints as well as weed control.

Figure 4.9 Number of environmental and other non-health complaints 2004/05 classified by sector.
Source HSE, 2005



Note: Only Confirmed/likely cases are included.

According to the annual report of the Wildlife Incident Investigation Scheme (WIIS) published by DEFRA (DEFRA, 2002b) a total of 346 incidents of pesticide poisoning in animals were reported, where 109 of these were confirmed as being caused by pesticides. There were 3 reported incidents arising from approved use of pesticides; 81 incidents were reported as a result of deliberate abuse of pesticides; 7 were reported as a result of misuse of pesticides, 17 cases were reported in which the cause was not identified as any of the above and 1 was caused by a veterinary product.

In support of the WIIS, the UK Agriculture Departments leads the Campaign against Illegal Poisoning of Wildlife. This supports the investigation of suspected incidents of deliberate abuse and can lead to prosecution of offenders[151].

[151] This campaign also advises farmers and land managers on legal ways of controlling pests and encourages the public to report illegal poisoning activities. Information about this campaign can be founded at www.pesticides.gov.uk/citizen/caip.htm

4.4 European Union (EU)

In the European Union, pesticides and their active substances are regulated under the Council Directive 91/414/EEC, which establishes a framework for the authorisation of agricultural pesticides in the EU, together with a number of EC Directives specifying Maximum Residue Levels (MRLs) in foods and feeding stuffs. The Directive was published in July 1991 and implemented by Member States in July 1993.

The main elements of the Council Directive 91/414/EEC are to harmonise the overall arrangements for the authorisation of pesticides within the European Union by matching the process for considering the acceptability of active substances in respect to environment and health and, by establishing harmonised risk assessment criteria for Member States to use a national level. The active substances authorised to use within EU are listed in the Annex I of the Directive, so Member States can not authorise the use of any active substance which is not listed in Annex I (except where transitional arrangements apply). The Directive also makes provision for a system of mutual recognition, in which Member States are obliged to grant authorisations on the basis if those granted in other Member States[152] (Smeets, 2003).

Under the basis of the Directive currently a two stages registration process has been established, where active substances are assessed for acceptability at the Community level, while the safety and efficacy of products and uses are evaluated at the Member State level. In parallel, there is an EC review for all existing active substances, defined as those on the market on one more member states in 1993.

The process of evaluation and authorisation by the European Community for both new and existing active substances implies firstly the initial expression of interest in supporting an active substance by a notifier, followed by submission of a dossier confirming to the data

[152] This is subject to comparability of the agricultural, plant health and environmental conditions in the two Member States.

requirements (Annexes II and III[153]) of the Directive. A rapporteur Member State then conducts an evaluation of the data submitted in the dossier producing a Draft Assessment Report (also known as draft monograph). The Draft Assessment Report is then considered via a technical peer review process in which other Member States jointly review the outcome of the evaluation conducted by the rapporteur and to identify any outstanding issues and confirm outstanding data requirements. Following peer review, the evaluation is discussed in a European Commission Working Group – Evaluation, at which all Member States have an opportunity to consider whether all the outstanding issues have been satisfactorily addressed[154]. After that the active substance is considered in the Working group –Legislation where the Commission will seek views on a proposal for inclusion in Annex I of the Directive, or not, as appropriate. A vote based on qualified majority will then be taken by the Standing Committee on Food Chain and Animal Health (SCFA). The outcome of the vote is then reflected in a Decision adopted and then published by the European Commission in the Official Journal.

The major area of activity has been the EC review programme. In 2005, a total of 967 active substances are due to be considered in a programme which last until 2008. To date 458 substances have been withdrawn, the majority for commercial rather than safety reasons and 54 added to Annex I. 455 remain under review. During the period of the review 63 new active substances have been also added to Annex I (Davis, 2005)[155].

Additionally, in order to facilitate the decision making process, the European Commission has limited its evaluation to specific uses of the substances, hence all the remaining uses would be evaluated for safety and efficacy during re-registration[156] at the Member State

[153] Annex II of the Directive setting up the data requirements for active substances and Annex III for plan protection products, The data requirements encompass six areas of the risk assessment: physical and chemical properties, environmental fate and behavior, ecotoxicology, mammalian toxicology, residues and (Annex III only efficacy).
[154] On some occasions either the peer review or Evaluation Group may refer a particular scientific issue to the Scientific Committee (now Scientific Panel) for an expert opinion before reaching a final judgement.
[155] It is important to stress that Article 8.2 of the Directive provides a derogation that allows Member States to continue to regulate products containing existing active substances in accordance with existing national legislation for a period of fifteen years from the date of the Directive coming in force, i.e. until 25 July 2003.
[156] The authorisation of products at Member State level is known as re-registration.

level, which visibly increase their workload and duplicate their efforts as all Member States will be evaluating the remaining uses at the same time (Flynn, 2003).

With regard to the evaluation of pesticides at Member States level is must follow the criteria established in the Article VI of the Directive, which sets out the so-called "uniform principles" for the assessment of the acceptability of products[157] (Flynn, 2003). However, there is not a standard format and every country carries out the evaluations according to their regulation system, which has created inconsistency in the decision making.

Facing these problems the European Union has established an expert-working group to consider the issues and develop proposals for a more harmonised procedure, similar to the programme of work-sharing established for the pre-Annex I. Specifically, the proposal should be based on the concept of mutual recognition[158].

After a revision of the Directive new authorisation regulations are being planed, which are expected to form part of a package of legislation within a "thematic strategy for the sustainable use of pesticides" including: 1) the 91/414/EEC replacement regulation; 2) A framework directive on the sustainable use of pesticides dealing with issues like the training of operators, the certification of spraying machinery and special protection measures for sites of particular conservation value and 3) a draft regulation on the collection of data on pesticide sales and use (Davis, 2005).

Table 4.9 summarises some aspects on the pesticide regulatory systems for the UK, USA, Canada and Mexico.

[157] The details of the uniform principles were published I Directive 97/57/EC (EC, 1997).
[158] The authorisations granted in accordance with the Directive in one Member State should be accepted by other Member State, subject to the establishment of comparable conditions, this is known as "mutual recognition".

4.5 The Organisation for Economic Cooperation and Development (OECD)

The OECD is an intergovernmental organisation which coordinates and harmonises government policies, addresses issues of mutual concern and responds to international problems. Its work covers economic and social issued from macroeconomics, to trade, education, development and science and innovation. Its publications, recommendations and statistics on these subjects are between its main contributions.

Due to the influence of pesticides on the economy, health and the environment, the OECD created a Pesticide Programme in 1992 whose aim is to improve the efficiency and effectiveness of pesticide regulation. The programme deals with both chemical pesticides and biological pesticides used in agriculture[159]. The programme supports three objectives, 1) help OECD governments share the work of pesticide registration and re-registration; 2) harmonise the data and methods used to test and assess pesticide risks and, 3) help OECD governments reduce the risks associated with pesticide use to supplement pesticide registration. The program is directed by the Working Group on Pesticides (WGP)[160].

OECD has carried out studies, formats, guidelines and surveys in order to create the basis for work sharing and star the process of harmonisation for regulatory approaches. One of the first activities consisted in the development of an inventory of national data requirements for pesticides, for which a survey was carried out among seventeen Member countries and the European Community. The results showed a high degree of similarity in the data required by OECD countries and by the EU for registration of conventional plant protection products. In most major tests areas, there was significant commonality both in the data elements themselves and in the frequency with which they were required, as well as in data required

[159] OECD work concerning antimicrobial pesticides or non-agricultural pesticides (e.g. disinfectants, antifoulants) is managed by the Biocides Programme.
[160] The Working Group on Pesticides is made up primarily of representatives of the 30 OECD governments but also includes representatives of the European Commission and other international organisations, the pesticide industry, and the environmental community.

for active ingredient or formulation (OECD, 1994). Despite this overlap, the survey also revealed some important areas of divergence, mainly in ecotoxicology and efficiency studies.

Table 4.9 Some data on the pesticide regulatory systems for pesticides in the UK, USA, Canada and Mexico.

	UNITED KINGDOM	UNITED STATES OF AMERICA	CANADA	MEXICO
REGULATORY BODY	Pesticides Safety Directorate (PSD)	Office of Pesticides (OP)	Pest Management Regulatory Agency (PMRA)	Inter-Secretarial Commission for the use and process of Pesticides, Fertilizers and Toxic Substances (CICOPLAFEST)
DATE OF CREATION (REGULATORY BODY)	1993	1979	1995	1988
MINISTRY IN CHARGE (LEADER)	Department for Environment, Food and Rural affairs	Environmental Protection Agency	Ministry of Health	Secretariats of Health, Economy, Environment and Natural Resources, Agriculture, Livestock, Fisheries, Food and Rural Affairs.
MAIN REGULATORY STATUTES	Food and Environment Protection Act 1985 (FEPA) and the Plant Protection Products Regulations 1995 (PPPR)	The Federal Insecticide, Fungicide, and Rodenticide Act 1947 (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA)	New Pest Control Products Act (PCPA) and Food and Drugs Act 1985	General Health Law 1984
PESTICIDE REGISTRATION FEES FOR A NEW ACTIVE INGREDIENT [TIME DECISION IN MONTHS]	Chemical pestidcide – $189,840[21] Biological or pheromones - $85,428[21] [30-36]	Chemical Pesticide - $475,000[18] [24] Antimicrobial pesticide- $150,000[19] [24] Biopesticide - $40,000[20] [18]	$167,439[17] + annual maintenance fee (3% of sales/year) [24]	Category I (extremely toxlc)- $4,109 Category II (highly toxic)- $3,423 Category III (moderately toxic) ...$2,282 Category IV (slightly toxic) .....$1,735[16] [4-5]
RE-REGISTRATION PROCESS	In place	In place	In place	No implemented
ANNUAL BUDGET	$24 million[1]	$137.7 million[4]	$30.5 million[9]	NA
NO. EMPLOYEES	200[2]	800[13]	486[10]	30-35[11]
NUMBER OF CASES OF POISONING IN HUMANS	50[12]	97,677[14]	1,650[15]	2,508[6]
INCIDENTS OF POISONING IN THE ENVIRONMENT	142[1]	NA	NA	NA
SALES OF PESTICIDES	800 million[3]	$11, 000 million[5]	NA	$571 thousands[7]
IMPORT	$473 million[3]	$1.0 billion	NA	NA
EXPORT	$491 million[3]	$1.6 billion	NA	NA
INTENSITY OF USE	3.4[22]	2.8[22]	0.9[22]	NA

[1]Annual Report and Accounts 2003/2004 (PSD, 2004). The budget comes from: fee paid work (22%), pesticide levy charged to industry (32%), direct government funding (42%) and Commission-funded work (1%). Exchange rate: 1 US dollar = 1.88 UK pounds
[2]Annual Report and Accounts 2003/2004 (PSD, 2004)
[3] UK Sales of Plant Protection Products 2003 (Crop Protection Association, 2004). Estimate considering an exchange rate: 1 US dollar=1.75 pounds.
[4] EPA Pesticide Programme FY 2004 Annual Report (EPA, 2005d).
[5] Donaldson et al. (2004) Pesticides Industry Sales and Usage: 2000/2001-Market estimates-
[6] Sistema Unico de Informacion para la Vigilancia Epidemiologica, (SSA, 2006).
[7] This value is an estimation from the national market value from the sales of the main companies in the country in 1999.
[8] Sales in 1995 (Cortinas C, 2000).
[9] PMRA (2004).
[10] The Regulatory Information Officer, PMRA.
[11] Capetillo, 2006; Personal Communication.
[12] Pesticide Incidents Report (HSE, 2005).
[13] Blondell (2004) .
[14] Watson *et al.* (2003).
[15] Centre Anti-Poison du Quebec (1997).
[16] Rate of exchange: 1 peso=0.09 US dollar (2006).
[17] Guidance Document on Pest Control Product Cost Recovery Fees, PMRA. At: http://www.pmra-arla.gc.ca/english/appregis/costrecoveryfees-e.html. Biopesticides and proposals for user requested minor use label expansion are exempt from fees. Rate of exchange: I Canadian dollar=0.89 US Dollar (2006).
[18] Fee registration for a chemical pesticide, food use (R1-56). Source: Pesticides; Fees and Decision Times for Registration Applications, EPA. At: http://www.epa.gov/fedrgstr/EPA-PEST/2004/March/Day-17/p6001.htm
[19] Fee registration for an antimicrobial pesticide, food use with tolerance (A39-37). Source: Pesticides; Fees and Decision Times for Registration Applications, EPA. At: http://www.epa.gov/fedrgstr/EPA-PEST/2004/March/Day-17/p6001.htm
[20] Fee registration for a biopesticide food use, microbial/biochemical with tolerance (B58-03). Source: Pesticides; Fees and Decision Times for Registration Applications, EPA. At: http://www.epa.gov/fedrgstr/EPA-PEST/2004/March/Day-17/p6001.htm
[21] PSD Fees Charged for Individual Application Types, PSD, 2006. At: http://www.pesticides.gov.uk/approvals.asp?id=50 Rate of exchange: 1 US dollar = 1.89 pounds.
[22] Source: Alberta Environment (2001). The UK and USA data are estimated using sales data in 1995 and for Canada 1988.
NA: No available

Following the survey results, a pilot project was carried out from 1993 to 1994 in order to compare how different countries and international organisations had evaluated the same or similar data on health and environment effects. The principal finding of this project was that in spite of the difference found in the evaluations there is a potential use of these reviews among OECD countries to complement independent reviews of the member countries and the possibility of beginning immediately the cooperation in re-registration programmes (OECD, 1995).

In 1998, OECD members agreed guidance concerning two formats to be used throughout member countries: one for industry to use with respect to the format and presentation of the documentation required to apply for a registration of an active ingredient or a plant protection

product (dossiers)[161] and one for the government to use when writing their evaluation reports of the application submitted for industry (monographs)[162]. These guidelines were updated in May of 2005. To complement these formats, the OECD initiated a new project to develop "templates" for the development of individual test studies (Sigman, 2005). The OECD is also developing one XML (Extensible Mark-up Language) "Schema" or electronic export format, for each template to be able to exchange data electronically. There are also guidelines for registration requirements for biological pesticides[163].

In 2001, the OECD carried out another survey aiming to define the best practices in the regulation of pesticides among OECD countries to support also comparisons, benchmarking and work sharing. Twelve countries participated in the survey and the best practices were (OECD, 2001a):

- Clearly defining of requirements
- Data screening and preliminary review for deficiency to ensure quality
- International harmonization of requirements, sharing of reviews and acceptance of data assessments from other countries
- The preparation, submission and tracking of information electronically
- The establishment of performance standards
- The use of third party accreditation and auditing of policies and practices
- Consultation with the public and with industry

[161] This is called the OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances, which can be consulted at: http://www.oecd.org/document/55/0,2340,en_2649_34383_33650359_1_1_1_1,00.html Last visited 22 January 2006.
[162] This is called the OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances, can be consulted at: http://www.oecd.org/document/12/0,2340,en_2649_34383_33650316_1_1_1_1,00.html Last visited 22 January 2006.
[163] a) Guidance for Registration Requirements for Pheromones and other semiochemicals used for anthropod pest Control. Consulted at http://www.oecd.org/dataoecd/44/31/33650707.PDF Last visited 22 January 2006.
b)Guidance for Registration Requirements for Pesticide Microbial. Consulted at http://www.oecd.org/dataoecd/4/23/28888446.pdf Last visited 22 January 2006.
c) OECD Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents (Dossier Guidance for Microbials), Series on Pesticides No. 23. Consultated at http://www.oecd.org/document/7/0,2340,en_2649_34383_32286855_1_1_1_1,00.html Last visited 22 January 2006.
d) OECD Guidance for Country Data Review Reports on Microbial Pest Control Agents (Monograph Guidance for Microbials), Series on Pesticides No 22.
http://www.oecd.org/document/4/0,2340,en_2649_34383_32289284_1_1_1_1,00.html Last visited 22 January 2006.
e) Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCAs). Consulted at: http://www.oecd.org/dataoecd/6/20/28725175.pdf Last visited 22 January 2006.

- Providing ready and wide public access to data and assessments and,
- Organising scientific expertise into multi-disciplinary groups

The OECD has also developed a database called Database of Government Review Schedules for Biocides and Pesticides, which lists many of past and current schedules for OECD government reviews of active ingredients in agricultural pesticides and biocides[164], thus it is easy to identify work sharing opportunities.

The OECD also seeks the harmonisation of the methods to evaluate pesticide risks to health and the environment to fulfil the pesticide registration data requirements. At present, it has developed a harmonised approach to the conduct of studies of occupational exposure to pesticides during agricultural application[165] and the guide for the analysis and evaluation of data from chronic exposures of toxicity test species to pesticides and other chemicals[166].

The OECD also promotes the use of Integrated Pest Management (IPM) as a way of reducing pesticide risks, the development of indicators that can help governments to track trends in these risks and recommend ways to eliminate obsolete pesticide stocks and avoid their accumulation.

However, the OECD recognises that in spite of work sharing is taking place this is still less frequent, so it mentions that a clear political will and increased resources are needed. In response, in 2004 the OECD adopted its vision which establishes the objectives to be reached in relation to harmonisation and work sharing. The vision ensures that by the end of 2014 the risks from pesticide use will be minimised to the extent possible and higher level of protection to human health and the environment will be enhanced. The regulatory system for agricultural pesticides will be harmonised and work-shared to the extent that data review

[164] This can be consulted at http://www.oecd.org/statisticsdata/0,2643,en_2649_34383_1_119656_1_1_1,00.html
[165] Guidance Document for the Conduct Studies of Occupational Exposure to Pesticides during Agricultural Application can be consulted at Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application.
[166] Guidance Notes for Analysis and Evaluation of Chronic Toxicity and Carcinogenicity Studies at http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)19.

report (monographs) prepared following the OECD format can be used to support independent risk assessment and independent regulatory decisions made in other regions or countries; data submissions following the OECD format will be accepted among OECD members, and industry will coordinate their preparation of data submissions to maximise work sharing between regulatory authorities. It is important to highlight that the vision does not exclude the need of developing particular assessments or supplementary data submissions to address local/national needs.

4.6 Other organisations

- European and Mediterranean Plant Protection Organization (EPPO)

EPPO is an intergovernmental organization responsible for international cooperation in plant protection in the European and Mediterranean region. In the sense of the Article VIII of the FAO International Plant Protection Convention (IPPC), it is the regional plant protection organization for Europe. Founded in 1951, EPPO now has 48 member governments including nearly every country of Western and Eastern Europe and the Mediterranean region (EPPO, 2006).

- North America Plant Protection Organisation (NAPPO)

Similar to EPPO, NAPPO is the intergovernmental organisation of the IPPC for the North America region. So, NAPPO coordinates the efforts among Canada, the United States and Mexico to protect their plant resources from the entry, establishment and spread of regulated plant pests, while facilitating intra/ interregional trade (NAPPO, 2006). It also provides support to NAFTA technical groups when required.

Both regional organisations cooperate with the IPPC in developing and promoting the use of international standards.

4.7 Discussion and conclusions

After the review of the regulatory systems for pesticides in the EU, UK, Canada and US it was clear that the current international trend of pesticide regulation shows three main lines:

- To harmonise registration processes with respect to data requirements, methodologies to carry out the studies required and mechanisms of evaluation of the applications and, the structure and content of the report of the evaluation. This aims to share the burden of pesticide evaluation among governments, reduce the need for duplicative testing by industry and easy trade.
- To re-evaluate old pesticides already registered through a process of re-registration in order to verify they meet the current standards of protection for human health and the environment.
- The minimisation of the risks from pesticide use through programmes of Integrated Pest Management, sustainable development and good agricultural practices, and encouragement of the use of alternative pesticides to chemical pesticides.

In this respect, in the European Union to date, new active substances are approved for their use at the Community level and plant protection products are approved at national level but following a set of common rules called the Uniform Principles stated in the Directive 91/414/EEC. The Community also aims for a mutual recognition of national authorisations and to provide protection of commercial information. Additionally, a major review programme for existing active substances is being carried out at the Community level and reforms to the Directive 91/414/EEC are being planned within a thematic strategy for the sustainable use of pesticides, which will include training to operators and special protection measures for sites of particular conservation value, among other.

For its part, the OECD's vision is that by 2014, OECD countries will routinely accept dossiers prepared from stakeholders in the OECD format: will routinely exchange "monographs" containing reviews of the data submitted, and will use OECD "monographs" as a basis of

independent risks assessments and regulatory decisions for new and existing pesticides (Sigman, 2005).

As a result of the participation in the OECD Pesticide Programme Australia and Japan have also begun work sharing information on pesticide registration. Japan has published English versions of its evaluation reports to facilitate it.

Within of the framework of NAFTA, Canada and the United States have developed common formats including electronic approaches for submissions and for their review, common test guidelines and data requirements for submissions. They are also matching their regulatory system for the joint establishment of MRLs on commodities imported into NAFTA countries, and have also completed the development of a pesticide applicator core exam. At present, joint reviews for new active substances and products are being carried out.

Chapter V Proposals to improve the regulatory system for pesticides in Mexico

This chapter provides a background to the proposed re-organisation and improvement of the performance of CICOPLAFEST, elaborating on both private and public bodies involved. On the basis of the findings of these studies and considering the shortcomings of the regulatory system for pesticides in Mexico highlighted in Chapter II, and the international trends in the regulation of pesticides explained in Chapter IV, three proposals are presented. In addition, qualitative assessments based on the economic, organisational/administrative and political feasibility of the proposals, as well as a general evaluation of their performance in terms of efficiency, effectiveness and relevance, have been carried out. Based on this evaluation one proposal is selected as the most viable to promote a meaningful improvement to the pesticide control in Mexico.

5.1 Background

In the section about CICOPLAFEST in Chapter II the three studies that evaluated its functioning and proposed alternatives to improve it were mentioned. The first one, carried out by Quantica S.A. in 1998, concluded that the best option to improve the regulatory

system for pesticides was to break up CICOPLAFEST and create a decentralised body[167] with legal power and its own infrastructure, which would concentrate all the responsibilities to regulate pesticides.

The second study was done by the Federal Regulatory Improvement Commission (COFEMER), which proposed that just one Secretariat should concentrate the legal powers to regulate pesticides and would be in charge of all issues related to these products (COFEMER 2000). However, it did not mention which Secretariat would be most suitable.

The National Institute of Public Management (INAP) carried out the third study in 2002 and proposed three possible scenarios: 1) to implement strategic management in CICOPLAFEST, which would imply changes in its organisation but without legal or structural modifications; 2) to create a decentralised body with legal power and its own infrastructure and, 3) to create a specialised body, similar to the European Commission, which would be based on principles of subsidiarity and co-decision among permanent commissaries that would have responsibilities in accordance with their role in the Secretariats.

INAP analysed qualitatively the political and economic feasibility of the scenarios, as well as their acceptability and adaptation, in terms of cost, time of implementation, degree of innovation, reaction of officials, coherence with the culture and adaptation to current organisational models. It determined that the best scenario, on technical criteria, was the creation of a decentralised body with legal power and its own infrastructure; however, it stressed that its acceptability would be low due to its high cost and time for implementation and hence there would be an unfavourable reaction by many officials. In consequence, this institute concluded the most viable scenario would be the first one, which would demand low cost of implementation and high acceptability among officials.

[167] Under Article 17 of the Ley Organica de la Administracion Publica (Public Management Law) (DOF, 1976) a decentralised body is defined a body created by law or decree of the National Congress or of the Executive government, which has juridical power and its own resources and infrastructure.

5.2 Proposals to improve the structure of the regulatory system for pesticides

Based on the findings of the studies aforementioned and considering the shortcomings of the regulatory system for pesticides in Mexico highlighted in Chapter II, and the international trend in the regulation of pesticides explained in Chapter IV, three proposals are presented in this work in order to analyse their viability and select the most viable. The proposals are the following:

Proposal 1 – A decentralised body

A decentralised body with legal power and its own infrastructure to regulate pesticides in an integral way considering economic, agricultural, environmental and health issues, which would imply to break CICOPLAFEST up and transfer the responsibilities to this body from the Secretariats involved in the regulation of pesticides. This body would have two advisory groups: the scientific and consultative committees. The funding would be provided by the government and by the recovery of fees for the services provided. This organisation would represent a suitable environment for an integrated improvement of the regulatory framework by addressing gaps in the regulation and strengthening those already in place. Additionally, it would also provide leadership and a unified representation of Mexico in international agreements and would be accountable to government on all matters concerning pesticides.

Proposal 2 –Leadership of the Health Secretariat on pesticide regulation

The concentration of the main activities to regulate pesticides in the Federal Commission for the Prevention of Health Risks (COFEPRIS) of the Health Secretariat (SSA) would provide the leadership to SSA for the control of pesticides in the country. So, the proposal implies the transfer of responsibilities from the Secretariats of Environment (SEMARNAT) and Agriculture (SAGARPA) to the SSA in the matter of registration of pesticides (including composition, labelling, packing and storage), Maximum Residue Levels (MRLs), import and some aspects related to manufacture, sale and use.

This office would be supported by specific advisors included in the scientific and consultative committees of the COFEPRIS and for an Inter-Secretarial Commission made up of SEMARNAT, SAGARPA, Secretary of Economy (SE), Labour Secretary (STPS) and the Secretary of Communications and Transport (SCT) for the definition of a national policy for pesticides. Financial support would be supplied by a readjustment to the governmental budget assigned to the SSA, which should compensate for these new responsibilities and by the recovery of fees.

Proposal 3 – A stronger, reorganised CICOPLAFEST

To reorganise CICOPLAFEST by providing more power to the President and Technical Secretary, creating a Technical Committee in charge of pesticide policy, two subcommittees related to training and diffusion and verification and enforcement, and the Scientific and Consultative Committees. As INAP also proposed, the Technical Secretary would be permanent and based in the Health Secretariat. A trust, funded by government would be created in order to provide economic resources to the Commission for the Technical Secretary's staff payroll and also to support programmes of monitoring, training and research.

5.3 Qualitative assessment

The evaluation of the proposals is based on a qualitative assessment of appropriate dimensions, which are considered to have a decisive influence in the definition of the viability of the proposals.

5.3.1 Dimensions

The suggested dimensions and their importance are described in the following paragraphs:

Policy. The government has been aware of the risks that the use of hazardous products represents to the human health and the environment and through its national programmes on health, the environment and agriculture have established strategies to address them, in which pesticides are included. So, political viability could be measured by determining the congruence of the policies established by the government related to hazardous products and particularly on pesticides with the impact that the proposals would have on the regulation of these products if they are implemented, in other words, whether the government policies can support or not such impact.

Economic resources. The current policy of economic austerity, national limited resources and the current lack of ambitious projects on the government side to update and improve the regulation of pesticides reduce the feasibility of high investment scenarios. In this perspective, an inverse relationship between the economic viability of the proposals and their investment and running costs can be inferred. That is, the viability would decrease if the costs increase. Therefore, a variable that directly infers the costs of the proposals will be defined and its values will be compared with each other in order to determine the economic viability of the proposals.

Administrative Organisation. The restructuring of the public administration and the adoption of new organisational models are a permanent task of the government to face the trends of regulation and demands of the country. So, some types of organisational models are favoured depending on the priorities or needs of the government that are required to be covered. In this case this dimension aims to determine the adaptability of the organisational models of the proposals to the current organisational structure of the public administration and to qualify their efficiency/effectiveness considering the performance of other organisations with the same organisational model.

Performance. The proposals present different structures of organisation, which implies different mechanisms of coordination, administration and operation that overall will define the

performance of the organisation and hence the straightforwardness or difficulty in which the goals will be achieved. The criteria proposed to analyse the performance are the following:

- Effectiveness. Successful in meeting targeted needs, achieving goals and how complete the coverage of issues is.
- Efficiency. How much output you get for each unit of input.
- Relevance. How appropriate the activities are in relation to institutional and stakeholder objectives.

5.3.2 Analysis of the dimensions

a) Policy

There are five policies that would have an impact on the viability of the proposals. They are listed in Table 5.1, which shows the congruence, positive (+) or negative (-), of the proposals with regard to them.

The agricultural productivity and trade liberalisation policies encourage a more intense use of pesticides through eliminating taxes on pesticides and trying to reach levels of production that compete in the international market (De Ita Rubio, 2003; Martinez and Martinez, 2005; SAGARPA, 2001; SEGOB, 2001). Because, the embracing regulation and attention that Proposal one would have on pesticides, the environmental and health issues would have an important influence, hence it would push to cancel the subsidy on pesticides and more restrictions on their use in favour of the protection to natural resources and health, and maybe to impose an environmental tax on these products, so Proposal one would present a marked incongruence with these policies. On the other hand, because of the limited change that Proposal three represents to the current regulatory system for pesticides and its lack of legal power to introduce deep changes in the regulation and its exclusive role as the coordinator body, it is expected that the Secretariats keep their support to their respective

policies. These policies would continue running, even though these are contradictory to the policy of protection of the population and the environment (changes to them would imply a long process due to the difficulties found to reach a consensus among the Secretariats involved). So, these policies would show congruency with Proposal three in the short and middle term but it will probably change in the long term when major information on human effects and environmental back stricter regulations on protection.

Proposal two would be in an intermediate position since the leadership of the Health Secretariat would be expected to put more attention on the protection of the population, although the presence of an Inter-Secretarial Commission would also introduce support to the economic aspects of pesticides.

The current policy on protection against risks by the use of hazardous substances is more inclined to create a global regulation through a protection to the population and workers against exposure to toxics substances, and it does not show a special trend for the regulation of pesticides (COFEPRIS, 2003; SAGARPA, 2001; SEMARNAT, 2001). Therefore, Proposal three shows more congruence with this policy because of the holistic cover of hazardous toxic materials in contrast with Proposal one that is specialised in pesticides. Proposal two would have a positive congruence although the focus on the regulation would have more weight on health issues.

The current policy of deregulation and administrative simplification that prevail in the country could support modifications to laws only if they represent a way to streamline regulatory processes (OECD, 2004; OECD, 2005; Morales, 2002). However, many legal reforms could represent an opposite trend within an administrative simplification policy and also considering modifications to laws are high time consuming. Additionally, Secretariats could show reluctance to concede their powers. So, because Proposals one and two demand reforms of at least five laws and two decrees, their congruency with this policy is low, although Proposal two would have an advantage over Proposal one because the consensus

among the officials of the CICOPLAFEST about the leadership of the SSA on pesticide regulation[168]. Hence, Proposal three would present strong congruency as its legal reforms include the modification of its decree of creation and its rules of work.

Proposal one also shows incongruence with the economic austerity policy, which aims to promote a more rational and efficient use of the government resources (Presidencia de la Republica, 2004), because it would imply the creation of new infrastructure without reusing the one already created and high costs of implementation and operation. Proposals two and three would imply less costs by the reuse of the infrastructure and the costs of operation for the centralised group in the SSA could be similar to the trust created to support the operation of CICOPLAFEST[169].

The policy analysis is summarised in Table 5.1, in which it can be seen that, according to the congruence assigned, Proposal three shows a high political feasibility, Proposal two is medium and Proposal one is low.

b) Economic resources

The current policy of economic austerity (Presidencia de la Republica, 2004), national limited resources and the current lack of ambitious projects by the government to update and improve the regulation of pesticides reduces the feasibility of high investment scenarios. In this perspective, an inverse relationship between the economic viability of the proposals and their investment and running costs can be inferred. That is, the viability would decrease if the costs increase.

[168] The new procedure to register pesticide appoints the complete responsibility of the Health Secretariat to authorise pesticide registration.

[169] In Mexico, the Inter-Secretarial Commission for Bio-security and Modified Genetically Organisms was initially supported by a trust but due to coordination problems (the shortcomings were similar to those found in the CICOPLAFEST) an Executive Office was created in the National Council for Science and Technology (CONACYT). So, the trust is being incorporated into the CONACYT budget to cover the expenses of the office; hence, in this case the costs of a trust and the funding for a centralised office are similar or easily adapted to both situations.

Table 5.1 Congruence of the proposals with relevant governmental policies.

POLICIES	PROPOSAL 1 A DECENTRALISED BODY	PROPOSAL 2 LEAD GROUP WITHIN THE HEALTH SECRETARIAT	PROPOSAL 3 A STRONGER, REORGANISED CICOPLAFEST
Protection against risks by the use of hazardous substances	---	++	+++
Agriculture productivity	---	-	++
Trade liberalisation	---	-	++
Deregulation and administrative simplification	+	+	++
Economic austerity	---	+	+++

Note: the signs + and - indicate a positive and negative congruence, respectively. The number of signs indicates the strength of the congruence being greater when there are three signs together and less when the number of signs is fewer.

In this way, the number of employees and that each proposal requires for its implementation can be used as an indicator of its costs and compared to each other in order to determine its relative economic viability.

The study of the INAP proposed that a decentralised organisation for the regulation of pesticides would demand at least 50 people, which would mainly be technicians (Tovar, 2004; Pers. Commun.). In order to obtain a more detailed estimation, a questionnaire was sent to the areas involved in pesticide regulation in the different Secretariats asking them about the number of people that every area proposed for the decentralised organisation would require, taking in account its responsibilities and structure. A gross average of 85 people was estimated for the new organisation (Table 5.2)[170] (Annex D.3). Personnel from the Secretariats would be redirected to this organisation. Approximately 38 people work on

[170] Fifteen questionnaires were sent to officials from the Secretariats of Agriculture, the Environment and Health, which are currently involved in pesticide regulation. Three officials from the Secretariats of Agriculture (2 people) and the Environment (1 people) only answered the questionnaire. Therefore, in order to include the expectations from the Health officials, it was possible to carry out three interviews to officials of COFEPRIS of the areas of registrations, analytic laboratory and training and diffusion by phone, which only answered the questions related to their area. So, the number of employees for the rest of the areas was proposed by consulting the current payroll of SSA and counting exclusively employees involved in pesticide control.

pesticide regulation in the current governmental administration: twenty five from SSA, eight from SAGARPA and five from SEMARNAT.

Table 5.2 Personnel estimated for the decentralised organisation for pesticide control.

AREA	NUMBER OF PEOPLE PROPOSED
Registration and authorisations of import and export	35
Management, finance and legal affairs	15
Analytic laboratory	12
Inspection and enforcement	10
Training and diffusion	4
Policy and planning	3
International affairs	2
Information systems	4
Total	85

With regard to Proposal two, currently 10 people work on pesticide registration in the SSA and 15 more employees support other activities such as authorisation for import and export, training and risk evaluation. Additionally, 4 and 3 people from SAGARPA and SEMARNAT, respectively, which are specialised on registration, would be redirected. According to Capetillo (Pers. Comm. 2006), another 10 people would be necessary to strengthen the process and support the establishment of MRL and monitoring and analysis. Additionally, one manager and three technical assistants would be required to coordinate the CICOPLAFEST and support the area for policy, planning and training. So, a total of 46 employees constitute the leader group on pesticides in SSA.

For Proposal three a Technical Secretary and three assistants would be needed to support the coordination of the CICOPLAFEST. So, a total of 4 additional people.

By comparing the demands of personnel of each organisation: 85 for Proposal one, 46 for Proposal two and 4 for Proposal three it is possible to infer that the costs of Proposal one would be much higher than Proposal two and the costs of Proposal two higher than Proposal three; therefore their economic feasibility would be high, medium and low.

c) Administrative Organisation

One of the main strategies of the permanent process of modernisation of the Mexican public administration is the decentralisation of its bureaucratic system, which has as one of its strategies the creation of decentralised organisations in order to cover priorities areas for the development of the country or to provide social or public service since its legal power and own infrastructure and resources allow it to streamline decision making (Cabrero, 1998; Guerrero, 1998; World Bank, 1998). However, through time, these organisations have been criticised by their complex and excessive administrative process or inefficient organisational structure but these critics have been also expressed for all the governmental system, they are not therefore exclusive to these organisations. In this context, the creation of a decentralised body for pesticides (Proposal one) would have high adaptability to the current organisational culture in the country[171] and due to the economic, administrative and legal independence their effectiveness/efficiency as an organisational model would be expected to be also high.

Proposal two implies the concentration of powers to regulate the main activities related to pesticide use in a subordinated body of the Health Secretary called COFEPRIS[172]. Despite the fact that the transfer of functions from one Secretariat to another is a common process, the transfer of specific functions is not (Fernandez, 2005; Pers. Commun.). The transfer and concentration of functions from one Secretariat to another is a general process to create a new Secretariat or to delegate a broad duty to another one, which responds to a strategic plan of the government to address demands of the country, generally, at the beginning of new administrations[173]. In this case Proposal two implies a partial transfer and concentration

[171] Currently, there are 76 decentralised organisations that cover issues such as Petroleos Mexicanos (PEMEX), which is in charge of the extraction, refining and sell of oil in the country; the National Producer of Seeds (PRONASE, by its abbreviation in Spanish) in charge of the production and certification of seeds to increase agricultural production; Bank of Mexico, whose goal is to try to keep the purchasing power of Mexican currency, and the National University of Mexico (UNAM).

[172] The creation of the COFEPRIS is part of the strategy to reform the health system in the country and it has been working since 2002. In 2003 there was a modification of its structure and at present there is no a report about its achievements.

[173] For instance, in 1992 the powers of the Secretariat of the Urban Development and Ecology were split among two new Secretariats: Secretariat of Social Development and the Secretariat of the Environment, Natural Resources and

of powers, for which at present a similar case has not yet been documented. So, its adaptability to the organisational culture of the public administration would be medium as it is viable in administrative terms but it is not a common organisational model. In general, the public administration has defined clearly the responsibilities of each one and this model implies a mixing of duties, for example COFEPRIS could require environmental information on pesticides and reject registrations that imply a risk to the environment.

With regard to its efficiency/effectiveness as an organisational model it could be expected to be also medium as the concentration of functions would not be complete; however, the administrative and technical independence of a subordinated body as COFEPRIS would help to streamline the decision making in respect to the main aspects of the regulation. It is important to mention that the creation of subordinated organisations is another strategy of the process of modernisation of the public administration. In general, they are created to provide major dynamism to specific functions of a Secretariat since they do not keep a hierarchical subordination with other offices within it and hence its demands are addressed directly by the Secretary[174]. However, as a part of the public administration these organisations have also suffered from excessive bureaucracy and they have therefore been subject to a policy of administrative simplification.

In relation to Proposal three, the creation of inter-Secretarial commissions came up in the late 50's as a necessity of the government to coordinate joint responsibilities among Secretariats due to the constant increase in the complexity of the public administrative processes (Morales, 2002). Currently there are 16 inter-Secretariat commissions running in the country. Therefore, this organisational model is highly adapted to the organisation of the government. With regard to the performance of this organisational model there are successful and limited experiences. In 1967 a study focused on commissions, councils or

Fisheries. Then, in 2000 fishery issues were addressed to the Secretariat of Agriculture, which currently has the power to regulate all the matters related to fisheries.

[174] Every Secretariat has a subordinated organisation to carry out a particular function (With exemption of the Secretariats of Labour and Foreign Affairs). At present there are 28 subordinated organisations. Examples of these organisations are the National Institute of Ecology (INE) of the SEMARNAT; the Federal Regulatory Improvement Commission (COFEMER) of the Economy Secretariat and the National Institute of Migration of the Secretariat of the Interior.

committees in charge of establishing mechanisms of inter-institutional coordination found that because of the great number of these organisations that accumulated through time, they had frequently obstructed administrative processes or delayed making decisions. Hence the study suggested a revision and reformation of these organisations (INAP, 2002).

Another evidence of the possible limitations of these organisations is constituted by the Inter-secretarial Commission of Biosecurity and Genetically Modified Organisms (CIBIOGEN), whose deficiencies in its performance promoted a modification to its structure by defining a permanent leader and administrator in the National Council of Science and Technology (CONACYT), and the shortcomings of the CICOPLAFEST reported in its first report (CICOPLAFEST, 2001). There are also examples in other countries such as Costa Rica, which has an inter-institutional advisory commission to support pesticide control that presents problems of attendance by its members and hence limitations to achieve its objectives (Agne, 1996).

On the contrary, the Inter-Secretarial Commission of Finance and Public Budget in Mexico, which has a similar organisation to CICOPLAFEST, has been working since 1979 and has been efficiently achieving its objectives (SE, 2004)[175]. Additionally, the creation of an Inter-Secretarial Commission for Tourism this year by the President reaffirms the reliance that the government places on this kind of organisation.

So, it seems that the limited tools of these commissions to enforce their objectives make them too dependent on the priorities and commitments of the Secretariats. In this case, economic issues seem to be high priorities for the Secretariats. Therefore, the efficiency/effectiveness of this model would be medium as this is dependent on the subject to be dealt with.

[175] This is made up by five Secretariats and one decentralised organisation, which jointly advise about the distribution and use of the public budget.

d) Performance assessment

The goal of the three proposals is to improve the regulatory system for pesticides in all its aspects, which includes health, environmental and economic issues. However, the efficiency and effectiveness to achieve this goal are influenced by the type of organization proposed and its organisational structure, since it determines the straightforwardness or difficulty to establish the distribution of information and channels of coordination to reduce uncertainty for decision making (Mintzberg 1993).

Proposal one implies the creation of a decentralised organisation, which is defined as an entity with legal power and its own infrastructure created through a decree by the federal government (DOF, 1976). The organisational structure proposed for this organisation is a functional design, which is specialised in operational areas and supports in-depth skill development. The structure is hierarchical with a top level manager who leads the organisation and makes the main decisions. This structure clearly defines the distribution of information and channels of coordination, so the information for making decisions is easily achievable. Another important characteristic of this organisation is the concentration of functions to promote an integral improvement of the regulatory system for pesticides as economic, health and environment matters are covered by main offices in the single body. So, this structure seems to offer a suitable environment to have effective and efficient performance to achieve the goal of the proposals.

With regard to Proposal three it is important to consider that an inter-Secretarial commission is a group of people who have been given the responsibility to undertake a task jointly, which is different from a single integrated organisation. In this way, the structure of Proposal three is designed to work as a point of coordination among a group of people from the various Secretariats participating in the CICOPLAFEST in order to define a joint regulation for pesticides. The organisational structure is hierarchical with a President, a Technical Secretary, committees and subcommittees, which would have regular meetings to define

coordinated activities for pesticides. Because the members are mainly influenced by the responsibilities, priorities and capabilities of their respective Secretariats, the flows of information and channels of coordination could be delayed as the time of response of each one can be different and also due to the potential difficulty to reach consensus to make decisions. The lack of legal power to oblige the acquiescence of the members for the achievement of the objectives of the Commission and of the leadership for the definition of a national policy are other factors that would limit the performance of the Commission. So, CICOPLAFEST would be less effective/efficient to reach the goal compared with Proposal one.

By its part, COFEPRIS presents a functional design similar to the structure of the decentralised organisation of Proposal one, with a hierarchical organisation, a chief commissioner as a leader, specialised operational groups, and the channels of coordination and the distribution of information are easily identifiable in its structure. Because COFEPRIS is a subordinated organisation of SSA, it has administrative and technical independence but it lacks of legal independence (DOF, 1976). The COFEPRIS would be in charge of the regulation of the main preventive mechanisms in the regulation of pesticides: the registration process, establishment of MRLs, import and some activities related to use, manufacture and sale. However, its attention is diverged to attend other responsibilities related to the prevention of risks by the use of medicines, cleaning products and other hazardous products. Additionally, this proposal (Proposal two) implies to keep a reformed CICOPLAFEST to introduce the economic, agricultural and environmental issues in the joint definition of an integral and national pesticide policy. So, the concentration of the main activities to control pesticides in the COFEPRIS would promote an improvement in the flow of information and coordination to attend these issues; however, the rest of the activities would be addressed through the CICOPLAFEST; which would generate problems of coordination and delays in decision making limiting a homogenous advance in the system.

Considering the importance of the availability of information and coordination among components, the ease or difficulty to manage flows of information and channels of coordination can be used as an indicator of the effectiveness/efficiency of the proposals to achieve the goal. In this way, Proposal one would be more effective/efficient than Proposal two, and Proposal two would be more effective/efficient than Proposal three, so Proposal one would be comparatively more efficient/effective than Proposal three (Proposal one>two>three). On the basis of these comparisons, the relative performance of Proposal one would be high, for Proposal two medium, and for Proposal three low.

With regard to the relevance of the activities of each proposal respect to the objectives of the Secretariats, it is important to take in account that pesticide control has been addressed by the government as a holistic regulation of hazardous substances; hence pesticides have not received a specialised attention. So, the activities of a decentralised organisation for pesticides would cover part of the objectives of the Secretariats to protect human health and the environment against hazardous substances since pesticides only represent a group of a great spectrum of hazardous substances. Proposal two would cover more these objectives as COFEPRIS could define a general policy on hazardous substances focused on health issues, in which pesticides would be included, and complemented with the issues that each Secretary would present in CICOPLAFEST. By its part, Proposal three would be relevant for the government as a point of coordination of the regulation due to the multisectoral characteristic of pesticide control, representing an open opportunity to cover the objectives of the Secretariats, although the priority to cover them would be dependent of the attention assigned by the Secretariats. So, Proposal two and three should be considered as highly relevant and Proposal One would have a medium relevance.

Table 5.3 summarises the evaluation of the proposals showing the value assigned to the dimensions in the qualitative assessment. It shows that Proposal one is the best option in terms of functioning but its economic and political feasibility and its costs mean a significant barrier for its implementation. The assessment for Proposal three indicates that its

performance has limitations; however it has a high political feasibility with costs and economic feasibility that could be adapted or negotiated for its implementation. Finally, Proposal two seems to be in an intermediate place between Proposals one and three, it offers better performance than Proposal three but with limitations compared to Proposal one. Its economic and political feasibility, similar to Proposal three, could be also negotiated highlighting its advantages of its performance.

Table 5.3 Qualitative assessment of the proposals.

DIMENSIONS		PROPOSAL 1 DECENTRALISED BODY	PROPOSAL 2 LEAD GROUP WITHIN THE HEALTH SECRETARIAT	PROPOSAL 3 STRONGER AND REORGANISED CICOPLAFEST
Feasibility	Political	Low	Medium	High
	Economic	Low	Medium	Medium
Cost		High	Medium	Medium
Performance considering its organisational structure	Effectiveness	High	Medium	Low
	Efficiency	High	Medium	Low
	Relevance	Medium	High	High
Administrative Organisation	Adaptability to the public administration	High	Medium	High
	Effectiveness/ Efficiency as organisational model	High	Medium	Medium

Note. The shading area in the table highlights the dimensions with greater importance to define the viability of the proposals.

It is important to mention the hierarchy of the dimensions in terms that are considered more important to a decision. The definition of a policy by the government to address the needs of the country is the first step to comply with its duties and on the basis of these needs priorities are defined and then the economic resources are allocated following the priorities. Once the objective and the available resources are defined government seeks the best administrative way to achieve the objective with effectiveness and efficiency. Following this sequence, the hierarchy of the dimensions should be, from high importance to low importance: policy,

economic resources and costs, performance, and administrative organisation. It is important to mention that the policy should be flexible to attend unexpected or emergent situations or adapted to changes in the budget, so it is possible that economic resources influences directly changes in the policy.

Now, it is appropriate to mention what the objectives of the governmental and social sectors and agricultural and pesticide industry could be in relation to these dimensions in order to have more elements to choose the most viable proposal.

5.3.3 Objectives of parties involved in relation to the regulatory system for pesticides

a) Government objectives

The Articles 4 and 27 of the Mexican Constitution establish the right that every Mexican has to the protection of his/her health and to live in a clean and safe environment. So one of the government's goals would be to protect the population and the environment from the negative effects of using pesticides without affecting the development of the country. In order to achieve this goal and address the stagnation in the regulations and the shortcomings of the CICOPLAFEST the government should restructure the system. This would allow it to develop, strengthen and improve its regulatory process and mechanisms of coordination and develop a definition of a national and integrated policy that specifies priorities and strategies, provides leadership and creates channels of communication with academic and industrial sectors.

So, considering that the government includes these points in its policy as priority issues, Proposals one and two should help to achieve the goal in terms of policy, performance and administrative organisation; although Proposal one would provide a better environment to promote an integral policy than Proposal two. However, in economic and cost terms it would back Proposal three.

b) Pesticide Industry

According to the National Association of Chemical Industry (ANIQ: Asociacion Nacional de la Industria Quimica) (SEMARNAT, 2003b), the regulatory policy should be based on the risks of the pesticides so that the regulations are stricter for more toxic materials and simpler for less toxic ones. Additionally, ANIQ indicated that the regulatory processes should be based on a rigorous scientific and technical support. Interviews with members of the Mexican Association of the Pesticide Industry (AMIFAC) (Personal Communications: Alarcon, 2004; Garcia, 2004) emphasized the need for administrative deregulation of pesticide control as there are some standards enacted by different Secretariats, which are repetitive and make the regulation complex. Moreover, these members demanded stricter enforcement of the regulations by the authorities since there are companies that are trading unregistered or forbidden pesticides, which affect their sales. So, the pesticide industry would support an integrated policy that simplifies administration and a more efficient regulatory process that does not hold the economy back.

Proposals one and two should cover these demands as the concentration of functions would allow authorities to visualise the set of regulations and identify possible ways of simplification and harmonise criteria of evaluation. The economic aspect is an appropriate issue for this industry as it should prefer a new organisation that does not imply a great economic investment and high costs of performance as the expense of the regulations could be reflected in the fees charged to it for the services provided. So, Proposal two would have an advantage over Proposal one.

The organisation of the structure should not be relevant for the industry as long as it is effective, integrated and efficient, particularly integration would be an important value for the industry as it is convenient for them to have one regulator to cover all aspects of its production.

c) Agricultural Industry

For its part, the agricultural sector should advocate a policy that promotes a great availability and diversity of pesticides in the market at an accessible price and in compliance with the requirements of effectiveness and conditions of security demanded by the authorities related to protection of human health and the environment. So, the quantity and quality of its production can not be affected because of the low availability or poor quality of pesticides. Training and broader diffusion of information to reduce the risks from pesticide use should also be among its priorities, as well as a constant updating of the regulations in accordance with the new demands of trade and markets.

Thus, the new organisation should optimise compliance and enforcement of the regulations focused on the production and sale of pesticides by extending the cover of the inspections, so it can ensure that pesticides in the market are in compliance with the conditions under which they were registered and also to suppress their illegal sale or inadequate distribution. Additionally, the new organisation should optimise programmes of training and diffusion by promoting good agricultural practices focused on good quality food and safe working conditions, so poisonings and negative impacts in the environment would be minimised.

Proposals one and two could cover these objectives and since the establishment of MRLs and pesticide approval are two main issues for the agriculture industry Proposals one and two would be equally supported in terms of policy. Since the costs of investment and operation of the new organisation could be included in the pesticide's price, this industry could support a new organisation with moderate expenditures and economic resources such as Proposals two and three, although this industry would also be attracted by a high performance organisation in terms of efficacy, integration and effectiveness, hence Proposal two would fulfil more appropriately its demands. The administrative organisation would not be relevant to this sector as long as the objectives aforementioned are reached.

d) Public

The attention of the population or general public with regard to pesticide policy should be centred on food quality and the prevention of accidents by domestic or commercial use of pesticides. Particularly, a non-governmental organisation called Pesticide Action Network of Mexico (RAPAM: Red de Accion sobre Plaguicidas y Alternativas en Mexico) presented to SEMARNAT (2003b) a set of initiatives to be included in a national pesticide policy. These include the establishment of broad channels of citizen participation through which their concerns can be expressed. Public access to information related to use and sales of pesticides, their level of hazard and their impact on human health and the environment, as well as access to scientific studies on their impact would be provided. Additionally, RAPAM suggested a gradual substitution of highly hazardous products by less toxic ones which could also lead to regulations favouring a sustainable agriculture.

So, in political and performance terms, Proposal one would be favoured by the public as its main interest is to pursue the highest standards of human and environmental protection. With regard to financial and organisational issues the sector would not show any preference as these do not have any direct effect on it.

Table 5.4 shows the proposals, in rank order, that meet the objectives of the parties aforementioned.

Based on Table 5.4 and giving a value of 3.0 to the proposal that was the first option for each combination of dimension/party[176]; 2.0 to the second option and 1.0 to the third one, it was possible to obtain a value that measured the preference of each party according to its objectives (Figure 5.1).

[176] The same value was assigned to the proposals in brackets.

According to the objectives proposed for each party the government would show more interest for Proposal three mainly due to its reduced costs of performance and economic impact and organisational structure as the creation of Inter-Secretarial commissions have been the common way in which the government has solved issues that involved the participation of more than one Secretariat.

Table 5.4 Preferences of the parties for the proposals, in rank order, that better meet their objectives.

PARTIES	DIMENSIONS				
	Political	Economic	Costs	Administrative Organisation	Performance
Government	(1,2)-3	3-2-1	3-2-1	3-2-1	1-2-3
Pesticide Industry	2-1-3	(2,3)-1	(2,3)-1	(1,2,3)	1-2-3
Agricultural Industry	2-1-3	(2,3)-1	(2,3)-1	(1,2,3)	1-2-3
Public	1-2-3	(1,2,3)	(1,2,3)	(1,2,3)	1-2-3

Note: 1: Proposal one; 2: Proposal two, and 3: Proposal three. Proposals in brackets mean that they have the same rank order. Proposals separated by hyphen indicate the rank order from high preference to low preference by the parties.

For its part, the pesticide and agricultural industries would show preference for Proposal two, since they is interested in regulatory reforms along with moderate expenses. Proposal three would constitute the last option for the pesticide and agricultural industry and the public mainly on account of its performance limitations.

The public would show more preference for Proposal one, principally because of the policy of protection to human health and the environment which can be reached more efficiently by Proposal one.

Figure 5.2 presents the weakness and strengths of the proposals taking into account the objectives of the parties. In political terms Proposal two seems to represent the point of convergence among the different interests of the parties. Proposal three represents greater

attraction due to costs and its organisational structure and Proposal one has strength in its performance.

Figure 5.1 Measure of the preferences of the proposals by the parties considering the combined values across the five dimensions shown in Table 4.4.

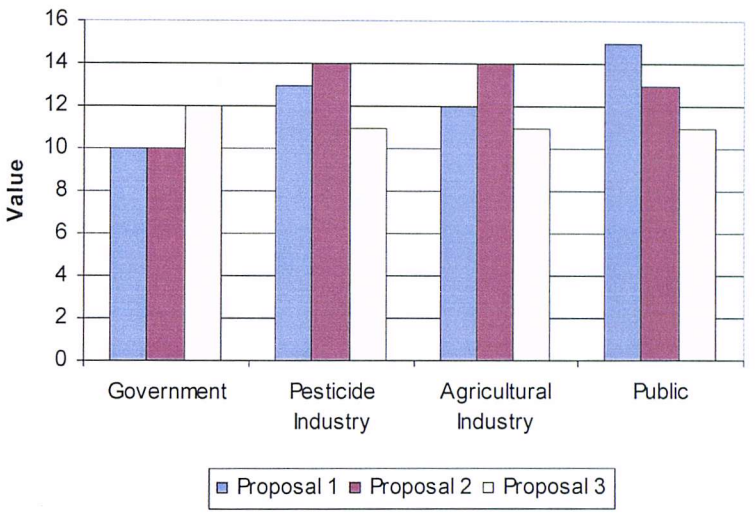
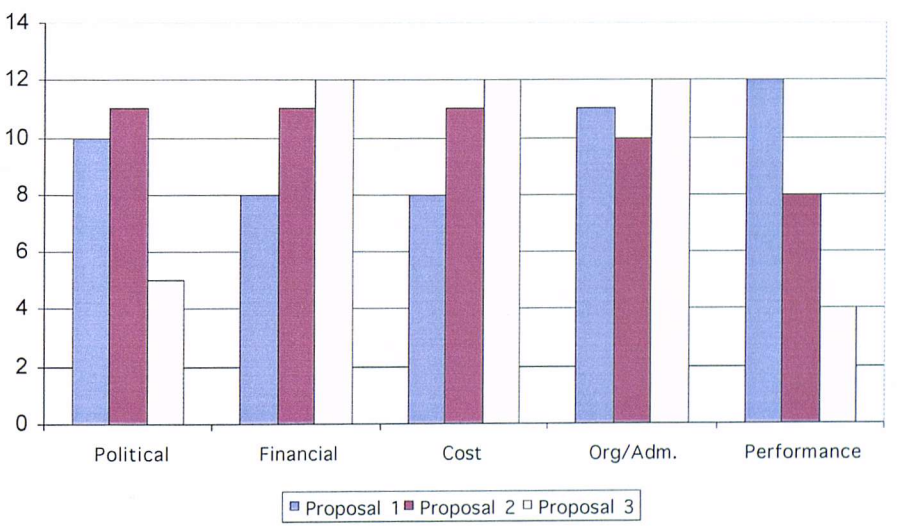


Figure 5.2 Weaknesses and strengths of the proposals considering the objectives of the parties.



5.4 Discussion and conclusions

Proposal one would be the best option in terms of performance, which would provide an important and decisive advance in the regulatory system for pesticides, but it is not backed due to the current policies of the government, the interests of the pesticide and agricultural industry and by the international trend since in most of the countries the administration of pesticides has some connection to an established Ministry or Secretariat, either Health or Environment. Proposal three has great attraction due to its reduced economic impact, low costs and its organisational structure but the process to reach a satisfactory improvement to the system would take a long time. Proposal two is in an intermediate position between Proposal one and three. This covers relevant political objectives of the parties and because it would be part of the Health Secretary its policies can be part of an all-embracing program for hazardous substances, but it also implies legal modifications and greater demand of resources that affect its viability.

As was mentioned in Chapter II, there is an immediate need to improve the current system for pesticides and on the basis of this qualitative assessment and of the objectives of the parties involved, in this work it is considered that Proposal two would be the most sensible way to start and encourage such improvement, considering the advantages that it offers to provide leadership and direction to pesticide policy, to focus the main attention on the prevention of risks from pesticide use, the promotion of a coordinated work through CICOPLAFEST and the optimisation of resources as its activities would be derived from an integral hazardous substances programme.

So, the leadership of the SSA on pesticide control through the concentration of powers to regulate the principal pesticide activities in the COFEPRIS is considered the most viable option in this study, hence its implementation is presented in the following chapter along with a policy analysis to provide the basis for the definition of a national policy for pesticides in Mexico.

Chapter VI Improving the regulatory system for pesticides: Proposal and policy analysis

As a way to improve the regulatory system for pesticides in Mexico, this chapter presents a proposal to provide the leadership in the regulation of pesticides to the Federal Commission for the Protection against Health Risks (COFEPRIS) of the Health Secretariat (SSA) by providing it enough power to control the process of registration, establishment of Maximum Residue Levels (MRLs), import and some aspects of the manufacture, use and sale of pesticides. First, a description of the structure of the COFEPRIS is presented, followed by steps for implementation of the proposal, supported by a policy analysis that presents the basis for the definition of an integral policy for pesticides in Mexico.

6.1 Structure of the Federal Commission for the Protection against Health Risks (COFEPRIS)

The Comision Federal para la Proteccion contra Riesgos Sanitarios (Federal Commission for the Protection against Health Risks) (COFEPRIS,) is a subordinate body of the Health Secretariat with technical, administrative and operational independence, created by Federal decree in 2001. Its aim is to define the national policy for the protection of the population against direct risks generated by the use of hazardous substances, biotechnological

products, tobacco, medicines, related product [177], services, and against indirect environmental contamination, that affect human health and the safety of food and water. It also has responsibility to issue regulations and to check their compliance and enforcement.

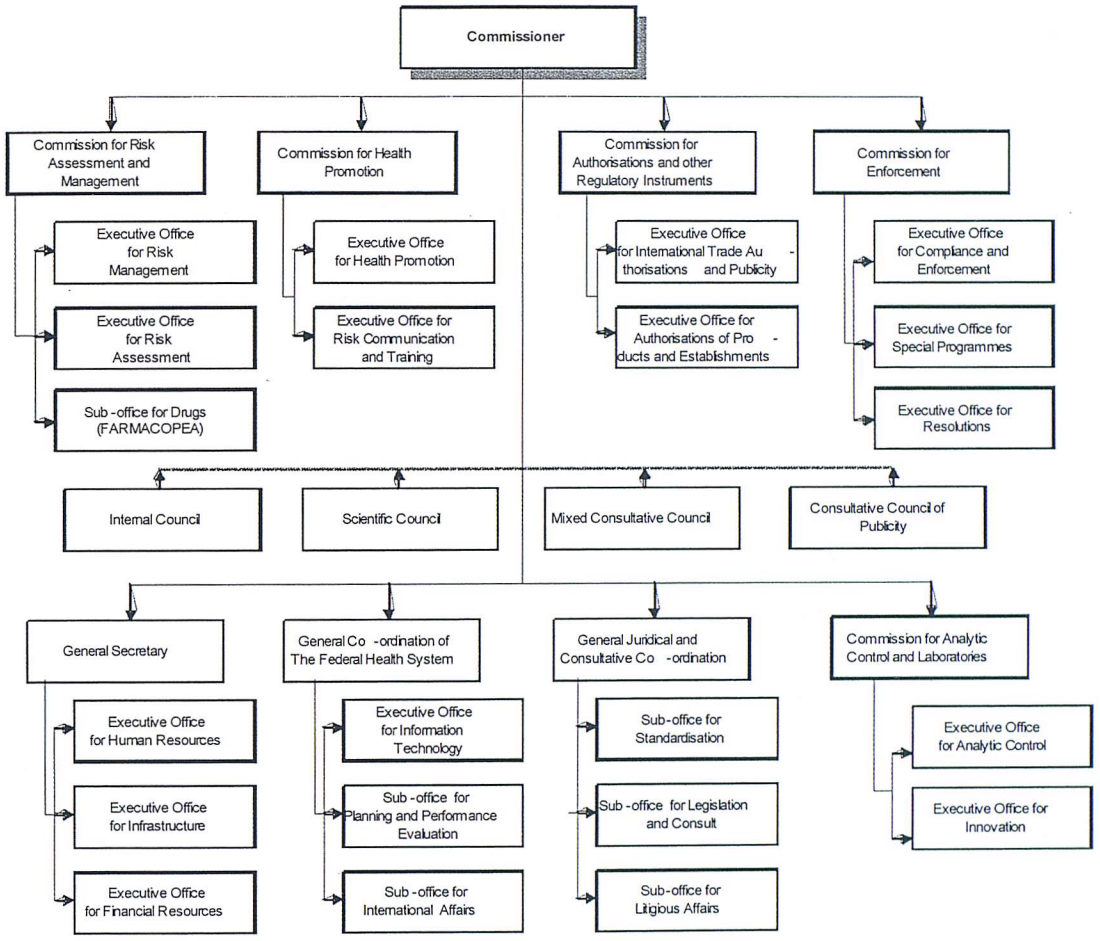
COFEPRIS is organised by processes (Figure 6.1). There is a chief Commissioner who leads the Commission and five subsidiary commissions and supplementary offices:

- **Commission for Risk Assessment and Management**: identifies and evaluates health risks and defines policies to prevent or minimise them along with the design of regulatory and non-regulatory instruments. It also participates in the creation of toxicological and epidemiological centres [178] and the design of catalogues of medicaments and hazardous and non-hazardous substances. It provides technical support to the other Commissions.
- **Commission for Health Promotion**: contributes to the prevention and minimisation of risks through the implementation of non-regulatory instruments, which include educational projects and training, programmes of communication and diffusion of preventive measures to reduce risks, self-regulation and stimulus for industry, among others. It also establishes programmes of cooperation with other governmental organisations and with academic, public and private organisations. It defines indicators of performance to evaluate the effectiveness and efficacy of COFEPRIS. Particularly, it is in charge of the participation of the Health Secretariat in the National Programme against Risks by Pesticide Use.
- **Commission for Authorisations and other Regulatory Instruments**: defines the regulatory instruments and administrative processes to control the establishments that manufacture, sell, import or export products, substances, or equipment or that provide a service related to them. It also controls centres of verification, laboratories, research centres, and bodies of certification that act as third parties. Specifically, this

[177] These include cleaning and beauty products and the raw material and other input necessary for their manufacture.
[178] The toxicological centres provide medical assistance to attend poisonings by phone and some of them are equipped with laboratories and outpatient service.

area has the duty to issue registration documents for pesticides and authorisation for their import.

Figure 6.1 Organisation of COFEPRIS



- **Commission for Compliance and Enforcement**: conducts compliance inspections and investigations to enforce regulations and the application of fines in case of failure. It also provides support to manage emergent situations, contingencies and accidents, in coordination with other authorities.
- **Commission for Analytical Control and Laboratories**: provides expertise in analytical testing and physical-chemical studies to assure quality of food and water, safety conditions in workplaces and effects of environmental factors on the health of the population. It is also responsible for the regulation of national and public

analytical laboratories, centres of verification and certification that act as third parties, which support its functions in the development of local or specialist tests.

- **Coordination of the Federal Health System**: coordinates the development and implementation of the programmes in the Mexican States and the participation of the Commission in international affairs. It is also in charge of information technology.
- **Legal Affairs**: represents the Commission in legal issues and provides legal advice to it and participates in the development of standards and regulations.
- **General Secretary**: manages financial and administrative issues.
- **Consultative and Scientific Committees:** provide advice and opinions with regard to COFEPRIS duties and activities.

The structure of COFEPRIS represents four essential areas that support an effective system to protect health from risks originated from pesticide use, since it includes: 1) risk analysis, 2) the development of regulatory mechanisms to control risks, 3) enforcement and compliance with regulations, and 4) training and education to support prevention of risks. However, there are further areas to incorporate and others that need to be strengthened in order to implement the selected proposal and therefore to improve the regulatory system. These additions are described in the next section along with a policy analysis of the regulatory system for pesticides in Mexico.

6.2 Implementation of the leadership on pesticide regulation in the COFEPRIS and policy analysis

The selected alternative proposes the improvement of the regulatory system by concentrating overall responsibilities for the registration, establishment of MRLs and import, and some activities related to manufacture, use and sale of pesticides in COFEPRIS, and by leading a re-structured CICOPLAFEST and the National Programme against Risks by Pesticide Use. The implementation of the proposal focuses on legal and administrative modifications, which would be incorporated in a national strategy that includes steps for

integral improvement of the regulatory system, along with measures, aims, outputs and targets for each activity or change proposed.

6.2.1 Integral strategy

The strategy comprises five initiatives, which take into account the recommendations of the International Code of Conduct on the Distribution and Use of Pesticides (FAO, 2002), the best pesticide regulatory practices suggested by OECD members (OECD, 2001a), the OECD future vision on pesticide regulation (OECD, 2004b) and the studies of Agne (1996) and Jungbluth (1996).

a) The safe use of pesticides:

- **Strengthening the regulatory framework.** More understandable pesticide legislation and better cooperation between the Secretariats involved would be enhanced by an exclusive law on pesticides that regulates the main aspects of pesticides, to avoid confusion and overlap in the regulations.

  The law should include statements to regulate:

  - **Registration**. It would control labelling, composition, quality, allowed uses, prevention and management of risks. To show pesticides comply with the characteristics under which their registration was authorised this law would provide powers to verify the manufacture and sale of pesticides, so powers to inspect industrial establishments and sellers would be stipulated.
  - **Import**. It would present the national requirements to authorise the import of pesticides into the country, as well as the requirements to comply with the Conventions of Vienna, Stockholm and Rotterdam and the Montreal Protocol.

- **Establishment of MRLs**. The duty to determine the methodology and process for the establishment of MRLs would be also incorporated in the law.

Additionally, this law should include:

- The mechanisms for a sensible collection of data and records from manufacturers, farmers, sellers and users; so reliable information can be supplied to decision makers and the public.
- The promotion of research, monitoring, training and the participation of different sectors in the regulation, as well as an intention to follow international harmonisation in order to be able to use reliable information generated in other countries.
- The introduction of a process of re-registration to re-evaluate old pesticides, which according to the current General Health Law would be every five years.
- Mechanisms of enforcement and compliance and penalties in case of failure to comply with the law. Additionally, it should define the powers of local, state and federal governments on pesticide matters, so mechanisms of cooperation and coordination can be established.

SSA would continue issuing the certificate of export to inform other countries that pesticides that will be exported are currently registered in Mexico.

Activities that would be not included in this law, and hence would be covered or shared by other Secretariats, would be:

- **Final disposal of empty pesticide containers and expired pesticides**. These activities would be regulated by the General Law for the Prevention and Integral Management of Residues enacted by the SEMARNAT in 2003.

- **Export**. SEMARNAT would continue authorising the export of pesticides exercising its power conceded in the General Law of Ecological Balance and Environmental Protection.
- **Training**. SSA would be the leader of the National Programme against Risks by Pesticide Use but the training provision would be provided co-ordinately among SAGARPA, SEMARNAT, SSA, STPS and industrial associations.
- **Transportation**. This activity would be exclusive to the Secretariat of Communications and Transportation (SCT), but it would work jointly with the SSA to create and update regulations.
- **Certification of applicators**. Due to the expertise of SAGARPA on technical aspects of the application of agriculture pesticides and related equipment, it would continue to be in charge of the certification of agricultural applicators, hence it would have the responsibility to define a core test to evaluate their skills and knowledge on the subject. Therefore, SSA would continue with the responsibility to regulate applicator for urbane services of fumigation and disinfection.

Additionally, SAGARPA would support SSA in the authorisation of third parties and laboratories for the evaluation of biological effectiveness. SEMARNAT would continue regulating pesticide manufacturers and formulators to prevent and control environmental pollution. STPS would continue coordinating regulations with SSA for labour protection.

Regulations and standards should also be enacted to describe specific mechanisms to comply with this new law, and also to fill the gaps in the overall regulatory framework for pesticides with particular attention to the final disposal of pesticide containers and expired pesticides, and the definition of limits of exposure of pesticides for workers and the public.

- **Strengthening enforcement and compliance.** In Chapter II it was estimated that 460,384 establishments[179] are subject to supervision from SSA and that only between 0.2% and 0.4% are verified per year. From this total, only 1% directly concerns pesticides (factories, traders and professional applicators). Considering the reports in Mexico on the use of forbidden pesticides, the import of banned pesticides, improper sale and storage, the high number of pesticide poisoning in the country, the presence of pesticide residues along the Mexican coast and the low percentage of inspections, it is considered that there is a clear need to strengthen the compliance and enforcement programme of the regulations, particularly for pesticides in SSA. Therefore, it would be recommended to define initially an annual inspection plan to verify compliance with the pesticide registration process, the sanitary licence issued to factories and applicators and with the notification of functioning for sellers. The plan would include carrying out three programmed inspections to pesticide facilities[180], sellers[181] and professional applicators[182] per day[183]. One of these inspections would have to be addressed to a pesticide factory and the last two to sellers and applicators. In this way, the total number of pesticide factories[184] would be verified annually and 17% of pesticide sellers and applicators would be inspected per year[185]. The following annual plan could include the verification of all those factories that receive the registration of a new pesticide or a sanitary licence in the country during the previous year, allowing the authorities to carry out more inspections to sellers and applicators, aiming to verify all the sellers and applicators in less than four years. So, an average cycle of one year is proposed initially to get through testing all pesticide factories and a four year cycle for sellers and applicators. After all pesticide factories are verified there would be a cycle

[179] These include chemical factories, health and food services, and traders.
[180] It would imply the verification of the composition of pesticides, their effectiveness, labelling, packing, storing and safety, which should be in compliance with the authorisation of their registration. Additionally, the health and safety programmes of the factory would be checked in compliance with the sanitary licence provided.
[181] These inspections would aim to check that only registered products are offered for sale, and that they are not being repacked or decanted, as well as to revise their storage and expire date.
[182] The inspections to applicators would consist of the verification of their professional expertise and conditions of the equipment used.
[183] It is unknown how many inspections are currently carried out for pesticide factories, sellers and applicators per year, so the definition of a target should be more objective.
[184] At present, SSA has 202 pesticide factories registered in its records.
[185] According to the records of SSA, there are 4,369 pesticide sellers and applicators registered in the country.

determined by the rate of new registrations issued. The programme would also include attention to complaints about sellers, manufacturers, applicators or the public with regard to the illegal use or trade of pesticides. Since SAGARPA would concede to SSA the responsibility to verify the effectiveness of pesticides, at least, one inspector from SAGARPA could be redirected to SSA to support the verifications. Additionally, SSA could coordinate its inspections to pesticide factories with SEMARNAT to optimise time, resources and exchange information.

Additionally, to optimise resources and coordination among the Secretariats a sub-committee on enforcement and compliance would be created in CICOPLAFEST.

- **Strengthening the registration process and establishment of MRLs**

The concentration of activities to register pesticides in COFEPRIS would constitute one of the strategies to strengthen the process as it would allow authorities to have an integral vision of the process and total control over it, which would facilitate the identification of areas that need to be improved and facilitate the flow of information and thus streamline the decision making process[186].

In Chapter II it was mentioned that the registration procedure relies heavily on experience from other countries to support the decision whether or not to register a pesticide in Mexico[187], which is not considered as a failure of the system; however, it is important to generate national information that allow authorities to protect the population and the environment more efficiently. To this end the following strategies are proposed:

[186] Basically, the new responsibilities of the SSA would be to evaluate the biological effectiveness and the results of ecotoxicological studies, which could be carried out by laboratories and companies, functioning as third parties, previously certified by it.

[187] The certificate of use in the original country as a compulsory requirement to apply for a registration; the use of international methodologies to carry out the scientific studies; the acceptation of Maximum Residue Levels (MRLs) considering the information provided by the CODEX Alimentarius (FAO/WHO, 2006) and the Environmental Protection Agency of the US (USEPA), are examples of this reliance.

- The definition of a methodology and procedure to establish national MRLs in order to determine with greater precision the dietetic risk in the Mexican population.
- To create a scientific subcommittee specialised on pesticides inside the scientific committee of COFEPRIS: 1) to support approval decisions, since at present there is no contact with this sector and according to the international community expert advice is needed to decide whether or to what extent and under what conditions some particular pesticides may be used effectively and safely in Mexico[188]. 2) to decide when studies from other countries can be used or when extrapolations can be valid[189]. This mainly applies to biological effectiveness and ecotoxicological studies, establishment of MRLs (for agricultural pesticides) and the consequent determination of dietetic risk[190] as they are sensitive to changes in climatic conditions and agricultural practices (in the case of agricultural pesticides) (Whitford *et al.* 2002). 3) to propose research on priority issues related to health and environment protection. For instance, better knowledge on chronic pesticide effects on farmers, including children and women in the country would allow authorities to define specific requirements, mitigations or restrictions to protect more efficiently to this population. Annex B presents a proposal of organisation of the Scientific Committee, the areas of expertise that should be required, a list of Mexican research institutes and universities with recognised proficiency in these areas and some resources to obtain funding.

[188] It is also important to consider that some pesticides can represent a more serious problem taking into account malnutrition of the people that are mainly exposed (farmers) or the low availability of protective equipment in many communities. So, socio-economic aspects also need to be considered in the overall evaluation of the registration process.

[189] According to FAO (FAO,1985) there are three main categories of data supplied for registration purposes, which should be accepted by governments: data obtained under controlled laboratory conditions following recognised international guidelines; data obtained under conditions which can be identified with, or related to, similar conditions or situations in other regions or countries and data obtained from valid extrapolations.

[190] It is necessary to consider that MRLs are based on Good Agricultural Practices (GAP), which are different from one country to another mainly due to differences of the conditions in which crops are cultivated. Additionally, because COFEPRIS based its dietetic risk assessment on information generated by FAO/WHO, which established dietetic regimes for regions, there is some uncertainty as by definition an international exposure assessment can be less specific compared with national approaches.

- To create guidelines that help the industry to have a better understanding of the registration procedures and data requirements, so they can provide better quality and more reliable information to the authorities.
- To certify laboratories that carry out the studies requested in the registration procedure as the new regulation on registration states that the requested studies need to follow guidelines that are internationally recognised. Mexico has no contracted laboratories certified to carry out these studies so they are carried out in other countries, which introduces some uncertainty about the efficiency and reliability of these laboratories. This is particularly important considering that Mexico does not repeat the studies in order to corroborate the validity of the information. So, the Mexican Body for Accreditation (EMA)[191] in collaboration with COFEPRIS, SEMARNAT and SAGARPA would need to define the criteria, requirements of equipment and infrastructure, and suitable calibration to international standards to certify laboratories that wish to carry out these studies in the country.

It would also be helpful to include in the requirements a list of the countries where the active ingredient or formulated product has already been registered, so it is possible to search for possible incidents related to it, and also to reassure the safety of the material by the significance of the countries, which have granted registration. The criteria to determine the significance of the countries could be if they have a well established process of registration that includes the approval of new active substances and the participation of scientific advisors in the process, a programme of re-registration and a low rate of human poisoning.

b) The prevention of risks:

[191] The Mexican Body for Accreditation (EMA) is an independent quality assurance organisation in charge of certifying testing laboratories, certification and verification units

- Providing training and education to users, sellers, manufacturers and the general public on the safe use, proper handling and distribution of pesticides, as appropriate, as well as to medical personnel and technical personnel for the adequate diagnosis, treatment and reporting of incidents of pesticide poisoning. Additionally, courses and talks to officials should be included to update their knowledge about new approaches on pesticide safety and control. For this, the National Programme against Risks by Pesticide Use should be formalised and extended to all the sectors mentioned above by first defining a leader. Due to the work already achieved by the Health Promotion Commission of COFEPRIS, its manager could be the most suitable leader. Second, the aims of the programme and an annual work plan with measures, targets and indicators to evaluate its performance should be defined. Third, the official publication and diffusion of its activities and achievements should be undertaken.

- Encouraging the introduction or expansion of Integrated Pest Management (IPM) Systems in order to reduce the environmental and health impacts of pesticides. In Mexico, these systems are mainly used for export products and organic agriculture; however, there is a need to define officially the criteria that define an IPM system and a kind of certification or validation, as the term is used broadly by farmers without any restriction. This seems to be a common problem around the world since countries such as Portugal and Indonesia have had to include an IPM definition in their regulation. So, a first step would be to define officially such criteria by SAGARPA and then to start a record on the area cultivated following an IPM system, the first estimation would be the baseline and the increase of this area would be an indicator of the expansion of these programs in the country, which would have to be correlated with the use of pesticides, so its pesticide impact can be determined – a reduction of pesticide use should be expected-. The baseline from time to time should be redefined to include possible changes to the definition of IPM.

- Evaluating the cost-benefits for the substitution of hazardous pesticides by assessing the following options: 1) subsidies for non-chemical pest control products that represent a potential opportunity to reduce or eliminate the use of hazardous pesticides in Mexico; 2) credit facilities for farmers that use IPM or organic technologies, which would be defined according to the area under an IPM programme and the type of measures applied in it, and 3) support for advertising food produced with IPM or organic technologies and environmental taxes for pesticides.

- Defining campaigns of monitoring residues in food. Due to the great number of pesticides and foodstuffs monitoring programmes are likely to be expensive, so a rational and focussed programme of monitoring is required. Currently, exported products are only analysed by SAGARPA to verify the level of pesticide residues as a support for their export, but products for domestic consumption lack verification. Considering that the SSA would have the new responsibility to check the compliance on MRLs, it would need to focus monitoring on products for national consumption at the retail outlets and public markets that are the main distributors of fresh produce in the country. Additionally, agricultural associations can promote the improvement of agricultural practices among their members by providing certification to farmers whose products are in compliance with MRLs, which would help to reduce the number of products to monitor.

c) The generation, collection and communication of information to the public about pesticide risks and the regulatory process:

- Supporting and encouraging research about pesticide use and its social, economic, health and environmental effects, including chronic effects by long exposures, effects on endemic plants and animals and sensitive ecosystems, estimation of indirect costs by pesticide use such as costs by poisoning treatment, and others.

Further research is an essential need for improving pesticide policies and at present it has been very limited, maybe because the responsibilities are distributed in different Secretariats, which have different priorities and hence a different way to use their resources. For instance, SEMARNAT has paid little attention to pesticides and their effects in the environment, since its regulatory framework on pesticides is scarcely developed and there is such limited information on pesticide effects in the environment. So, a way to promote research and an equal commitment of resources from the Secretariats, and to optimise resources, would be through a trust, in which the Secretariats could assure their appropriate participation in the regulation. Another alternative to the trust would be to create a coordinated research committee or introduce a new regulation in which Secretariats could be required to demonstrate each year that they had supported research. In Annex B a list of research institutes, centres and universities is presented as a potential pesticide scientific community.

- Collecting and recording reliable data on the import, export, manufacture, sales and use of pesticides in order to follow trends in pesticide use, to evaluate effectiveness of policies and for economic studies. As was specified previously, the new law on pesticides would provide power to the SSA to request this information from the pesticide industry and sellers. So, an official standard or other legal instrument would need to be created to specify the methodology to collect data and the format for reporting them. In this way the homogeneity of the information and its reliability can be assured and it would be possible to make comparisons across years. It also includes updating the catalogue of pesticides.

- Collecting and recording reliable statistics on environmental contamination and reporting poisoning incidents related to pesticides to assess the extent of any possible effects on human health or the environment. The collection and recording of pesticide poisonings are carried out by the Epidemiological Surveillance Programme (SINAVE) of the Epidemiology General Direction (DGEPI) of SSA following the

stipulations of the official standard NOM-017-SSA-1994 (DOF, 1999). According to this standard, the hospitals and health centres located around Mexico that belong to the National Health System must keep a record of the poisonings and send them to the DGEPI. However, because these hospitals and centres do not provide medical attention by phone to attend poisoning cases and because this system does not include records from the toxicological centres (TC) distributed in the country[192], the statistics of poisoning incidents are incomplete. Additionally, in the First Diagnostic of Environmental and Occupational Health (SSA, 2002a), inability to accurately diagnose pesticide poisoning in rural communities, where the majority of the poisonings occur, as being one of the causes for an under reporting of incidents. In order to overcome these two deficiencies, two strategies are proposed:

i) To expand the coverage of the SINAVE of the DGEPI. The creation of a new law on pesticides would provide the legal basis for the expansion of the coverage of the SINAVE through the inclusion of the toxicological centres to the system. This would also imply to develop and diffuse uniform criteria and a format to harmonise the collection and record of the incidents. ii) The second strategy would be to continue providing training to medical personnel on the diagnosis of poisonings mainly to doctors from rural communities through the National Programme against Risks by Pesticide Use, and to evaluate the effectiveness of the courses. In the next chapter an indicator on the pesticide poisoning trend is defined in order to measure the effectiveness of the strategies to prevent and control risks by pesticide use.

With regard to environmental incidents, SEMARNAT could start a campaign to encourage citizens to report chemical incidents in wildlife by phone, personal communication in the SEMARNAT offices or through the website. It would imply the creation of a group of inspectors in the Federal Attorney's Office for Environmental Protection (PROFEPA) of the SEMARNAT to verify the cause of the incidents,

[192] In 2004, 21 Toxicological Centres were reported working in a national toxicological network (RETOMEX) in Mexico, which provide health assistance to treat poisoning by toxic substances by phone and some of them have an outpatient service and toxicological laboratories. The network is independent from the SSA and its funding comes from NGOs.

classify them and keep a record of them. So, a reporting centre would need to be created by SEMARNAT to record and validate the reports.

- Publishing and ensuring that information reaches the public and all sectors involved through websites, fora and specialised publications on pesticides. One of the main problems around pesticide control is the lack of information; however, during the development of this work was realised that some information exist but it has not been published or its diffusion is deficient. For instance, the epidemiological bulletin of the SSA reports only the total number of pesticide poisoning incidents in each State; however, the National Epidemiological Surveillance System (SINAVE) has another database, which, according to DGEPI, contains information more detailed on the incidents (age and sex of the people affected, cause of the poisoning – accidental or intentional-, chemical involved, date and location of the cases), but this information is not published and even people from the COFEPRIS do not use it in their reports, hence its existence can go unnoticed by stakeholders and general public. So, a greater diffusion of this database is recommended. The unpublished data and activities on the National Programme against Risks by Pesticide Use are another example of the lack of organisation to gather the information available and publish it. The new law should facilitate the access to pesticide information by stakeholders and public by forcing authorities to publish it.

d) The participation in joint tasks and cooperation with different sectors to optimise resources and summon efforts for the protection of human health and the environment:

- Creating closer contact with the academic sector to support scientific research. One of the best practices reported by members of the OECD in a survey on pesticide control was to ensure that pesticide policy development is well informed by science issues (OECD, 2001a), hence a close contact with the scientific sector should be

implicit for the governments. Countries such as the UK, Canada, Denmark and Sweden have a council of scientific experts as advisors, which provide their opinion before new laws or statutory orders are decided (OECD, 2001a). Particularly, the UK has an independent Advisory Committee on Pesticides consisting of experts from a wide range of scientific specialists, which provide recommendations to ministers with regard to effectiveness and safety of pesticides; hence ministers base their decisions on its recommendations. The UK has low rates of pesticide poisoning[193] and incidents in wildlife[194], which can be used as indicators of an effective pesticide control system. So, this strategy reinvokes again the need to create a subcommittee of scientific advisers specialised on pesticides in the scientific committee of COFEPRIS, which should also back the development of new regulations or updating the ones already running and the implementation of innovative strategies to control pest (Annex B).

- Creating specialised discussion fora among the stakeholders (pesticide and agricultural industries, officials and public associations) to take into account their concerns and opinions for the definition of the pesticide policy. According to the Law on Standardisation (Ley Federal sobre Metrologia y Normalizacion) (DOF, 1992), the publication of new regulations demands a public consultation to hear comments on it. So, CICOPLAFEST would provide the forum to hear the comments of the sectors involved or that would be affected by the new regulations. The Technical Committee would be in charge to lead the fora and decide when and what stakeholders would be summoned. It would be advisable to create specialised fora to discuss technical issues and other to discuss more ideological themes in order to promote an active participation of the stakeholders. It would also be recommended to avoid putting together stakeholders that represent an explosive combination in which it could be difficult to reach consensus. Additionally, other issues than regulations can be put on the table for discussion, such as initiatives from the industry to mitigate pesticide

[193] According to the Pesticide Incidents Report, fifty health complaints involved allegations of ill health during the period 2004/2005 were reported (HSE, 2005).
[194] With regard to environmental and other complaints during the period 2004/05 there were 95 incidents reported (DEFRA, 2002b).

impact or to discuss restrictions on the use of a specific pesticide or the participation in international agreements. It would be expected that these fora would help to fill the gaps of stakeholders representation in Mexico.

- Creating and strengthening networks for information exchange among Secretariats and governmental institutions and participating in joint tasks to optimise resources. For this, CICOPLAFEST would provide the forum to do it and be in charge to manage a joint database.
- Creating and strengthening networks with international, regional and subregional organisations to harmonise regulatory process according to the needs of Mexico and creating a closer exchange of information among them to take advantage of international knowledge and experience. A more active participation in priority projects in the work group for pesticides and the Commission for Environmental Cooperation of NAFTA and Mercosur[195] is advisable, because these are the principle trading partner regions for Mexico.
- Continuing with the participation in international agreements to comply with the international responsibility of protecting human health and the environment and support the advance of the country by using resources and facilities that these agreements can offer. The most immediate activities would be to define the work plan for the implementation of the Stockholm Convention, and an integrated national strategy to harmonise work plans of government agencies to comply with the commitments of the PIC and Stockholm and Basel Conventions.

e) A stronger CICOPLAFEST:

CICOPLAFEST would provide the forum for the discussion and planning of the national policy for pesticides as the continuing success of the scheme depends on frank discussions and cooperation being maintained among the Secretariats involved at all times. There are seven main areas where cooperation is essential:

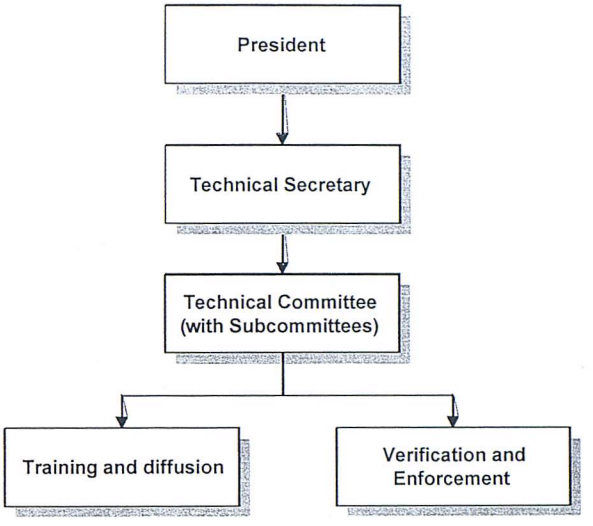
[195] Mexico has officially requested the accession to the Common Market of the South (Mercosur) as an associate member (http://www.mercosur.int/msweb).

- formulation of regulations to control pesticides, including the definition of any proposed financial instrument, such as taxes.
- definition of an Action Plan for the National Programme against Risks by Pesticide Use
- definition of joint programmes for inspection and enforcement
- restriction or prohibition of certain pesticides that cause particular environmental, economic or health concern in the light of experience of each Secretariat
- generation and exchange of information on all issues related to pesticides
- proposal of scientific research on topics of concern
- reaching consensus for the participation in international agreements and international cooperation
- organisation of fora to promote stakeholders participation

To comply with these new responsibilities a modification of the current structure is proposed (Figure 6.2). It would have a rotating President among the Secretariats involved, a permanent Technical Secretary based in COFEPRIS, who would coordinate the meetings and keep records of the agreements and commitments and follow their achievements; a Technical Committee, which would be in charge of the definition of a national pesticide policy and issues of mutual concern, and two subcommittees, one for the coordination of the National Programme against Risks by Pesticide Use (Training and diffusion) and the second one for enforcement and compliance programmes.

Each Secretariat would commit resources, whose amount would be defined through a consensus to ensure its appropriate participation, so a trust would be created. CICOPLAFEST may from time to time establish one or more technical subcommittees to look into specific problems and to provide recommendations. It is essential that members of such subcommittees should come from appropriate government agencies and universities and be knowledgeable on the subject.

Figure 6.2 Structure proposed for a reformed CICOPLAFEST.



6.2.2 Structural and administrative changes

In order to implement the proposal and the suggested strategies mentioned above, it is necessary to consider the next structural changes to COFEPRIS and CICOPLAFEST.

6.2.2.1. Changes to COFEPRIS

- To create a policy group. As a leader of the regulatory system for pesticides, COFEPRIS will need the creation of a specialised Policy Group, which at the moment is missing, for the evaluation, implementation and improvement of these initiatives, which can be integrated into its Action Plan. At present, every Commission of COFEPRIS defines its policies according to this Action Plan; however, there is not a specific group that evaluate the efficacy of this Plan and integrates all the achievements and limitations of COFEPRIS. In fact, the Plan needs to be improved by including measurable aims and periods of time to reach them. So, this Policy Office could help to carry out these activities. This policy group could be part of the area of the Chief Commissioner.

- To expand the Pesticide Registration and Import Groups in the Commission for Sanitary Authorisation, which would imply contracting new personnel and redirecting personnel from SAGARPA and SEMARNAT.
- To expand the Dietetic Risk Group in the Commission of Assessment and Management of Risks for the establishment of national MRLs, and the Commission for Compliance and Enforcement to strength the adherence to the regulations.
- To create a specialised group on pesticides in the Scientific Committee of the COFEPRIS
- Additional arrangements in the other commissions to support the new initiatives for pesticide regulation. The reforms to the Commission for Compliance and Enforcement would demand greater support from the Commission for Analytical Control and Laboratories to do chemical analysis and field sampling. Also, the Commission for Health Promotion would need to make adjustments to lead the National Programme against Risks by Pesticide Use. Finally, due to the increase of personnel, the General Secretary would require to do changes to incorporate them to the payroll.

In Chapter V it was estimated that a total of 46 people would be necessary to cover the overall responsibilities of COFEPRIS on pesticides, of which 25 people are currently working in it, 7 would be redirected from SAGARPA and SEMARNAT and 14 new staff would be hired.

Additionally, SAGARPA and SEMARNAT would need to make administrative and structural changes to implement the duties established in the new law and the strategies assigned to improve the system.

6.2.3 Legal changes

The creation of a leader group on pesticides in COFEPRIS entails the concentration of powers to regulate pesticides in a specialised law, which implies:

- To reform the following laws in order to cancel the statutes related to registration (including labelling, packing, storage, use and manufacture), import and establishment of MRLs for pesticides.

    - Law of the Public Administration (LOAP)
    - General Law of Health (LGS)
    - General Law of Ecological Balance and Environmental Protection (LGEEPA)
    - Federal Plant Health Law (LFSV)
    - Federal Animal Health Law (LFSA)

- To modify the regulations and official standards derived from these laws related to the activities aforementioned to make reference to new law, new powers and new regulatory authorities. To create a new law for the regulation of the registration, import and establishment of MRLs. To modify the decree of creation of CICOPLAFEST and its statutes of coordination
- To cancel the official standards NOM-033-FITO-1995 and NOM-034-FITO-1995 and NOM-022-FITO-1995 and other standard related to pesticides used in animals, enacted by the SAGARPA.

6.2.4 Repercussions and changes for the pesticide industry in Mexico

The main challenge for the pesticide industry in Mexico derived from the implementation of the leadership of the COFEPRIS, the creation of a specialised law on pesticides and the other strategic changes already mentioned would be the compulsory reporting of sales and production as it has been very difficult to publish this information even for the authorities. So, they may demand protection for trade secrets and some limitations on the provision of financial and commercial information. However, a better knowledge of the pesticide market in the country may allow more efficient planning of its production and marketing.

The modifications foreseen for the registration and import process would represent a positive change for it as the concentration of the process would allow COFEPRIS to streamline approvals and provide greater support for the appropriate reporting and presentation of the information required by or from the industry. Because, Mexico does not register new active ingredients, the requirements are less strict than in other countries such as Canada and the US, and considering that the majority of the industry is multinational, compliance with the requirements may not represent an obstacle that would affect the market. However, the need to contract more personnel to support the process could lead to a moderate increase in registration fees.

So, in general the implementation of the proposal looks more beneficial than detrimental for the pesticide industry in Mexico.

As a summary of this chapter Table 6.1 presents the changes and strategies proposed for the implementation of the proposal as well as the aims, outcomes, measures and/or targets.

A set of indicators is presented in the next chapter as a complement to this policy analysis to improve the regulatory system, since it would help to evaluate its efficacy and effectiveness.

Table 6.1 Initiatives proposed for the implementation of the proposal focused on the creation of a lead pesticide group in COFEPRIS and for the overall improvement of the regulatory system for pesticides in Mexico.

STRATEGY	AIMS, MEASURES, OUTPUTS OR TARGETS
a) To ensure the safe use of pesticides	
- strengthening the regulatory framework	- to create an exclusive law for pesticides that covers registration, import and establishment of MRLs
	- to enact regulations, official standards and other legal instruments for the implementation of the new law and to fill gaps in the overall regulatory framework with special attention in the final disposal of empty pesticide containers and expired products, and the establishment of limits of pesticide exposure for workers and public
- strengthening compliance and enforcement	- To define an annual inspection plan in which all pesticide factories would be verified and a four year plan in which all sellers and applicators would be also inspected.
	- to create a subcommittee of compliance and enforcement in CICOPLAFEST
- strengthening the registration process	- to concentrate the registration process in COFEPRIS
	- to establish a methodology and process to establish national MRLs
	- to create a scientific subcommittee specialised on pesticides inside the scientific committee of the COFEPRIS
	- to create guidelines to help the pesticide industry to provide better quality information for the registration process
	- to certify laboratories that carry out studies requested in the registration procedure that meet international guidelines
b) To prevent risks by pesticide use	
- to provide training and education to users, sellers, manufacturers, general public, medical and technical personnel.	- to appoint a leader for the National Programme against Risks by Pesticide Use, to define its aims and a plan work, and publish its advances.
- to encourage the introduction and expansion of IPM systems	- to define officially the criteria that characterise a IPM system
	- to determine the land cultivated following a IPM system in the country, which would be taken as a baseline.
	- to record the behaviour of this area for the measure of targets
- to promote the substitution of hazardous pesticides	- to evaluate the cost-benefits of: 1) subsidies for non-chemical pest control products 2) credit facilities for farmers that use IPM systems or organic technologies, and 3) support for advertising food produced with IPM or organic technologies and environmental taxes for pesticides
- to design campaigns of monitoring of residues in food	- to define a rational programme of monitoring focused on products for national consumption at level of retailers and public markets and for exporting products
	- to encourage agricultural associations to design a certification for farmers who apply good agricultural practices

Table 6.1 initiatives proposed for the implementation of the proposal focused on the creation of a lead pesticide group in COFEPRIS and for the overall improvement of the regulatory system for pesticides in Mexico (continuation).

STRATEGY	AIMS, MEASURES, OUTPUTS OR TARGETS
c) to generate, collect and communicate information to the public about pesticide risks and the regulatory process	
- to support and encourage research about benefits of pesticide use and its social, economic, health and environmental effects	- to create greater trust among the members of CICOPLAFEST to support research on pesticide effects on human health and the environment.
- to collect and record reliable data on the import, export, manufacture, sales and use of pesticides	- to create an official standard or other legal instrument that defines the methodology and process for the collection and report of the information that will be provided by the pesticide industry and sellers.
- to collect and record reliable statistics on poisoning incidents and environmental contamination due to pesticide use.	- to develop and diffuse a uniform criteria and format to report pesticide incidents
	- to train medical personnel for the correct diagnosis of poisonings and technical personnel for the correct collection and recording through the National Programme against Risks by Pesticide Use.
	- to extend the network of toxicological centres by designating personnel responsible for the collection and report of pesticide poisoning cases in local hospitals and surgeries.
	- to design a campaign to encourage citizens to report pesticide incidents in wildlife due to pesticide use and a group to validate that their reports were accurate.
- to publish and ensure that information reaches all stakeholders and general public	- to include in the website of the COFEPRiS the reports of the National Programme against Pesticide Use, the results of the programmes of enforcement and compliance and monitoring and the status of pesticide approval.

Table 6.1 Initiatives proposed for the implementation of the proposal focused on the creation of a lead pesticide group in COFEPRIS and for the overall improvement of the regulatory system for pesticides in Mexico (continuation).

STRATEGY	AIMS, MEASURES, OUTPUTS OR TARGETS
d) To participate in joint tasks and cooperate with different sectors	
- to create closer contact with the academic sector	-to appoint a group of academic advisers that would make up the scientific subcommittee of COFEPRiS.
- to create specialised discussion fora made up of industry, officials and/or public associations	- to organise specialised fora to discuss the development and final enactment of new regulations and when an issue of mutual concern demands the participation of specific stakeholders.
- to create and strengthen networks for information exchange among Secretariats and other governmental institutions	- CICOPLAFEST will organise periodical meetings among its members and manage joint database.
- to create and strengthen networks with international, regional and subregional organisations	- to participate more actively in international fora such as the work group for pesticides and the Commission for Environmental Cooperation of NAFTA and Mercosur.
- participation in international agreements	- to define the work plan for the implementation of the Stockholm convention
	- to define an integral and national strategy to harmonise the work plans to comply with the commitments of the PIC and Stockholm and Basel Conventions.
e) To strength CICOPLAFEST	
- to modify its current structure	- to establish a forum among the current members to start the discussions of its reform
- to create trust to support its activities	- the members of CICOPLAFEST would need to define the resources that they can afford to create the trust.

Chapter VII Proposal for a set of indicators to evaluate a national pesticide policy for Mexico

The aim of this chapter is to develop a conceptual set of indicators to measure the effectiveness of the changes and initiatives proposed in the Chapter VI, and in general, to evaluate a national pesticide policy. The methodology published by Segnestam (2002) is followed for the selection and development of the indicators. Due to the scope of this work and the lack of immediately available data, the indicators proposed are not validated; however two ways of validation are described along with further activities following their implementation.

7.1 Background

Indicators, which are objectively derived from data, are commonly the first and most basic tools for analysing change in society. These have been used for a long time as a means by which more judgements can be made about issues as varied as people's health, weather, and economic welfare and recently for environmental and sustainable development issues (Segnestam, 1999; Hart, 1999; OECD, 2006; Atkinson et al. 2002; WHO, 2004b). These are considered as an analytical tool since they can work as a basis for assessment by providing information on conditions and trends of a process or system, which can provide input to

policy formulation processes and can facilitate communication between different groups. (Figure 7.1) (Imperial College London, 2005).

Figure 7.1 From data to information.

Taken from Notes of the C101 Sustainable Development: Approaches and Indicators (2005). Distance Learning Programme, Imperial College London (2005).

Depending on the objective, indicators can be simple or complex but they should be practical to use while providing accurate and meaningful information. They should be replicable and their relevance to the issue should be clearly described.

Some common frameworks for indicators are given by Segnestam (2002). These provide the means to structure indicators in a way that would facilitate their interpretation as it presents the aspects that need to be monitored and their interrelation, as well as the identification of possible trends and dynamic developments. The following list is based on Segnestam's observations:

a) Project-based framework which is used in the monitoring of the effectiveness of projects whose objective it is to improve the state of the environment. It is also referred as the Input-Output-Outcome-Impact framework.

b) Pressure-State-Response (PSR) framework developed by the Organisation for Economic Cooperation and Development (OECD) for national, regional and international level analyses, which has currently three different versions: the first version replaces the pressure indicator category with a category of driving force indicators (DSR); the second variation adds a category of impact indicators, transforming it into a Pressure-State-Impact-Response (PSIR) framework, and the third version includes all five indicator categories creating a DPSIR framework.

c) A framework based on environmental or sustainable development themes. Themes and subthemes can facilitate the identification of core issues for sustainability to national level, which are commonly used by organisations that work on a combination of aspects such as the ones composing sustainable development.

7.2 Pesticide indicators

Due to the increase of evidence on the negative effects of pesticides on human health and the environment, governments, farmers, consumers, food retailers, agribusinesses, among others, have started to move towards pesticide risk reduction policies or activities directed to more rational use. Along with these initiatives there has been an increased need to develop pesticide indicators to measure the adequacy or inadequacy of such strategies and their progress.

Different types of indicators are being developed, including farmer decision tools[196], eco-labels[197] and policy tools for decision makers (OECD, 1997)[198]. As the objective of this chapter is to provide the basis for the evaluation of the national pesticide policy, policy tools are the main interest for this work. So, policy tools as indicators can be used (Levitan, 1997):

- To assess preliminary data for danger signals about new or potential pest controls
- To monitor trends in pesticide use and risks over time
- To compare risks of using different pesticides and pest management regimes
- To evaluate potential risks from individual pest control products and practices
- To use as the basis for regulations, restrictions and warnings
- As criteria for programs to tax pesticide use
- To evaluate the success and/ or costs and benefits of programs and policies

[196] The objective of this type of assessment tool is to inform people who make pest management choices about potential environmental consequences of their decisions. For that purpose companies have developed computational programmes that predict the possible environmental risks for using a specific pesticide in a determined area.
[197] Eco-labels are tools designed to influence consumer opinion and market behaviour.
[198] The structure of the indicators can be from simple algorithm or mathematical formula to a complicated computer models.

- To assess adoption of IPM on farms and set IPM research and extension priorities

The United Kingdom, for instance, has set indicators proposed by the Pesticide Forum[199] to reflect the impact of government, users and industry efforts to encourage responsible use of pesticides, which cover trends of use, risks to aquatic and terrestrial life, human exposure, changing behaviour, among others (Table 7.2) (Pesticide Forum, 2004).

However, governments have mainly focused their attention on the development of pesticide risk indicators to evaluate the progress of their pesticide risk reduction policies; although the task has not been easy since difficulties have been found in defining a target that adequately measures a reduction in risk[200] (Watts, 1997).

7.2.1 Pesticide risk indicators

In the framework of the OECD Pesticide Risk Reduction Project, an expert group of the OECD developed, tested and evaluated three indicators for tracking aggregate aquatic risk resulting from agricultural pesticide use[201], as well as indicators developed in member countries from 1998 to 2001 (OECD, 2002). The OECD indicators derived from this project have proven easy to use in pilot testing showing general trends of risk across pesticides, crops and regions and appointing what of these contribute most to the aggregate risk. However, gathering all the necessary data has also proven to be difficult and expensive (OECD, 2002).

Other examples of pesticide risk indicators currently used by governments are: Frequency of Application (FA) and Load Index (LI) implemented by Denmark to measure the advance in

[199] Pesticide Forum was created in 1996 and is made up by organisations that make, use or advice on pesticide as well as those interested on environmental, conservation and consumer aspects.
[200] The most commonly used targets have been those of a specified reduction in the total volume of active ingredients used in agriculture; however, the resultant volume reduction does not necessarily equate to a risk reduction as new formulations imply less dosages of application. Additionally, this indicator does not include chronic health risks or ecological risks. Therefore, it has been necessary to define other indicators that define health and environmental risks individually.
[201] The three indicators are: REXTOX (Ratio of Exposure to Toxicity), ADSCOR (Additive Scoring) and SYSCOR (Synergistic Scoring) an explanation is provided in the further section.

the reduction of pesticide use (Møhlenberg et all, 2001). SYNOPS and SyPEP used by Germany and Belgium, respectively, to identify pesticides posing an unacceptability high environmental risk (Reus et al, 2002). PRI-national and PRI-farm developed by Sweden to indicate national risks trends and farm level trends, as appropriate (Bergkvist, 2004)[202]. The Norwegian aquatic risk indicator (NARI) used as an environmental risk indicator (Spikkerud E. 2002) is another example. Other governments are in their way to develop this kind of systems such as New Zealand that is aiming to implement a Hazard Scoring System as an adjunct to a national risk reduction strategy (Watts, 2004).

In the next section the development of a set of indicators is presented to evaluate the effectiveness of the changes and initiatives proposed in the Chapter VI, and in general, to evaluate a national pesticide policy and promote its ongoing improvement[203]. So, pesticide risk indicators will be proposed along with indicators that include social, economic and legislative aspects of the policy.

7.3 Development of indicators

The methodology to be followed is those described by Segnestam (2002), which shows the basic steps to develop indicators for sustainable development. The search of indicators reported and used by other governments is included as another step since it is important to take advantage of the information and experiences from other countries.

i. Selection of an indicator's framework to organise the information.

Since the evaluation of the pesticide policy is at a national level and that pesticide problem responds clearly to a cause-effect-response process and the integral

[202] Both models are based on the same approach, where data on hazard and exposure is scored and combined with data on use intensity.
[203] A problem innate in a policy without clear goals or methods of measurement is that the absence of evidence can be interpreted in two ways: either progress is being made but cannot be clearly identified, or progress is not being made because of policy inadequacies (Watts, 2004).

character of the policy (as it covers health, economic, legislative, institutional, social and environmental aspects) it is considered that a Driving Force-State-Response framework is adequate to develop the indicators, as it is based on the concept of causality where the human activities that guide the use of pesticides, their effects on the environment, human health and economy, and the responses of the government, industry, sellers, users and public can be identified, and measured over the time, and their respective interactions visualised. Besides, according to Segnestam (2002) this framework is suitable for national, regional and international level analyses. Driving Force Indicators were preferred instead of pressure indicators (included in the original version of the OECD) as according to Segnestam (2002) driving forces can include social, economic and institutional aspects and pressure indicators are advocated mainly for environmental issues. In addition, driving forces sound more positive and can thus be used as explanations to both positive and negative impacts.

ii Definition of selection criteria. In order to define precisely the indicator initiative and make it communicable to various stakeholders a selection of criteria needs to be established and agreed upon. The criteria to define and select the indicators are:

- Indicators should be suitable to evaluate in an integrated way the adequacy of the changes proposed and of a national pesticide policy thus they should cover social, human health, environmental, economy and legislative issues and track their changes over the time.
- Due to the scarce resources to gather and collect information on pesticides along with the economic limitations of the government, indicators should be simple, practical and relatively inexpensive. Thus data required should be easy to obtain by using database already existing, improving those whose data are not reliable or comparable to national level, or creating them through questionnaires or surveys, reports from industries, organisations or from international literature reviews. Where the indicators require monitoring this should be coordinated among the various

Secretariats involved, covering different objectives to optimise resources. In the same way, the development and implementation of the indicators should be straightforward, without complicated analysis to extract the relevant information.

- The target group of the indicators will be the policy makers involved in the regulation of pesticides, thus indicators should provide information of easy interpretation for them (without many technical terms) but with the sensibility required to identify problem areas where the policy may need to be reformed.
- Data should be reliable, thus its collection should follow an objective science-based methodology and its analysis should also be scientifically robust. The personnel that will collect and analyse the data should be adequately trained to assure the quality of the results and their interpretation.
- The temporal scale of the indicators should be annual as the majority of the data reported by the government and organisations are collected in annual basis.

iii Search for indicators reported in the international literature

Table 7.1 presents indicators developed as policy tools used by governments to measure the progress of their policies. Table 7.2 presents exclusively indicators used in the UK to measure the impact of the efforts of different sectors involved to promote a responsible use of pesticides.

The number of indicators is still limited since many countries are in the planning stages to define a policy for pesticide reduction and the development of indicators is mainly an initiative of developed countries with a well based pesticide policy working from fifteen years ago on average, which has allowed them to have available information to develop and implement the indicators, such is the case of UK, Netherlands and Sweden[204]. By contrast, developing countries are increasing their

[204] The UK and the Netherlands were amongst the first to pay attention to a pesticide reduction policy: in 1983 the Dutch Ministry of Agriculture announced its aim of reducing use (Jansma *et al.* 1993); also in 1983 the U.K. government agreed to reduce use of pesticides to a minimum consistent with efficient food production (Pesticides

dependence on the use of pesticides (CropLife International, 2004) and their policies to reduce risks by pesticide use are competing with other priority issues which allow them only isolated actions without a clear advance to prevent and control risks by pesticide use.

IV Definition of a set of indicators. Based on the framework, the identified selection criteria and the search of indicators in international literature, a set of indicators is proposed, which is showed in the Table 7.3

Trust 1992). It was Sweden however that installed, in 1986, the first comprehensive plan to reduce the risks associated with pesticide use (Watts, 1997).

Table 7.1 Pesticide risk indicators used as policy tools for governments.

DEFINITION	DESCRIPTION	COUNTRY OF ORIGIN
Frequency of Application (FA)	Simple mathematical expression that indicates spraying or treatment intensity and environmental impact. It considers the quantities of each active ingredient (ai) sold, the standard dose of each ai in each crop/crop type and the area of arable land. It requires longer periods to obtain significant trends.	Denmark
Load Index (LI)	Simple mathematical expression that calculates the ratio between total sale of different pesticides:toxicity summed for all active ingredients providing a relative measure of environmental load concerning specific type of toxicity. It can be used for terrestrial and aquatic ecosystems. It requires longer periods to obtain significant trends.	
SYNOPS_2	Computational model designed to assess the environmental risk potential of a plant protection strategy in a region and to compare different strategies using different plant protection agents. The eco-toxicological effects on soil organisms (earthworms) and on aquatic organisms (algae, daphnia, fish) are considered. Data required are amount of pesticide applied, exposure parameters and site-specific input data such as characteristic of water and soil to estimate degradation rate and pesticide adsorption.	Germany
System for predicting the environmental impact of pesticides (SyPEP)	SyPEP is a computational programme that addresses toxicity and aggregate Toxicity Exposure Ratios for ground and surface water by pesticide spraying. The model uses a risk ratio approach.	Belgium
Pesticide Risk Indicators to national and farm level (PRI-national and PRI-farm)	This is a complex model using two types of pesticide risk indicators, one related to the fate and impact on ecosystems and one related to operator health. The estimation of the risks includes hazard and exposure scoring, inclusion of reduction factors (when mitigation measures are on place) and calculation of consumer risks. Data on hazard and exposure is scored and combined with data on use intensity.	Sweden
Norwegian aquatic risk indicator (NARI)	This indicator monitors environmental risks including aquatic and terrestrial effects caused by pesticide use considering the processes of bioaccumulation, persistence and mobility. It takes in account the contamination of surface water by spray drift, surface runoff and runoff into drainage systems.	Norway
Ratio of Exposure to Toxicity (RETOX)	REXTOX links use data, fate variables and application site variables to estimate pesticide concentrations in surface waters. This estimate is then multiplied by the total amount used to obtain scaled estimates of exposure. These exposure estimates are linked to hazard data to estimate risk, and finally the exposure and risk values are combined across all uses of all pesticides to yield the aggregate indicator.	OECD
Additive Scoring (ADSCOR)	ADSCOR uses tables to convert true values to scores for use variables including the method of application, the dose rate, the frequency of application, and observance of buffer zones. These scores are added together to obtain an unscaled exposure score for each use, multiplied by the actual area treated to obtain a scaled exposure score for each use, and summed across all uses to get an aggregate exposure score for each pesticide. Then exposure and risk values are combined across all uses of all pesticides to yield the aggregate indicator.	
Synergistic Scoring (SYSCOR)	SYSCOR converts to scores all exposure-related variables (including area treated) and all hazard variables. The scored variables are combined logically, using predefined tables, to yield an overall 'penalty' score for each use; these 'penalties' are then summed across all uses and all pesticides to yield the aggregate indicator.	

Table 7.2 UK pesticide indicators.

CATEGORY	INDICATOR
Pesticide use	Crop areas (ha)
	Sales of active ingredients (tonnes)
	Pesticide use in wheat (kg ai per ha crop grown)
Pesticides in water	Number of samples exceeding the maximum concentration of pesticides allowed by the authority
	Number of substantiated water pollution incidents involving agricultural and non-agricultural pesticides
Risk to aquatic life	CSL aquatic risk indicator based on the methods of assessment used during evaluations of aquatic risk for pesticide registration
Terrestrial wildlife population trends	Population trends for grey partridge, yellowhammer and corn bunting (Index 1970=100)
Impact on terrestrial wildlife	Number of wildlife incidents accounted by the Wildlife Incidents and Investigation Scheme (WIIS)
Reduction of impact	Area of cereal field margins in the UK (ha/year)
Operator and human exposure	Number of alleged ill-health complaints
Pesticide Residues in food	Number of samples exceeding the Maximum Residue Level of UK grown produce
Changing behaviour indicators among pesticide users	Arable area under Crop Protection Management Plans (Sprayed Area, ha)
	Number of agronomists who have obtained the BETA (Biodiversity and Environmental Training for Advisors) qualification
	Number farmers who have obtained the new Farm Environmental Management - Crop Protection Certificate
	Number of products with Environmental Information sheets published
	Number and percentage of operators on the Operator Register
	Number of Half Day Operator Roadshow events
	Number of product labels amended in line with CPA guidance on clarity
	Percentage of active agronomists on Professional Register
	Number of sprayers tested under National Sprayer Testing Scheme
	Number of members in the National Register of Spray Operators
	Percentage of sprayers with low-drift nozzles

Source: Pesticide Forum (2004).

Table 7.3 Set of indicators proposed to measure the progress of the changes and initiatives proposed in Chapter VI, and in general, to evaluate a national policy of pesticides for Mexico.

Framework	Indicator	Definition	Methodology	Data Sources[1]	Origin
Driving forces	Indicators of demand	Sales of pesticides by their type (herbicides, fungicides, insecticides) (tonnes/year)	- To create a legal instrument that states the compulsory report of pesticide sales from pesticide industry -	CICOPLAFEST Industry associations: AMIFAC S.A.	UK, Sweden, Denmark, Italy, Germany, among others.
	Indicators of use	Crop areas (type of crop and region (ha/year)	- To collect agricultural data reported by SAGARPA	Sistema Integral de Informacion Agroalimentaria y Pesquera	UK
	Indicators of intensity of use	Frequency of Application (FA)[3]	- To use the formula: $FA = \sum_{\text{individual ingredients}} \frac{\left(\frac{SA_{\text{individual ingredient crop}}}{SD_{\text{crop}}}\right)}{AGRA_{\text{year}}}$ where: SA is the amount sold of individual active ingredients per year; SD the standard dose for each ingredient in each crop/crop type, and AGRA the arable land in the country.	- Sistema Integral de Informacion Agroalimentaria y Pesquera (SIAP) Annual Report of Sales of the pesticide industry (Pesticide industry through its industry association called AMIFAC Catalogue of agriculture products published by SAGARPA Registration submissions, USEPA's database and international literature (SSA, USEPA, international organisations)	Denmark
State	Indicators of human health impact	Number of human poisonings reported by type of pesticide, cause (accidental or intentional), gender and age (number/year)	-To re-activate all the Toxicological Centres in the country -To harmonise and validate the methodology for the report of pesticide poisoning (diagnostic and report) -To extent the information required in the reports to include data on cause of poisoning, gender and age of poisoned people.	Epidemiological Bulletin of the SSA COFEPRIS of the SSA	US, UK, WHO
	Indicators of good agricultural practices	No. cases exceeding MRLs (number/year)	-To identify priority agricultural goods (for export and national consumption) with problems exceeding residue limits -To establish a permanent monitoring campaign -To analyse the samples to verify compliance with MRLs	Analytic Laboratories in SAGARPA and SSA	UK

Table 7.3 Set of indicators proposed to measure the progress of the changes and initiatives proposed in Chapter VI, and in general, to evaluate a national policy of pesticides for Mexico (continuation).

Framework	Indicator	Definition	Methodology	Data Sources	Origin
State	Indicators of drinking water quality	- Number of samples exceeding the maximum concentration of pesticide residues allowed by the NOM-127-SSA1-1994 (number/year)	- To collect the results of the physical-chemical monitoring carries out by water supply bodies in compliance with the official standard NOM-179-SSA1-1998 and NOM-014-SSA1-1993.	- Water supply bodies	UK
	Indicators of risk	Load Index (LI)[3]	- To use the formula: $LI = \sum_{allactiveingredient} \frac{Sales_{eachactiveingredient}}{TOX * AGRA_{year}}$ where: TOX, represents acute or long-term LC50 or LD50 values; Sales, is the amount sold of individual active ingredients per year, and AGRA, the arable land in the country.	- Sistema Integral de Informacion Agroalimentaria y Pesquera (SAGARPA) -Annual Report of Sales of the pesticide industry (Pesticide industry through its industry association called AMIFAC. -Registration submissions, USEPA's database and international literature (SSA, USEPA, international organisations)	Denmark
	Indicators of wildlife impact	No. wildlife poisoning incidents (number/year)	- To establish a system of report of wildlife poisonings in the country in which authorities, farmers and general public participate.	SEMARNAT	UK
	Indicators of economic loss	Rejections of goods due to pesticide residues at the border US-Mexico (number/year)	- To make an agreement for information exchange between Federal Drug Administration (FDA) and SSA to create a register of amounts of goods rejected in the border due to pesticide residues.	FDA	Own elaboration
Response	Indicators of legal framework development	No. of regulations enacted by type (regulation, decree or standards) (number/year)	- To register the number of regulations published by the government on pesticides	Diario Oficial de la Federación (Official Gazetta)	Own elaboration
	Indicators of compliance and enforcement	No. inspections of manufacturers and sellers (number/year)	To define and implement a permanent campaign of inspections to manufacturers and sellers to check adherence to regulations	CICOPLAFEST	Own elaboration

Table 7.3 Set of indicators proposed to measure the progress of the changes and initiatives proposed in Chapter VI, and in general, to evaluate a national policy of pesticides for Mexico (continuation).

Framework	Indicator	Definition	Methodology	Data Sources	Origin
Response	Indicators of changing behaviour	Area using an IPM system (ha/year)	- To collect information on surface under an IPM system	Sistema Integral de Información *Agroalimentaria y Pesquera* (SAGARPA)	USA
		No. doctors, farmers, sellers and manufacturers trained/educated (number/year)	- To collect data on number of people trained/educated in the National Programme against Risks by Pesticide Use	National Programme against Risks by Pesticide Use	Own elaboration
		No. applicators certified (number/year)	- To define and implement a system of certification for applicators	CICOPLAFEST	UK
	Indicators of international participation	Participation in treaties (number/year)	- Number of international treaties related to pesticides signed and ratified by Mexico, in which the country has already established a work plan and a schedule to comply with their objectives.	Diario Oficial de la Federacion (Official Gazetta)	The World Bank (World Development Indicators 2005)
	Indicators of Infrastructure development	No. certified laboratories (number/year)	- To define and implement a system of certification of laboratories that carry out toxicological and ecotoxicological studies following international guidelines	Entidad Mexicana de Acreditacion (EMA)	Own elaboration

As it was set up in the criteria of selection, once the data are obtained the use of the indicators is straightforward with the exception of the Frequency of Application (FA) and Load Index (LI) which needs the use of a simple mathematical equation to obtain the information. Annex C contains an example of how use them and more detailed information about them.

ii. Establishment of participatory and consultative network and data search.

In Table 7.3 the sources to obtain the data necessary to develop the indicators are presented, which would firstly make up the participatory network; however, this list is not exhaustive and more Secretariats and organisations can be added according to the needs of the indicators. The integration of this network is crucial for the creation and sustainability of the indicators as it can be seen much all the data required are not immediately available, so it is important to meet all the organisations and bodies involved to inform them the needs of data and star to harmonise activities, generate the database required and sharing results. The Technical Committee of the CICOPLAFEST would be in charge of the coordination and development of the indicators and the Technical Secretary would be in charge of their publication and distribution to the stakeholders.

7.3.1 Next steps for the development of indicators.

Due to the scope of this work and the lack of immediately available data some steps of the methodology will not be carried out; however, the pending activities are described in the next points:

a) Validation. Two ways to validate the set of indicators proposed in Table 7.3 are recommended. The first one consists in assuring the thoroughness in data search and the development of databases (EPA, 2000). The methodologies to collect data

needs to have scientific foundations and their compliance for all the participants need to be verified. The harmonisation of criteria is another key issue to assure the reliability of data and their adequate interpretation. Particularly, the diagnostic and report of pesticide poisoning in humans needs to be standardised as in the current practice pesticide poisonings are sometimes confused with other chemical poisoning or data reported are not homogeneous, so comparison among cities can not be possible and an estimation of a national pesticide poisoning with this information is not reliable, and also to include the records from the Toxicological Centres. The techniques to carry out the monitoring of pesticide residues in water and agricultural goods must be based on the methodologies required by the official standards[205] or following reliable international guidelines, a statistically reliable experimental design is also recommendable. With regard to response indicators, which do not require monitoring it is necessary homogenise criteria to collect the information and create the database.

The second way to validate the indicators is through the evaluation of an expert committee made up by scientific and policy makers that determined the economic, administrative and scientific viability of the set of indicators considering their expertise in the area[206] (Ugwu, 2006; Sustainable Seatle, 2006; Rosenstrom, 2006).

b) Development of capacities and tools to visualise information and analyse cause-effect relationships.

The information generated by indicators need to be presented in a way that enables analysis of causal links and visualises the results of such analysis. Moreover, results need to be communicable in a way that can be useful and convincing for decision

[205] If they are obsolete or inadequate to collect data an updating would be necessary.
[206] The validation of pesticide risk indicators such as FA and LI can be validated by comparing outcomes with environmental effects in the field, but this kind of validation is extremely complicated and can only be carried out if indicators produce output which can be measured in the field, like concentrations in surface water or groundwater, which is not the case for these indicators. So, an evaluation by an expert group and the assurance of quality data is proposed as their validation.

makers. There are many methods of presentation that can be used such as textual presentations, graphs, numerical presentations, tables and maps. As the aim of this set of indicators is to show changes in response to the implementation of the policy through time, graphs should be suitable to show the results; however, the way of presentation will depend on the target group that require to see the results and the facilities available to present them.

For the analysis of indicator values it is fundamental to use comparators, baseline values, thresholds, and/or targets, so the values can be meaningful and provide information about whether the changes in the different aspects covered for the national policy have been positive or negative. Table 7.4 summarises the use of baselines, thresholds and targets.

c) Design of actions and implementation.

To achieve the final objective an indicator initiative could include a step of designing actions, mitigating measures and their implementation. As Segnestam (2002) mentioned, this step is crucial for the success and meaningfulness of an indicator initiative but he stated that this does not have to be part of the initiative *per se*.

So, once indicators are implemented and clear trends can be seen it would be possible to identify whether targets have been achieved or not, or whether trends showing positive changes are expected. If targets have been almost achieved authorities can decide whether to continue with the same strategies to achieve the target or to improve them; if the targets have been completely achieved they should define the next steps to go on progressing. If negative effects continue or are increasing this would indicate that strategies may need to be reformed and mitigating measures would have to be established to remediate, prevent or control the damage or negative effects. If no positive or negative change can be observed

over time it is also important to consider that maybe the indicators are not adequate to measure the trend or effects of that particular process, so this should be replaced for another that present the appropriate characteristics.

Table 7.4 Proposal to use comparators.

	FOR WHICH ACTIVITY	WHEN TO USE	HOW TO ESTABLISH	PROPOSAL TO BE USED
BASELINE[1]	For any activity whose impacts one wishes to follow	To monitor changes (positive or negative) due to an activity	When used for monitoring a change, the baseline should be established at initiation of the activity. When used to illustrate total change the baseline should be set at zero	-Sales of pesticides by their type -Crop areas -Frequency of application (FA)[2] -Number of human poisonings -Load Index (LI)[2] -No. of regulations enacted by type -No. inspections to manufacturers and sellers -No. samples monitored of fresh products -Land using an IPM system -No. doctors, farmers, sellers and manufacturers trained/educated -Participation in treaties -No. certified laboratories
THRESHOLDS	To control an activity that may have a negative impact	To monitor negative impacts which should not exceed a pre-determined threshold	Establish threshold through determining the carrying capacity of the system	
TARGETS	For activities which aim to improve the state of the environment, sustainable development, activity or process	To monitor that positive impacts of an activity are sufficiently large	Establishment depends on the objective of the activity	-No. cases exceeding MRLs -No. cases exceeding concentration of residues in water allowed -Frequency of application (FA)[2] -Load Index (LI)[2]

[1] In this work, the baseline would be established at the beginning of the implementation of the national pesticide policy.

[2] FA and LI values can be compared with a baseline established at the moment of the implementation of the national pesticide policy or they can also be used to propose targets of reduction of risks (30% of risk reduction in FA in 10 years, for instance).

However, this part of the initiative is seen as a relatively large challenge since the implementation of these actions demands resources, political willingness and further monitoring, which sometimes governments are reluctant to accept.

Segnestam (2002) also considers the publication of the project results, testing results and the tools necessary for the project to be replicable in other parts of the world as another important step in the development of the indicators, so experiences can be shared and more work can be done in the area that entails to a permanent improvement.

7.4 Discussion and Conclusions

Pesticide indicators are becoming an essential part of a pesticide policy to measure progress and adequacy or inadequacy of its strategies; however, their use is still limited due to lack of information and limitations to find a proper balance between scientific robustness and simplicity for an easy interpretation for users. So, pesticide indicators are commonly used in countries with a well established pesticide reduction policy. However, it might be expected that public awareness on pesticide effects, export market demands and pressure from international organisations to develop pesticide risk reduction policies encourage the development of more pesticide risk indicators by governments.

The set of indicators proposed in this work would allow the authorities to include measurable targets to evaluate the effectiveness of the reforms and initiatives suggested in this thesis to improve the pesticide regulation system in Mexico and, in general, its national pesticide policy. The proposed indicators cover important aspects of the causes that promote the use of pesticides, its co-lateral effects on human health, the environment and economy, and the effectiveness of the strategies to reduce them as well as the change of behaviour of the involved actors. However, their validation has to be carrying out to assure their viability and reliability.

The indicators are simple, practical and data-moderated as they do not required complicated processes for their implementation and interpretation since the values can be obtained in a very straightforward manner. The collection of data may be costly in view of the monitoring required to count the violations in the MRLs and concentrations of pesticide residues in

water, the inspections to check adherence to the regulations and the register of pesticide poisonings and wildlife incidents; however, most of these activities are currently carried out and it would only be necessary to verify their reliability, adjust the frequency of the monitoring and gather the information. In this context, the creation of a pesticide network for the development of the indicators would be very important to obtain the information, homogenise criteria, gather data, share results and optimise resources.

However, the implementation of the indicators, along with the overall implementation of the national policy, represents a challenge for the government and the organisations involved since it demands important legal and administrative changes, harmonisation of activities, permanent exchange of information, generation of information systems and high level of coordination, hence its execution would depend greatly on the willingness of policy makers and resources available.

Chapter VIII Final discussion and conclusions

This chapter is divided into four sections which bring together the findings from the work carried out in the previous chapters. The first section discusses on the limitations of an Inter-Secretarial body as a coordinator of the administration of pesticides in Mexico, which were derived from the analysis of the regulatory framework for pesticides and the performance of CICOPLAFEST carried out in Chapter II. It also highlights the need for a reformation of the current pesticide regulatory system, considering the effects on the population and the environment, and the need to comply with the international commitments described in Chapter III and IV as appropriate.

The second section highlights the importance of selecting an alternative to improve the system taking in account the main dimensions that would affect its viability and comply with an integrated set of objectives for the various parties involved with the safe, efficient and effective use of pesticides, since at present contradictory policies prevail in Mexico. Additionally, it presents the main points of the policy analysis for the overall improvement of the system. The basis for this discussion comes from the results obtained from the qualitative analysis to select the best alternative to improve the system carried out in Chapter V and the implementation of the proposal and policy analysis elaborated in Chapter VI.

The importance of measuring and evaluating the performance of a pesticide policy through indicators, which were proposed in Chapter VII, is discussed in the third section as a way to assure an ongoing improvement.

Finally, the limitations of this work and recommendations for further studies are described in section four.

8.1 Limitations of the current pesticide control arrangement in Mexico.

There are three factors that constitute objective evidence of the need to reform the pesticide control arrangement in Mexico:

i) Deficient structure and organisation of CICOPLAFEST. Boardam (1986) stated that pesticide control arrangements are multi-sectoral and as a result have produced a particular type of politics. Historically, Mexico has addressed multisector issues through the creation of inter-Secretarial commissions that work as coordinator bodies. While there are successful experiences with Inter-Secretarial commissions in Mexico such as the Inter-Secretarial Commission for Public Budget and Funding (CIGF) (DOF, 1979) and the Metropolitan Environmental Commission (CAM), the case of CICOPLAFEST shows a different outcome. Comparing the differences among them, three characteristics were found to have an influence on the performance of the commissions: adequate legal power to achieve the objectives, control of their own resources to support necessary activities, and the significance of the issue to coordinate. In this way, CIGF has the task to define the distribution of the public budget, which is considered a high priority for its members. For its part, CAM has enough legal power to force constant participation of its members, as well as economic resources to support its work. However, CICOPLAFEST lacks legal power and its own resources, and the lack of scientific information that describes the

magnitude of the side effects of pesticide use in the country has undermined the technical and scientific basis for its actions. So, it is suggested that these characteristics have provoked:

- a limited interest from high executives and decision makers to participate actively in the activities of the Commission
- the lack of exclusivity of the members dealing with the Commission's responsibilities since at present only the Technical Committee holds regular meetings and the other groups have been disintegrated due to problems of attendance.
- the lack of formality and continuity to achieve its objectives and define a plan of work
- difficulty to reach consensus among the members due to the lack of a leader
- misunderstanding of the coordination process as Secretariats were taking responsibilities without any legal power to do so.

Additionally, it is known that compliance and enforcement of pesticides regulations is *per se* a difficult task due to the number of companies and users to regulate and the high costs of monitoring (Agne, 1996 and Jungbluth, 1996).

So, these deficiencies have limited the achievement of the objectives of CICOPLAFEST, with no significant advance in the development, implementation, compliance and enforcement of the regulatory framework for pesticides and complementary tasks.

ii) Effects on health, economy, society and the environment due to pesticide use. In spite of the reduced number of studies on environmental, social and health effects and the under reporting of pesticide incidents in Mexico, the available information provides a cause for concern about the effectiveness of the

protection of the population and the environment in Mexico. Analysis on the rejections of Mexican foodstuffs at the Mexico-USA border due to pesticide residues shows that Mexico had the highest number of rejections due to pesticide residues in the period June 2004 to May 2005, but it was also the main exporting country of fresh vegetables to the USA. The rejections represented a negligible economic loss for the Mexican economy; however, this represents a clear evidence of the misuse of pesticides and undermines the perceived quality of Mexican products.

iii) The need to comply with international commitments. Currently, Mexico is a member party of the Conventions of Stockholm, Basel and Rotterdam and the Montreal Protocol, which implicitly or explicitly demand a control on pesticide import, reduction and prohibition of improper use. Additionally as a member of NAFTA and OECD, Mexico is engaged to harmonise its regulatory procedures to facilitate trade of pesticides and food goods. Specifically, OECD's vision establishes that for the year 2014, its member countries will routinely accept and exchange dossiers to support pesticide approvals.

8.2 Improvement for the Pesticide Control Arrangement in Mexico.

It has been suggested in different studies (Agne, 1996 and Farah, 1994) that the current economic environment and government policies related to pesticides, and to pest management in general, in developing countries, induce excessive (above the socially optimal level) chemical use, which is associated with negative externalities. According to Farah (1994), subsidies provided for pesticide imports, local manufacture and use represent one of the main factors that induces the excessive use. In Mexico, pesticides are exempted from sale tax and there is facilitation to import pesticides for agricultural organisations. Muñoz *et al* (2005) pointed out the lack of coordination in public policies in Mexico since the agricultural policy entails an increase in agriculture production by subsiding water, energy

and pesticides, while SEMARNAT is aiming to control the over-exploitation of water resources and their contamination with pesticides and SSA is dealing with the prevention and minimisation of risks by pesticide use.

So, the qualitative analysis carried out to select the most suitable proposal to improve the pesticide control system in Mexico incorporates the objectives of the different parties involved or affected by the pesticide regulation (government, pesticide and agriculture industries and public) and puts together the economic, political, administrative and performance dimensions to select a realistic and integrated proposal that covers the expectations of the parties and includes the national context . In this way, the leadership of SSA on pesticide control through the concentration of the main regulatory activities in COFEPRIS, the creation of an exclusive law for pesticides and the presence of a reformed CICOPLAFEST was found as the most sensible way to improve the system and pursue a balance in the public policies by giving an appropriate weight to the negative effects on human health through a strengthened registration process and establishment of national MRLs and keeping a reformed CICOPLAFEST to incorporate the needs from the other Secretariats, so a national pesticide policy can be defined.

The policy analysis carried out along with the implementation of the lead group in COFEPRIS proposes five initiatives that would complete the overall improvement of the pesticide control system:

a) To ensure the safe use of pesticides by strengthening the regulatory framework, the compliance and enforcement and the registration process. It is supported that legislation is the short-term solution to pesticide problem.
b) To prevent risks by pesticide use by providing training and education to users, sellers, manufacturers, general public, medical and technical personnel; encouraging the introduction and expansion of IPM systems; promoting the

substitution of hazardous pesticides, and designing campaigns of monitoring of residues in food.

c) To generate, collect and communicate information to the public about pesticide risks and the regulatory process by supporting and encouraging research about pesticide use and its social, economic, health and environmental effects; collecting and recording reliable data on the import, export, manufacture, sales, use of pesticides, poisoning incidents and environmental contamination, and publishing and ensuring that information reaches all stakeholders and general public.

d) To participate in joint tasks and cooperate with different sectors by creating a closer contact with the academic sector; organising specialised discussion forums made up by industry, officials and/or public associations; creating and strengthening networks for information exchange among Secretariats and other governmental institutions and with international, regional and sub-regional organisations and participating in international agreements.

e) To strengthen CICOPLAFEST by modifying its current structure and creating greater trust to support its activities.

It is also supported that the implementation of these strategies and initiatives may constitute a long term solution to pesticide problem.

Table 6.1 presents the aims, outcomes, measures and/or targets of these initiatives.

8.3 Evaluating pesticide policies

Pesticide indicators are becoming an essential part of a pesticide policy to measure progress and adequacy or inadequacy of its strategies; however, the number of indicators is still limited since many countries are in the planning stages to define a policy for pesticide reduction and the development of indicators is mainly an initiative of developed countries with a well based pesticide policy working from fifteen years ago on average and with

complete and reliable databases. By contrast, developing countries are increasing their dependence on the use of pesticides and their policies to reduce risks by pesticide use are competing with economic policies, which allow them only isolated actions without a clear advance to prevent and control risks by pesticide use.

The set of indicators proposed in this work will allow the authorities to include measurable targets for its national pesticide policy to evaluate its effectiveness. However, the implementation of the indicators, along with the creation of a lead group in COFEPRIS and the overall implementation of the policy initiatives proposed in Chapter VI, represent a challenge for the government and the organisations involved since it demands legal changes, harmonisation of activities, permanent flux of information, generation of database and high level of coordination, hence its execution would depend greatly on the willingness of policy makers and resources available.

8.4 Limitations of the work and future recommendations

The lack of immediately available information on pesticide use, cost recovery fees, results of the programmes of enforcement and compliance of the Secretariats and more detailed information on pesticide poisoning, as well as updated data on sales and regulatory activities of the government such as the number of pesticide registrations or import authorisations issued, constituted the main barriers to have a more quantitative diagnosis of the current administration of pesticides in the country, and also to validate the set of indicators presented in Chapter VII. Some of the missing information could exist but there is no person in charge to gather it and put it in an appropriate format to allow public access or the information is for exclusive use of the authorities, such as the results of the enforcement and compliance programmes.

As future work it is recommended:

- To estimate the costs for the implementation of a lead pesticide group in COFEPRIS considering the expenses of hiring new personnel that support the development of the new responsibilities involved and the need of additional infrastructure.

- To do cost-benefit analyses of the strategies proposed in the five initiatives mainly those related to subsidies that support the substitution of use of hazardous pesticides by less toxic alternatives.

- To validate the set of indicators proposed.

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Annex A

A1. Mexican Official Standards (NOMs) derived from the Regulation for the Land Transport of Hazardous Materials and Wastes 1993.

- NOM-002-SCT/2003. List of hazardous material and substances more commonly transported.
- NOM-021-SCT2-1994 determines the stipulations for transporting no hazardous materials or wastes in specialised vehicles for the transport of hazardous material or substances.
- NOM-003-SCT-2000 establishes the characteristics of labels and packages for the transport of hazardous material, substances and wastes.
- NOM-023-SCT2-1994 defines the technical information of the labels of the containers of hazardous materials and wastes.
- NOM-004-SCT-2000 establishes the system of identification of vehicles used for the transport of hazardous substances, materials or wastes.
- NOM-024-SCT2-1994 specifies the characteristics of the containers of hazardous materials and wastes.
- NOM-005-SCT-2000 sets forth the data and describes the specifications that must be provided in Emergency Information for the land transport of hazardous substances, materials and wastes.
- NOM-025-SCT2-1994 defines the requirements of packing of class I (explosives) of hazardous substances, materials and wastes.
- NOM-027-SCT2-1994 defines the requirements of package and packing and transport of subclass 5.2 (organic peroxide) of hazardous substances, materials and wastes.
- NOM-006-SCT2-2000 defines the basic requirements for the daily revision of vehicles used for transporting hazardous materials and wastes.
- NOM-028-SCT2-1998 establishes the special provisions to determine the package and packing risk group of hazardous substances and wastes of class 3 (flammable liquids) transported.
- NOM-007-SCT2-1994 sets forth the characteristics and specifications that must be complied for the marking of packages and packaging intended for the land transport of hazardous substances and Wastes.
- NOM-009-SCT2/2003. sets forth the compatibility criteria to be used for the transport of hazardous materials, substances and wastes of Class 1 (explosives).
- NOM-010-SCT2-1994 determines the compatibility and segregation provisions that must be applied for the transport of hazardous substances, materials, and wastes.

- NOM-011-SCT2-1994 sets forth the provisions that are prescribed for the transport of small quantities of Classes 2, 3, 4, 5, 6, 8 and 9 hazardous substances, materials and residues.

- NOM-032-SCT-1995 requirements for the construction and reconstruction of portable tanks designated for multimodal transport of classes 3, 4, 5, 6, 7, 8 and 9.

- NOM-018-SCT2-1994 establishes the general provisions for the loading, packing and unloading of hazardous materials and wastes in railroad haulage.

- NOM-045-SCT2-1995 defines the general characteristics for the transport of hazardous materials and wastes in railroad haulage.

- NOM-019-SCT2-2004 sets forth the general provisions for the cleanup and control of residues in the units that carry hazardous materials and wastes.

- NOM-020-SCT2-1995 defines the requirements for the design and construction of tank containers for the transport of hazardous substances and materials.

- NOM-051-SCT2/2003. It defines the requirements of package and packing and of subclass 6.2 (infectious agents) of hazardous substances, materials and wastes.

- NOM-043-SCT-2003. Shipping hazardous substances, material and residues.

- PROY-NOM-074-SCT2-2002. Compatibility and segregation for dragging units that transport hazardous material and residues.

Annex B

B1. Scientific subcommittee on pesticides

B1.1. Organisation and duties

The scientific subcommittee would play an important role as advisor of COFEPRIS and CICOPLAFEST, which should be consulted for:

- registering pesticides (new active ingredients to be used in Mexico or substances already registered, for which there is concern about their safety and effectiveness in Mexico).
- developing new regulations or updating current regulations in order to back a pesticide control policy on sound science
- implementing innovative strategies to control pest
- supporting research on pesticide effects on the environment and human health.

The scientific subcommittee should have a coordinator, who would lead and represent the subcommittee and promote its satisfactory performance. The coordinator would be the liaison between the subcommittee and COFEPRIS and CICOPLAFEST. For its part, CICOPLAFEST and COFEPRIS should ensure that the subcommittee is kept informed of developments in policy and administration that concern them.

The subcommittee should be independent of the government and the pesticide industry and their members should be selected by open competition by the technical committee of the CICOPLAFEST. The members are expected to observe the highest standards of impartiality, integrity, objectivity and high level of expertise in their area.

According to the activities involved in pesticide control the subcommittee should be made up of experts in the following areas:

- Toxicology (both experimental and clinical)
- Assessment of risks (including consumer exposure, dietary modelling and occupational hygiene)
- Chemistry (concerning chemical analysis and metabolism)
- Epidemiology

- Ecology and ecotoxicology (relating to conservation, sustainability, biodiversity and toxicological effects on plants and animals)
- Environmental fate and behaviour of pesticides in the environment
- Agricultural trials and practices (including pest biology, control and resistance to pesticides, effectiveness of pesticide products, alternative techniques in controlling target pests and agricultural practices)
- Organic farming, Integrated Pest Management and sustainability

B1.2. Potential scientific community

The Mexican institutes and academic centres with recognised proficiency in these areas are the following:

Chemistry, toxicology and epidemiology

- Centro de Investigación y de Estudios Avanzados (CINVESTAV) of the Instituto Politécnico Nacional Unidad Zacatenco
- Toxicological centres of the Mexican Toxicological Network (RETOMEX) equipped with toxicological laboratories.
- Department of genetic and environmental toxicology of the Instituto de Investigaciones Biomedicas of the Nacional University of Mexico (UNAM)
- Department of Pharmacology of the Facultad de Quimica, UNAM
- Centro de Investigación en Salud Poblacional of the Instituto Nacional de Salud Publica.

Assessment of risks

- Centro Interdisciplinario de Investigaciones y Estudios sobre Medio Ambiente y Desarrollo (CIIEMAD) of the Instituto Politecnico Nacional
- Food Analysis Laboratory of the Universidad Autónoma de Nuevo León
- Universidad Autónoma de San Luis Potosí
- Environmental Department of the División de Estudios de Postgrado de la Facultad de Ingeniería, UNAM
- Centre for Environmental Quality (Centro de Calidad Ambiental) of the Instituto Tecnologico y de Estudios Superiores de Monterrey

Ecology and ecotoxicology

- Centro de Investigaciones y de Estudios Avanzados (CINVESTAV) of the Instituto Politecnico Nacional –Unidad Irapuato-
- Centre for the Development of Biological Products (Centro de Desarrollo de Productos Bioticos) (CEPROBI) of the Instituto Politecnico Nacional

- Centre for Ecosytem Studies (Centro de Investigaciones en Ecosistemas), UNAM
- Institute of Ecology (Instituto de Ecologia) of the UNAM
- Instituto de Ecologia (INE) of the Environmental Health Secretariat (SEMARNAT)

Environmental fate and behaviour of pesticides in the environment

- Interdiciplinary Centre for Environmental and Development Research (Centro Interdisciplinario de Investigaciones y Estudios sobre Medio Ambiente y Desarrollo) (CIIEMAD) of the Instituto Politecnico Nacional
- Department of Genomic Medicine and Environmental Toxicology of the Instituto de Investigaciones Biomedicas, UNAM
- Institute of Engineering (Instituto de Ingenieria), UNAM
- Centre for Development of Biological Products (Centro de Desarrollo de Productos Bióticos) (CEPROBI) of the Instituto Politecnico Nacional
- Biotechnology Centre (Centro de Biotecnología) of the Instituto Tecnológico y de Estudios Superiores de Monterrey
- Centre for Environmental Quality (Centro de Calidad Ambiental) of the Instituto Tecnologico y de Estudios Superiores de Monterrey http://uninet.mty.itesm.mx/

Agricultural trials and practices and organic farming, Integrated Pest Management (IPM) and sustainability

- Department of Parasitology of the Universidad Autónoma de Chapingo
- Institute of Plant Health (Instituto de Fitosanidad) of the Colegio de Postgraduados
- Universidad Autónoma Agraria "Antonio Narro"
- Universidad Autónoma de Sinaloa
- Universidad de Colima
- Institute of Agricultural Sciences (Instituto de Ciencias Agrícolas) of the Universidad Autónoma de Baja California
- Department of Tropical Agricultura of the Universidad Autónoma de Chiapas
- Centre for Agricultural and Biological Sciences (Centro de Ciencias Biológicas y Agropecuarias) of the Universidad de Guadalajara
- Centres for Agricultural Research and Production (Centro de Investigaciones Agropecuarias and Centro de Producción Agropecuaria) of the Universidad Autónoma de Nuevo León
- Centre for Advanced Studies (Centro de Investigaciones y Estudios Avanzados), Instituto Politécnico Nacional –Unidad Irapuato-

B1.3 Research Funding

Funding sources can be obtained from:

- a trust created among the members of CICOPLAFEST
- government and pesticide industry funding
- implementing a fees recovery programme and environmental tax for pesticides
- participation in the Fondos Sectoriales y Mixtos created between the Federal and local governments and the National Council on Science and Technology of Mexico (CONACYT) [1].

[1] This funding is offered to Mexican research centres and universities registered in the Registro Nacional de Instituciones y Empresas Cientificas y Tecnologicas (RENIECYT) (Reyes, 2003 Pers. Commun.). CONACYT announces every year an open competition to obtain the funding. More information can be obtained at http://www.conacyt.mx/fondos/index.html Last visit 18 April 2005.

Annex C

C1) Frequency of Application

The indicator Frequency of Application (FA) is regarded as an indicator for the spraying or treatment intensity as well as a risk indicator of the environmental impact of pesticides (Møhlenberg, et all. 2001; Danish Environment Ministry *et al.* 2000). FA considers the quantities of each active ingredient sold, the standard dose of each active ingredient in each crop/crop type and the area of arable land in the respective country:

$$FA = \sum_{Allactiveingredients} \frac{\left(\frac{SA_{individualactiveingredients}}{SD_{crop/croptypes}} \right)}{AGRA_{year}}$$

where: SA is the amount sold of individual active ingredients per year; SD the standard dose for each ingredient in each crop/crop type, and AGRA the arable land (ha).

C2) Load Index

Load Index (LI) is a complementary indicator of FA used to track changes in potential pesticide impact on environment and health (Møhlenberg and collaborators, 2001). This indicator calculates the ratio between *total sale of different pesticides:toxicity* summed for all active ingredients providing a relative measure of environmental load concerning specific type of toxicity:

$$LI = \sum_{allactiveingredient} \frac{Sales_{eachactiveingredient}}{TOX * AGRA_{year}}$$

where: TOX, represents acute or long-term LC50 or LD50 values; Sales, is the amount sold of individual active ingredients per year, and AGRA, the arable land.

C1. Example of calculation of FA:

Product	Sales (kg/year)	Crop[1]	Percentage of use	Dose (kg/ha)	Area treated[2] (ha/year)	AGRA[3] (ha/year)	FA
Herbicide 1	2,000	Maize	42	0.5	1,680		
		Sugar cane	26	0.2	2,600		
		Pineapple	32	0.8	800		
Herbicide 2	1,500	Maize	22	0.4	825		
		Tomato	34	0.4	1,275		
		Strawberry	12	0.7	257		
Herbicide 3	·	·	·	·	·		
·	·	·	·	·	·		
·	·	·	·	·	·		
·	·	·	·	·	·		
All herbicides		Maize			428,580	398,956	1.07
		Sugar cane			513,421	482,210	1.06
		Pineapple			25,325	21,563	1.17
		Tomato			190,235	175,000	1.09
		Strawberry			69,582	57,897	1.20
		·			·	·	·
		·			·	·	·
All herbicides		All crops			2548957	2989654	0.85
All fungicides		All crops			854,214	2989654	0.29
All insecticides		All crops			2,024,258	2989654	0.68
All growth regulators		All crops			85,147	2989654	0.03
All pesticides		All crops			5,512,576	2989654	1.84

[1] Crops can be grouped, for instance, spring-summer cereals and autumn-winter cereals or oilseeds, vegetables and fruits and so on.
[2] Area treated=Sales (kg/year) / Dose (kg/ha)
[3] Total area of the crop

This indicator is calculated separately for mammals, birds, earthworms, fish, crustaceans and algae using a value (average, min or max) for chronic or acute toxicity of individual pesticides. The calculated values are designated "load indices for mammals", "load indices for fish", etc.

C2) Example of calculation of LI:

Product	Sales (kg/year)	Organism	Toxicity LC50 (mg/l)	Number of toxicity doses[1]	AGRA[2] (ha/year)	Load Index
Herbicide 1	1,000	Fish	1 mg/l	1×10^9		
Herbicide 2	.	.	.	.		
	.	.	.	.		
	.	.	.	.		
All herbicides		Fish		$5{,}903 \times 10^6$	2,361,233	2500
All fungicides		Fish		$2{,}007 \times 10^6$	2,361,233	850
All insecticides		Fish		$35{,}417 \times 10^6$	2,361,233	15000
All growth regulators		Fish		0.71×10^6	2,361,233	0.3
All pesticides		Fish		$43{,}328 \times 10^6$	2,361,233	18350.0

[1] Number of toxicity doses= Sales (kg/year) / Toxicity LC50 (mg/l). It is necessary to homogenise units for the calculation, although they are not relevant for the value of LI.
[2] Total area of the crop

C3) Assumptions and observations of FA and LI:

- FA and LI are indicators data moderate and simple
- FA and LI do not measure the risk but show the trend of it
- FA assumes that pesticides are used according to the prescribed normal dosages
- Sales data provide an adequate substitute for actual use to determine broad national risk trends
- In the case of variations in the dosages recommended by different formulations to calculate FA, the average, minimum or maximum value can be used, but its use has to show consistency during all the study
- LI can be calculated using different type of toxicity, for instance, LC50 (24 hours), LC10 (24 hours) or NOEC (24 hours) and so on, but the same type of toxicity has to be used during the calculation of the index. Every type of toxicity can also have different values reported in the international literature or in the pesticide registration submissions, thus the minimum, media or maximum value can be used keeping the same criteria during the calculation
- FA and LI are less responsive than OECD aquatic pesticide risk indicators and require longer periods to obtain significant trends
- FA and LI were found to show similar risk trends when compared with OECD's risk pesticide indicators

- Experimental and modelling studies have indicated that FA is a reasonable risk indicator for terrestrial and aquatic ecosystems. However, it can not predict temporal variations in risks associated with adoption of spray buffer zones required for risk mitigation, and also found some restrictions to be used in some non-target organisms.
- Similar to FA, LI is not a measure of actual effects on populations or ecosystems in the field but calculates a relative risk that can be compared between years. LI does not also include information on exposure risks or buffer zones required for risk mitigation therefore it does not predict temporal variations in risks.

Annex D

D.1) Estimation of the number of establishments under verification by the Health Secretariat (SSA).

The Health Secretariat (SSA) has the responsibility to enforce the General Health Law (LGS). According to this law, industrial establishments, services (including restaurants, health and social services) and sellers have to be verified in order to prove that their activities are in compliance with the regulations protecting the Mexican people. Because the number of establishments that have to be verified by SSA was not available, an estimate was obtained using data reported by the National Institute of Statistics, Geography and Informatics (INEGI), including only those industrial branches, services and sellers that may be a priority for the SSA due to their effects on human health. The total number of establishments estimated was of 460,384 (Table D.1).

Table D.1 Estimation of the number of establishments under verification by SSA.

	No. establishments	Source
Industrial sector	5,988[1]	Environmental Data Report (INEGI, 2006)
Services	367,399[2]	Economic Census 2004 (INEGI, 2004)
Sellers	86,997[3]	
Total	460,384	

[1] Only includes establishments whose activities are classified by SEMARNAT as being highly polluting.
[2] Only includes food and health services and social assistance units.
[3] Only includes big scale sellers.

D.2) Questionnaire applied to pesticide sellers

To determine the level of knowledge of pesticide sellers on the regulation of pesticides, a questionnaire was given to those sellers that attended the workshop on 'Regulation and Reduction of Risks' organised by SAGARPA on February 12th to 13th, 2004. The questionnaire is given below in Spanish and English:

D.2.1 Spanish version:

Curso-Taller sobre Regulación y Reducción de Riesgos dirigido a Empresas Comercializadoras de Plaguicidas Agrícolas La Piedad, Michoacán. 12 y 13 de febrero de 2004

A. Datos Generales

Puesto en la empresa _____ Antigüedad _____

Edad _____ Nivel de estudios _____

B. Cuestionario

Marque con una X la respuesta que considere apropiada.

1. Conoce la norma NOM-033-FITO-1995 en la que se establecen los requisitos y especificaciones fitosanitarias para el aviso de inicio de funcionamiento que deberán cumplir las personas físicas o morales interesadas en comercializar plaguicidas agrícolas

   a) nada O b) poco O c) regular O d) mucho O

2. El aviso de inicio de funcionamiento lo considera como un trámite (puede seleccionar más de una opción):

   a) innecesario O b) no importante O c) necesario O d) importante O

3. Las visitas de inspección a su empresa por parte de la autoridad para vigilar el cumplimiento de la norma NOM-033-FITO-1995 las considera (puede seleccionar más de una opción):

   a) innecesarias O b) no importantes O c) necesarias O d) importantes O

4. El llenado del formato de aviso de inicio de funcionamiento lo considera:

   a) muy difícil O b) difícil O c) fácil O d) muy fácil O

5. Los compradores de plaguicidas le piden asesoría para seleccionar el plaguicida adecuado:

   a) nunca O b) casi nunca O c) frecuentemente O d) siempre O

6. Su conocimiento sobre el uso y manejo adecuado de plaguicidas lo considera

   a) nulo O b) regular O c) suficiente O d) muy bueno O

7. Considera útiles los cursos de capacitación sobre el uso y manejo adecuado de plaguicidas

   a) nada O b) poco O c) regular O d) mucho O

8. Si tiene algún comentario, duda o sugerencia a cerca de la regulación a empresas comercializadoras escríbala a continuación: _____

_____

D.2.2 English version:

Workshop on Regulation and Reduction of Risks addressed to Agricultural Pesticide Sellers
La Piedad, Michoacan city. 12th and 13th of February 2004

A. Personal Information

What is your job title? _____ How many years have you been working in the company? _____ How old are you? _____ What is your level of education? _____

B. Questionnaire

I. Please answer the following questions by filling the appropriate circle.

1. What is your knowledge on the standard NOM-033-FITO-1995, in which the phytosanitary requirements and specifications on the notification of beginning of activities for people interested in selling pesticides are set?

   a) none O b) poor O c) sufficient O d) excellent O

2. The notification of beginning of activities is a requirement:

   a) essential O b) trivial O

3. The verification to pesticide sellers to enforce the standard NOM-033-FITO-1995 is a requirement:

   a) essential O b) trivial O

4. The application for the notification of beginning of activities is a requirement:

   a) complex O b) very complex O c) easy O d) very easy O

5. Do farmers ask for advice to buy the adequate pesticide?

   a) never O b) rarely O c) sometimes O d) often O d) always O

6. Your knowledge on pesticide use and handling is:

   a) none O b) poor O c) sufficient O d) excellent O

7. Are workshops on pesticide regulation and safety useful?

   a) never O b) rarely O c) sometimes O d) often O d) always O

8. If you have any comment or question on the regulation of pesticide sellers please write it down:

_____

D.3) Estimation of the number of employees for the proposed decentralised organisation.

To determine the number of employees that a decentralised organisation would require, a questionnaire was sent to fifteen officials from the Secretariats of Health (SSA), Agriculture (SAGARPA) and the Environment (SEMARNAT), which asked them about the number of people required for every area in the proposed decentralised organisation, taking into account its responsibilities and structure. The questionnaire is presented in the following tables (Spanish and English versions):

D.3.1 Spanish version:

Cuestionario:

Con el objetivo de estimar con mayor precisión el numero de empleados que un organismo descentralizado necesitaría para regular plaguicidas le envío este cuestionario , ya que considerando su conocimiento y experiencia en el área usted tendrá mayor conocimiento sobre las necesidades y responsabilidades que una regulación integral de plaguicidas demandaría . Por favor llene la columna de la derecha con el número de empleados que cada área necesitaría .

AREA	NUMERO DE EMPLEADOS PROPUESTO
Registr o y autorizaciones de importación y exportación de plaguicidas	
Administración de personal y área jurídica	
Lab oratorio de análisis	
Inspección y vigilancia	
Capacitación y difusión de información	
Política y planeacion	
Asuntos internacionales Sistemas de información y atención al publico	

D.3.2 English version:

Questionnaire :

In order to have a more detailed estimation of the number of employees that a decentralised organisation to regulate pesticides would require I am sending to you the following questionnaire , since your knowledge and experience in the area would provide a more realistic information on the needs and tasks that an integrated regulation of pesticides would demand . Please, fill the column with the number of employees that every area proposed would need.

AREA	NUMBER OF PEOPLE PROPOSE D
Registration and authorisations of import and export	
Management, finance and legal affairs	
Analytic laboratory	
Inspection and enforcement	
Training and diffusion	
Policy and planning	
International affairs	
Information systems	

Two officials from SAGARPA and one official from SEMARNAT answered the questionnaire. They suggested the ideal number of employees required to efficiently cover pesticide-related tasks. Their answers are presented in Table D.3.1.

Since there was no answer from the officials at the SSA the questionnaire was conducted over the phone. Three officials from the areas of Registration, Analytic Laboratory and Training and Dissemination of information provided the information required exclusively for their areas. For example, the official for Registration only gave an estimate of the number of employees for the area of Registration and Authorisation rather than an estimate for all areas of the decentralised organisation. So the number of employees for the rest of the areas was estimated by consulting the current SSA payroll and counting all those employees involved in pesticide control. The number of employees proposed was added by each Secretariat to obtain the total number for each area of the decentralised organization (Table D.3.1).

Table D.3.1 Number of people required for a decentralised organisation for pesticides.

Area	SAGARPA*	SEMARNAT	SSA	TOTAL Number of people proposed
Registration and authorisations of import and export	5	5	25	35
Management, finance and legal affairs	6	2	7	15
Analytic laboratory	2	2	8	12
Inspection and enforcement				10
Training and dissemination of information	1	1	2	4
Policy and planning	1	1	1	3
International affairs	1	NA	1	2
Information systems	1	1	2	4
Total				85

NA: No available.

* These estimates are an average of the information proposed by the two officials.