Convergence of GM maize labelling policies: A comparative assessment between the EU and the NAFTA region

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ABSTRACT

The aim of this study is to analyse the convergence of genetically modified (GM) maize labelling policies in the European Union (EU) and in the region defined by the North American Free Trade Agreement (NAFTA). To investigate this, an examination of each region's policies, which are shaped according to the respective levels of integration, is systematically undertaken. With this, GM maize labelling policies that are based on agricultural efficiency, human health, environmental concerns and consumers' right to information delimit the extent and the manner in which convergence takes place. The resulting policy outputs in each region are different. The EU develops harmonised policies that establish mandatory labels for GM maize in terms of both product and process with the purpose to inform consumers about the origin of the products they acquire. In contrast, North America has homologated national policies to an extent that does not affect national preferences and interests. These different approaches demonstrate that nation-states are the most influential actors in policy-making, setting up GM maize labelling policies according to their own backgrounds, preferences, and interests. Regional institutions also participate, but they do so according to the level of integration achieved. Subsequently, different levels of participation and different policy outputs develop out of each region. It is observable that the EU has moved towards the establishment of stricter rules, as according to Vogel's concept of 'trading up'. A different case is the NAFTA region, where the level of convergence has been preserved despite the approximation of policies.

CONTENT

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ACRONYMS

AAFC	Agriculture and Agri-Food Canada
APEC	Asia-Pacific Economic Cooperation
BEUC	*Bureau Européen des Unions de Consommateurs*. The European Consumers' Organisation
BSE	Bovine Spongiform Encephalopathy
Bt	*Bacillus Thuringiensis*
CARD	Committee on Agriculture and Rural Development of the European Parliament
CBD	Convention on Biological Diversity
CEC	Commission for Environmental Cooperation
CEPHCP	Committee on the Environment, Public Health and Consumer Policy of the European Parliament
CFIA	Canadian Food Inspection Agency
CFSP	Common Foreign and Security Policy
CGSB	Canadian General Standards Board
CIBIOGEM	*Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados* Inter-Ministry Commission on Biodiversity and Genetically Modified Organisms
CIETRE	Committee on Industry, External Trade, Research and Energy of the European Parliament
CIMMYT	*Centro Internacional de Mejoramiento de Maíz y Trigo* International Maize and Wheat Improvement Centre
CONASUPO	*Compañía Nacional de Subsistencias Populares* National Company for Popular Subsistence
CPB	Cartagena Protocol on Biodiversity
DG	Directorate General
DNA	Deoxyribonucleic Acid
EC	European Community
EDD	European Development Days

EEC	European Economic Community
EESC	European Economic and Social Committee
EFA	European Free Alliance
ELDR	Group of the Alliance of Liberals and Democrats for Europe
EMU	European Monetary Union
ENGO	Environmental Non Governmental Organisation
EP	European Parliament
EPA	Environmental Protection Agency
EPP	Group of the European People's Party (Christian Democrats)
EU	European Union
EuropaBio	European Association for Bio-Industries
FAITC	Foreign Affairs and International Trade Canada
FAO	Food and Agriculture Organisation
FARS	Food and Agriculture Regulatory Systems Working Group
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GM	Genetically Modified
GMF	Genetically Modified Food
GMO	Genetically Modified Organism
GUE/NGL	Confederal Group of the European United Left - Nordic Green Left
JHA	Justice and Home Affairs
LBOGM	*Ley de Bioseguridad y Organismos Genéticamente Modificados* Law on Biodiversity and Genetically Modified Organisms
LMOs	Living Modified Organisms
MEP	Member of the European Parliament
NAAEC	North American Agreement on Environmental Cooperation
NABI	North American Biotechnology Initiative

NAFTA	North American Free Trade Agreement
NI	Non-Inscrits (Independent)
OECD	Organisation for Economic Cooperation and Development
PSE	Group of the Progressive Alliance of Socialists and Democrats
QMV	Qualified majority voting
RLBOGM	*Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados* Regulations for the Law on Biosecurity and Genetically Modified Organisms
SAGARPA	*Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* Ministry of Agriculture, Livestock, Rural Development, Fisheries and Alimentation
SECON	*Secretaría de Economía* Ministry of the Economy
SEMARNAT	*Secretaría de Medio Ambiente y Recursos Naturales* Ministry of the Environment and Natural Resources
SPP	Security and Prosperity Partnership
SPS	Sanitary and Phytosanitary Measures
SSA	*Secretaría de Salubridad y Asistencia* Ministry of Health and Assistance
TACD	Trans Atlantic Consumer Dialogue
TBT	Technical Barriers to Trade
UEN	Union for Europe of the Nations
UK	United Kingdom
USDA	United States Department of Agriculture
USFDA	United States Food and Drug Administration
USTR	United States Trade Representative
WHO	World Health Organisation
WTO	World Trade Organisation

INTRODUCTION

There is a trend among nation-states to form regional trading blocs. This means the suppression of trade barriers, as in the case of tariffs. In addition, there are other barriers that can impede trade. This is the case of regulatory barriers, which take the form of strict policies that national governments implement due to a number of issues: to protect the environment, to reach a certain degree of citizenry's trust, to shield local industry from unfair external competition, etc.

The differences portrayed by such national policies between nation-states, and their potential convergence have signified one of the major debates in political science, which centres on the question as to whether and why different countries develop similar policies over time. Knill (2005: 764) suggests that there are two different types of responses. The first one refers to studies emphasising a certain degree of policy convergence and its underlying causal factors. The second one is advocated through studies that modify or challenge any expectation of policy convergence by emphasising differences in national institutions and opportunity structures for domestic actors.

It is thus the purpose of this study to explain the dynamics of policy convergence, while observing its causal mechanisms. To achieve this, genetically modified food (GMF) labelling policies are examined. This is because a biotechnology product is not merely another complex product about which consumers want and need substantial information in order to determine their purchasing behaviour. Scientific development, trade processes, as well as regulators determine the appropriate policies in the field due to the information they possess (Hadfield and Thomson, 1998: 552). In this sense, emphasis has been given to the agricultural advantages that GM crops entail, as well as to the information that should be provided when these products are commercialised.

Differences in perspectives, due to domestic preferences and interests, can reveal that convergence at the regional level has not happened smoothly. Such differences have propelled a series of actions from national governments and regional institutions, which in turn lead to outcomes that differ between regional settings. Convergence outcomes can thus take the form of either stricter or laxer rules. If they become strict, they experience what is termed as 'trading up'. If the opposite happens, a 'race to the bottom' is likely to be suggested.

In order to understand and explain policy convergence, as well as to determine the existence of 'trading up' or 'race to the bottom', I am examining two different policies on labels for GM maize in two different regional settings: the European Union (EU) and the region where the North American Free Trade Agreement (NAFTA) has taken place. For this, their policies are explained through the analysis of the progress of each of the regulatory frameworks.

Of all the food and crops that have been developed by biotechnology means, the case of maize assists in providing a deeper insight due to the following reasons. This crop has been at the core of regulatory processes in both regions because of its level of production and importance as food staple. GM maize is the only GM crop cultivated within the EU, has been the object of specific legislation, and is one of the GM crops with the most authorisation requests for release. Also, Mexico has developed more stringent rules about this crop with respect to its North American neighbours. This is because Mexico shows specific features due to the cultural, social, environmental, and economic implications of maize. This thus means that selecting maize as the crop to analyse assists in narrowing what otherwise could lead to a vast amount of information to examine.

With maize selected as the crop to scrutinise, I examine specific legislation at regional and national levels depending on the region in question. With respect to the EU, a list of initial issue-related regulations is assessed, like Regulation 1813/97 establishing labelling rules for GM maize. Nonetheless, emphasis is made on the legislation that sets the policy followed at present: the EP and Council Regulation 1830/2003 relating to the traceability and labelling of GMOs and GMF. Other legislation and two reports examining the implementation of regulations are also assessed.

With respect to the NAFTA region, the analysis is centred on national policies. This is the case of the Mexican Law on Biodiversity and GMOs, which details that GM maize seeds need to be labelled prior to entering the country. Furthermore, focus is given on a Trilateral Agreement on the Documentation Requirements for Living Modified Organisms for Food or Feed signed among the USA, Canada, and Mexico. The reason for this is that this document establishes the context in which GMF labels take place currently.

With this in mind, the purpose of my study is to examine the manner and the extent to which GMF labelling policies have converged in two different regional settings. This examination is carried on by assessing legal measures that govern the labelling issue and that have been developed by regional and national governmental institutions. Such an assessment thus provides an insight about how, and under which circumstances, nation-states have agreed on the approach to follow.

Moreover, this study aims to examine the potential appearance of ‘trading up’ as a pattern in an area that has been regulated at different levels in two different regions. These different levels refer to convergence being achieved through international agreements and through regulatory competition. On one side, the EU has adopted the strictest regulatory approach so far by requesting Europe-wide mandatory labels to all GMF. Such a stance is the result of the EU aiming to provide consumers with information about these products; that is, with the right to choose. On the other hand

is North America, where national policies focusing on the equivalence between GMF and conventional food, as long the former preserve the same characteristics as the latter, is the approach followed. However, North America shows exceptions with regard to GM maize seeds.

The politics of GM differ between the EU and the NAFTA region due to a series of factors that can induce policy change: policy problems, policy legacies, policy preferences, political-institutional capacity, and discourse. All of them have appeared or been used according to the regional setting in question.

The approaches to label in each region can potentially differ due to the institutional frameworks and political preferences. On one side, the EU develops a complex institutional setting that allows for a regional institution to initiate and to attempt influencing outcomes derived at satisfying the citizenry. Furthermore, by establishing mandatory labels, the European Commission has closed ranks with national governments, who have tended to take a strict stance towards GMF. On the other side, North America entails an intergovernmental institutional setting that does not allow for a regional/supranational institution to enjoy roles as those implied in the EU. Subsequently, this means that all powers rely on national governments that tend to take on labelling according to their own domestic features. It is in this regard that all three nation-states have reached agreements on the equivalence between GMF and non-GMF. However, maize represents a different aspect that has led Mexico to take a slightly different approach to those of its northern counterparts.

These policy preferences relate to policy problems that have been far more reported in Europe than in North America, like the BSE crisis. This is an issue that has made European consumers to be more wary towards GMF than Americans, Canadians, or Mexicans. This comes despite the discovery of GM maize mixed with conventional maize in cultivation areas in North America. Furthermore, sensibility towards maize

in Mexican culture led the government to take a stance towards labelling sacks of maize seeds. Hence, these examples show that food crises and agricultural views have driven the cultural perspectives followed in each of the regions. The EU has approached wary consumers suspicious of GM products, while North America has focused on the agricultural advantages of GM crops. Like this, some other examples provide details of how these factors have made regional policies different between the two regions.

The role of national governments presumably becomes the leading force in driving the manner and the extent to which policies have been converged. They have agreed to approximate their domestic policies for the sake of the market. They have committed to this through international agreements. This is the case of North America, where approximation of national policies has also taken place. Hence, a combination of regional and national policies appears to have driven the context in which policies succeed. The EU presents a case where nation-states share some of their policy-making roles to the regional institutions, mainly the European Commission, as its role of policy initiator implies, and the European Parliament (EP), with a role through the co-decision procedure. However, it has been up to nation-states to decide the approach to follow.

The structure of the present study is as follows. The second chapter offers an overview of GMF, their benefits and risks, as well as the context in which GM maize is situated in each region. Besides, it presents the importance of labels from economic and political perspectives. Furthermore, this chapter provides for an introduction on the integration process of each region. This entails the number and diversity of membership, degree of institutionalisation, power of regional institutions, and decision-making procedures. A further point refers to the definition of national preferences in each region, which in turn define the position of the entire region.

Lastly, the international context is also commented, explaining the reasons behind the clashes within the WTO realm and their implications.

Chapter three explains the methodology used. The reasons behind qualitative methods and its use in the purpose of this study, the means to gather empirical and secondary information, and their respective shortcomings are also detailed. Afterwards, Chapter four details theoretical insights on policy convergence, its relationship with policy diffusion and policy transfer, the types and indicators of policy convergence. In addition, this chapter features the assessment of 'trading up', its causes, and the respective linkage this concept has with causal mechanisms of policy convergence. This leads to appreciate the relevance of the concept of international cooperation and regulatory competition. Their subsequent explanation is presented, which in turn allows speaking of policy change potentially taking place in domestic and regional levels. Lastly, the overall literature is linked with broader International Relations theory that emphasises on the relevance of institutions and the manner through which international agreements are formed.

Chapter five focuses on the assessment of European law on GMF labelling. Different regulations are examined, with Regulation 1830/2003 concerning the traceability and labelling of GMF being the focus of the assessment. Furthermore, the analysis of reports assessing the implementation of this regulation is done with the purpose of portraying the implications of the convergence reached. The interaction of the actors involved in the process of formulating this regulation is also stressed.

Chapter six portrays the rules on GMF labelling in the NAFTA region. It begins with the assessment of each of the North American nation-states' development of policies on GMF. Emphasis is made on the case of Mexico because it shows different features with respect to its counterparts. Furthermore, there is an assessment of the Trilateral Agreement on the documentation requirements for living modified organisms for food and feed. Actors' views on this agreement are also addressed, which in turn assist in understanding the approach followed at the national level.

Chapter seven provides for a comparison of the convergence reached in each of the two regions in terms of the literature on 'trading up' as well as on policy convergence. In addition, an evaluation of the extent to which regional institutions and national governments have influenced or driven the policy formulated is also included.

Lastly, chapter eight relates the information and the findings with policy convergence and trading up. Also, the contribution that this study provides for is included, as well as the examination about reaching its objectives.

CHAPTER 2: RAISON D'ÊTRE OF GMF LABELLING AND BACKGROUND OF THE EU AND THE NAFTA REGION

It is argued that genetic modification is a term that covers many processes, some of which have been used for thousands of years. However, the term has come to be used for 'genetic engineering', where newly developed processes of molecular biotechnology are employed to modify single cells of a given organism (Tester, 2001: 9). This type of research has been divided into two streams, labelled "red" for biomedicine and "green" for agriculture and environment.[1] Under the green heading, there are four main classes of genetic traits with commercial value: tolerance to commercial herbicides; pest resistance to viruses, bacteria, insects, nematodes, or fungi; improvements to product quality such as the type of oils, starches, sugars or cellulose in the plant; and improvements to agronomic characteristics such as yield or salt, drought and cold resistance (Jasanoff, 2005: 34; Van Beuzekom and Arundel, 2009:78). These manipulations often involve cross-species transfers of genetic material, resulting in GMOs that could not have been produced naturally through traditional means of mating or natural recombination (Strauss, 2006: 95).

The production of GMOs, for use in the food industry, has been a source of a fierce debate between GM-supportive and GM-sceptical groups. This has caused a 'new preoccupation' of nation-states because there is a new arena in which citizens demand and contest the exercise of state power. This preoccupation has been transferred to the regional level, at which governments are required to adopt a stance that partially reflects the respective degree of consumer concern for GMF (Gruère, 2006: 159). Their decisions are based on assessments of both benefits and risks of producing, commercialising, and labelling GMF.

[1] Red biotechnology is not assessed in the present study; therefore, it is not commented upon.

Among the benefits are higher production yields; the possibility of increasing food availability, which could alleviate hunger in underdeveloped nation-states; and the reduction of pesticide requirements resulting in less environmental damage. Risks include possible negative long-term effects on human health such as toxic effects, allergic reactions, changes in nutritional composition, and the effects of genes resistant to antibiotics. There are risks of possible negative long-term effects on the environment, such as an increase of herbicide resistant or insect resistant transgenic plants used to produce GMF, and risks of out-crossing with wild and weedy relatives and other unintended environmental effects, perhaps a loss of biodiversity; and the risk of companies practising agricultural biotechnology amassing too much power (Gracia and Albisu, 2003: 665 – 6).

Besides benefits and risks, there are also ethical questions raised by GMF. They are identified as the consumers' right to be informed; and people's feelings against the 'unnatural' manipulation of nature, both of which relate to the social and cultural characteristics of different societies. Hence, their labelling becomes a reliable option to make consumers aware of what they are purchasing and consuming. Nevertheless, there are deeper insights about the reasons to label, which need to be addressed.

2.1. Importance of labels

The value of labels depends on the importance consumers attach to certain attributes, identified as search, experience, and credence attribute. Search attributes are those for which consumers examine product characteristics, such as price, size, and colour, before purchasing. Experience attributes are those that consumers evaluate after purchasing the product. Credence attributes refer to what consumers cannot evaluate even in use.

With respect to food, labelling is generally proposed with the aim of achieving a social goal, like improving human health and safety, mitigating environmental

hazards, averting international trade disputes, or supporting domestic agricultural and food manufacturing industries. They develop from different views, which represent different perspectives from consumers, companies, third-party entities, and governments. All of them play a role in determining which of a food's many attributes are described on food labels.

> Consumers use their purchasing power (their consumption choices) and political activities to help determine which attributes are described on labels. Private firms seek out attributes that are attractive to consumers and voluntarily provide information about these attributes when the benefits of doing so outweigh the costs. Third-party entities, including private organizations, governments, and international organizations contribute to enhancing the intelligibility and credibility of information about some food attributes through standard setting, certification, and enforcement. These services can increase the amount of information supplied by labels. Governments may require that information on some attributes be included on food labels (Golan et al, 2001: 117 – 8).

Among these influential actors, governments carry a most relevant duty due to their role in the policy-making process, which would aim to serve three main purposes: to ensure fair competition among producers, to increase consumers' access to information, and to reduce risks to individual consumer safety and health (Hadden, 1986). Another purpose, Golan et al (2001: 118) explain, refers to governments influencing individual consumption choices in order to align them with social objectives.

Governments, jointly with consumer groups, producer associations, and international organisations help strengthening labelling claims through standard setting, testing, certification, and enforcement (Golan et al, 2001: 130). Standards establish the level of quality that a good must possess. Using them enhances market transactions as they

are recognised by numerous producers and consumers. Testing services can also assist by strengthening producers' claims of product quality by providing a more objective measure of product attributes. Certification provides assurances to consumers that the information supplied by firms is correct. Lastly, governmental enforcement of quality standards provides further assurances that quality claims are valid.

Also, firms use labels as one of many advertising options. A label is intended to help consumers differentiate the labelled product from otherwise similar products. Thus, the information that labels provide can be important to consumers as they can respond by changing their purchase decisions. Another aspect of the differentiation that firms establish through labels is that they can inadvertently alert consumers to negative aspects of products. Known as the 'unfolding theory' (Ippolito and Mathios, 1990), such alert develops when consumers become suspicious of products that fail to make claims that other firms' products explicitly state. Thus, the unfolding theory implies that the presence of advertising, as it is the case of labels, is a signal of quality and that competitive products without such advertising are alerting consumers to its absence.

As with any policy, the costs and benefits of government intervention in labelling must be weighed. For this, governments need to take into account economic efficiency, producer and consumer concerns, political expediency, public opinion, and current events. Golan et al (2001: 119) consider that the appropriate level of government intervention in labelling decisions depends on the type of information involved and the level and distribution of the costs and benefits of providing information. In this regard, selecting mandatory labelling, voluntary labelling, or no labelling at all can relate to the extent of the government's involvement, the most influential positions, and the economic and political gains of the policy adopted.

National governments can demand mandatory labelling on the grounds of consumer right to information and calls for fair competition. Generally, mandatory labelling arises in two economic situations: 'when the market does not supply enough information to allow consumers to make consumption choices mirroring their individual preferences (asymmetric or missing information), and when individual consumption decisions affect social welfare differently than they affect the individual consumer's welfare (externality problems)' (Golan et al, 2001: 136). Situations of asymmetric information appear when the producer or seller knows relevant information about a product that the buyer does not know. This case can be a problem in markets for foods with negative credence attributes. Markets do not work efficiently since goods that would be profitable with full disclosure may go unproduced, while those of lesser value to consumers are produced instead. The objective of government intervention in this type of cases is not about altering consumption behaviour; instead, it is to increase informed consumption (Magat and Viscusi, 1992). With respect to aims about correcting externality problems, governments may establish mandatory labels in cases when food consumption choices affect the welfare of others. That is, individual consumption decisions can have social welfare consequences, such as effects on the environment, health, labour conditions, and farm and industry structure. Therefore, governments may decide to intervene to try to maximise social benefits by imposing labels that provide information influencing consumer decisions. Magat and Viscusi (1992) consider this government policy as 'information provision programs to alter people's economic behaviour'.

Whether the government's mandate to label is successful would depend on the perspective in question. From the economic standpoint, the costs of labelling are likely to be passed on to consumers. This means higher prices that can affect the decisions that consumers make if they do not value the added information. From the purpose of the label itself, posing too much information can reduce the chances that consumers will read it or evaluate its importance. Under these circumstances,

labelling policies that impose costs on certain critical groups, even if they confer benefits on a wide variety of groups, may be undesirable from a political perspective. With this in mind, mandatory labels can result in confusion and can increase transaction costs unless labels are 'supported by clear, achievable, quality standards, testing services to measure the validity of labelling claims, certification services substantiating the validity of the quality claim and mechanism for enforcing labelling rules, including mechanisms to punish producers who make fraudulent claims' (Golan et al, 2001: 146)

2.1.1 Observations on GMF labels

There are opposing views on whether labelling is a successful approach for GMF. On one side, labels cannot prove useful if they aim to inform on complex information that can be difficult to consumers to digest. Furthermore, they can impose extra costs on producers (whether they label their food as GM or non-GM). On the other side, views on the need to label GMF have also been regarded as adequate. For Hadfield and Thomson (1998: 551), labelling means an attempt to respect both the real nature of consumer concerns about GMF and the environment of uncertainty in which any regulatory policy for biotechnology operates. Nevertheless, they realise labels can be of limited value to consumers. Therefore, they suggest a comprehensive approach to information policy for consumers in order to use labelling requirements to harness the incentives of producers and private entities to convey to consumers what they want and need to know. Based on consumers' protection policy, such an approach has concerns regarding fraud and misrepresentation. To being with, consumers can be underinformed or misinformed precisely because the high cost of becoming informed is relative to the perceived value of information. The complexity with which GMF is produced, nevertheless, goes beyond the mere information of where the food they are consuming is coming from. For example, there are risks that, by introducing new genetic material, food sources can acquire new allergenicity that consumers may not

be aware of (Hadfield and Thomson, 1998: 555). A further aspect to bear in mind is the possible toxicity that GMF may entail. That is, GMF can contain genes that have not previously existed in conventional food. This can come as the result of transferring different material to newly developed food. Therefore, it seems approachable to assess their potential toxicity and to inform consumers about it. Besides allergenicity and toxicity, GMF could modify the nutritional content of GMF (Kessler et al, 1992). Then, under these circumstances, it looks like GMF producers have not achieved complete control over the expression of novel foods. Due to all this possibility, scientific knowledge has important ramifications for consumer protection policy.

> It is simply a feature of the world in which consumers live that there is some doubt about the long-term or hidden safety of foods. Consumers cope with this uncertainty by assuming that government regulation and producer self-interest (mediated through reputation and legal liability) combine to ensure that food products are basically safe – or at least, that immediate risks are absent (Hadfield and Thomson, 1998: 561).

Another approach to labels is known as 'paternalistic' (Viscusi, 1994). By having the goal of inducing consumer behaviour, this concept regards consumers' beliefs in selecting products to be in line with scientific risk assessments. If a gap were to exist between consumers' perceptions and scientific assessments, the latter would be considered as the point of reference. However, consumers' risk assessments may exceed those of the scientific community. As stated previously, some consumers have concerns about nutritional, health, environmental, and ethical issues, besides scientific concerns. The observable divergence between what consumers expect and what they get can be regarded as the driving force to setting policies with respect to information through labels. Subsequently, some degree of monitoring GMF could be suggested in order to obtain a comprehensive understanding of the risks they pose beyond the scientific spectrum. With this, an effective consumer protection policy can

help consumers to align their knowledge and expectations for a particular type of food to their experiences.

The effective consumer protection can, thus, follow one of two approaches to labelling. The paternalistic one is the first. That is, if best-practices health and safety regulation clears a specific GMF, then there is no scientific basis for additional label of food. This assumption implies that unknown or unidentified risks are regarded by producers and policy-makers as not a risk at all. Nevertheless, the idiosyncrasy of consumers' demands, allergic responses, nutrition, and diet are all excluded in this approach. The second approach would regard providing information about what is known about the GMF and any potential deviation between the GMF and conventional counterparts. However, this is not an easy, maybe neither feasible, approach as consumers may not be able to process such information or to value it. In fact, an excess of poorly understood information can have a negative impact on valuable information already existing on labels.

To be able to overcome the deficits of both approaches, Hadfield and Thomson (1998: 570 – 1) propose minimal labelling alerting consumers on the divergence in production process and any other difference posed. Then, this 'simple alert labels' can allow to distinguish GMF from conventional products. Whereas consumers who want to avoid GMF have a way of doing so, other consumers are allowed to demand more information that the market would be prompted to satisfy. In fact, providing required information can assist to overcome the overestimated risks of biotechnology, perhaps proving that aversion to GMF is rooted in affect rather than information. The key point, they claim, is that the function of the regulatory label should not be to provide information, but rather to structure the market mechanism that would provide information. That is, if producers become aware that consumers avoid GMF due to lack of information, they would devote resources to providing it. However, for Golan et al (2001: 177), the effectiveness of GMF labelling for addressing problems of missing or asymmetric information and externality problems is questionable: 'A simple label proclaiming "this product contains biotech ingredients" does not convey any information about potential costs and benefits or responsibilities. Though such

labelling may be informative to some consumers, it may also lead to greater confusion on the part of others and reduce, rather than enhance, economic efficiency'.

A further comment that needs to be stressed is that, despite mandatory GMF labelling being suggested as an addition to producers' costs, labelling policies may prove unsuccessful if it is to transfer the costs of segregation between GMF and non-GMF. Even when GMF producers may need to label and certify their products, non-GMF producers would also need to do so. Under these assumption comes the assessment on whether benefits outweigh costs.

> Labelling advocates cite social benefits ranging from informed consumers to reduced risk of ecological disaster. Labelling opponents claim that the cost of labelling (and segregation) would be so high that food manufacturers would be forced to stop using biotech crops, thereby reducing the demand for biotech crops to the point that biotechnology would be abandoned (Golan et al, 2001: 178).

Whether to label thus influences the attitudes of the actors involved in the regulation process. Producers do not have the incentive to label products. This can be the result of positive producer attributes, like cost reducing and yield enhancing, being more important than positive attributes for consumers, like better flavour or nutritional components. On the opposite hand, if companies were to pursue a non-GMF strategy, they would need to eliminate GM ingredients from the product, label the product as non-GM, and then market the product to consumers who place a value on knowing that their food does not contain GM ingredients. Then, it seems likely that firms would prefer to avoid any potential label on the product, either as GM or non-GM. The costs that could appear could derive in companies losing a segment of the food market (that of price-driven consumers). However, companies could benefit from other aspects. For example, labels can enhance the firm's reputation for safety or

environmental leadership, thereby strengthening the firm's marketing position. In addition, pursuing a non-GM strategy can be the best manner to access certain markets.

It is possible to argue that governments have a relevant authority in the context of GMF labelling. They do so by influencing companies on whether to reduce the costs of GMF labelling or increasing the benefits of labelling non-GMF. Standards, testing, certification, and enforcement can all facilitate the development of these markets. One example refers to biotech standards on tolerance levels, also known as threshold, of GM ingredients so the product in question can be regarded as non-GMF. On the opposite direction is the standard of considering GMF equal to non-GMF in terms of risk assessment and product equivalence. Despite being contradictory, both standards are backed by the respective testing, certification, and enforcement methods. This thus means that, in the absence of a consensus on risk, tolerance levels for GM content can be driven by other factors, like consumer demand, the feasibility of testing technologies to test for GM content, and the lobbying skills that companies have when approaching policy-makers.

Irrespective of the approach followed, governments can ensure that information provided is accurate by monitoring producers. This is, if governments take the paternalistic approach, they guarantee that GMF are safe on scientific grounds. On the other hand, they can also propel reliable information in markets through a combination of market incentives and legal liability. The point of this is for the governments to regulate it so as to alert consumers about the value of information and therefore create a demand for information, instead of attempting to satisfy such demand directly.

2.2. The GM maize context

In recent years, techniques of genetic modification have made significant advancements. By 2009, there were 35 varieties of GM maize registered with the OECD (OECD, 2009). From those, there were 29 varieties registered in any of the three North American countries, from which only 19 have been registered in the EU.

GM maize has been cultivated since 1995 for production of food, food additives, feed, and feed additives. There are two varieties of commercially released transgenic maize produced by means of genetic engineering: BT maize, which produces an insecticide for certain types of insects and herbicide-resistant maize; in addition there are hybrid combinations of both (OECD, 2003). However, research is on-going, and its aim is to improve specific characteristics such as the adaptability to harsh environmental factors like drought and high salt and high heavy metal-containing soil, and to altered composition like the enhancement of specific amino acids (Chiueh et al, 2002: 25).

GM maize has the potential to modify the environment, as could other crops such as GM soybeans, and might affect wildlife and biodiversity. One aspect of this is the danger that this crop can cause when spreading either by cross-pollination with non-GM maize or by establishing itself outside the area where it was planted (Cook, 2005: 135). A famous case in this regard was the reported evidence of GM maize varieties appearing mixed with native Mexican maize, although this report was dismissed by GM-supporters stating that there was no interference with the ecosystem of the Mexican region in question. Another concern is the fact that GM maize can

potentially damage the biodiversity of ecosystems as well as the biodiversity of maize itself.[2]

Different biotechnology transnational companies have been producing diverse types of GM maize. In the EU, Monsanto is the main company receiving authorisation to introduce MON810-6 insect-protected maize, MON863 insect-protected maize, NK603 Roundup Ready maize, GA21 Round up Ready maize, as well as the hybrid combinations NK603 x MON810 maize, MON863 x MON810 maize, GA21 x MON810 maize, MON863 x NK603 maize, MON89034 maize, and MON88017 maize. Syngenta comes second with Bt11 maize, Bt176 maize, and MIR604. Pioneer is another company, with authorisations for DAS1507 maize, DAS59122 x NK603 maize; and jointly with Dow Agroscience Europe, DAS59122 maize and DAS1507 x NK603. Lastly comes Bayer CropScience, which has T25 maize authorised (European Commission, 2010). Of all of them, only MON810 maize is currently being in commercial use and with cultivation on a very limited scale (European Commission, 2009).

In North America, there are more GM maize varieties besides the ones authorised for consumption in Europe[3] (OECD, 2009). Here, Monsanto also produces REN00038-3 maize, MON801 maize, MON802 maize, MON805 maize, MON809 maize, MON830 maize, MON831 maize, and MON832 maize. Mycogen Seeds produces TC6275 maize. Aventis produces MS6 maize. AgrEvo produces CBH-351 maize for animal feed purposes and T14 maize. Pioneer produces 676 maize, 678 maize, and 680 maize. Dekalb Genetics produces DBT418 maize and DLL25 maize. Plant

[2] For a clear explanation of the diversity of maize as well as its definitions, see Bellon, M.R. and Berthaud, J. (2006). 'Traditional Mexican agricultural systems and the potential impacts of transgenic varieties on maize diversity'. *Agriculture and Human Values* 23: 1. March 2006. 3 – 14.

[3] In the NAFTA region, Bt11 maize is produced by Northrup King, T25 maize by AgrEvo, and Bt176 maize by Ciba Geigy.

Genetic Systems produces MS3 maize for animal feed purposes. Most recently, Renessen[4] received authorisation for LY038.

From all these varieties, the US government has authorised all GM maize varieties, while Canada has done so with respect to 19 varieties.[5] Mexico has only authorised 4 varieties.[6] The authorisations happening in North America result from the performance that the USA has as the world's main producer of GM maize. In 2008, its production of national maize crop was of 35.3 million hectares, of which 85 percent was biotech.[7] During the same year, global production of GM maize was of 37.3 million hectares. In total, American participation at worldwide level was of 78 percent (James, 2008: 6 – 8). Canada is another nation-state in which GM production has reached a share of 50 percent of its total maize national production (Chiueh et al, 2002: 25), and this amounted to about 7.6 million hectares in 2008. Mexico is a different case in that, despite assigning 0.1 million hectares to GM crops – cotton and soybean – it has actually forbidden the cultivation of GM maize in its territory. This fact becomes more relevant in a country where maize production accounts for the largest share of agricultural activity (Levy and Van Wijnbergen, 1992: 15 – 17), and from which around 75 percent of the population get their basic nutritional needs (Guerrero Andrade, 2005: 20).

In the EU, there are a smaller number of hectares allocated for cultivating GM maize, although this is increasing. While in 2005 Spain, France, and Germany accounted for 58,000 hectares, 100 hectares, and 100 hectares respectively (Pew Initiative on Food and Biotechnology, 2005: 54), the following year saw a significant increase of hectares being used for such purpose. Spain has continued to be the leading nation-

[4] Renessen is a joint venture of Cargill and Monsanto.
[5] MON88017 maize, MON802 maize, MON809 maize, DBT418 maize, DLL25 maize, MS3 maize, DAS06275-8 maize, LY038 maize, T14 maize, MON810 maize, MON863 maize, NK603 maize, GA21 maize, NK603 x MON810 maize, Bt11 maize, Bt176 maize, DAS1507 maize, T25 maize, and DAS59122 maize.
[6] DAS1507 maize, NK603 maize, MON810 maize, and GA21 maize.
[7] It is estimated that 8.7 million hectares of biotech maize was devoted to ethanol production (James, 2008: 16).

state with 60,000 hectares. France and Germany have increased over five-fold their production, and jointly with Portugal, Poland, the Czech Republic and Slovakia represented a production of approximately 8,500 hectares (James, 2006: 3).[8] Growth in these seven nation-states has increased to the point of reaching 107,719 hectares in 2008, which is equivalent to a 21 percent year-on-year increase equivalent to 19,046 hectares (James, 2008: 11).

An opposite stance is taken by Austria, Italy, Luxembourg, Hungary, and Greece, all of whom have banned the production and the introduction of GM maize in their countries. Although this disagreement within the EU has led to conflicts between governments, it has not deterred nation-states eager to produce GM maize from doing so.

Differences in the number of approved GM maize varieties, cultivated hectares, number of nation-states per region, and number of producers relate to differences inner to each of the geographical regions. For this reason, it is necessary to delimit their historical and structural features, which can in turn provide insights about the manner and the extent labelling policies are addressed.

2.3. Regional features of Europe and North America

The NAFTA region and the EU share basic elements in terms of regional integration. I consider the NAFTA region as being a low level of integration because it focuses only on the removal of trade barriers among its participant nation-states. The NAFTA region can also be considered as 'negative' integration according to Scharpf's classification (1999: 45). On the other hand, the EU represents a higher level of integration because it relates to a common market where the unification of a number

[8] Romania is also keen on cultivating GM crops, although its emphasis is made on soybean, and this has reached a million hectares (James, 2006: 4).

of sensitive policies has taken place. This means that the EU embraces 'positive' integration (Sharpf, 1999: 45).

2.3.1. The European Union

The European Union is an economic and political union of 27 member nation-states,[9] which was established by the Maastricht Treaty on 1993 upon the foundations of the EEC. Such creation formed a three pillar structure: the European Communities, a Common Foreign and Security Policy (CFSP); and Cooperation in the Fields of Justice and Home Affairs (JHA).

It is with the First Pillar that the EU has developed a single market through a standardised system of laws that apply to all member nation-states. The other two pillars delimited cooperation in areas sensitive to the performance of nation-states governments.[10] Thus, it is the First Pillar that states the development of a single market through a standardised system of laws which apply to all member nation-states, ensuring the free movement of people, goods, services, and capital.

Considered as an international organisation, the EU operates through a hybrid system of supranationalism and intergovernmentalism. In certain areas, decisions are made through negotiation between member nation-states, while in others; independent supranational institutions are responsible without a requirement for unanimity

[9] Founding members: Belgium, France, West Germany, Italy, Luxembourg, and the Netherlands. The United Kingdom, Denmark and Ireland (1973); Greece (1981); Spain and Portugal (1986); Austria, Finland, and Sweden (1995); Hungary, Estonia, Latvia, Lithuania, Poland, the Czech Republic, Slovakia, Slovenia, Malta, and Cyprus (2004); Bulgaria and Romania (2007).

[10] The CFSP has as a main objective to safeguard the common values, fundamental interests and independence of the EU, and to develop and consolidate democracy and the rule of law, and respect for human rights and fundamental freedoms. JHA entails the following areas as matters of common interest: asylum policy; rules governing, and controls on, the crossing by persons of the external borders of the member nation-states; immigration policy and residence rights of third-country nationals; combating drug addiction, combating international fraud; judicial cooperation in civil matters; judicial cooperation in criminal matters; customs cooperation; and police cooperation to combat terrorism, drug trafficking and other serious crime through an EU-wide police intelligence office (Nugent, 2003: 67 – 68).

between member nation-states. Relevant institutions of the EU are the European Commission, the Council of Ministers, the European Council, and the European Parliament. There are other institutions that express their opinions with respect to the decisions made. Among them, the Economic and Social Committee and the Committee of the Regions are found.

2.3.1.1 Institutional structure of the EU

The European Commission is centrally involved in EU decision-making at all levels and on all fronts. This is because the Commission enjoys policy-initiating, decision-making and supervisory powers. In this regard, the work of the Commission is divided into separate policy areas in a similar way as national governmental responsibilities are segmented between ministries. The Commission's best known and most common organisational units are Directorates General (DGs), like the DG for Environment, and the DG for Health and Consumer Protection. These DGs vary in size, and they are divided into four to six directorates, which in turn are each divided into three or four units.

With these duties at European level, the members of the Commission (Commissioners) are not supposed to be national representatives, but should be completely independent in the performance of their duties due to the general interest that they should search for in the benefit of the Community.

The Council of Ministers is the principal meeting place of the national governments. Its main responsibility is to take policy and legislative decisions. The extent to which the Council must work with the Commission and the EP with regard to these decisions varies between policy areas and according to what type of decisions are being made. This is, the Council has the most room for independent manoeuvre when

it is acting under pillars two and three of the EU. The Council is less independent under pillar one, mainly when legislation is concerned. The reasons for this are that, firstly, the Council can only act on the basis of proposals made by the Commission. Secondly, it shares legislative decisions with the EP according to the type of legislative procedure employed.[11] Irrespective of this share of power, the political weight of the Council is such that the Commission is bound to pay close attention to the ministers' wishes.

A hierarchy exists in the Council. It consists of ministers, the Committee of Permanent Representatives (COREPER),[12] and other specialised high level committees, middle-ranked committees, and working groups. Decisions taken by this institution are reached through three different ways: unanimity, qualified majority vote, and simple majority vote.

Legally, there is one Council of Ministers. However, there are more in the sense that the Council meets in different formations to deal with different policy areas.

The European Council refers to the meetings of Heads of Government. The main reason for its creation was the perception that the Community was failing to respond adequately and quickly enough to new and increasingly difficult challenges (Nugent, 2003: 179). Through the Maastricht Treaty, the European Council was assigned responsibility for identifying the general direction of the EU's development; it was given certain duties and important powers both in the CFSP pillar, and with respect to the European Monetary Union (EMU).

[11] Legislative procedures are described shortly.
[12] There are two COREPERs. COREPER II is made up of the Permanent Representatives plus staff. It is the more political of the two COREPERs and works mainly for the Foreign Ministers and economic matters. COREPER I consists of the Deputy Permanent Representatives and support staff. It mainly deals with policy areas like environment, social affairs, transport and internal market.

The European Parliament (EP) is an institution that has been increasing its influence over time. This influence is exercised in three ways: through the legislative process, through the budgetary process, and through control and supervision of the executive. With respect to influencing legislation, the EP sometimes participates in policy discussions with the Commission at the pre-proposal legislative stage. Also, the EP can formally adopt its own ideas for suggested legislation. Thirdly, the EP's views must be sought in connection with important and sensitive legislation.

On the opposite side, the EP's performance outlines certain weaknesses. Firstly, the EP does not have full legislative powers. That is, it does not have the final say over what is and what is not to become law. Secondly, it is not unusual for the Council to take decisions or to adopt common positions having the EP's opinion pending. Thirdly, the EP is not consulted on all Council legislation. Fourthly, the EP does not need to be consulted on Commission legislation.

Much of the EP's work is carried out by committees, which are classified as standing committees and ad hoc committees. The latter are established to investigate specific problems and topics. The former perform various duties, such as exploring ideas with the Commission, fostering own initiative reports, and discussing developments with the President-in-Office of the Council.

The most important task of Standing Committees is to examine Commission proposals for legislation. This procedure starts with the proposal being referred to an appropriate committee. Afterwards, the Committee appoints a rapporteur for drawing up a report. The resulting draft[13] is produced for consideration of the committee according to an agreed timetable. The next step entails the rapporteur acting as the committee's main spokesman when the report is considered in the plenary. In this capacity, he or she may have to explain the committee's view on amendments put forward by non-committee members. Lastly, there are cases when the committee has to issue a second reading, which should be carried out in a similar way as the first

[13] Drafts are normally presented in four main parts: Amendments to the Commission Proposal; a Draft Legislative Resolution; an Explanatory Statement; and Annexes, including the opinions of other committees.

reading. One example of such committees is the Standing committee for Environment, Public Health and Consumer Policy.

Other institutions expressing their opinions are the Economic and Social Committee (ESC) and the Committee of the Regions (CoR).

The Economic and Social Committee (ESC) is composed of representatives of socio-economic interests. Its functions rely on issuing information reports, liaising with a host of other international bodies, and seeking to promote understanding between sectional interests. But its main role is to provide a forum in which sectional interests express their views on EU-related matters and in so doing could supplement the popular will as expressed via parliaments. The manner in which the ESC issues its opinions depends on a three set of circumstances: mandatory referral, optional consultation, and own initiatives. Nevertheless, the influence the ESC can exert is limited. That is, the ESC mainly issues recommendations that cover relatively minor points. Therefore, neither the Council nor the Commission are obliged to act upon its views.

The work that the ESC undertakes is carried out by different sections that are made up of related interest groups. There are six sections: Agriculture, Rural Development and the Environment; Economic and Monetary Union and Economic and Social Cohesion; Employment, Social Affairs and Citizenship; External Relations; The Single Market, Production and Consumption; and Transport, Energy, Infrastructure and the Information Society.

The Committee of the Regions (CoR) was established to develop a regional dimension of Community affairs. That is, the EU is known for covering both wealthy and poor areas. In this sense, regional and local groupings aim to attract the attention of funds for their own development. They do so by providing advice under the Council or the Commission's request.

The size and national composition of the membership of the CoR is the same as that of the ESC. Furthermore, most of the work is channelled through six specialised committees, called commissions. These are: Territorial Cohesion Policy; Economic and Social Policy; Sustainable Development; Culture and Education; Constitutional Affairs and European Governance; and External Relations.

There are other institutions and political actors that participate in the EU. Among them are the Court of Justice, the European Investment Bank, the Court of Auditors, and different interests (private and public companies, national interest groups, and Eurogroups[14]). All of them play different roles according to particular policy areas and diverse circumstances other than biotechnology and labelling of GMF.[15]

2.3.1.2 EU's policy process

There is no standard policy-making process in the EU. Multiple actors interact with one another through different channels. The actors are classified in three different sets: those associated with EU institutions, with member nation-states' governments, and with interests from national and European levels. The channels vary in four manners: in the complexity of the decision; in the relative importance of EU, member nation-state and subnational processes; in their levels of seniority; and in their degree of formality and structure.[16]

Generally, Commission legislation is subject to less review and discussion than Council or EP and Council legislation. The reason for this is that the Commission

[14] Eurogroups draw their membership from several nation-states and operate at the EU level.
[15] See George and Bache (2001).
[16] For further reading see Nugent, N. (2003), *The Government and Politics of the European Union*, Palgrave Macmillan, 5th Edition.

legislation is usually of an administrative kind. On the other side, some Council and all EP and Council legislation are subject to a full legislative procedure. This latter case becomes the subject of representations and pressures from many interests, is also assessed by the EP and often also by the ESC and the CoR.

Four full legislative procedures have been properly defined with the Maastricht Treaty: consultation, cooperation, co-decision, and assent.

The consultation procedure refers to a single reading procedure in which the Council is the sole final decision-maker, subject to an EP's opinion and, in some cases, to opinions of the ESC and the CoR. The cooperation procedure entails a second reading process, in which the EP can exert pressure by amending or rejecting the Council's common position agreed in the first reading. However, despite the EP's views being taken seriously, they do not amount to vetoes. The assent procedure implies that the proposed measures have to be approved by both the Council and the EP, where the EP must consider proposals at a single reading and without provision for amendments. In this case, the EP has veto powers. Co-decision is the most complex of the legislative procedures. It grew out of an extended cooperation procedure in an attempt to increase the efficiency and speed of decision-making processes, and to respond to pressures for more powers to be given to the EP. The former was achieved by enabling the use of QMV in the Council, while the latter was achieved by increasing the EP's influence over the Council at the second reading. The co-decision procedure gave the EP veto powers.

The consultation process is mainly used for agriculture and JHA issues; the cooperation procedure is confined to four areas of the EMU; the assent procedure is used for special cases, like international agreements and EU enlargements; and co-decision is the procedure used for the majority of legislation with respect to the first pillar.

2.3.1.2.1 Co-decision procedure

Due to its relevance on GMF labelling and its common use, the stages of co-decision need to be explained. The first stage comes with a proposal that the Commission elaborates and publishes. This is examined by the relevant committee in the EP and by working groups and COREPER in the Council. Furthermore, the ESC and the CoR are consulted on the proposal. If the EP and the Council agree on its contents, the text can be adopted at the first reading. If they do not agree, the Council adopts a common position through QMV after receiving the EP's opinion. The second stage appears with the second reading on the proposal. In this case, the EP can approve, amend, reject or take no action on the common position provided by the Council. If the EP approves or takes no action, the Council can adopt the proposal as legislative act. If the EP rejects the common position by an absolute majority of its members the proposal collapses. Otherwise, if the EP amends the common position by an absolute majority of its members and the Council is unable to accept the text approved by the EP, a third legislative stage happens. This third stage takes place with the proposal being referred to a conciliation committee composed of an equal number of Council and EP's representatives. If the conciliation committee agrees on a joint text, the proposal is referred back to the Council and the EP for final adoption. In this final vote, the EP acts by a majority of votes and the Council through QMV.

After adoption, there are three situations that can happen to legislation. One variation is that legislation may require the adoption of additional legislation. This addition can be of three manners. First, initial EP and Council legislation may need to be supplemented by implementing legislation so as to fit it to particular circumstances and keep it updated. Second, besides implementing legislation, further policy legislation may be required so as to cover in a detailed manner any issue that may fall within the remit of the framework. Third, there is a 'new approach' (Nugent, 2003:

354) that consists of producing texts that lay down essential requirements, mainly in terms of health and safety and of consumer and environmental protection. Another situation is the transposition of legislation. This refers to directives, which do not become mandatory until they have been transposed into national law by the appropriate national authorities. This takes place by attaching administrative measures to existing primary or secondary legislation, introducing new secondary legislation, or adding new clauses to already planned primary legislation.

The last situation appears with the need to apply legislation. In this case, it is crucial to identify where responsibilities between the Commission (mainly DGs responsible for particular policies) and national authorities lie. On one hand, the Commission oversees the implementation of day-to-day policy. On the other hand, national and subnational authorities do most of the frontline work.

The overall policy process is influenced by different supranational and intergovernmental participant institutions, different legislative procedures, and different ways of supervising policy implementation infer in the relative efficiency of the overall policy process.

The EU lacks a fixed, central authoritative stage where priorities can be set out and choices between competing options can be made. It is true, the Commission drives policy initiation and therefore attempts to establish general priorities; however, it does not have decision-making powers to carry them through. In addition, the Council of Ministers present troublesome features, as sectoral Councils do not link up with one another in a satisfactory manner and are not properly integrated in long-term programmes. Besides, some policy areas are less integrated than desirable. Member nation-states regard this as an excessive transfer of powers to the EU (Nugent, 2003: 362). Because of this, diverse legislative procedures take place. Member nation-states have, through treaty provisions, assigned the manner in which different policy areas should be dealt with. GMF and its labelling are included within the remit of pillar one, implying that it is under the co-decision procedure that legislation has been

made. The assessment of its implementation falls, as expressed previously, within the Commission duties once this institution has received the information from the appropriately appointed national bodies.

2.3.2. The region of the North American Free Trade Agreement

Entering into force in 1994, the NAFTA has shown features never seen before. The participation of nation-states with different levels of development, economic performance, societies' involvement, and cultural views have made North America an interesting case for regional integration.

With regard to maize, the NAFTA found opposition from different groups in each nation-state. One case was the comparative advantage, in terms of methods of production and efficiency, of Canadian and American farmers with respect to Mexican counterparts. Another case was Mexican public opposition to this policy area. They claimed they were sidestepped by government officials drafting the FTA, who considered that it was in the best interest of the country to switch to the production of other crops, such as vegetables and fruits aimed at the American market (Carlsen, 2005), and the manufacturing of a wide range of items through the *maquiladora* scheme[17] (Nadal, 2006: 33).

The idea of entering the Mexican maize market without restrictions attracted great interest from Canada and the USA, whose governments were lobbied by biotechnology transnational companies fascinated by the size of the market and the possibility of entering it in order to strengthen their competitive position (Brown and Oliver, 1992: 1507). However, American drafters were uneasy at the prospect of

[17] The term *maquiladora* refers to a factory that imports materials and equipment on a duty-free and tariff-free basis for assembling or manufacturing and then re-exports the assembled product, usually to the original nation-state. *Maquiladoras* are generally set in Mexican towns and cities along the border with the USA.

including maize in the FTA because they acknowledged how sensitive the crop was for Mexico, and further realised the potential implications for the USA (i.e. illegal immigration coming from rural areas of Mexico). Despite these worries, maize ended up being included in the agreement. This then opened the possibility for American biotechnology companies to gain access to the Mexican market. Each NAFTA nation-state, though, has followed different pathways and timelines in the regulation of biotechnology.

2.3.2.1 NAFTA's institutional structure

To oversee that national developments are undertaken according to the regional agreement, the NAFTA established the creation of institutions formed by representatives of the three nation-states. This thus shows the international – and intergovernmental – character of the region. The central institution is the Free Trade Commission, which consists of cabinet-level representatives from each nation-state with the purpose of supervising the implementation and further elaboration of the agreement. They gather once a year, which mean they do not follow closely the performance of the agreement. For this purpose, the position of NAFTA coordinators was created. They are senior officials from each nation-state's trade departments focusing on day-to-day management of the NAFTA, which is a duty where they are assisted by over 30 Working Groups, Committees and other subsidiary bodies. In turn, such groups and committees have been established to facilitate trade and investment and to ensure that further work is carried on towards fulfilling the objectives of the FTA. Lastly, there is a NAFTA Secretariat, which is responsible for the administration of the dispute settlement provisions of the agreement. Specifically, this institution administers dispute resolution processes under Chapters 14 (Financial Services), 19 (Review and Dispute Settlement in Antidumping and Countervailing Duty Matters), and 20 (Institutional Arrangements and Dispute Settlement Procedures) of the NAFTA.

On the policy area that concerns this study, a trilateral Committee on Agricultural Trade has been created as established in Chapter 7 of the NAFTA. Although this institution's functions focus on monitoring and promoting cooperation on the implementation and administration of agricultural trade (Art. 706, NAFTA), it lacks responsibilities beyond those referred to administrative tasks. However, this Committee relies on an Advisory Committee on Private Commercial Disputes regarding Agricultural Goods (Art. 707, NAFTA), which issue recommendations to achieve effective resolution of disputes. This thus means that the national representatives, through the Committee, are allowed to resolve the differences between them. Nevertheless, if no mutually acceptable solution is found, the NAFTA provides for panel procedures, where the work of the NAFTA Secretariat is based on the dispute settlement provisions of the WTO, as provided on the objectives of the Chapter 20 provisions. Therefore, NAFTA rulings are following a pattern similar to that of an international organisation, which is an aspect that confirms the intergovernmental character of the agreement and the extent to which decisions on daily issues are made. Moreover, a 'Committee on Standard-related Measures' was created, designed to facilitate the process by which member nation-states could make compatible their technical measures (Art. 913, NAFTA). The Committee is in charge of enhancing cooperation on the development, application, and enforcement of standard-related measures according to what had been established in international and regional agreements. It can also create working groups that can consult non-governmental bodies as well as scientists if they deem it necessary. One of the functions of this Committee is that it addresses issues related to labelling, although they emphasise requirements to facilitate textile trade, rather than acting potential GM status of food products.

Besides trade-related institutions, the NAFTA framework has entailed the signing of two side agreements that in turn have provided for the establishment of regional institutions. Labour and environment were contending issues during negotiations and subsequent acceptance of the NAFTA. For their appropriate observance, a

Commission for Labour Cooperation and a Commission for Environmental Cooperation (CEC) were set up, which would also function as a point of contact for civil society. The latter Commission had a participative role with disputed aspects of GM maize and its potential labelling, as it is explained further in the chapter. However, its lack of influence meant that trade-related perspectives prevailed. In any case, with such an institutional framework, where trilateral Commissions and Committees are at the core, North American nation-states have pushed an agenda of market liberalisation through a free trade agreement. This is characterised by tariff barriers on manufactured products, foods and crops being reduced gradually. In this context, the inclusion of maize trade was carefully handled because of different national backgrounds.

2.3.2.2 NAFTA's policy process

The NAFTA aims to eliminate barriers to trade and facilitate the cross-border movement of goods and services between the territories of the member nation-states, to promote conditions of fair competition, to increase investment opportunities, to provide protection and enforcement of intellectual property rights, and to establish a framework for further trilateral, regional and multilateral cooperation to expand and enhance the benefits of the NAFTA (Art. 102 NAFTA).

These objectives delimit the context in which member nation-states set out their trade policies. These policies cover a wide range of areas. One of such policies is the notion of national treatment for goods from another member nation-state, which goes in accordance with Article III of the GATT. Another established policy has been the gradual elimination of tariffs in a series of goods subjected to customs duties. A further, relevant, aspect has been the development of the clause of Most Favoured

Nation (MFN).[18] A fourth policy is the elimination of non-tariff measures, understood as import and export restrictions, customs user fees,[19] and export taxes. Besides this, there are other relevant policies that have been set up within the NAFTA framework. Issues on rules of origin, customs procedures, agriculture and SPS measures, standard-related measures, investment, cross-border trade in services, telecommunications, financial services, competition, and intellectual property are observed in this agreement.

In addition to these trade policies being addressed, the NAFTA allowed for the creation of a dispute settlement process. This process takes different forms according to the context of the dispute. One of them is cooperation, in which member nation-states should attempt to arrive at mutually satisfactory resolutions of any matter (Art. 2003). A second form is dispute settlement under WTO, although this procedure takes place when member nation-states cannot reach agreement at a previous, bilateral or trilateral, stance. WTO dispute settlement is used in cases of Sanitary and Phytosanitary (SPS) measures and Standard-related measures. That is, when disputes refer to human, animal, or plant life and health protection, to the environment, safety, and directly related scientific matters (Art. 2005). A third form is consultation, which takes place when a member nation-state requests it regarding any measure that might affect the operation of the NAFTA (Art. 2006). If consultation is unsuccessful, any of the member nation-states involved may request a meeting of the Commission, who may call on advisers, conciliate, mediate, make recommendations, or request for an arbitrary panel[20] (Art. 2007). If the latter is the case, the panel may issue a final report that disputing member nation-states shall conform with. When there is no compliance, the disputing member nation-state may seek to suspend benefits in the same sector or in another.

[18] The MFN clause is a non-discriminatory trade policy commitment offered by one country to another on a reciprocal basis. Both countries apply the lowest import-duty and quota-restrictions on imports from each other, which they apply on similar imports from any other country.

[19] The term 'customs user fees' refers to a number of fees imposed by the USA for the processing by the US Customs Service of passengers, conveyances, and merchandise entering the USA.

[20] The panel is formed by five members, who are members of the complaining and complained against member nation-states. One of them acts as chair of the panel under agreement of the member nation-states involved.

The NAFTA has established a number of trade policies that should be observed by its participant nation-states. In case of potential disputes, there are settlement processes from different contexts that denote the intergovernmental and international characters of this region. The intergovernmental character appears with the creation of an institutional structure that performs a role that pretends to reinforce the international character of the NAFTA's processes. That is, the institutions created aim to reinforce trade developments reached at international stances, from where plenty of NAFTA's legal features rely on.

This thus allows speaking of the level of integration in the NAFTA mirroring that of international organisations sharing similar outcomes. Reliance on GATT references reinforces the commitment that participant nation-states have with regard to their legal and trade obligations as members of this organisation. The explicit inclusion of SPS measures and Standard-related measures in NAFTA's text therefore deserves special mention when understanding the context of GMF labelling.

2.4. International aspects of GMF labelling

Biotechnology and GMF have been dealt with at the international level through different agreements. They are perceived from different perspectives, leading to different ways to approach policies on labelling GMF, including GM maize.

In the WTO context, two international agreements with different perspectives can relate to biotechnology products. One is the Sanitary and Phytosanitary (SPS) Agreement. It establishes that its member nation-states have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health (Art. 2.1), provided that such measures do not contravene international trade. Any of the measures taken should be based on scientific principles and not maintained without sufficient scientific evidence (Art. 2.2). A key issue contemplated

in this agreement is that member states should accept the sanitary and phytosanitary measures of exporting member states as equivalent if they demonstrate that their measures achieve the adequate level of the importing member states (Art. 4.1). This aspect relates to GMF in the sense that governments cannot restrict its handling, transport and packaging with regard to safety or health unless they have a sufficient 'scientific basis' for this step. This thus would exclude any social, cultural or economic consideration from playing a role in setting health or safety standards.

The other is the Technical Barriers to Trade (TBT) Agreement. It establishes that technical regulations should not be more trade-restrictive than necessary to fulfil a legitimate objective, such as the protection of human health or safety, animal or plant life or health, or the environment (Art. 2.2). In this framework, labels can be deemed a technical regulation[21] or a standard[22] (Annex 1).

This agreement also refers to products imported from any member state being given same treatment to those of national origin (Art. 2.1).

This agreement is worth mentioning because its contents refer to halting the introduction of technical measures that could impede free trade, unless human health or safety, animal health, plant life fertility and robustness, or if the environment were threatened (Art. 2.2 of the TBT Agreement). Within this framework, labelling is also included.

One difference is observable between the SPS and the TBT Agreements. The former advocates that member nation-states should accept each other's measures in as much

[21] A technical regulation lays down product characteristics or their related processes and production methods. It can also include or deal exclusively with terminology, symbols, packaging, marking, or labelling requirements as they apply to a product, process or production method (TBT Agreement).
[22] A standard is a document approved by a recognised body, which provides for common and repeated use, rules, guidelines or characteristics for products. It may also include terminology, symbols, packaging, marking or labelling requirements (TBT Agreement).

as they are deemed satisfactory. The latter agreement 'encourages' member nation-states to negotiate the mutual recognition of assessment procedures.

There are views about both the TBT and the SPS Agreements in terms of GMF labelling. On one side, the TBT Agreement is considered to suggest compulsory labelling of GMF because it ensures that consumer information is provided (Burchardi, 2001: 87, 101). On the other hand, the SPS Agreement suggests that there are no reasons to label GMF as there is no scientific information indicating risks to health and safety (Makuch, 2004).

The SPS Agreement is explicitly included in the NAFTA under Chapter 7, which defines the context in which agricultural trade should take place. However, there is no reference to terms such as 'biotechnology', 'genetically modified' or 'genetically engineered'. This is perhaps the result of the SPS Agreement considering GM crops as equivalent to conventional crops.

Chapter 9 of NAFTA makes explicit reference to the TBT Agreement when determining standard-related measures. This requires the avoidance of unnecessary obstacles to trade when products comply with national requirements and would have the same purpose as similar products (Art. 907, NAFTA). In these terms, the potential labelling of GM maize can be understood as a technical barrier since the product is considered equivalent to conventional maize. Chapter 9 clearly provides for exemptions when there are 'fundamental climatic, geographical, technological or infrastructural factors' that can be justified scientifically according to national levels of protection (Art. 905, NAFTA).

Both the SPS and TBT Agreements take into account a third perspective, that of the Codex Alimentarius, which is a joint programme of the FAO and the WHO and consists of a collection of internationally recognised standards, guidelines and recommendations in food, food production and food safety; while emphasising consumer protection (Codex Alimentarius, 2007). The Codex Alimentarius aims to reinforce the notion of validating the 'substantial equivalence' between both GM and non-GM maize advocated by the USA and Canada and, subsequently, has resulted in the formulation of international labelling standards (Makuch, 2004:228) that evade stating the GM status of products. Its commission is recognised as the international authority in this sphere by the WTO. With respect to labelling, the Codex Alimentarius establishes that it should be provided only for nutritional purposes, or when it contains allergens. The reason for this position is that GM and traditional crops are equivalent in the way in which they are produced

Another international agreement is the Cartagena Protocol on Biosafety (CPB).[23] Its objective is to contribute to ensuring an adequate level of protection and safety during the transfer, handling and use of GMOs. It lays down the procedures for granting authorisation, following notification, for living modified organisms (LMOs) as well as a system of notification for LMOs intended for direct use as food or feed, of for further processing. A cornerstone of the CPB is the adoption of the precautionary principle.[24] In this context, labelling is considered necessary for the introduction of GM seeds into a certain nation-state for cultivation. This is in order to verify that such GMOs have been authorised and that they comply with CPB guidelines.

[23] The Cartagena Protocol on Biosafety was adopted at the Conference on the Convention on Biodiversity held in Montreal on 29 January 2000, which concern transboundary movements of GMOs.

[24] The precautionary principle refers to measures imposed to an activity that raises threats of harm to human health or the environment, even if some cause and effect relationships are not fully established scientifically. In this context, the proponent of the activity, rather than the public, should bear the burden of proof. It involves an examination of the full range of alternatives, including no action (Science and Environmental Health Network, 1998).

The protocol includes documentation requirements for transboundary movements of LMOs for research, for environmental release, and for food, feed, and processing. Article 18.2(a) requires documentation accompanying LMOs for food, feed, or processing to clearly state that they may contain LMOs. The reason behind this, Andrée (2007: 6) argues, was a perceived domestic economic interest in exporting GM crops, combined with grain traders' fears that even shipments with minimal GM content might be caught in new regulatory burdens enabled by a strong protocol.[25] The resulting outcome is that liability may happen if unintended LMO presence is not documented. Besides, importing countries may develop a multitude of policies and regulations.

The issues that were developed under the CPB suffered a major setback that had major implications for the direction of discussions on documentation issues. Article 18.2(a) was one of the most difficult issues in the CPB negotiations.[26] Then, in an attempt to overcome this aspect, the USA,[27] jointly with Canada[28] and Argentina, held two meetings[29] of LMO exporting nation-states to seek agreement on documentation requirements. The work of these two meetings concerned specific elements for a common approach on bilateral arrangements with importing nation-states, assigning responsibility for provision of documentation accompanying a shipment, resolution of issues and adventitious presence (Lin and Ching, 2004).

[25] In turn, this led Canada to chair the Miami group, which sought to minimise the potential impact of the CPB on the international grain trade.

[26] At the Second Meeting of the Parties of the Cartagena Protocol on Biosafety (COP-MOP2, Montreal, 30 May – 3 June 2005) despite intense efforts of the great majority of Parties negotiations collapsed and the meeting failed to take a decision on the detailed documentation requirements for transboundary movements of living modified organisms intended for direct use as food or feed, or for processing. After intense and controversial talks the decision on Article 18.2(a) BS-III/10 was adopted at COP-MOP3 (Curitiba, 13-17 March 2006). .

[27] According to John Pitchford, who was was the Director of International Affairs at the USDA at the time of CPB negotiations; the documentation requirements of the CPB were not clearly stated in the protocol, leaving room for multiple interpretations. In his view, the CPB had the potential to disrupt American export trade (USDA, 2003).

[28] This country went from being a key supporter of the Convention on Biological Diversity (Montreal was appointed as the home of the secretariat for the convention), to becoming the third only to the USA and Argentina in the uptake of GM seeds in agricultural production.

[29] March and June 2003.

The outputs from the meetings were a framework and model arrangement for bilateral agreements between exporter and importer nation-states. The stated intention was for the exporting nation-states to make similar deals with importing nation-states in order to facilitate the trade of GM products once the CPB was in force. This was possible because the CPB allows bilateral and regional agreements with non-parties. Nonetheless, they have to be consistent with the objectives of the CPB, without resulting in a lower level of protection. Subsequently, the agreement reached between these exporting nation-states envisaged that documentation would be triggered only with transboundary movements of LMOs that are authorised in the exporting country, except in cases when signatories of this type of bilateral agreements contractually defined that a shipment of 95 percent non-GMO content is considered as non-GMO shipment. Thus, a 5 percent threshold for unintentional presence of living GMOs before shipment was agreed to be tagged with the 'may contain' phrase.

In this way, the USA and Canada, both non-signatories of the protocol, signed a trilateral agreement with their NAFTA partner, Mexico. This trilateral agreement became important in subsequent CPB meetings, like the one held in Kuala Lumpur in 2004 because Mexico was unwilling to agree to any decision that was not in line with this trilateral agreement. Also, Mexico opposed the introduction of new documentation requirements for living GMOs (ETC Group, 2004; Andrée, 2007: 260).[30] Reaching consensus during this meeting proved difficult. For this reason, it was agreed that identification requirements for living GMOs, the form of the documentation, and the threshold for adventitious presence that would trigger identification requirements would be set in the following meeting. This was also because there was the perception of many delegates feeling that a minority position was overrepresented when a chair's text looked to retain the 'may contain' language (Andrée, 2007: 262). In Montreal in 2005, documentation issues remained

[30] In views of Andrée (2007: 260), trade relations with the USA were evidently a higher priority for Mexico than standing firm with most other protocol parties on detailed documentation requirements.

contentious. This included a shift in previously like-minded countries,[31] which in turn meant that the draft conclusions draft required further negotiation. These took place in Curitiba, Brazil, in 2006. At the host's proposal, there were ideas about including the text of 'containing' GMOs. However, Mexico was again at odds with its counterparts, arguing against any 'contains' language that did not have a 'may contain' option. This country's position was based on the possibility of maintaining a series of trade agreements with other countries, as well as on its commitments to the USA and Canada.[32] With this, Mexico insisted on inserting a paragraph stating that the specific documentation requirements being negotiated would not apply to trade with non-parties to the protocol.

The final outcome was that 'may contain' labels would be used in cases when the living GMO was not known, while 'contain' labels would apply when the living GMO was identified. With the latter phrase, listing living GMOs of species other than those that constitute the shipment would not be required. In either phrasing, exporters would be expected to provide common, scientific, and commercial names, unique identifier codes, and transformation events with a view to considering a decision to ensure that all relevant shipments clearly state that they 'contain' or 'may contain' living GMOs.

Furthermore, there was no agreement on whether to use commercial invoices or a stand-alone document. The final decision was to leave it up to nation-states to establish their own requirements. Overall, this was considered as a victory of Mexico and its allies (Andrée, 2007: 268).

[31] Brazil and New Zealand were initially in favour of GM-free and GMF labelling regimes, respectively. However, as negotiations went through, they supported the 'may contain' language. The reasons behind this were due to change in trading patterns. See Andrée (2007).

[32] Comments made by Mr. Marco Antonio Meraz, member of the Mexican delegation, quoted in Andrée (2007).

2.4.1 Transatlantic conflict at the WTO level

The USA and Canada have been at odds with the EU on certain issues regarding biotechnology. Nevertheless, the dispute between them appeared external to biosafety talks. This was the case of the use of growth hormones in beef production.

The EU had justified a ban on hormones in beef imports since 1981, on the basis of their potential risks to human health. By the mid-1990s, the USA and Canada took action on this issue by working through the Codex Alimentarius in order to have international standards adopted that would accept residual levels of certain hormones in meat. With this, both North American countries lodged complaints that led a WTO dispute resolution panel to rule against the EU in 1997, stating that the EU's ban was not WTO-compliant because it was not based on international standards, like the TBT Agreement or the SPS Agreement. The panel agreed that the EU could have higher standards than the international standard of the Codex Alimentarius, but such standards would have to be scientifically justifiable. The panel also noted that despite the fact that the EU was providing studies demonstrating health risks of hormones themselves, these studies were inadmissible, as the issue was about the specific risks of hormone residues in foods.

The EU appealed this decision in late 1997, referring to the precautionary principle, which it argued was an accepted general rule of international law applying not only to the management of risks, but also to their assessment (Andrée, 2007: 165). The EU position stated that provisions of the SPS Agreement dealing with precaution, including Article 5.7[33] on provisional measures did not stop the applicability of the principle. Subsequently, the EU argued that these provisions did not prevent member nation-states from being cautious when setting health standards in the face of conflicting scientific information and uncertainty. At the end, the EU lost its appeal. However, despite being ruled against twice, the EU did not agree to let hormone beef

[33] Article 5.7 of the SPS Agreement allows nation-states to adopt SPS measures in cases where relevant scientific evidence is insufficient, provided that they seek to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly.

into its territory. Instead, it said it would undertake further studies to demonstrate the risk of the hormones in a way that would satisfy the SPS Agreement. The response from the USA and Canada was to impose trade sanctions.

That this case occurred at the time when negotiations were starting on the CPB was of great significance to the biosafety talks. The outcome of the hormone dispute case was a debate between sound science and precaution in the context of a discourse focused on human health risks (Andreé, 2007: 166).

With regard to GMF, there was a dispute among the same parties. This seemed to take place because the American government viewed the EU's moratorium and approval process as 'overly politicised at best and protectionist at worst' (Young, 2003: 470).

Unlike the meat hormones dispute, the USA initially refrained from bringing a WTO claim over EU restrictions on GMF, preferring to conduct bilateral and multilateral discussions. Four reasons were listed for this approach.

> (1) US authorities, in consultation with US industry, understand that EU authorities are severely constrained by the demands of EU consumers and member state politicians, and they believe that bringing a WTO case at this time could be counterproductive; (2) media coverage of the dispute has significantly affected the political and commercial playing fields within the United States itself; (3) following the mass demonstrations at the WTO ministerial meeting in Seattle, US authorities are reticent to initiate a new controversial WTO case; and (4) European concerns over genetically modified foods have growing support around the world [...] (Pollack and Shaffer, 2001: 167).

Despite this, the EU imposed a moratorium on the approval of GM products from June 1999.

According to the US Trade Representative,[34] EU's actions had 'perpetuated a trade barrier unwarranted by the EC's own scientific analysis, which impedes the global use of a technology that could be of great benefit to farmers and consumers around the world'. Also, the USA claimed that the EU procedure to grant authorisation requests was based on political expediency more than on health or safety concerns. Those claims were dismissed by the European Commission, arguing it had already approved a number of GM products for marketing in the EU (Euroactiv, 2006). In addition, the EU's trade Commissioner questioned the reasons behind the US case, and denied the EU's regulatory system was discriminatory (BBC, 2003).

Then, in August 2003, the USA, Canada and Argentina filed a complaint in the WTO about the moratorium on the introduction of GMF into its territory. These three countries requested the establishment of a Panel to examine the matter. Acting on this request, the Dispute Settlement Body established a panel towards the end of August 2003. This panel identified three categories of complaints. One referred to the general EU's moratorium on approvals of biotech industry. Another was that various product-specific EU measures were affecting the approval of specific GM products. The third category related to the safeguard measures prohibiting the import and marketing of specific GM products (WTO, 2006: 1069).

By September 2006, the WTO Panel issued reports that examined the complaints against the EU's measures affecting the approval and marketing of biotech industry. In such reports, the outcome reached by the WTO Panel did not include opinions on whether GM products were safe, were equivalent to their conventional counterparts, or required pre-marketing approvals. However, the WTO Panel considered that the EU's procedures for the approval of GMOs 'are SPS measures within the meaning of

[34] The US Trade Representative was Robert Zoellick, he was quoted by the BBC, on News Online (2003).

the SPS Agreement' (WTO, 2006: 1068). On an opposite view, the WTO Panel determined that the moratorium was not in itself a SPS measure.

On the conclusion itself, the WTO Panel affirmed that the EU acted inconsistently with its obligations of the SPS Agreement.[35] It also regarded that the moratorium as affecting the operation and application of the EU's approval procedures because it resulted in a failure to complete individual approval procedures without delay, hence giving rise to an inconsistency with the SPS Agreement.[36] Moreover, the WTO Panel considered that safeguard measures taken by some member nation-states[37] were not grounded on new relevant scientific evidence on risk assessment meeting the requirements of the SPS Agreement.

A key aspect to note here is that the case did not involve nation-states that were both members of the WTO and members of the CPB. The EU was beholden to both treaties, but complainants were not. As a result, even though the EU referred to the protocol in its defence, the WTO dispute resolution panel held that nation-states could be held to account only for their obligations to treaties they had formally ratified. Hence, it was only on WTO grounds that the EU was held accountable for.

[35] Specifically, with the obligations established under Annex C(1)(a), first clause, and Article 8 of the SPS Agreement.
[36] This referred to terms inferred in Article 8 and Annex C of the SPS Agreement (WTO, 2006: 1068).
[37] Austria, Belgium, France, Germany, Italy, and Luxembourg. With regard to maize, the following were the GM cases included: T25 maize, Bt-176 maize, MON810 maize, Bt-11 maize, and MON809 maize.

CHAPTER 3: METHODOLOGY

This study focuses on the assessment of GM maize labelling policies in two regions. In this sense, it is necessary to delimit the kind of policy analysis to carry out. Such analysis is classified as 'analysis of policy' and 'analysis for policy' (Gordon, Lewis and Young, 1977; Hogwood and Gunn, 1984). The former focuses on policy content, policy processes, and policy outputs; while the later emphasises on evaluation, information for policy making, process advocacy, and policy advocacy. For the context and purpose of this study, in which the examination of how policy convergence takes place over time and between two different regional settings, the study of policy outputs is the most appropriate type of policy analysis. In this regard, policy outputs are not usually developed out of a single decision. Instead, they are defined in terms of a series of decisions that may change over time. In this sense, the ways in which policy outputs appear pose certain problems for research (Hill, 2005: 14). This refers to the object of study in policy outputs, which is generally a unique sequence of events. This means that little scope exists for testing earlier research by looking for a situation in which a process is replicated. Hence, the political environment in which policy experiments are conducted mean that they are unlikely to happen without ongoing adjustments; that is, policy change.

As this study aims to analyse policy convergence, it is necessary to address the question of how convergence can be measured and evaluated empirically. In this regard, the common way of assessing policy convergence is to examine the extent to which policies of nation-states have become more similar to each other over time. With this in mind, I make use of σ-convergence (sigma convergence). Such a concept focuses in the evaluation of the potential decrease in variation of policies among a certain group of nation-states (Knill, 2005: 769). Furthermore, by making use of the empirical evidence, this study concentrates on the direction that policy convergence has taken in each region. This is where the concept of 'trading up' comes to the fore

as an upwards movement of GM maize labelling policies may be observable. This situation happens when policies become stricter while reaching the regional level. Besides of the direction, this research emphasises on a specific timeframe, based on the development of the legal framework created to regulate labelling of GMF. This is because the 'time factor' is an important category as it relates to the degree of precision with which studies examine policy similarity over time (Heichel et al, 2005: 819).

Any discussion of the policy outputs needs to be grounded within the context of the policy process, and in an extensive consideration of the nature of power in the state. This results from the notion that any consideration of how the process works tends to involve propositions about who dominates. Omission of this, in statements about the policy processes, tends to have implications that there are no dominant elements in the state (Hill, 2005: 13). A further contribution of how the process works is provided by regional institutions; although they appear influenced by nation-states' views. In addition, international organisations can add their position to the process by prescribing policies developed within their area of remit.

For this, reference for nation-states and regional institutions needs to be made in the form of variables influencing policies that lead to such similar activities. Their participation differs due to different institutional configurations; that is, to the extent to which nation-states and regional institutions participate in the convergence achieved.

Studying policy outputs is generally carried out through the assessment of case studies, using qualitative methods (Hill, 2005: 14). To be able to analyse the factors that determine whether convergence and trading up occur and if they are successful, this study presents one case study on two regions that presuppose different levels of economic integration. One is being regarded as the highest level of economic

integration, including political integration, which refers to the EU. The other is showing basic approaches to economic integration in the form of an international agreement: North America.

In this sense, as this study relies on qualitative methods, it is necessary to justify this choice and delimit its use in the context of the convergence of GM maize labelling policies.

There is the general conception that qualitative methodology narrows its scope when considering a reduced group of modes of data gathering and its non-numeric characteristics. In addition, there is the simplistic view that qualitative methods are anchored around single case studies, eschewing theoretical concerns (Henwood and Pidgeon, 1992: 101). Subsequently, qualitative methods can be viewed with some scepticism. One of the main criticisms levelled at qualitative research is that it is too subjective and that findings can be influenced by the personal beliefs and preconceptions of the researcher. Thus, it can be difficult to establish what the researcher actually did and how he or she arrived at certain conclusions. Often qualitative findings are based on only a small number of subjects or anecdotal evidence.

Qualitative methods are more than simply data collection and perceptions of the researcher. The gathering, analysis and interpretation of data are always conducted with some broader understanding of what constitutes legitimate enquiry and warrantable knowledge. Qualitative methods also emphasise description and explanation, the representation of reality, an attitude towards theorising, and the view that a scientific process generates working hypotheses rather than simply assembling immutable empirical facts (Henwood and Pidgeon, 1992: 98). For these purposes, qualitative methods assist in explaining the manner and the extent to which each region's policies have taken different pathways. To achieve this, I designed a methodological framework that associates the hypothesis and objectives of the study

with the analysis of theory, which is deferred until the information is collected, structured and examined.

This study also makes use of a comparative approach that seeks to explain similar activities in different countries or regional settings. This is because comparison is the methodological core of the scientific study of politics. Comparative analysis also helps to explain and test theories about the way in which policies are developed (Almond et al, 2004: 31). Hence, comparing the EU and the NAFTA region can allow assessing the manner in which policy convergence takes place. In fact, the most obvious and simple comparative question about the policy process is whether systems tend to converge or diverge (Hill, 2005: 105).

For the context of biotechnology and GMF, there are many relevant activities that are hard to observe. This relates to certain processes being covert, where official secrecy is used as a justification for restricting access to situations or data necessary to evaluate policies. In fact, 'very much more is just kept secret without any attempt to offer a justification for doing so' (Hill, 2005: 15). Retrieving information from sources heavily involved in the policy-making of GMF and GM maize labelling policies has proven difficult. In some cases, only official documents were accessible; while reaching elite participants, such as policy-makers, posed several difficulties. However, transcripts of debates and documents from which official documents were issued assisted in picturing the framework by which GMF and GM maize labelling policies have been developed. The subsequent findings have provided a deeper insight than that of merely using official data. It is noticeable that a key difference has existed among participants in terms of accountability and provision of information. It was more accessible to obtain data from parliamentary bodies than from executive bodies. The cases of the EP and the Mexican Congress, from which retrieval of sensitive information was possible, differ from those of ministries depending from

executive governments. The USDA, SAGARPA, and the EU Council of Ministers exemplify this regard as official documents were the main source of information.

Besides the depth of the information that was retrieved from these sources, it is necessary to bear in mind the usage given to language and the presentation of texts. Official documents and statements are written in a manner that differs from the context in which debates are held, as their transcripts demonstrate, and questionnaires, from which personal viewpoints and diverse insights over the same issue are obtained. In this regard, the interpretation of such texts can influence the presentation of findings. For this reason, it has been necessary to define the sort of questions to ask. How policy convergence takes place? To which extent GM maize labelling policies are converged? To which extent has trading up taken place? Their answers will thus contribute to the understanding of the development of a specific policy output. To answer these, we need to be conscious that claims provided in texts retrieved from different sources are influenced by the most dominant positions. In fact, these views are those driving the manner in which policy convergence takes place in the two regional settings and, subsequently, affect the resulting policy outputs.

Due to the type of information to gather, interviews were planned. For this purpose, I intended to contact participants involved in the development of policies in the EU and in the three North American nation-states. This action was not successful whatsoever due to the reluctance of potential interviewees to participate or the busy agendas they had when interviews were requested. Nevertheless, I was able to contact Mr. Yannis Karamitsios, who is a Legal Officer of the Biotechnology, Pesticides and Health Unit (Unit D.4.) of the DG on Environment. The relevance of his information refers to him drafting the Commission's second report on the implementation of Regulation 1830/2003. He provided copies of member nation-states' feedback not only of the

said report, but also of the feedback provided to issue the first report.[38] Such information assisted in evaluating the position of national authorities before and after the implementation of labelling policies, as well as other important information. In turn, this assisted in assessing the extent and the manner in which policy convergence has been achieved, as well as the potential direction that the policy may evolve to.

Another useful source of information was the retrieval of debates held among the MEPs, and between MEPs and Commissioners. As they led to the establishment of Regulations that are at the core of the present study (Regulation 1829/2003 and Regulation 1830/2003), they have provided useful insight on the manner in which the EP reached to its position during legislative procedure. This included the stance that each MEP had, which relied in two factors. First was the political group they belonged to. Second was the country of origin. A similar search for information was attempted for the Commission and the Council of Ministers. Nevertheless, public information is not as deep as in the case of that retrieved from the EP. This thus meant that a partial insight from EU institutions was obtained. However, official documents and information from NGOs and other websites allow positioning the other institutions' views within the legislative framework. In addition, the position of national authorities on the implementation of GM labelling rules assists in setting parameters for studying policy convergence.

With regard to the NAFTA, a similar approach was attempted. The focus was to get the Mexican representative that signed the trilateral agreement on transboundary movement of GMOs. However, he was unavailable to be interviewed as he moved in to another position at the Inter-American level. Due to this, I tracked, among his subordinates, a person who could adequately contribute to my research. This action led me to contact Ms. Alma Liliana Tovar Díaz, who is the Deputy Director for the Regulation of Genetically Modified Organisms within the National Service of Agro

[38] To be able to have access to these documents, I had to wait for Mr. Karamitsios to consult with individual member nation-states on the disclosure of their respective feedback, as established on Regulation 1049/2001.

Alimentary Health, Safety and Quality. She refused to be interviewed, arguing that she was too busy. However, she was keen to provide information via e-mail. Unfortunately, her eagerness to assist to my research did not match the depth of information I expected for. In addition, it was proposed to obtain NABI insights from involved officials. However, a Canadian official refused to provide such information, arguing that information was shown only on a private website to which only involved government officials had access.

These actors' refusal to participate can be related to a perceived lack of transparency that politics of GMF seem to have. This can be corroborated by observing that the Mexican representative signing the Trilateral Agreement with the USA and Canada did so at his own expense. And it was 10 months later that the Mexican Congress called him upon explaining the reasons behind such action.[39]

Despite these shortcomings, the information retrieved has permitted to reach the aims of this study. Used correctly, documentary sources are a reliable data source facilitating the study of evolving accounts and attitudes of significant events. Documents do offer strengths of pointing clearly to what was done when and what the position of certain actor was. Nevertheless, a serious issue when dealing with documents is the question of their representativeness and meaning. In this sense, with written documents in the form of pieces of legislation, international agreements, news from different sources, transcripts, and websites; I have been able to retrieve sensitive data that proves my claims about convergence of GM maize labelling policies.

With this in mind, the methodological structure for the present study is the following. Firstly, I am presenting the theoretical approaches that relate to the topic in question. Policy convergence, its causal mechanisms, the concept of trading up, as well as their link to broader International Relations theories set the parameters on which the

[39] The Mexican Senate requested the presence of Dr. Víctor Villalobos Arámbula on 11 August 2004.

information is found. Secondly, issues pertaining to each of the two regional settings are developed in separate chapters. The analysis of the information collected extends the scope of the theory and contributes to scientific knowledge through the operationalistic testing of the hypothesis against the empirical findings (Flick, 2002: 41) obtained through the analysis of the two case studies. Subsequently, I compare the evidence shown from this empirical information. In turn, I offer a structural explanation for the observed variance. By comparing the selected cases, I am able to establish the circumstances in which the theory prove viable or not (Yin, 2003). Then, I develop propositions about determinants of convergence, cooperation, and trading up. Concomitantly, the findings from the analysis of policies determine the manner in which convergence of GM maize labelling takes place when national governments and regional institutions formulate them. Lastly, I summarise the results and speculate on the significance of this work for I research at large. Links across empirical chapters and theoretical information are inserted so as to determine the manner and the extent to which the objective of this study was reached. The determination of the hypothesis as a proven or refuted one is also expressed, which is an issue that helps to assess the validity of my contribution.

The information presented in this study is gathered from different sources. Background information on the importance of labels, biotechnology, environment, regional features on maize production and varieties, implications for trade and consumers, as well as on International Relations, is retrieved from academic journals, books, and websites. The same sources are used for gathering information on theoretical issues about policy convergence and 'trading up'. This in turn provides me with the necessary tools to assess policy convergence; thus developing a critical assessment of its relevance as well as its shortcomings. This methodological structure assists in exploiting information helping to present a new perspective or a new conceptual focus (Fielding, 2004: 98, 100). With this, relying on earlier research allows setting the framework of this study on reliable, previously examined, grounds.

The chapters detailing each region's case study play 'a supportive role' (Stake, 1998: 88) since they facilitate the understanding of policy convergence by explaining historical developments to the policy area in question in two different regions. The information for these chapters is collected and classified through different means. Primary data provides the background information necessary to monitor the development of GM maize labelling. In this regard, official documents are analysed. For the case of the EU, regional legislation serves as Regulations on GM maize labelling and its related features present detailed information. All the gathered documents are selected according to the insight and contribution that they provide so as to show as deeper a perspective as possible. With respect to the NAFTA region, the analysis emphasises national regulations, the NAFTA document itself, as well as the trilateral agreement stating thresholds for labelling GM maize seeds.

It is important to remark that information from literature is used without a biased approach despite its origins. Thus, for example, when using industry-based documents, information is used as merely providing the facts, without attempting to express the industry's views on the matter in question.

CHAPTER 4: LITERATURE REVIEW – POLICY CONVERGENCE AND TRADING UP

4.1 Policy convergence

The development of public policies at the regional level can be classified as convergent, divergent, identical and synchronous, or indeterminate (Seelinger, 1996: 287). Under this classification, it has been noted that convergence appears when policies become similar over a defined time period. This would imply that initial differences existed previously between national policies. However, if the differences remained or increased after a specific time period, the resulting policy development would be divergent. Identical and synchronous development refers to national policies changing in the same direction and with the same magnitude, while indeterminate development means that parallel policy developments persist at different levels of stringency, but with the difference remaining the same.

As one of the purposes of the present study is to explain the dynamics of policy convergence by observing its causal mechanisms, it is necessary to clearly define the concept of convergence. It has consensually been described as the tendency of societies to grow more alike, to develop similarities in structures, processes, and performances (Kerr, 1983: 3). However, there are different partially overlapping concepts that can lead to analytical confusion (Knill, 2005: 765 – 6). Policy transfer and policy diffusion relate to what seems to be an implicit convergence. Nevertheless, when they are examined it turns out that they focus on different aspects.

To begin with, policy transfer is defined as a process by which knowledge about policies, institutions, and ideas in one political system is used in the development of policies, institutions, and ideas in another political system (Dolowitz and Marsh, 2000: 5). Policy diffusion is observed from two different perspectives. One refers to it

being the spread of policies across and within political systems, 'reaching from the voluntary adoption of policy models that have been communicated in the international system, diffusion processes triggered by legally binding harmonisation requirements defined in international agreements or supranational regulations, to the imposition of policies on other countries through external actors' (Knill, 2005: 766). The second view considers policy diffusion as a causal factor that directs international policy convergence (Busch and Jörgens, 2005: 818). The difference between both views is that the latter narrows the scope of the definition. It does so by considering causal mechanisms of policy convergence, like international harmonisation, imposition and voluntary diffusion, as policy diffusion.

Besides the difference in concept appreciation between policy transfer, policy diffusion, and policy convergence, another variation is observable. This refers to the analytical focus: Diffusion and transfer are concerned with process patterns, while convergence focuses on effects. Specifically, policy transfer focuses on content and processes, policy diffusion on adoption patterns, while policy convergence seeks to explain changes in policy over time.

Then, following the explanation of the related concepts, it is possible to define policy convergence as

> [...] any increase in the similarity between one or more characteristics of a certain policy (e.g. policy objectives, policy instruments, policy settings) across a given set of political jurisdictions (supranational institutions, states, regions, local authorities) over a given period of time. Policy convergence thus describes the end result of a process of policy change over time towards some common point, regardless of the causal processes (Knill, 2005: 768).

To be able to measure and evaluate policy convergence, it is necessary to determine the extent to which national policies have become similar to each other over time. The most basic manner to do so is by making use of σ-convergence – sigma convergence – understood as the approach that explains whether policy convergence occurs when there is a decrease in variation of policies among different nation-states (Holzinger and Knill, 2005: 776; Knill, 2005: 769). In addition to it, there are three other ways of assessing it. Findings from Heichel et al (2005: 832 – 4) convey that β-convergence – Beta-convergence – can occur when poor, laggard, nation-states grow faster than rich, leader, nation-states. Such catching-up may entail overtaking and thus create a greater similarity than before. A further form is γ-convergence – Gamma-convergence – which explains convergence by assessing nation-states' rankings for different points in time in order to examine their mobility. Convergence occurs if nation-states in the first ranks fall behind and subsequently catch-up over time. Lastly, there is δ-convergence – Delta-convergence – basing the approach to convergence on the decreasing distance of policies towards an exemplary model. If nation-states reach total similarity to a policy model, variance between them is therefore reduced.

All four types of convergence emphasize on different, although interlinked, aspects. This means that the empirical results retrieved from each of them might be interpreted differently. In addition, evidence of one form of convergence does not necessarily mean that there is evidence of another form of convergence. Under this assumption, it is mandatory to define the specific type of convergence to be examined. This brings back the notion about the relevance of σ-convergence as the most basic form for the assessment of regional policies.

4.1.1. Indicators of policy convergence

To be able to assess convergence, it is necessary to define the basis on which policies across nation-states become similar over time, considered as the degree of

convergence. To achieve this, it is essential to clarify the differences between policy outputs (policies adopted by the government) and policy outcomes (effects of the policy in terms of goal achievement). Policy outputs are the focus in this research as the examination of governments' actions is of central relevance. This is because they 'are the agents reacting to problem pressure, experience gained elsewhere, pressure of powerful external actors, economic pressure, and legal obligation' (Holzinger and Knill, 2005: 776). Hence, studying the outputs of policies of two different regional settings can thus provide an insight into the manner in which the degree of policy convergence is reached by governments when comparing the regions.

Another indicator of σ-convergence is the scope. It refers to the number of nation-states and policies that are potentially affected by the convergence. Scope is generally associated with the degree of convergence. This claim refers to cases when an increase in the number of converging nation-states reduces the variation of policies among all nation-states, although the opposite can also be the case. Thus, there is no straightforward relationship between scope and degree of convergence (Holzinger and Knill, 2005: 778).

Lastly, the direction of convergence indicates the extent to which σ-convergence coincides with an upward or downward shift of the mean from a specific time to another. Subsequently, convergence at the top or bottom can refer to a decrease of standard deviation and a shift of the mean (Botcheva and Martin, 2001: 4). In other words, different national policies may converge while becoming stricter or laxer; thus setting a new parameter with respect to the converged policy. In this regard, the context and patterns of the direction of convergence have been examined through studies focusing on stringent and laxer regulations that have adopted 'trading up' and a 'race to the bottom' respectively.

4.2. Trading Up

It is a pattern among nation-states to converge policies when they see benefits out of them. In order to achieve so, they have agreed on the extent to which policies should be converged, and the direction it should take. Mainly in economic terms, this increase in interdependence relies on the compatibility between domestic regulations, where one of them is being internationalised. The resulting consequences can have opposite directions. This is, if nation-states interested in converging policies share a similar level of strictness, convergence would succeed smoother in a strict direction. The same would happen if they share views on lax policies. However, the impact in their economic interdependence can be greater in cases where nation-states involved do not share common views on the direction to converge policies, despite of them being interested in reaching a common position. In such situations, the role of the most influential and powerful nation-states would be determinant in the agreed direction.

As previously explained, the direction of convergence can take the form of strict or lax policies. From an economic perspective, the implications of a specific converged policy can result in the establishment of a form of regulatory competition described as a 'race to the bottom' (Vogel, 1997: 556; Scharpf, 1997: 521), also known as the 'Delaware effect.'[40] In such case, less costly regulatory and tax regimes attract producers who want to avoid burdensome regulations and taxes. Subsequently, a continuous relaxation of policies can take place, leading to the gradual spiralling down of regulatory standards (Princen, 2004: 127). However, this is not always the case as there are suggestions that the opposite can take place.

The 'California effect'[41] or 'trading up' praises otherwise as regulatory competition can induce nation-states to raise the level of regulatory requirements. This can happen

[40] The 'Delaware effect' is named after the American state that was able to attract companies by offering the least demanding standards for their corporation (Cary, 1974).

[41] 'California effect' is illustrative of the history of American automobile emission standards. Clean Air Act Amendments have allowed California to enact stricter emission standards than the rest of the

through three different mechanisms: terms of market access, international agreements, and informal mechanisms (Vogel and Kagan, 2004: 14 – 5). The argument behind the first mechanism is that 'trading up' can be portrayed as protective regulations producing benefits for both the public and domestic producers.[42] On one side, the public can perceive an increase in their living conditions, for example, in terms of strengthening environmental standards (which is the policy area where trading up was initially developed). On the other side, strict regulations can create a competitive advantage for domestic industries by making it more difficult for foreign producers from nations with weaker domestic standards to sell their products. Once producers comply with the strict regulations of the importing market, they would be encouraging their governments to strengthen their standards in the home market as well. This stricter approach generally takes place with respect to product regulation, which differs from that of process regulation. The ways in which a product is produced may not be deemed determinant by self-interested consumers (as opposed to what they can see, like the product itself); therefore, complying with process standards can lead to exert downwards economic pressures on national regulations. However, the final outcome of such pressures would be influenced by the strength of political pressures, which can maintain existing levels of regulation (Scharpf, 1997: 524). Under these circumstances, the terms of market access are one of the mechanisms by which trading up can take place.

Besides the market access, another mechanism that can foster trading up is international agreements. Through them, an increasing scope of regulations and directives can be developed, resulting in strengthened, legally binding, standards established by international institutions. This thus provides institutions with a core role when setting stricter policies. But for the establishment of the regional policy to succeed, the participation of richer nation-states is essential as they provide less

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U.S. This has meant that other American states have had the option of choosing between national and California standards (Vogel, 1997: 561).

[42] Princen (2004: 129) comments that the regulations adopted can be perceived as either adopted due to protectionist reasons (favouring producers) or as a way to protect non-economic values (considering consumers' views).

affluent nation-states with the means and incentives to modify their lax policies (Vogel, 1997: 566 – 8). Hence, the role of power is relevant in this context.

The third mechanism is the informal mechanisms, like the political mobilisation of civic interest groups, producers, and political entrepreneurs. Young (2003: 458 – 9) comments that it is indeed political mobilisation what is most commonly referred to as trading up. If it is sufficient, it will induce policy change. This can take place when political concerns in one geographical area can prompt political mobilisation in another; with the potential outcome of change of preferences among consumers and of views among producers in another area. Young explains this with an example about how the EU influences the USA.

Regardless of the mechanism through which trading up takes place, there are three conditions that are needed if the California effect is to appear. Firstly, the imposition of stricter standards should be supported by domestic producers, who are interested in imposing costs on their foreign competitors, and by public interest groups, who see strengthening of standards as a good in itself. Second, the nation-state trying to impose its standards needs to have a large and rich market. That is, the country's market should sufficiently be attractive to exporters. If this is the case, they can support the strengthening of standards in order to preserve market access. Third, a California effect is more likely if there are strong international institutions that can harmonise policies establishing standards across nation-states.[43] Under this assumption, if one nation-state with strict regulatory standards succeeds in having its policies adopted at the regional level, then the rest of nation-states would need to raise their levels of standards.

[43] Princen (2004) suggest EU institutions as good examples of this case because they can adopt regulations and directives that are binding to all member nation-states

These issues allow considering the California effect as the reason behind a shift in political balance (Princen, 2004: 129). This is, if producers from the exporting nation-state strengthen their regulatory standards as the result of the importing nation-state's restrictions to trade, they can skip potential import bans. This causes a redirection of the position not only of exporting producers, but also of a combination of different, related, interests. Thus, the adoption of strict standards in the domestic realm is the result of the political balance between the different preferences and constraints of the government and involved interest groups.

The potential change is more likely to appear if benefits outweigh the costs of establishing stricter standards. From the exporting side, government and interest groups will induce a change if the imposition of trade restrictions is credible. Credibility will largely depend upon the domestic support for the strengthened standard. In other words, credibility of these standards will be proportional to the support they receive in the domestic sphere. It is in this sense that Vogel's concept of 'Baptist-bootlegger' takes relevance as the domestic support can increase the likelihood of the California effect. However, there is the opposite view that such support can only reinforce exporting actors' opinions about protectionist measures. Such suspicions can subsequently reduce any willingness to adopt stricter standards, thus hampering the appearance of the California effect (Princen, 2004: 129, 139).

There is another perspective that needs to be taken into account. Besides credibility and protectionist measures, there are domestic preferences that can be perceived to serve a non-economic value rather than protectionist interests. The arguments provided for taking such a decision can, thus, have a great impact on the acceptance of adopting the strict standard. If the argument used for setting the domestic strict standards tie in with the preferences of the importing nation-state's actors, or they are perceived as genuine, the California effect can take place. Ideally, strengthening standards should go hand in hand with values and perceived problems of domestic actors of the exporting nation-state. This way, an important support for stricter standards, racing to the top, can be gained (Princen, 2004: 139).

Besides moving to the top or to the bottom, Radaelli (2004: 7, 9) proposes to consider that policies can move 'sideways'. This third view refers to policy transfer, which allows governments to imitate, translate, transfer, draw lessons, and 'model' each other. In fact, based on Braithwaite and Drahos' work (2000), he argues that such 'modelling'[44] has been the most important mechanism in global business regulation. However, transferring policies means an upward or downward movement (or top and bottom, stricter or laxer) from the original position of the policy in the receiving country.

4.3. Causal mechanisms of policy convergence

General literature on convergence presents a wide range of causal factors that assist in explaining the similarity of policies across nation-states and time. They have been segmented in two groups: causal mechanisms prompting convergent policy changes and facilitating factors that affect the effectiveness of these mechanisms (Knill, 2005: 769).

Regarding the former, different contributors have listed a series of mechanisms. Bennett (1991: 220 – 9) considers that convergence might arise from four processes: emulation, implying that policies are copied from elsewhere; elite networking, which results from transnational policy communities; harmonisation through international regimes; and penetration by external actors and interests. Drezner (2005: 841) claims that, through policy coordination, convergence can take place either in the form of international harmonisation or competition. Holzinger and Knill (2005: 779 – 86) widen Drezner's scope by adding imposition, independent problem-solving, and

[44] Modelling is understood as an action that can constitute a process of displaying, symbolically interpreting, and copying conceptions of action and the process itself (Braithwaite and Drahos, 2000: 581).

transnational communication. For being the most complete, it is their classification of mechanisms that becomes the object of my analysis.

First come convergence through imposition, which Holzinger and Knill (2005: 781) define as occurring whenever an external political actor forces a government to adopt a certain policy. This mechanism can be related to that of Bennett's convergence by penetration, which appears when nation-states are forced to conform to actions taken elsewhere by external actors (1991: 227). In both imposition and penetration, there is the assumption of asymmetry of power from the policy provider. There are two cases in this regard, the unilateral imposition of a policy on a nation-state from another nation-state, and the conditionality by an international institution. Generally, the adoption of the policy is exchanged for economic resources.

Transnational communication is another mechanism. It compiles a wider set of mechanisms: lesson drawing, transnational problem solving, emulation of policies, and international policy promotion (Holzinger and Knill, 2005: 783 – 5). All of them share an important feature presupposing nothing but information exchange and communication with other nation-states. Lesson drawing refers to policy transfer in which national governments apply policies used previously somewhere else. Transnational problem-solving happens within transnational elite networks that consider joint development of common problems and solutions, and their consequent adoption at domestic level. Emulation merely implies the simple copying of policies adopted elsewhere. Lastly, international policy promotion appears when international institutions promote the spread of policy approaches they consider promising or relevant.

The third mechanism is independent problem-solving. In this type, it is claimed that convergence can appear as the result of similar but independent responses of political actors to parallel problem pressures (Hoberg, 2001: 127; Holzinger and Knill, 2005: 786). This thus implies that there is no communication between each other nation-states, since under this mechanism nation-states do not behave in response to each other's actions.

Listed as the fourth causal mechanism, international harmonisation leads to convergence when nation-states comply with the legal obligations established in international and supranational law. But for these common policies to appear, interdependencies or externalities that push national governments to work together should exist. Knill (2005: 770) suggests that harmonisation is an outcome of international cooperation, where nation-states find it compulsory to adopt common policies as part of their commitment as members of international institutions. Therefore, cooperation within an international institutional framework results in reshaping national policies, which in turn implies the sacrifice of some independence. That is, once constructed, institutions constrain and shape behaviour, even as they are constantly challenged and reformed by their member nation-states (Martin and Simmons, 1998: 743).

Lastly, regulatory competition is regarded as another important factor that drives the mutual adjustment of policies across nation-states. It develops when nation-states face competitive pressure to mutually adjust their policies in order to avoid regulatory burdens restricting competitiveness of national industries. Such pressure has been explained as either leading to a race to the bottom (Hoberg, 2005: 127 – 30; Holzinger and Knill, 2005: 782), or by developing stricter policies (Vogel, 1997: 556). Irrespective of the outcome, this causal mechanism refers to the adjustment of trade-related policies, such as product or process standards.

4.3.1. Policy change

Whichever the causal mechanism that could take place when policies are converged, there are facilitating factors that affect their effectiveness. They have been presented as the second group of causal factors of policy convergence and they are formed by the characteristics of the underlying policies: the type of policy and the policy dimensions. On one side, the type of policy can influence the chances of convergence being successful. This issue relates to the extent to which policies are distributional.

Holzinger and Knill (2005: 770 – 1) comment that 'policies involving high distributional conflicts between domestic actor coalitions will diffuse and hence converge to a lesser extent than regulatory policies with comparatively small redistributional consequences.' On the other side, different policy dimensions infer in the manner in which convergence can take place. Hall (1993: 278) suggests that there are three variables that need to be considered: the overarching goal that guides policy in a particular field, the techniques or policy instruments used to attain those goals, and the precise settings of these instruments. From all three, it is suggested that techniques and settings can be adjusted easier than the ideas/goals, which are embedded according to the dominant beliefs of the actors involved. Hence, convergence on the manner, rather than on the reason, is more likely to occur.

Another view about the facilitating factors of policy convergence is the one provided by Howlett and Cashore (2007), who claim that both type and dimension can be compiled within policy change. They suggest that this concept can be classified into three types according to different rates and different consequences (2007: 6). There is a first order of change when 'calibrations' of policy instruments take place within existing institutional structures. The second order of change refers to 'alterations to dominant types of policy instruments' used within an existing policy regime. And the third order of change involves 'shifts in overall policy goals'. These classifications refer to first and second orders being the result of activities endogenous to an existing policy. The third order refers to a different feature: the exogenous element, which denotes the existence of a 'paradigmatic policy change process.'[45]

For change to happen, it is clear that a number of factors need to be present in order to bring about changes in the way in which policies had been previously developed. These are the policy problems that establish the need for change, the policy legacies that may or may not relate to proposed policy solutions, the policy preferences that

[45] Paradigmatic change exists when there is a fundamental realignment of most aspects of the policy development. It is also understood to occur when policy institutions themselves are transformed (Howlett and Cashore, 2007: 4).

may or may not change in the light of the problems and proposed solutions, the political-institutional capacity of actors to respond to the problems through new policy initiatives, and the discourse that serves to enhance capacity by altering perceptions of problems and legacies and by influencing preferences (Schmidt and Radaelli, 2004: 186).

With respect to policy problems, it is argued that they might come from the international, regional and/or local environments, and may have an effect at regional, national and local levels. In the international arena, global challenges in technological change and economic competition, trade negotiations, and the like, can lead to competition aimed at creating or strengthening markets. Consequently, problems may arise due to discrepancies between neighbouring nation-states or trading partners. Furthermore, there is the possibility of problems arising from crises internal to the nation-states, which may originate from diverse causes. Policy problems tend to become greater when they demand major changes in national policies, which may be the result of a sudden event or disaster. It is important to notice, however, that issues can be considered as problems according to different perspectives. So, what may be deemed as a problem in a region or nation-state may be considered an opportunity to redirect any given policy to fulfil either public or private demands for change. Such readjustments may mean that problems should be dealt with gradually via sensible decisions, rather than through grand designs with long range outcomes (Braybrooke and Lindblom, 1963: 119 – 121).

Solving policy problems depends upon the 'goodness of fit' between a proposed regional policy and long-standing national policy legacies, which constitutes the second factor inducing policy change (Schmidt and Radaelli, 2004: 187). Policy legacies influence policy change proportionately to the similarity of national policies: the better the 'fit' of national policies with regional policies, the more likely it is for a nation-state to have fewer problems absorbing the regional policy; the worse the 'fit', the greater the need for a transformation in national policies. Such appropriateness

can be politically constructed, so it is up to political agencies at both regional and national levels to determine what constitutes a good 'fit'. This means that there are 'adaptational pressures' coming from different sources (Radaelli and Schmidt, 2004: 377).

The possibility of change in policies may depend on how readily involved actors are able to tolerate reforms in cases where regional policy opposes national policy legacies. If preference is given to national policies, then regional policies may end up blocked. However, it can be the other way round, as when regional policies are preferred at the local level and undermine national policies that are not viewed positively. Irrespective of the direction that preferences can take, it is obvious that they evolve considerably and constantly, thus refuting the usual misconception that preferences are static (Van den Hoven, 2004: 256). Preferences may change in the course of negotiations (Schmidt and Radaelli, 2004: 187 – 8), and can transform the manner in which policies have been carried out up to a specific moment in those negotiations.

If preferences and legacies remain opposed to the policy change agreed at the regional level, policy change can occur anyway due to the fourth factor, that of political-institutional capacity. In this concept are encompassed the political interactions that can happen within a nation-state – party politics, elections, interest coalitions, etc – since they can have problem-solving capacities while interacting in different institutional settings. Such settings include single-actor systems, where the executive has the capacity to impose a decision, and multi-actor systems, in which the executive does not have the power to impose and therefore must negotiate with a wide range of other involved policy actors (Schmidt and Radaelli, 2004: 188). It is necessary, in this context, to consider the characteristics of bureaucracy and the bureaucratic structures that surround any given executive power. The political-institutional capacity implies agreement between – and within – governmental actors and interest groups, which relates to bargaining activities designed to achieve, if not consensus, at least a majority in the making of the decision.

The fifth and last mediating factor affecting policy change is the discourse, regarded as a set of policy ideas and values that focuses on policy formulation. It is considered a crucial part when analysing public policy and understanding policy change (Fouilleux, 2004: 236), because it involves knowledge, policy analysis, information about problems, actors and resources, and a more normative activity of assessing and judging reality, which refers to the world of norms, values and principles (Radaelli and Schmidt, 2004: 364). However, there is the question as to whether, and how, discourse affects the scope and substance of policies (Skogstad, 2000: 826).

The interactions between these factors do not mean that all of them need to coexist so as to induce policy change. A specific factor may be irrelevant or unworthy to consider when inducing policy change according to the context in which the other factors appear. This can be the case of policy problems, which may be deemed as such within a certain nation-state/region, while within another nation-state/region the same issue may not be considered as problematic at all. This can be the result of own policy preferences and discourses, for citing an example. Thus, the five factors identified in this study merely list the possible circumstances that may drive a specific policy to change in a given direction.

In addition, it appears that there is a process of policy learning implicit in the development of policy change that directs the convergence of policy. In fact, policy learning is defined as a change in the behaviour of political actors rooted in altered beliefs and attitudes:

> In addition, learning can be based on historical experiences and/or experiences in other countries; change can also refer to goals, tools and instruments, institutions, ideologies, and so on. Learning is more likely to occur in policy areas in which uncertainty about outcomes of decisions and contested normative values have a

> great influence, because they require higher adaptation to new knowledge or criteria (Abels, 2005: 340).

The policy change caused by policy learning may influence a change in policy styles, which vary among nation-states and which refer to distinct standard operating procedures in policy-making and implementation that may differ between nation-states. Here, a number of factors influence the decision of governments such as their approach to problem-solving, the nature of interactions between state and society, the formality of rule-making, administrative cultures, the de-/politicisation of issues, or the willingness to consider public input (Abels, 2005: 341). All these procedures refer to procedural aspects of regulatory policy-making that in turn develop into convergent policies in specific territories.

Differences in policy style, causing policy problems, respond to the political culture of each nation-state because culture shapes the politics of science and technology. Political culture implies that certain actions and the positions adopted by nation-states' governments are taken 'almost by default' due to cultural commitments to forms of legitimisation that conform to the routines of what is thought of as normal politics (Jasanoff, 2005: 21 – 2). But this does not mean that culture is resistant to change. Instead, as it has been observed with policy change, policy learning, and policy style, political culture can be redirected, constructed, and subjected to renewal, and this may well lead towards a policy convergence that could be reached at regional level.

4.4. Policy convergence and links to broader IR theories

The literature on policy convergence relates to broader theories of International Relations. This refers to the relevance and involvement of nation-states and regional/international institutions when setting up international agreements. In this

sense, three traditions have provided different views on the problems and politics of international cooperation. One is that of realists and neo-realists, who suggest that international relations are based on attitudes towards each other under an anarchical system and international conflicts (Waltz, 1979: 102). Another is the neoliberal institutional tradition, which sees international cooperation succeeding when nation-states work together to realise joint gains, and when institutions are set up to monitor compliance, increase transparency, reduce transaction costs of cooperation, and prevent cheating (Keohane and Nye, 2001). The third approach is cognitivism or constructivism, which examines how states respond to, and how international cooperation is shaped by, the introduction of new information or ideas, or by international norms (O'Neill, 2009: 11).

From all three traditions, neoliberal institutionalism is the one better equipped to address issues not only of international cooperation, but also of 'trading up.' This refers to the common trend to establish organisations and agreements for the correct supervision of the cooperation. In practice, international cooperation consists of negotiations of international regimes[46] by nation-states. This in turn implies the creation of organisations to govern those agreements, as well as the establishment of decision-making processes for future negotiations on the same or related issue. To be able to follow these steps, the formation of an international regime involves the participation of different factors. Interests and preferences, relative bargaining leverage of state representatives, role of domestic and transnational actors, and the context surrounding the issue in question, like crises, can all influence the outcome of the regime achieved.

The process of regime construction, which includes bargaining, negotiation and compromise (O'Neill, 2009: 81) can relate to Moravcsik's work known as liberal intergovernmentalism. He aims to explain why sovereign governments have chosen repeatedly to coordinate their core economic policies and surrender sovereign

[46] Regimes are classically defined as 'sets of implicit or explicit principles, norms, rules and decision-making procedures around which actors' expectations converge in a given area of international relations (Krasner, 1983: 2).

prerogatives within an international institution (Moravcsik, 1998: 1). Using a tripartite framework, he asserts that the first step is to formulate national preferences – economic or geopolitical – that take into account endogenous features to the nation-states, which in turn mirror the concerns of domestic interests (Putnam, 1998: 434). However, this assumption does not establish if the most affected groups, or those lobbying the most, are the ones that outline the national preference (Dimitrakopoulos and Kassim, 2004: 247). The second step refers to nation-states engaging in bargaining so as to select the best collective choice. Moravcsik claims that governments reach agreement through a system of unanimous voting, although nation-states may differ in terms of power and influence. Once the choice is made, the third step takes place. It refers to governments aiming to establish an institutional framework that can be selected either by pooling or delegating sovereignty.[47]

It is in this last step where liberal intergovernmentalism relates to international regime and to international cooperation. Theories of international regimes and institution-building can help to understand the conditions that make international cooperation possible, and the ways in which institutional design can help to overcome divergent national interests and collective action problems (O'Neill, 2009: 200).

A rather different view of international cooperation is the one proposed by Botcheva and Martin (2001: 2), who claim that studies of patterns of convergence and divergence can supplement studies of international cooperation. Their assumption is based on the argument that convergence will occur when the cooperation problem states are trying to solve involves substantial externalities to state behaviour and when the institutions that states craft have adequate mechanisms to overcome collective dilemmas. One way to observe this is when a coordination problem involves high positive externalities, which means that states benefit from choosing

[47] Pooling sovereignty happens when national governments agree to decide future matters by voting procedures other than by unanimity. Delegating sovereignty means that a supranational actor is allowed to take specific autonomous decision without an intervening interstate vote (Moravcsik, 1998: 67)

the same course of action. Another is through punishment within a highly interdependent nature of state choices. This is, choosing to cooperate is contingent on the other state's ongoing cooperation. Thus, if deflection exists, it would lead to a punitive strategy that will lead the defector to return to a cooperative strategy. In this regard, the functions that institutions perform to assist in overcoming coordination problems differ between both cases. In the case of coordination, institutions would effectively provide for an effective solution by providing information on the action to take. On the other hand, if potential deflection exists, then institutions would need to have strong monitoring capacities in order to allow member nation-states to implement enforcement strategies.

4.5. Observations

There has been consensus on the manner in which policy convergence should be conceptualised, which has included clarifications about confusions that may arise with respect to concepts such as policy transfer and policy diffusion.

The manner in which policy convergence can be examined varies according to different perspectives, implying the accomplishment of different results. This is therefore why it is necessary to define the type of policy convergence that is assessed in this study: σ-convergence. From this regard, it is noticeable that the three indicators need to be taken into account if one is to get a complete view on the manner in which policy convergence has been attained. In this sense, the core examination is found around the degree and the direction of convergence. On one side, the degree can offer the possibility to define whether convergence has indeed been achieved. On the other side, the direction of the convergence can show a deep insight into the manner in which convergence is achieved. This is, by observing the direction of convergence is possible to define whether a 'race to the bottom' or 'trading up' has taken place in the convergence of policies. By focusing on the latter, the assumptions derived from the potential findings thus allow for further enquiries

on the way such direction has followed. Whether as opportunities for market accesses, through international agreements, or due to informal mechanisms; it is observable that 'trading up' establishes parameters that allow relating this concept with others such as international harmonisation and international cooperation. In both cases, policy changes take place as normal drivers and outcomes; hence, setting parameters inducing the reader to suggest that policy convergence and 'trading up' have strong links with a wider literature on International Relations theories. In fact, it is such linkage what recognizes that institutions created for convergence purposes play a great role in defining the extent of the convergence. Nevertheless, nation-states, through their governments, remain the core actors in establishing the degree and the direction of the policy to converge.

CHAPTER 5: GM MAIZE LABELLING POLICY IN THE EUROPEAN UNION

This chapter presents, in chronological order, the legal measures developed to deal with the labelling of GMOs present in food, as well as those related to the labelling of GM maize.

There are different types of legislation that have set up the legal framework for GMO labelling. They have dealt with issues on biotechnology, labelling, and different type of products, like food, feed, seeds, and crops. Despite of them being briefly assessed in this chapter, emphasis is made in the procedure and the outcome reached with Regulation 1830/2003, which is the latest legal measure taken by the EU in terms of labelling of GMF, and which includes issues pertaining to the labelling of GM maize. Further to this, analysis is provided on the two reports that the Commission issued in 2006 and 2008 assessing details pertaining the implementation of Regulation 1830/2003.

To begin with, legislation about food labelling started to take form with Council Directive 79/112/EEC,[48] which aimed at approximating laws on labelling among member nation-states. Such law contributed to the smooth functioning of the common market, while covering the need to inform and protect consumers. By 1997, Directive 79/112/EEC was amended by Directive 97/4/EC.[49] However, Directive 79/112/EEC remained the basis for subsequent legislation on labelling, influencing directly the creation of GMO and GMF labelling legal framework.

[48] OJ L 33, 08.2.1979, p.1.
[49] OJ L 43, 14.2.1997, p. 21.

On the topic of GMOs, the first legal measure to appear was Directive 90/220/EEC,[50] which would deal with the deliberate release of GMOs into the environment. This directive appeared as a response to a number of member nation-states already moving to adopt a range of national measures, threatening to disrupt the single market. In this sense, the respective proposal led the Commission to note a huge diversity of existing national regulations across different member nation-states. Examples of this were (a) a ban on deliberate release in Denmark and Germany; (b) a case-by-case approach to the release of individual GMOs in the UK, France, Belgium, Netherlands and Luxembourg; and (c) an absence of legislation in Ireland, Greece, Italy, Spain, and Portugal (Pollack and Schaffer, 2009: 60). At the end, the Commission's proposal focused on a regulatory scheme that would provide for case-by-case assessment and authorisation of release of GM varieties into the environment. Nevertheless, other perspectives were taken into account. For example, the primary model for this directive was Denmark's Gene Technology Act,[51] which relied on production techniques and genetic modification, rather than on safety, quality, and efficacy of a specific product (Patterson, 2000: 321). Also, this primary model considered that the Minister of Environment would be heavily involved in this policy area. Subsequently, Directive 90/220/EEC considered different national viewpoints and approaches.

Also, Directive 90/220/EEC stated a number of substantial and procedural rules for pre-market authorisation and experimental release based on risk assessment and on a precautionary approach. This would take place within the nation-state where the GM product was intended to be placed on the market for the first time. In this context, member nation-states would be responsible for assessing the notifications submitted by anyone intending to release GMOs. Such notifications would include self-proposals for labelling. Subsequently, an analysis of the same notification would follow at the regional level. In case of disagreement between member nation-states,

[50] OJ L 117, 8.5.1990, p.15.

[51] Gene Technology Act was adopted in Jun 1986. Denmark became the first country to adopt a specific Act regulating biotechnology (Jelsoe et al, 1998: 31).

the Commission would take a decision, which would be agreed in accordance with a committee of representatives of nation-states. If agreement could not be reached, the Commission would have to submit a proposal for GMO release to the Council, who would act through QMV. Once the notification was authorised, all member nation-states would be bound to comply with the Directive. Nonetheless, there was the proposal of a safeguard procedure whereby a member nation-state could provisionally restrict or prohibit the use or sale of an approved GM product on its territory, when considered necessary according to evidence of serious risk to people or the environment. This thus denoted the unwillingness of member nation-states to accept each other's risk assessments, and became a significant barrier to a peaceful authorisation process. The resulting disagreement meant that the more complicated and time-consuming 'Community' procedure had become the norm for decision-making (Law, 2008: 66, 72).

From the mid-1990s, food safety became a salient issue in the EU: food scandals such as dioxin-contaminated feed, foot-and-mouth disease, the cross-pollination of GM oilseed rape with non-GM varieties in the UK, and, most of all, the BSE crisis (also known as 'mad cow disease') stirred public outrage. In some countries, citizens started to distrust their governments and the Commission's actions, which had a great effect on the GM debate (Abels, 2005: 344). However, other countries' governments got citizen support for their national policies on GMF as well as labelling.

For example, Denmark had a restrictive GMF policy that was a parameter of what could be called a 'GMO-cautious majority' in Parliament (Toft, 2004). Among its features, labelling appeared as a key policy issue by 1997 (Grabner et al, 2001: 24; Jelsoe et al, 2001: 158). The argument was that labels allowed choice in cases where consumers regarded the safety of GM products as uncertain.

> Labelling has traditionally been a major point in former Danish debates on food issues from the principle that positive labelling prevails (meaning that products containing something should be labelled) and negative labelling is problematic (if a product contains too many negative appraisals) (Toft, 2004).

Austria was another case were population supported governmental actions on biotechnology. After an enquiry in 1992,[52] there was broad consensus on the government's proposed recommendations, which included mandatory labelling of GM products (Grabner et al, 2001: 24). Of course, conflicts arose within conservatives, the industry, and scientists, who preferred to maintain the status quo that allowed for self-regulation. Nevertheless, public opposition to GM products increased by the time of release proposals; mainly because GM crops were seen as a threat to Austria's organic agriculture, to the environment, as well as because of low acceptance and low factual knowledge[53] (Wagner et al, 1998: 17).

Finland exemplifies another case where citizens supported their government. This happened with a pro-biotech approach though, since Finnish people usually have had a pragmatic and optimistic perception of biotechnology[54] (Rusanen et al, 1998: 44). In fact, the Finnish biotechnology industry was the sixth largest in Europe (Rusanen et al, 2001: 172). This has been the result of official bodies encouraging the participation of institutions and organisations in the preparation of laws; rather than them being actively seeking to participate. Irrespective of the wide range of peer contributions, the 1995 Finnish Gene Technology Act was, in general, slightly more restrictive than the minimum level defined in the EU directive. It should be pointed

[52] Before joining the EU in 1995.

[53] For a deep explanation on Austrian attitudes see Wagner, W., Torgersen, H., Seifert, F., Grabner, P., and Lehner, S. (1998), 'Austria,' in Durant, J., Bauer, M. W., and Gaskell, G. (eds.) *Biotechnology in the public sphere: a European sourcebook*; Cromwell Press; 15 – 28.

[54] This relates to research activities being presented generally in a positive tone in the media. Biotechnology has been presented as a series of breakthroughs and achievements that would improve living standards. This results in relatively little criticism towards the legislative process in biotechnology (Rusanen et al, 1998: 46).

out, however, that no major GM crops have been cultivated in Finland. Hence, no calls for special legislation were voiced and Finland aligned to EU law development, including regarding the position on labels.

France represents a different case in that her government changed views about biotechnology. This depended according to the political environment at the time. To begin with, France has had a long-standing involvement in this area because of its tradition of research and the importance of its agriculture.[55] Authorities set up a partnership with industry and research to control GMOs on a self-regulatory basis. Nonetheless, France has experienced a decrease of biotechnology firms over time.[56] Different actors have been taken into account according to the role they play in what De Cheveigné et al (1998: 54) describe as an 'opportunistic' approach. This, they claim, has resulted from the perceived lack of real political stakes in this policy area. With respect to maize, Boy and De Cheveigné (2001: 182) comment that on February 1997 the then right-wing government decided not to authorise its growth in the country in application of the precautionary principle. In turn, in November of the same year the new left-wing government authorised the planting of GM maize. However, no new varieties were authorised afterwards. Hence, the hesitation surrounding GM maize in France has illustrated the uncertainty of official positions on the matter. Moreover, trade unions have not appeared to have played a major role in initiating or implementing public policy in biotechnology; while consumer associations have slowly increased their participation once GM products appeared in the market. This in turn has resulted in them affecting and encouraging a stringent labelling policy. With this, France became one of the countries most opposed to transgenic food in Europe (Grabner et al, 2001: 25).

[55] France is the biggest agricultural producer in Europe.
[56] During 1990 and 1995, the decrease experienced was from 70-90 down to 50-70 ((De Cheveigné et al, 1998: 51).

Germany has been known for its biotechnological research, although it has been decreasing.[57] This aspect mirrored the experimental release of crops, which situated Germany well below other member nation-states. Up until 1995, there were 49 experimental releases in Germany, compared to 113 in the Netherlands, 133 in the UK, and 253 in France (Hampel et al 1998: 64). However, public debate of issues happening elsewhere in Europe had a profound effect on German views about biotechnology. Because of this, mandatory labelling became an issue with the Novel Foods prescription, while laboratories detecting GMF emerged. After tracing them, producing companies removed them from the market. Subsequently, almost no products labelled as GM were available despite no official withdrawal of GMF from German markets (Hampel et al, 2001: 192).

Greece exemplifies an interesting case. Her citizens have been regarded as the less informed across Europe and with the lowest objective knowledge (Marouda-Chatjoulis et al, 1998: 80 – 1). This aspect has related to media coverage on the topic, which has been minimal. Until 1996, Greece had stood out as one of the most supportive countries of biotechnology. But a dramatic shift in 1999 led Greece to become one of the most critical countries in Europe (Grabner et al, 2001: 25). Subsequently, Greeks have tended to be pessimistic and distrustful when it comes to biotechnology and its regulation. Jointly with this, Greece has been second only to Austria in terms of the percentage of people who believe that only traditional breeding and cultivating methods should be used. Hence, they have been regarded as very wary of GMF. This has related to labelling. For example, by 1997, 8 out of 10 people wanted to see labels on these foods in the market place.

[57] The German world share of inventions in biotechnology and genetic engineering decreased from 12 percent in the 1980's to 10.3 percent in 1989 – 90, and to 9.7 percent in 1992 – 94 (Hampel et al, 1998: 63).

The Netherlands has been another case where biotechnology has found relative support. To begin with, because of its characteristics in terms of size and level of industrialisation, this member nation-state has strongly invested in the development of biotechnology. This science-based perspective has implied consensus conferences, a wide range of publications, and public bodies' recommendations, among others. In fact, when the first GM products approached the market in early 1997, the Ministry of Health issued, within the framework of Food Law, a labelling directive on the use of GM soya and maize imported from the USA in 1996. However, such directive was rejected by Dutch courts because Food Law could not be used to differentiate between products (Midden et al, 1998: 103 – 8).[58] This, nevertheless, has not influenced consumers' views about biotechnology, which seem to have been driven by media covering mainly positive aspects; hence, the Netherlands has experienced little polarisation.

The UK represents a unique case. This member nation-state has combined governmental support for biotechnology with its respective consumer rejection. On the one side, the UK has been a prominent player in the field of biotechnology and with a history of policy-making in this policy area. This was to the point of considering concerns not based on scientific evidence as irrational, ignorant or at best irrelevant (Lee, 2008: 49). Furthermore, a perception that the national regulatory environment of this policy area initially advanced as response to developments happening at European level has also existed.[59] Besides, the UK has regarded itself at the forefront of efforts to persuade the Commission to adopt a product-based approach to regulation (Bauer et al, 1998: 164). In fact, food companies were able to introduce GMF in the UK market.[60] Nonetheless, issues on segregation and labelling became contentious and public debates sensitised stakeholders to the importance of

[58] This aspect did not imply changes because European regulations appeared shortly afterwards.
[59] Bauer et al (1998: 164) exemplify this case by stating that the 1990 Environmental Protection Act and the 1992 regulations on deliberate release on the environment represented the UK response to the implementation of Directive 90/220.
[60] From 1995 British supermarkets retailed Zeneca's tomato paste made from GM fruit and, although not legally required, labelled it voluntarily as such (Grabner et al, 2001: 23).

preserving consumer confidence in new foods. Food[61] and research[62] scandals and happened in the UK. Subsequently, the government appeared committed to public consultation. By March 1999, all foods, additives, and flavourings that entered the market since September 1, 1998 and that contained more than 1 percent GM content were labelled. In April 2000, the Food Safety Agency extended such provision to all GMF, additives, and flavourings, including those on the market before 1998. There were also required labels for restaurant meals with GMF. Furthermore, the UK empowered local authorities to enforce the system and adopted a range of financial penalties for mislabelling of products (Phillips and McNeill, 2000: 222). This, however, has resulted in polarised views about GMF,[63] which have been joined by a series of food scandals[64] and controversial previously unpublished experiments.[65] In turn, this led the government to establish a new Food Standards Agency and to overhaul the entire advisory system on biotechnology (Grabner et al, 2001: 25).

Despite all these differing national views, a pattern supporting the implementation of GMF labels has been observable in a number of member nation-states. Indeed, France and Greece changed perspectives over time, which in turn confirmed that the majority of member nation-states aimed at a similar policy. These views related to citizens' perspectives on the topic. A study from Bauer et al (1998: 262) indicates that, from the then existing 15 member nation-states, there was a mean of 74.9 percent respondents supporting putting labels on GMF, while only 16.4 percent disagreed with this issue.[66] Nevertheless, from the member nation-states that adopted or

[61] In 1998 and 1999 a series of high-profile actions took the attention of the media. Individuals and groups destroyed trial fields of GM crops, in front of both cameras and the police (Lee, 2008: 19).
[62] Scientific evidence provided by Dr. Arpad Pusztai affirmed that rats fed on GM potatoes suffered from stunted growth, suppressed immune systems and reduced body weight.
[63] The UK public are more polarised in their attitudes than the average European (Bauer et al, 1998: 168).
[64] Previously commented.
[65] In February 1999, researcher Arpad Pusztai announced that feeding GM potatoes to rats had negative effects on their stomach lining and immune system.
[66] Pending 8.7 percent referred to not knowing whether to support labels.

announced plans to implement mandatory labelling systems, only the UK formally implemented labelling rules[67] (Phillips and McNeill, 2000: 220).

At the regional level, there was a general agreement that all products based on genetically engineered processes should be labelled individually on the product packaging. Also, some ministers of Environment and Agriculture in charge of this policy in their respective countries, called for documentation and labelling of GM crops, as well as clear labels on seeds. Hence, it is in this context that governments attempted to influence the regulation of GMF in the EU (Jelsoe et al, 1998: 32).

Under these circumstances, and despite objections from most member nation-states where public annoyance was apparent, the Commission issued the Decision 97/98/EC,[68] which would allow the placing of Bt-176 maize on the European market without any label beyond indicating the 'new characteristics' of the crop. This Decision stated that labels should indicate that maize protected itself against corn borer and that it had increased tolerance to a specific herbicide. The 'GM status' of the crop was not required. This Decision shows that the Commission concluded that there was no reason to believe that the introduction of GMOs into maize would have any adverse effects on human health or the environment. Consequently, the Commission decided that there were no safety grounds for mentioning on the label that the product was obtained through GM techniques.

This action was parallel to the mobilisation of consumers boycotting GM producers and retailers, activists uprooting GM plants, and the christening of this type of

[67] Information as of August 2001. However, 3 countries that join the EU in 2004 (Hungary, Poland, and the Czech Republic) also proposed mandatory labelling, but there was no available evidence that these countries developed domestic systems to manage such regulations at the time (Phillips and McNeill, 2000: 220).
[68] OJ L 31, 1.2.1997, p.69.

product as 'Frankenfoods' in, for example, the UK. The EP overwhelmingly denounced the Commission's decision, and a number of ENGOs cast GM crops as a threat to sustainable agriculture. In addition, food suppliers decided to exclude GM ingredients from their own brand products. The EU was lacking a straightforward way to accommodate the protest originated from the combination of these reactions.

> […] member states imposed their own bans or restrictions on GM crops. Commercial cultivation required national approval […]. Using this procedure, France and Spain granted a time-limited approval, requiring companies to monitor fields for all risks which were cited in the public debate. Bt maize was banned at various times by Austria, Italy and Germany (Levidow and Murphy, 2003: 63 – 4).

Commercial blockage and political protest led to more cautious regulations in the EU. Amid public hostility, extra demands and restrictions tended to circulate among member nation-states and labelling became a key topic. This was apparent when the EP and the Council issued Regulation 258/97/EC[69] concerning novel foods and their ingredients. In this, general concerns, raised previously in Directive 90/220/EEC when referring to the harmonious functioning of the internal market, were taken into account. Furthermore, issues on public health, the environment and consumer information were addressed. It was also established that products containing GMOs must be labelled when they could no longer be considered substantially equivalent to their conventional counterpart. For this, two types of information became compulsory on the labels. Firstly, labelling should state clearly when it was apparent that the product contained GMOs. Secondly, labels should state when there was the possibility of GMOs being present in the product. This refers to 'contain' and 'may contain' phrasing labels. A third, voluntary option, was considered. It would refer to consumers being informed that the product was GM free (NERA, 2001: 2 – 5).

[69] OJ L 43, 14.2.1997, p.1.

However, despite the relevance of this regulation in setting the labelling requirements of GMOs, the list of GM products was too wide and maize was not specified even when Bt-176 maize was already authorised for marketing.

As this GM maize variety was not covered by the EP and Council Regulation 258/97/EC, some member nation-states started to adopt safeguard measures. This was the case with Austria and Luxembourg, who prohibited the sale of Bt-176 maize on their territories soon after the Commission authorised the crop for commercialisation. The argument for such an action was that possible risks were very hard to assess and therefore should be avoided while scientific discussions were taking place (WTO Panel, 2006: 885). Furthermore, for Austria, the controversy started because a GMO field trial had got out of hand and created in the public a reaction against biotechnology. In this context, and in order to avoid any potential escalation of the conflict to the regional level, the Commission issued Regulation 1813/97,[70] which clearly emphasised the establishment of labelling rules for the GM maize variety authorised under Decision 97/98/EC across member nation-states. Significantly, though, this regulation also emphasised that there were no safety grounds to label and that the regulation was designed to ensure that consumers were informed of the presence of GMOs in foodstuffs, that they were told of any health concerns (allergenic), and that ethical issues were considered.

Despite efforts to appease concerns, Regulation (EC) 1813/97 appeared too late. The controversy of marketing maize without labelling its GM status had an effect throughout Europe. Debates on biotechnology became constant throughout 1997 and 1999 in Greece, Ireland, Italy, the UK, France, Denmark, and the Netherlands (Franz, 2006: 5 – 7). Regardless of such national disquiet, the Commission issued Decision 98/292/EC[71] and Decision 98/294/EC[72] dealing with the placing on the market of Bt-

[70] OJ L 257, 20.9.1997, p.7.
[71] OJ L 131, 5.5.1998, p.28.
[72] OJ L 131, 5.51998, p.33.

11 maize and MON810 maize respectively. The Decisions listed the labelling requirements stated in the Commission Regulation 1813/97.

Soon afterwards, the Council issued Regulation (EC) 1139/98,[73] which amended Commission Regulation 1813/97. It provided for the compulsory labelling of GM maize and GM soybeans when transgenic DNA could be found in the final food products. This was the result of the Council considering urgent action to lay down detailed uniform Community labelling rules, specifying the manner in which phrases detailing the existence of GMOs should be written.[74] This was at the time when Austria exerted more pressure on the EU policy framework by banning the second GM maize variety (MON810) from entering its territory (WTO Panel, 2006: 893).

Furthermore, no applications for authorisation of GMOs reached the end of the decision-making process between 1998 and 2004, and a number of member nation-states introduced measures barring national market access to GMOs that had already been authorised. This was most immediately prompted by two declarations from twelve of the then fifteen member nation-states stating that they were opposed to further authorisations of GMOs. One declaration was issued by the Danish, Greek, French, Italian and Luxembourg Delegations. The other declaration included the views of the Austrian, Belgian, Finnish, German, Dutch, Spanish and Swedish Delegations[75] (Lee, 2008: 3). With slightly different emphases, both declarations stated the need to impose a moratorium and the intention of member nation-states to block the authorisation of GMOs in the Council of Ministers pending the adoption of a new and stricter regulatory system that would ensure labelling and traceability of GMOs and GMO-derived products (Pollack and Shaffer, 2009: 67 – 8).

[73] OJ L 159, 3.6.1998, p.4.
[74] Article 2 states that the words 'produced from genetically modified maize' should have appeared on the labelling of the food regardless of whether a list of ingredients existed. Otherwise, the words 'contains ... produced from genetically modified maize' should appear on the labels.
[75] The two declarations were made in the 2194th Council Meeting of 24-25 June 1999.

Ireland, Portugal and the UK did not join either declaration. Nevertheless, despite not taking part in the decisions, they did not push ahead with GMO authorisations because the nature of the concern was sufficiently profound, and with sufficient impact on the commercial prospects of agricultural biotechnology (Law, 2008: 222).

Two years later, Regulation (EC) 1139/98 was amended by Commission Regulation 49/2000,[76] which established that labelling was necessary if a maximum threshold of 1 percent tolerance level for presence of GM-material in a non-GM background was surpassed. However, the amending regulation was criticized by the EP in two manners. Firstly, the Committee on the Environment, Public Health and Consumer Policy (CEPHCP) called the Commission to propose that co-decision should apply to the adoption of the measures suggested[77] (European Parliament, 1999/a). The reason behind this was that the EP had no chance to propose amendments on what they considered a confused approach to GMF. That is, this legislation was considered as another part of a jigsaw, which led the EP to perceive that consumers could be puzzled about what exactly the EU was proposing and how it would impact on them, on the food they eat, and on the labels they read.[78] Secondly, the CEPHCP was heavily concerned about the maximum 1 percent content level. MEPs had different views about such threshold, with the majority of them being against the percentage proposed. For example, some MEPs[79] argued that the threshold could be lower as supermarket chains around the EU, they claimed, were confirming that 0.1 percent content level was feasible. Other MEPs[80] wanted further clarification of the meaning of the percentage. That is, the manner by which accidental GMO presence should be

[76] OJ L 6, 11.1.2000, p.13.
[77] This area was dealt with under cooperation procedure.
[78] Comments made by Caroline Jackson (PPE – DE, UK) on a debate about labelling of foodstuff produced using GMOs. Debate held on Monday, 13 December 1999 in Strasbourg, France. Mrs Jackson (PPE – DE) was the *rapporteur* of the CEPHCP when sustaining the EP's views before the Commission.
[79] Mrs. Jackson (EPP – DE, UK), Mr. Trakatellis (EPP – DE, EL), Mr. Bowe (PSE, UK), Mrs. Vachetta (GUE/NGL, FR), Mr. Lund (PSE, DA), and Mrs. Sandbaek (EDD, DA).
[80] Mr. Sterckx (ELDR, NL), Mrs. Breyer (Greens/EFA, DE), and Mrs. Oomen-Ruijten (EPP – DE, NL).

permitted or not. On the opposite hand, another MEP[81] claimed that the threshold was too strict for the industry to accomplish it. His argument was that this could end up labelling everything as potentially containing GMOs (European Parliament, 1999/b).

Despite the views of the CEPHCP, the Commission maintained the 1 percent threshold. Subsequently, the Commission's attempts to calm down some member nation-states' unease proved fruitless. Austria prohibited T25 maize, while Germany did the same with Bt-176 maize during the same year. Italy went even further by suspending the entrance of T25 maize, MON810 maize, MON809 maize, and Bt11 maize from its national market[82] (WTO Panel, 2006: 876, 912, 925).

These prohibitions placed the Commission under great pressure to come to terms with the revision of Directive 90/220/EEC (Abels, 2005: 345). The result was a proposal that would in turn become the EP and Council Directive 2001/18/EC.[83] This directive established that both traceability and labelling would be interlinked as the latter would become a means to reach the former. This is, labelling GMOs or products containing them would assist in tracing GMOs. In addition, unique codes relating to each GMO would need to be set up, which would include requirements to specify the identity of the GMOs, as is foreseen under the Cartagena Protocol on Biosafety. Member nation-states were required to take the relevant measures to ensure that labelling of GMOs would take place at all stages of their placing on the market.[84]

However, Directive 2001/18/EC did not appear smoothly. While the majority of the EP supported tighter regulations, member nation-states had mixed views. While some appeared to do whatever possible to ensure that no GM crops would be grown in their territories, like Austria and Luxembourg; others were torn between demands of GM opponents and those of the biotech industry, as in the case of Germany and the UK.

[81] Mr. Bushill-Matthews (EPP – DE, UK).
[82] Greece banned oilseed rape in 1998. France did the same in 1999, and then banned MS1/RF1 oilseed rape in 2003 (WTO Panel, 2006: 900, 908, 919)
[83] OJ L 106, 17.4.2001, p.1.
[84] Art. 21 of Directive 2001/18/EC.

A conciliation committee drafted the final text, which was characterised by a ratcheting-up of regulatory requirements for GMOs in order to assuage GM-sceptical member governments and MEPs. Despite this effort, Directive 2001/18/EC did not satisfy Denmark, Austria, France, Greece, Luxembourg and Italy. All of them were insisting on continuing with the moratorium (Pollack and Shaffer, 2009: 239).

Seeking to remove national bans and to overcome the impasse on approvals, the Commission developed proposals in order to improve the legislative framework. For this reason, provisions on the marketing of GMOs were replaced by two new regulations: The EP and Council Regulation 1829/2003[85] on genetically modified food and feedstock and the EP and Council Regulation 1830/2003/EC[86] relating to the traceability and labelling of GMOs and GMF, both of which established the level of harmonisation on the policy concerned. Also, these regulations were intended to operate in tandem and rely on each other for certain requirements. Notably, Regulation 1830/2003 provides traceability requirements for all food and feed products that fall under the scope of Regulation 1829/2003.

As with other stages on the development of these policies, some member nation-states expressed their particular views on labelling. Because of its consummated opposition to GMOs, Austria is used as an example. It is true that Austrian consumers have been wary of these products; however, organic farming has been the sector that has most perceived the threat that GM crops can pose for its development. In fact, Austrians have been, on average, the most critical of modern biotechnology in Europe (Wagner et al, 1998: 17, 19). They still think that existing regulations are insufficient to protect people from any risks derived from genetic modification. In this sense, it appears that labels become an irrelevant aspect of GMF. In other words, Austrians have not trusted this technology; hence labels stating that GM processes have

[85] OJ L 268, 18.10.2003, p.1.
[86] OJ L 268, 18.10.2003, p.24.

occurred can be regarded as non-sense. However, the Austrian delegation participating in drafting Regulation 1829/2003 encouraged the establishment of labelling requirements by proposing the inclusion of declarations in notifications as to when and in which way products would be labelled (European Commission, 2004).

In Regulation 1829/2003, labelling was understood to be a procedure that would prevent consumers from being mislead about methods of production and enable them to make informed choices. For this, Regulation 1829/2003 laid down the different contexts in which labelling should take place; that is, when foods contain or consist of GMOs, or are produced from or contain ingredients produced from GMOs. In this sense, clear labelling was stated for genetic modification resulting in the final product. It was also stated that the adventitious GMO traces in conventional food would not be subject to labels. For this, a threshold for technically unavoidable traces was established. Jointly with the confirmation that labelling should be provided at all stages of placing on the market, such threshold was included in both Regulation 1829/2003 and Regulation 1830/2003.[87] Although both of them deal with similar issues in their contents, as it is the case of delimiting the threshold and the type of food subject of labelling, there are reasons behind developing two pieces of legislation. According to the Commissioner for Health and Consumer Protection[88] the difference relies in that Regulation 1830/2003 'is a horizontal piece of legislation as is Directive 2001/18. In Directive 2001/18 it was envisaged that there would be sectoral legislation, brought forward in due course.' That is the piece of legislation [Regulation 1829/2003] he was promoting and that was required when Directive 2001/18 was voted for.[89]

[87] Explanations on the threshold and the links in the development of both regulations are explained in the following section.
[88] Mr. David Byrne was the Commissioner for this DG at the time of developing these regulations.
[89] Comments made by Mr. Byrne during a debate on the EP's position regarding the first reading of Commission proposals that in turn became Regulation 1829/2003 and Regulation 1830/2003 (European Parliament, 2002/b).

5.1 Regulation 1830/2003 – The main legislation for GMF labelling

Regulation 1830/2003[90] was developed out of a Commission proposal[91] intending to strengthen the position on traceability and labelling of GMF that the EU reached with Directive 2001/18/EC.

At this point, the UK was opposing EU-wide labelling rules (FOE, 2002),[92] while also pushing for lifting the moratorium imposed on licensing new GMF and crops, and calling instead for a 'GM-free' label. This came despite the UK being already enforcing EU rules.[93] However, other countries were already keen on establishing labels. This was the case of the Netherlands, being one of the first member nation-states to enact mandatory labelling since the late 1990s (Kalaitzandonakes et al, 2007: 113).[94] Another case was France, where the approach towards GMF and their labels shifted over time. As previously told, GM technology was largely viewed at the beginning as a matter of progress and competitiveness.[95] However, after having supported the approval of one type of Bt corn, France banned the same corn by blocking it from being listed in France's national seed catalogue. After a couple of shifts on this policy in 1997, the French government became one of the backers of the moratorium on new approvals and legislation being adopted. It also imposed national safeguards against two varieties that received EU approval (Pollack and Shaffer, 2009: 74).

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[90] Due to its importance in the context of the present study, this regulation is the object of in-depth analysis detailing the manner in which it was developed. In turn, such examination illustrates observing the complex relationship of the relevant actors involved in reaching agreement on the legislative outcome.

[91] COM(2001)182 final. OJ C 304 E, 30.10.2001, p.327.

[92] According to FOE (2002), the UK government was the only member nation-state to oppose the Commission's proposals to ensure that GMF was properly labelled when Environment Ministers discussed the issue in Luxembourg on October 17, 2002.

[93] All foods, additivies, and flavourings that have entered the market since 1 September 1998, and that contained GM content have been labelled (Phillips and McNeill, 2000).

[94] Kalaitzandonakes et al (2007: 113) estimate that about 200 prepared and processed foods carried such labels in the Dutch market during the late 1990s.

[95] As late as 1997, France was the second most popular country – only after the USA – for GMO field experiments (Sato, 2006, taken from Pollack and Shaffer, 2009: 74). As a result, companies most frequently applied in France for approvals of GM varieties under Directive 90/220/EEC.

With the aim to harmonise national laws, the proposal for this regulation focused on two issues. Firstly, it properly defined the concept and objectives of traceability. Secondly, labelling of GMOs was extended from GMF to products produced from GMOs. In addition, this proposal considered as sufficient information to label pre-packaged GMO products only with the words 'This product contains genetically modified organisms'. This aspect presupposes that labelling should be provided in the first stage of market placement, with its subsequent inclusion in all types of packages until reaching the final consumer. This, in turn, would enable producers and consumers to exercise their freedom of choice. However, a key, controversial, aspect of this proposal was that the Commission suggested that if GMO traces were technically unavoidable or adventitious, labelling and traceability would not be necessary.

With this proposal, the Council consulted the European Economic and Social Committee (EESC). The Section for Agriculture, Rural Development and the Environment adopted its opinion on a number of issues.[96] Overall, the EESC welcomed such a proposal as it considered that legislation existing at the time was 'inconsistent and incomplete'. In this regard, the committee suggested that traceability of GMOs and GMF should be identical to the traceability rules established on the general principles of food law. Furthermore, the committee commented that traceability requirements should be strengthened by including a series of additional checks and inspections by producers, retailers and supervisory authorities. On labelling, the EESC requested clarification on the liability for adventitious contamination on organic farming. In addition, the EESC considered fraud and unfair practice if a product was not labelled in cases when GMOs were used but were not present in the final product.

[96] OJ C 125, 27.05.2002, p.69.

The Committee of the Regions was another body that also expressed a supportive opinion on the Commission proposal,[97] reaffirming that all purchasers – be they intermediate users or final consumers – should be enabled to exercise freedom of choice. The Committee, however, suggested that the Commission should also be authorised to seek to harmonise assessment procedures for GMOs and GMF, as well as to seek to align EU traceability measures with those applicable at the international level, like the ones set out in the Cartagena Protocol.

As the proposed regulation would be achieved through the co-decision procedure, the Commission proposal was sent to the EP for its first reading. Within it, the Committee on the Environment, Public Health and Consumer Policy (CEPHCP) would be responsible for presenting the EP´s position, while the Committee on Industry, External Trade, Research and Energy (CIETRE) and the Committee on Agriculture and Rural Development (CARD) would only issue their respective opinions.

The debate held within the EP, and at which the Commissioner for Environment[98] and the Commissioner for Health and Consumer Protection[99] assisted, showed the different perspectives that MEPs had with respect to the proposed policies.[100] Every MEP that participated in the debate agreed to provide information through labels. The idea behind this was to ensure the internal market would operate efficiently while consumers could be better informed (European Parliament, 2002/a). However, there were strong disagreements across the diverse political groups in two areas: the

[97] OJ C 278, 14.11.2002, p.31. This document entails opinions not only about the Proposal for Regulation 1830/2009 (COM(2001) 182 final – 2001(0180 (COD)), but also about the Proposal for Regulation 1829/2003 (COM(2001) 425 final – 2001/0173 (COD)), and the Proposal for Regulation 1946/2003 (COM(2002) 85 final – 2002/0046 (COD)).
[98] Mrs. Margot Wallström was the Environment Commissioner at the time.
[99] During that time, Mr. David Byrne was the Commissioner for Health and Consumer Protection.
[100] The debate took place on Tuesday 2 July 2002, in Strasbourg. Besides dealing with the proposal that in turn led to issuing Regulation 1830/2003, this debate also took into account issues pertaining to the proposal that became Regulation 1829/2003.

products to be labelled and the threshold percentage to be used.[101] Referring to the products to be labelled, the majority of the political groups[102] converged on the idea of labelling not only GM products, but also products derived from GM food and feed. The argument was that consumers should be informed as to whether a product consists of, contains, or has been made of GMOs. That is, to be informed both about the content of the food and the methods used to produce them. With this, rules on labelling and traceability would also become relevant because effective control could be carried out so that products could be withdrawn from the market if unforeseen damage to consumers' health or the environment should occur.[103] On the opposite view were the members of the European People's Party (EPP).[104] They all argued that labelling should be product-based, instead of process-based. Their argument was that truthful information could be achieved if only products that really contain GMOs were labelled as such, with the need for scientific proof as a prime requirement. Besides, they commented that if labels were extended to products which have come into contact with GMOs, without proving genetic modification in the end product, it would lead to the majority of products in the market to be labelled as containing GMOs.[105] The EPP was supported by some members of the ELDR, who wondered whether they would be helping consumers if labels were process-based.[106]

[101] The first disagreement was related to the Commission proposal that would become Regulation 1830/2003, while the second disagreement was related to the Commission proposal that became Regulation 1829/2003.

[102] Except for the EPP; PSE, ELDR, Greens/EFA, GUE/NGL, UEN, and Independent MEPs were supporting this view.

[103] Comment made by Mr. Torben Lund (PSE, DA) during the debate held on 2 July 2002 in Strasbourg (European Parliament, 2002/a). A similar position was adopted by Mr. Jonas Sjöstedt (GUE/NGL, SV), Mrs. Hiltrud Breyer (Greens, EFA), Mrs. Nicole Thomas-Mauro (NI, FR), Mr. Chris Davies (ELDR, UK), Mrs. Jillian Evans (Greens/EFA, UK), Mr. Guido Sacconi (PSE, IT), Mr. Karl Erik Olsson (ELDR, SV), Mr. Liam Hyland (UEN, IR), Mrs. Danielle Auroi (Greens/EFA, FR), and Mrs. Catherine Stihler (PSE, UK).

[104] EPP members participating in the debate were Mr. Trakatellis (EL), Mrs. Redondo Jiménez (ES), Mrs. Sommer (DE), Mrs. Grossetête (FR), Mrs. Oomen Ruijten (NL), Mr. Purvis (UK), Mrs. Doyle (IR), Mrs. Müller (DE), Mrs. Keppelhoff-Wiechert (DE), Mr. Fiori (IT), Mrs. Flemming (DE), and Mrs. Klass (DE).

[105] Comments made by Mrs. Renate Sommer (EPP – DE, DE) during the debate held on 2 July 2002 in Strasbourg (European Parliament, 2002/a).

[106] Mr. Dirk Steckx (ELDR, NL) views were expressed during the same debate (European Parliament, 2002/a).

With respect to the other disagreement, that of the threshold percentage to be used for labelling, MEPs again expressed differing views. Overall, there were diverse thresholds proposed: 0 percent, 0.1 percent, 0.5 percent, and 1 percent. Except for the EPP, whose MEPs claimed that that setting a limit lower than 1 percent would be a blocking, unrealistic and political value that would have no scientific basis;[107] the rest of the political groups were supportive of a threshold of less than 1 percent.[108] There were various comments on the reasons why they were proposing such diverse range of percentages. For example, 0 percent was considered to be the necessary measure by the strictest MEPs. The argument behind this was that no GMF should be allowed to reach the market;[109] otherwise any type of threshold would turn food legislation on its head.[110] Other MEPs had similar stringent views in that they supported a threshold of 0.1 percent. They based their arguments on comments from the scientific community affirming that such threshold could be observed.[111] The slight majority of MEPs viewed a 0.5 percent as the most adequate threshold,[112] although some of them would have preferred it to be lower.[113]

The position of the two Commissioners involved in the debate was not totally convergent with the EP's views. They agreed that consumers' health, the environment, and freedom of choice should be protected. However, they disagreed in some issues. The Commissioner for Environment made it clear that labelling products manufactured from GM feed would be impossible to implement and would not be in keeping with Community law; although she did so without explaining the reasons behind her position. On threshold values, the Commissioner´s argument was that traces of GMOs in imported food was practically unavoidable due to the increasing cultivation of GM crops around the world. In a more conciliatory stance was the

[107] Comments from Mrs. Sommer (EPP – DE, DE).
[108] The only MEP not belonging to the EPP but supporting the 1 percent threshold was Mr. Paul Lannoye (Greens/EFA).
[109] Mrs. Evans (Greens/EFA, UK), Mrs. Breyer (Greens/EFA, DE), Mrs. Corbey (PSE, NL)
[110] Mrs. Breyer (Greens/EFA, DE).
[111] Mr. Papayannakis (GUE/NGL, EL) and Mrs. Auroi (Greens/EFA, FR).
[112]Rs. Scheele (PSE, AT), Mr. Sterckx (ELDR, NL), Mrs. Thomas-Mauro (NI, FR), Mr. Davies (ELDR, UK), Mr. Olsson (ELDR, SV), Mrs. Stihler, (PSE, UK).
[113] Mr. Lund (PSE, DA), Mr. Sjöstedt (GUE/NGL).

Commissioner for Health and Consumer Protection, who proposed to expand labelling requirements to food ingredients produced from GMO, even when modified DNA was not detectable. However, he wanted to emphasises this was not due to safety reasons. Instead, labelling would serve the purpose of informing consumers and allowing them to exercise choice. On labelling thresholds, he explained that it would not be feasible if the proposal did not provide for tolerance for small traces of GMOs in food. This was because it was technically unavoidable using GMOs during cultivation, harvest, transport and processing. Thus, he supported the 1 percent limit of GM material, which was the threshold established in previous legislation[114] that take into account technological and scientific progress.

Besides the debate where each MEP was able to express his or her position, the committees of involved areas were requested to suggest amendments to the Commission proposal. The CEPHCP suggested including references to the precautionary principle and to the traceability requirements not only for GMF but also for animal products derived from animals fed with GM feed (Amendment 2). On the Commission's position about dispensing with labelling requirements in case of adventitious or technically unavoidable GMO traces, the CEPHCP disagreed, counter-proposing that a GMO threshold should be set below which such products would not have to be labelled (0.5 percent). In addition, the CEPHCP suggested that the threshold values should be revised and adjusted according to scientific, socio-economic, health and environmental analyses of GMO effects in the short, medium, and long terms (Amendment 5). Another aspect was the emphasis on stating that the regulation would provide a framework to ensure giving consumers the right of free and independent choice (Amendment 6). In addition, the CEPHCP proposed to double the time necessary for keeping traceability records for GMOs. This was because the Commission proposed five years, but the CEPHCP considered that ten years should be the absolute minimum timeframe necessary, as health and other

[114] Regulation 49/2000 and Directive 2001/18.

problems may take time to become evident (Amendment 22). An amendment was suggested to encourage member nation-states to draw up guides segregating GMOs and GMF from conventional products, so as to avoid the risks of adventitious or technically unavoidable contamination (Amendment 27).

From the side of the CIETRE there was a claim that traceability and labelling requirements were complex, costly, and could cause trade disputes. Instead, they were proposing 'GM free' labelling since it would provide clear and accurate information to the consumer without adding what they considered 'unjustifiable costs and disputes' on industry (Amendment 2). Furthermore, the CIETRE considered that seeds containing adventitious or technically unavoidable traces of GMOs and highly processed food in which GMOs were not verifiable should be exempt from labelling requirements (Amendments 4 and 5).

The CARD was expressing concerns over the adoption of the Commission's proposal as it could lead to international trade conflicts, since the measures put forward were construed by some external nation-states as barriers to trade. In this regard, they were supportive of incorporating into the proposal CPB provisions, which could minimise the risk of trade conflicts (Amendments 10 and 15). Nevertheless, they pointed out that labelling was no guarantee of safety thereof. Hence, reliable checking and authorisation schemes should be designed. In this regard, they supported a maximum of 0.9 percent threshold of adventitious presence of GMOs in food (Amendment 14).

The legislative resolution adopted by the EP on the first reading[115] (2002/b), ended up including views from the CEPHCP, which was the Committee in charge of drafting the EP's stance. Amendments referred to the need to ensure consumers could receive

[115] OJ C 271 E, 12.11.2003, p.196 – 275. The position was adopted by QMV without the support of the delegations of Denmark, Luxembourg, the Netherlands and the United Kingdom, all of whom had concerns on the application of the regulation and the effectiveness of the measures proposed (EP, 2003).

information, through labels, where GMO products were produced from (Art.4). The precautionary principle would need to be addressed (Art. 1), while thresholds allowance would need to be stated. In addition, keeping records of GMO transactions was suggested to be of ten years (Art. 5).

The amendments proposed by the EP were partially accepted by the Commission, who made the pertinent corrections to an amended proposal for the Regulation. On amendments about labelling, the Commission would rephrase the proposed wording in order to indicate in labels the name of the GMO used, instead of merely stating that the product contained GMO. On the other hand, the Commission rejected the proposal to establish the detailed history and origin of each individual GMO, through a traceability system. In addition, there was a rejection towards including the precautionary principle in the Regulation. The Commissioner for Environment emphasised that such a principle can be applied on the authorisation based on risk assessment, but not on the implementation of traceability and labelling systems.[116] In addition, the Commissioner commented that there were no practical reasons for extending the information to be kept with purposes on traceability from five to ten years.

These and other remarks were sent to the Council, where the Ministers for Environment of the member nation-states agreed to request the Permanent Representatives Committee to follow up on the issue.[117] One of the most contested issues about this was the proposed threshold. An initial compromise by the Danish Presidency, backed by the UK and 7 other member nation-states, set a figure of 1 percent, but it was not accepted by Germany, Austria, Belgium, France, Italy, Luxembourg, and Portugal. All of them recommended limits of between 0.1 percent (Austria) and 0.5% (most of the others). To wrench an agreement out of the 15

[116] Commissioner Wallström pointed at this issue earlier in the process during the debate she held with MEPs when the EP was discussing its position at first reading (European Parliament, 2002/b).
[117] 2457th Council Meeting on the Environment, held in Luxembourg on the 17 October, 2002. Reference: PRES/02/320.

ministers, the Council's Presidency proposed a threshold of 0.9 percent. Such view would end up being supported by the Commission, thus shifting the balance towards this percentage (European Report, 2002).

After this, the Council presented a common position,[118] accepting to label products as proposed by the EP and to ensure consumers' freedom of choice. However, the Council was keen to support the Commission by omitting to phrase 'risk assessment', stating that effective inspection and control would constitute risk assessment measures. Furthermore, the Council supported the proposal to establish an operational traceability system for specific GMOs to be released into the environment. Nonetheless, they rejected the idea of establishing this system for GMOs intended for food, feed or processing where, they would claim, any potential environmental risk was extremely limited. EP's suggestions on extending traceability information from five to ten years also faced strong opposition within the Council, stating that the benefits of the gathered information would be minimal and would have no practical value. Instead, such action would impose an unnecessary burden on traders and inspection authorities.

Following the co-decision procedure and leading to express its opinion through the second reading, the EP held a debate[119] on the amended proposal. In it, there was disbelief by some MEPs with respect to the threshold raised from 0.5 percent that the EP proposed at the first reading, to 0.9 percent proposed by the Council.[120] For other MEPs, there was satisfaction with this threshold.[121] This of course was related to the position that each MEP expressed during the debate of the first reading, as well as to

[118] OJ C 113 E, 13.05.2003, p. 21 – 30.
[119] As with the debate held during the first reading, the EP discussed issues pertaining to proposals both for Regulation 1829/2003 and Regulation 1830/2003 (European Parliament, 2003/c).
[120] Introductory comments made by Mrs. Scheele (PSE, DE), Mr. Lund (PSE, DA) and Mrs. Breyer (Greens/EFA, Mrs. Auroi (Greens/EFA, FR), Mr. Bernié (EDD, FR), and Mrs. Ferreira (PSE, FR).
[121] Mrs. Sommer (EPP – DE, DE) expressed her views at her initial participation in the debate. EPP MEPs agreed with her stance.

the political group they belonged to. Despite these continuing differences, there were requests to vote for a text as closed as possible to the Council´s position.[122]

The resulting report (European Parliament, 2003/a) would consequently become their second reading[123] (EP, 2003/b). In such, the EP proposed that the Commission should report to the EP and the Council on the implementation and effectiveness of rules of traceability and labelling (Amendment 3). Mentioning the precautionary principle to facilitate accurate labelling, as well as comment on providing consumers with the right of free and independent choice, were also included (Amendment 5). Furthermore, the EP reinforced intentions to keep traceability records for ten years, as opposed to the five years proposed by the Commission (Amendment 8), as well as those related to coexistence measures (Amendment 16).

In contrast to the first reading, it should be noted that changes proposed by the EP on the second reading did not attempt to change the substance of the provisions of the Council's common position. This action was pre-emptively made taking into account the experience of the final voting of the first reading; that is, when there were different opinions as to whether to vote for or against certain amendments, which resulted in a weak majority (Trakatellis, 2003).[124] Following this, the Commission gave an opinion on the second reading (2003), stating that the proposal for the regulation would be amended according to the EP's and Council's views. Subsequently, the final legislative act was set up.[125]

Since then, Regulation 1830/2003 appears as the cornerstone for labelling GMOs and GMF, where maize is also included. Nonetheless, despite setting rules on traceability and labelling, persistent divisions among member governments continued in related

[122] Suggestion made by Mr. Trakatellis (EPP – DE, EL), who was the rapporteur drafting the EP's position at first and second readings.
[123] OJ C 074 E, 24.03.2004, p.99 – 611. The position at the second reading was approved by 33 votes to 15, with 0 abstentions (European Parliament, 2003/d).
[124] Antonio Trakatellis, responsible of the Committee on Environment, Public Health, Consumer Policy of the EP at the time, was in charge of drafting the EP´s positions and recommendations related to Regulation 1830/2003. Comments were made in the text of the EP's Recommendation for second reading (2003/a).
[125] OJ L 268, 18.10.2003, p. 24 – 28.

areas, such as the standards to apply to the scientific evaluation of new products. This was the case of NK603 GM maize, which was approved by the Commission in July 2004 after the Council of Environment Ministers failed to reach agreement on the issue: nine members, including four of the new members[126], reportedly voted against, nine in favour, while seven abstained. Other GM crops experienced the same fate.[127]

These features denoted that the new member nation-states would not serve to the biotech industry purposes, as it was initially expected[128] (Inglis, 2003). Instead, the ambivalence towards agricultural biotechnology in 'old' Europe has been shared in the public opinion and governmental positions of EU's new members as well.[129] Hence, support from a majority of member nation-states when it comes to implementation, specifically the adoption of decisions on specific products, has proven difficult. Despite this, the legislation itself, including labelling, has not been contested.

5.2 National views on the implementation of Regulation 1830/2003 and further developments

It was established that Regulation 1830/2003 would request the Commission to submit a report to the Council and to the EP on the implementation and on the

[126] At the beginning of the same year, the EU enlarged to include Eastern Europe, Cyprus and Malta, reaching up to 25 member nation-states.

[127] Also in 2004, the Environment Council reached an impasse with the Commission's proposed approval of GT73 GM rapeseed. Six of the ten new member nation-states (Cyprus, Estonia, Hungary, Malta, Lithuania, and Poland) joined six existing members (Austria, Denmark, Greece, Italy, Luxembourg, and the UK) in voting against the approval. With six countries in favour and the rest abstaining, the final decision was granted to the Commission (Pollack and Shaffer, 2009: 246).

[128] This thought appeared because some the new member states were engaged in small-scale cultivation of GM crops, often without adequeate controls (Inglis, 2003).

[129] Pollack and Shaffer (2009: 247) comment that a 2003 survey of citizens of EU's ten new member nation-states pending accession showed that 68 percent held negative views towards GMOs. On specific cases, they pointed at Hungary adopting some of the strongest anti-GMO policies issuing safeguard bans and adopting strict coexistence laws. Poland was also commented as she adopted a strict law forbidding the cultivation and markeintg of all GMOs. In fact, the Polish position was supported by the Commission with Decision 2006/335: To prohibit the use of 16 GM varieties of maize due to climatic and agricultural factors posing a permanent obstacle to cultivating them.

effectiveness of the rules on traceability and labelling. In this sense, the Commission has drafted not one, but two reports, which were drawn from information obtained from different sources. Authorities from member nation-states, stakeholders from involved sectors, like members and associations of food, feed and seed industries, trading partners, and NGOs[130] provided feedback on other questions about traceability, labelling, exemptions, inspections and control measures.

The first report dates back to 2006.[131] In this, the Commission presented to the Council[132] the results of a questionnaire submitted to different actors. Such has been the relevance of GM maize that one of the listed questions required comments on the control measures taken in a specific case involving the adventitious presence of an unauthorised variety of GM maize in an authorised GM maize variety batch.[133] According to this report, the Commission affirmed that only a limited number of GMF was marketed and GM material was not used in food products to a great extent. This was the result of the industry responding to consumers' demands of non-GM products.[134] In addition, the Commission acknowledged that trading partners were affected by this regulation, which they claimed included onerous and costly mandatory traceability requirements. Specifically, this was attributed to the 0.9 percent threshold for adventitious presence. In particular, the US government was

[130] They are listed in Annex 1 of the COM(2006) 197 final. Among them, Ministries of Agriculture, Food, Environment, Health, Rural Affairs, Trade and Industry, and Economy of different member nation-states, like the UK, Spain, Hungary, Greece, Slovenia, Lithuania, Finland, the Netherlands, Estonia, the Czech Republic, and Belgium responded to the questionnaire. Greenpeace, EuropaBio, BEUC, and the US government also provided feedback.

[131] COM(2006) 197 final.

[132] 2740th Council Meeting on the Environment, Luxembourg 27 June 2006.

[133] This referred to the adventitious presence of Bt10 maize in Bt11 maize batches imported to Europe. Authorities in Austria (Dr. Eva Claudia Lang, Ministry of Health, Family and Youth), the Czech Republic (Mr. Martin Vosta, Ministry of Agriculture; and Mrs. Zuzana Doubkova, Ministry of the Environment) and Denmark (Mrs. Gitte Rasmussen and Mr. Jens Litske Petersen, of the Danish Plant Directorate) affirmed that they had no knowledge about this situation happening in their respective countries. However, they all ensured they were ready to carry out inspections and control measures.

[134] Among stakeholders expressing these views was Mrs. Maryse Hervé, of the Federation of European Food Additives and Food Enzymes Manufacturers, located in Brussels, Belgium. However, she commented that the thresholds for GM material were low; that is, that the analytical detection limits were higher than the acceptable thresholds. This resulted in complications for the food industry to document towards authorities, NGOs, retailers, and consumers that the necessary steps to avoid GMOs have been taken.

listed as urging the Commission to join with trading partners to work towards harmonisation and some form of mutual recognition on the trade of GM products.

The Commission also confirmed that cultivation of GMOs was not practised in the vast majority of member nation-states, although approximately 60.000 hectares of Bt-maize were commercially grown in Spain. In addition, France, Germany, the Czech Republic, and Portugal were also growing other maize varieties on a much smaller scale. The harvested product of this crop was largely used for animal feed, as well as for processing via the starch industry.

Overall, the report concluded that no difficulties were found in implementing the regulation. In fact, requirements of documentation of transactions and labelling of GM varieties seem to have been implemented as a standard business practice. The majority of member nation-states regarded the regulation as having a positive effect on the provision of relevant information and consumer choice. NGOs shared views on these aspects. Nevertheless, national authorities considered that there was not sufficient period of time to gather relevant experience and information concerning the implementation of the regulation. A further issue was that some national authorities were experiencing difficulties in sampling and testing so as to detect the adventitious presence of GMOs.[135] To overcome this, there was a general consensus among national governments to harmonise procedures, either through further legislation, an operating manual, or the exchange of more information and experience. A harmonised format for documentation to assist operators and national authorities was also suggested by some member nation-states.

While information for the report was being gathered, some member nation-states attempted to further toughen their own national policies on GMOs. One case was when Cyprus tried to notify a measure requiring supermarkets to keep GMF on

[135] According to Dr. Takis Antoniou, from the Department of Agriculture in Cyprus, this nation-state experienced this case. He even suggested that labelling should be more detailed and that additional rules should be incorporated.

shelves separate from non-GMF on consumer protections grounds.[136] Another was when Hungary proposed coexistence measures by requiring crops produced in a 'refuge zone'[137] to be labelled as 'plants modified by gene technology,' regardless of how much GM material was present.[138] Nevertheless, these attempts went without success thanks to the Commission's reluctance to support such actions.

The second report was issued in 2008[139] with input submitted by 23 member nation-states as well as EuropaBio and the American Soybean Association. The questionnaire used showed that no new patterns appeared. Retailing industries remained resistant to marketing GMF, while the majority of GM products placed in the market were still destined for animal feed and originated from imported commodities, mainly soybean and maize. There was only one GM crop cultivated: MON810 maize. Spain, Germany, Portugal, the Czech Republic, Slovakia, and France increased their cultivated area from 60.000 hectares to 110.000 hectares in a year.

In detail, feedback provided by stakeholders in both 2006 and 2008 reports showed common patterns among respondents. There was the thought that the 'may contain GMO' labelling was unclear. There was also acceptance towards labelling GM-free products, as it would assist consumers with correct information. Furthermore, the implementation of the 0.9 threshold was considered as having no practical purpose if GMOs were authorised.

[136] This position was rejected by the Commission with Decision 2006/255 as it was inadmissible under Article 95(5) of the EC Treaty (Law, 2008: 95).
[137] A refuge zone is the area within the buffer zone surrounding a cultivation of GM plants cultivated with plants of identical species which are not genetically modified.
[138] The Commission issued Notification 2005/634-637/HU to Hungary, insisting that labelling was not required of products containing traces of GMOs that do not exceed 0.9 percent provided that these traces were adventitious and technically unavoidable.
[139] COM(2008) 560 final. The report was transmitted to the Council and the EP on the 18 September, 2008.

Little knowledge about processes was a common pattern among stakeholders answering the questionnaires provided by the Commission. For example, some respondents[140] were not aware about whether any meal was a mixture or only one kind of GMOs. Other examples referred to operators not obtaining documents with the required GMO data from suppliers,[141] and to some local control services asking for a self declaration from importers, stating that the imported material contained GMOs in case of labels specifying that the product 'may contain' GMOs.[142]

A further type of confusion consisted in the wrong interpretation regarding the threshold. Up to 0.9 percent GMO allowance was falsely interpreted as GMO free or non-GMO at all.[143] In other cases, there were comments that such threshold was too low in practice,[144] or that it was difficult to set it up due to measurement uncertainties between laboratories.[145]

Other cases stated that it was not possible to control traceability and labelling, since hardly any foodstuff in the market contained GMOs. This was the result of operators intentionally avoiding importing and using GMOs in the production of food. However, there was the possibility of over-the-limit threshold GMOs appearing included in imports from third countries that did not label their bulk consignments. In these cases, traceability was difficult to achieve.[146]

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[140] Claim made by Mrs. Aurelia Konanova, of the Central Controlling and Testing Institute for Agriculture, located in Bratislava, Slovakia; and by Mrs. María de Lourdes Camilo, of the Portuguese General Direction for Fiscal Control of Food Quality.

[141] Feedback provided by Dr. Marjeta Recek, of the Ministry of Health, in Ljubljana, Slovenia.

[142] Dr. Theodoros Varzakas, of the Ministry of Development, Hellenic Food Safety Authority, Greece.

[143] Comments made by Dr. Eva Claudia Lang, of the Ministry of Health, Family and Youth, located in Vienna Austria.

[144] In Finland, contamination thresholds of GM material of between 1 and 4 percent have been found. The contamination seems to be technically unavoidable and is proven so on document and raw material checks.

[145] Different contact people from Finland addressed this view: Mrs. Leena Mannonen (Ministry of Trade and Industry), Mrs.Sari Sippola, Mrs. Sanna Viljakainen, Mrs. Tiina Seppälä, and Mr. Erkki Vesanto (Finnish Food Safety Authority Evira), and Anna-Riita Savolainen (Cutoms Laboratory).

[146] These comments are made by different bodies with respect to the case of Finland: the Board of Gene Technology (Mrs. Irma Salovuori), the Ministry of Trade and Industry (Mrs. Leena Mannonen), the National Food Agency (Mrs. Sari Kankaanpää and Dr. Auli Suojanen), the Customs Laboratory (Mrs. Anna-Riitta Savolainen), the Plant Production Inspection Centre (Mrs. Tiina Seppälä), and the National Product Control Agency for Welfare and Health (Mrs. Sari Tähtiharju).

Legal views were also expressed. These exemplified how Regulation 1830/2003 provided parameters to avoid GM crops entering the EU.[147] However, there were other views considering the existence of legal loopholes in its application.[148]

Furthermore, there were proposals on prescribing a compulsory size of characters for the indication appearing on the label,[149] and on establishing a common GMO sign to be added on labels.[150] This action would in turn homogenise the manner in which information could be presented to consumers across the whole EU. Besides, labelling properly would assist in solving problems concerning traceability and enforcement that have been present with products from third countries.[151] Furthermore, there were suggestions that labels should take place if companies did not take adequate precautionary measures in order to avoid contamination.[152]

There were also comments on the need to establish thresholds for the presence of GMOs in seeds. This opinion resulted from the practical difficulties of analysing a mixture of grains, flours, or processed products, as they might contain different ingredients produced from the same raw material, like starch and flour from maize.[153]

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[147] Mrs. Glenda Townsend, from the Department for Environment, Food and Rural Affairs, based in London, UK, commented about a case when authorities in Northern Ireland were alerted to the import of Bt10 maize. The complete consignment was quarantined and returned intact to the supplier. None of the unauthorised material entered the food chain.

[148] In views of Mr. José Ignacio Arranz Recio, who is Executive Director of the Spanish Agency for Food Security, Regulation 1830/2003 does not provide for operators sampling and analysing GMO presence in a given product across the commercialization stages.

[149] Ms. Énikö Zobor, from the Hungarian Ministry of Agriculture and Rural Development.

[150] Dr. Danius Lygis, of the Latvian Ministry of Environment.

[151] Lysanne Van Der Lem, Martin Hennecken, and Ronal Zwart, from the Dutch Ministry of Health, Welfare and Sport, the Dutch Ministry of Agriculture, Nature and Food Quality, and the Dutch Ministry of Housing, Spatial Planning and the Environment, respectively.

[152] Views from Mr. Gorm Lunn, from the Danish Plant Directorate, in the Ministry of Food, Agriculture and Fisheries.

[153] Issues pertaining the labelling of seeds are addressed shortly.

In the broad sense, the reports showed that the experience of GMOs in the food sector remained modest, mainly due to the limited number of GMF and derived products being marketed in the EU. The industrial sector also continued to argue that Regulation 1830/2003 introduced excessive administrative burdens and that labelling thresholds were arbitrary choices. However, the Commission considered that the requirements for labelling aimed at delivering free choice for traders and consumers, and should not be considered as an obstacle to marketing authorised GM products.

5.2.1. Further developments on GMF labelling rules

Once Regulation 1830/2003 set up the labelling rules for food produced from GMOs, legislation on seeds labelling have become the next step. Since 2004, the Commission has attempted to deal with this issue. However, deep divisions from within this institution have not allowed new plans to come forward. At that time, the Commissioner for Environment[154] and the Commissioner for Agriculture[155] were proposing to require maize seeds to be labelled in cases where 0.3 percent or more of their DNA was GM. This proposal would exempt labels when traces were technically unavoidable. But the Commissioner for Health and Consumer Protection, the Commissioner for Trade and the Commissioner for Science and Research strongly opposed the 0.3 percent threshold requirement. They said this was too costly for the seed industry (European Voice, 2004). The result was that talks stalled and no proposal was developed.

The EP retook the issue in 2006. It suggested establishing a labelling approach in the seed legislation as regards to GM adventitious presence. This was considered to be in line with the existing seed legislation, which foresees no labelling of presence of other varieties present below a certain level in a given variety sold to the farmer (European Parliament, 2006). In this case, seeds thresholds should be the same

[154] Mrs. Margot Wallström.
[155] Mr. Franz Fischler.

threshold as food labelling threshold. Following this pattern, any seed lot containing GM seeds authorized for the cultivation in the EU would have to be labelled as containing GMOs. The Council of Ministers on Environment supported the EP's views and, by 2008, was welcoming the completion of the Commission impact studies on the establishment of seed thresholds, which should be set at the lowest practicable, proportionate and functional levels for all economic operators.[156] In addition, comments reinforcing the need to ensure freedom of choice to producers and consumers of conventional, organic and GM products were made. Despite the Commission not being able to provide a timeframe to finalise its impact assessment,[157] there have been comments that the Commission is considering a scale that stretches from 0.1 percent up to 0.9 percent adventitious presence.[158] That is, the same threshold used for labelled GM food and feed would be used for GM seed.

Besides this, the Council of Ministers has encouraged the Commission to further improve harmonisation of member nation-states' assessment practices. The basis of this harmonisation would be established by the findings of a report with information provided by member nation-states by June 2010 (Council of the European Union, 2008). In such, the involvement of national authorities, to which environmental risk assessment is delegated, should be clearly pointed out. This should be made because member nation-states' position varies; some of them consistently follow the advice of their own scientific bodies, which sometimes diverge from the EFSA assessments. In turn, EFSA risk assessment procedures are perceived by national governments as non-transparent, uncooperative, closed to input from EU member governments, and biased in favour of the biotech industry. Furthermore, most member nation-states appear to vote consistently for or against approval of any GMO, thus reducing any chance for their national representatives to change their national positions on the basis of information presented in the Council (Pollack and Shaffer, 2009: 248 – 51). Austria, Italy, Luxembourg, Greece and Hungary exemplify this regard as they

[156] 5th December, 2008, in Brussels. Published as *Conclusions*, 16882/08, AGRILEG 223, ENV 961.
[157] The Commission confirms that it is currently carrying out an impact assessment for the establishment of labelling thresholds for seeds, which will form the basis for a forthcoming Commission legislative text (European Commission, 2009).
[158] This information was retrieved from Agra Europe Weekly, published on 21 August, 2009.

remain firm opponents of GMF by taking critical positions about any legal development on the matter. Nevertheless, other member nation-states change their approaches towards GMF according to the political context in which they are found at a given moment and to the political party in power. Ireland experienced a radical shift in the Council of Ministers after the 2007 elections; when the Green Party leader became the Minister for Environment and publicly backed Austria's anti-GMO position and looked for a GM-free Ireland. France has also experimented swifts in approach towards GMOs.[159] While voting against new approvals, it has also increased four-fold cultivation of GM maize. At the time of its EU Presidency, France issued a paper proposing, among others, labelling thresholds for GM seeds.

Parallel to developments leading to legislation on labelling for GM food, feed and, potentially, seed; there have been features aimed at conferring powers to the Commission. In Regulation 298/2008,[160] which amends Regulation 1829/2003, certain explanations about these new powers are specified. The Commission is now able to define whether a type of food or feed falls within the scope of Regulation 1829/2003, to adopt measures on labelling and information requirements incumbent on operators, and to lower the thresholds on labelling of adventitious and technically unavoidable GMOs in food and feed.

It is important to remark that Regulation 298/2008 passed without any problems after a first reading from the EP, which was the same text that the Council adopted. Thus, as no issues were raised in reaching agreement regarding this legislation, it is observed that EU institutions have allowed the Commission to increase its participation in decision-making in this sector.

[159] A brief summary about France's context is provided by Pollack and Shaffer (2009: 257 – 8).
[160] OJ L 97, 09.04.2008, p. 64 – 66.

There are legislation proposals worth mentioning since they corroborate that a constant approach towards thresholds and labels is happening in the EU. They refer to allowances of a certain GMO threshold on organic products. This aspect became controversial as the high majority of MEPs involved in the respective debate[161] were outraged at the possibility of allowing a 0.9 percent threshold of GMOs in organic products. With this position, the Commissioner[162] drafting the proposal agreed to amend it. This issue was solved with Regulation 834/2007[163] by establishing that if a product requires labelling due to the admixture of GMOs, it cannot be marketed as an organic product. However, one issue should be pointed out. The Commission proposal intended to increase participation of GM crops in the food chain, regardless of the context in which food production takes place.

5.3 Observations

The legislative regulatory framework for labelling GM maize has developed out of different sources. From directives detailing the rules for general food labelling, to regulations specifically concerned with GM maize labelling. In addition, the present law on GMF labelling has been linked to related topics, such as the release into the environment, consumers' choice, placing on the market, and traceability. The relationship that labelling has attained with these areas demonstrates that it has been deeply intertwined with the manner in which legislation on GMF has evolved. Nonetheless, such a relationship was not as strong at the beginning as it is now. By observing the development of the regulatory framework, it is noticeable that the establishment of labels at EU level has been gradual. It has related to concerns from

[161] Debate held on Wednesday, 28 March 2007. Among MEPs disagreeing with a GMO threshold in organic products were Mrs. Kathy Sinnot (NI, IRL), Mrs. Marie-Hélène Aubert (Greens-EFA, FR), Mr. Roberto Musacchio (GUE(NGL, IT), Mrs. Agnes Schierhuber (EPP-DE, DE), Mrs. Roberta Angelilli (UEN, IT), Mr. Friedich-Wilhem Graefe zu Baringdorf (Greens-EFA, DE), Mr. Vincenzo Aita (GUE/NGL, IT), Mr. Marc Tarabella (PSE, FR), Mrs. Bernadette Bourzai (PSE, FR), and Mr. Gábor Harangozó (PSE, HU).
[162] Mrs. Mariann Fischer Boel, Commissioner for Agriculture and Rural Development.
[163] OJ L 189, 20.07.2007, p. 01 – 23.

the citizenry and governments of some nation-states, which developed from a series of problems that they experienced. The resulting consumers' rejection and governments' refusal to grant easy access to GMOs signified the establishment of compulsory labels with the purpose to strengthen consumers' right to be informed on the ingredients and origins of the products they buy. With time, and in order to avoid potential obstacles to trade in this area; EU bodies decided to toughen the legislative framework on labels despite opposition of certain groups. In this regard, environment and consumer friendly governmental instances have driven the manner in which legislation has been built. Examples of these are observable. To begin with, national laws advocating the implementation of labels have influenced the context in which regional developments have taken place. Another example refers to the EP's position on the first and second readings that led to the creation of Regulation 1830/2003. Such position was the one expressed by the Committee on the Environment, Public Health and Consumer Policy (CEPHCP). A second example refers to the Commission's reports to the Council and the EP on two different updates about the implementation of Regulation 1830/2003, which was issued by the DG on Environment. Nevertheless, these examples do not mean that the legislative framework has been one sided, or biased. The legislative procedure that led to the present regulation has entailed discussions and debates between opposing groups within the EP and outside it, also between governments of member nation-states with opposed views. Besides stating that regulations on GMF labelling have been developed in a consumer and environment friendly direction, the implementation of GMO legislation aimed at improving scientific consistency and transparency for decisions on GMOs and at developing consensus between all interested parties is observable.

CHAPTER 6: GM MAIZE LABELLING POLICY IN THE REGION OF THE NORTH AMERICAN FREE TRADE AGREEMENT

This chapter presents developments carried out at both national and regional levels. This is the result of policies on GMF and its respective labelling being treated in a slightly different manner among the three nation-states. Nevertheless, certain agreements have been reached within a regional framework that has evolved intertwined with the maturity of the NAFTA.

6.1. The American perspective

The American framework for regulating biotechnology was established in 1986. Known as the Coordinated Framework for the Regulation of Biotechnology, its main argument was the principle of 'the substantial equivalence of products developed using biotechnology and those produced by traditional means'. Thus, GMF was not considered different from conventional food (Young, 2003: 462). This in turn has implied that there is no need for special regulatory mechanisms.

By 1992, the USFDA issued a 'Statement of Policy for Foods Derived from New Plant Varieties'[164] in 1992. It was stated that the aim was to ensure that relevant scientific, safety, and regulatory issues were resolved prior to the introduction of GM products into the market. Emphasis was placed on the type of scientific information necessary to satisfy the USFDA requirements. In addition, comments on social or environmental concerns were contemplated in a guideline allowing the development of performance trials on new GM crop varieties before introducing them into

[164] Published in the Federal Register, 29 May, 1992. Vol. 57, No. 104.

agricultural practice. A major feature of the Statement was that it considered GMF and conventional foods as equals as far as an assessment of safety according to their characteristics was concerned, but not equal in terms of new methods employed. In this regard, scientific issues relevant to public health such as unexpected effects, nutrients, new substances, antibiotic resistance and possible allergic reactions, were addressed. It was in the latter that labelling was recommended because GMF could contain potential allergens, of which consumers would need to be informed. Another reason for labelling was established in cases where new GMF differed significantly from their traditional counterparts to the point that the traditional name could no longer be applied. Thus, the USFDA established that labelling was required for the product, and not the process.

> [US]FDA believes that the new techniques are extensions at the molecular level of traditional methods and will be used to achieve the same goals as pursued with traditional plant breeding (USFDA, 1992: 22991).

At the time, it was clearly stated that there was no intention of creating a new regulatory obligation for GM crop producers. The 1992 Statement was brought about to describe safety and nutritional concerns, rather than performance characteristics for which the GM crops had been developed.

This type of assessment excluded consumer opinions. By July 1999, the USDA realised that consumers were showing resistance and great cynicism toward biotechnology.[165] Therefore, consumer acceptance should be of importance. For this, a role could exist for information labelling, but this labelling should not undermine

[165] Comments made by Mr. Dan Glickman (1999), who was the US Secretary of Agriculture at the time.

trade and this 'promising new technology'.[166] This issue would be overcome by focusing on strong public education showing the benefits of GM products, where responsibility of the private industry would not be at its own expense. American consumers had trust and confidence in food safety efforts of the USDA, the USFDA, and the EPA because these agencies were considered competent and independent from the industries they were regulating (Glickman, 1999).

In November of the same year, the USFDA conducted three public hearings in which the results showed very limited awareness and understanding of GMF. Nonetheless, some of the public were not convinced that the USFDA's regulatory approach was adequate, while opinion was divided over whether GMF should be labelled (Young, 2003: 471). Subsequently, in 2000 the USFDA conducted a series of consumer 'focus group' meetings to help better understand how American consumers thought about this issue. The final report from these groups showed that there was very limited consumer knowledge, and that this was related to the fact that some of them were aware that Europe did not want to import this type of food, although most of these consumers were, in fact, uncertain about the reason behind the decision (USFDA, 2000/a). There was also concern about unknown long term health effects and the realisation that these were not possible to prove under the current scientific research being undertaken:

> Some participants complained consumers [were] used as "guinea pigs" and many were doubtful that government regulators and scientists have the ability to counteract the powerful profit motives of industry and producers (USFDA, 2000/a).

However, according to USFDA's own findings, the main issue at stake was the linguistic evaluation of terms because of the lack of knowledge on the part of consumers. The possibility of using words such as 'genetically engineered',

[166] Ibid.

'genetically modified', or 'bioengineered' was considered by USFDA as inappropriate since most people were unfamiliar with the terminology, and that such labelling would imply that GMF were different or contained different organisms. In fact, according to USFDA, people thought these labels were inaccurate and unappealing. Irrespective of this, USFDA acknowledged that consumers preferred GMF to be labelled so they could tell whether a given food was a product of the new technology. They wanted labels to provide information about how the food was produced, rather than the compositional effect of the process on food.

The study conducted by USFDA showed that consumer groups wanted to be informed through labels not just on any specific health and safety concerns about the product, but also on concerns about unknown long-term consequences. This would imply there was the right to choose between GMF and non-GMF. However, there were other consumers concerned about the practicality of such labelling, questioning whether it might be too wordy or too complicated for the average consumer to understand. The information obtained through the consumer focus groups revealed very strongly held but divergent views as to whether or not GMF should be required to bear special labelling. It seemed that consumers who participated in these groups were divided about the manner in which labelling should be approached. Irrespective of these divergences, consumers were mainly disturbed by the lack of public information and public input. Some went even further by claiming that this was 'evidence of a conspiracy to keep consumers in the dark, that is, the rationale for not informing the public must be that there is something to hide' (USFDA, 2000/a).

The findings of the 2000 Report on consumer focus groups led to the creation of the 'Guidance for Industry,'[167] which represented USFDA's views proposing voluntary labelling indicating whether foods were genetically modified or not. The argument

[167] Link: http://www.cfsan.fda.gov/~dms/biolabgu.html. Retrieved on 26 November 2006.

that prevailed was that labelling could be misleading if it failed to reveal facts that were stated on labels, and that concerns about labelling were mere expressions of unease about the unknown (USFDA, 2001/a). In addition, labelling could be required only when labels contained information about consequences that may result from the use of food. About this, there was the perception that there were institutional impediments to change labelling requirements (Young, 2003: 472). In fact, there also seemed to be constitutional obstacles to require labelling of GMF.[168]

Subsequently, USFDA reaffirmed its decision not to require special labelling of GMF; instead, labelling requirements would be those applying to all foods. But if producers wished to voluntarily label their foods to inform consumers and respond to their wishes, then they should follow the Guidance for Industry guidelines to help ensure that labelling would be truthful and not misleading.

A further element recognised in the Guidance for Industry was the possibility of labelling the other way round; that is, to use the term 'GMO-free' to indicate an absence of bioengineering processes. However, USFDA claimed that this would be inaccurate since it did not have information with which to establish a threshold level of GM ingredients for using such a definitive label. The conclusion was that GM-free labels could be misleading as they would imply that this type of food was superior to foods not labelled as such (USFDA, 2001/b).

Besides this, there have been law proposals introduced in the House of Representatives and in the Senate during 1999 and 2000, calling for mandatory labelling and instructing the USFDA 'to treat genetic modification as a food additive'

[168] There is a legal precedent from the US Court of Appeal for the Second Circuit, which states that labelling products derived from dairy cows treated with a synthetic growth hormone used to increase milk production, as required by a Vermont Law, was not constitutional. The reason was that such action was perceived as violating the US Constitution's First Amendment and Commerce Clause (US Court of Appeals, Second Circuit, 1996).

(Young, 2003: 473). However, politics were considered as the reason for this not happening.[169]

The American labelling approach to GMOs and GMF has been that of trying to avoid confusing consumers with wording that may result too complex for them to understand, or that may deviate their thoughts towards the perception that GMOs and GMF can pose substantial threats to human health and the environment.

This has allowed the elimination of potential labels, although producers can do otherwise if they feel advantages could be gained for their product by giving consumers information. While these aspects are generalised and ostensibly apply to GMOs and GMF, it is understood that they are applicable to GM maize, as there is no specificity about the crop in the Statement, the Report, or in the Guidance for Industry.

The labelling approach in the USA has developed from features within the country. However, there have been external aspects that have influenced the manner in which biotechnology developments are dealt with. This is the case of the reduced number of GM crops approved in the EU. American agricultural producers have attempted to alleviate this policy by two means. The first one is by keeping non-EU approved GM varieties separate from the rest of the crops. About this, Young (2003: 468) comments that American maize refiners have been establishing identity-preservation systems that enable them to reassure their European customers that they use only EU-approved maize varieties. Also, there is a program that assists maize producers by informing them on the selection of GM maize varieties approved for EU export,[170] so they can optimize resources in finding the best option for the sale of their products.

[169] Young (2003: 473) comments that the Democrats sponsoring these legislative initiatives would not have an impact on the Bush's administration hostile attitude towards regulation.

[170] Program 'know where to go', developed by the National Corn Growers Association (NCGA/2010/a). In case a given maize variety is not authorized for EU sale, the NCGA assists in allocating in one of three markets. Those markets could be their own livestock rations, domestic livestock feeding channels, or other customers accepting grain not yet approved in the EU (the section of this program is called 'know where to go'.

The second aspect refers to maize producers giving all consumers what the most demanding accept (Young, 2003: 468). In this sense, the National Corn Growers Association (NCGA) has affirmed its support for the commercial release of GM maize only when it has received full approval by American and Japanese regulatory agencies. Once approved, the product registrant is 'aggressively pursuing approval in every country or bloc that requires approval prior to importation' (NCGA, 2010/b). Furthermore, the NCGA is requiring the seed industry to label and identify the approval status of all events through a communications program targeting customers, while voluntary labelling is supported for indicating whether food have been developed using biotechnology.

Besides maize producers, certain major food companies[171] also communicated that their products would be GM free due to American consumers' concerns and pressure from activist groups (Pollack and Shaffer, 2001: 168). These concerns took form when the main US consumer organisations joined with their European counterparts on a Trans Atlantic Consumer Dialogue (TACD).[172] After the TACD was created, it put mandatory labelling of GMF throughout the entire production, processing and distribution chain, at the top of its list of recommendations.[173] Soon afterwards, some agricultural producers started to look for regulatory changes. Young (2003: 478 – 9) comments that some producers were intending to limit their exposure to conflicting approvals, others were aiming at bolstering consumer confidence at home and abroad, while others began to support mandatory premarket notifications to the USFDA. However, the issue of labelling remained the same. That is, support continued to be on voluntary labelling. In fact, most producers have remained opposed or silent on the issue. This reluctance to establish labels develops from the increase in marketing costs of advertising and promoting GMOs and GMF. Besides, such reluctance may

[171] These included McDonald's, Gerber, Heinz, Unilever, Nestlé, Seagram, Frito Lay, and *Grupo Maseca* (Mexico's largest tortilla maker).
[172] The TACD was established in September 1998. It is a forum of US and EU consumer organisations that develops and agrees on joint consumer policy recommendations to the US government and the EU to promote consumer interest in EU and US policy making (TACD, 2010).
[173] This took place at a meeting in Brussels on the 23-24 April, 1999 (TACD, 1999).

relate to a potential backfiring strategy. That is, consumers may stop buying these products after being aware of the origin of these products.

6.2 The Canadian perspective

Canada has developed an approach similar to that of the USA by giving GMF equal treatment with conventional products, and it has formulated a series of guidelines on the matter, which were drawn up after consultations with a wide range of interested agencies. According to the Canadian Food Inspection Agency (CFIA), the information gathered in these consultations reflected a general consensus which supported a set of requirements for mandatory labelling when there were health and safety concerns. Where this was not the case, voluntary positive and negative labelling[174] could be allowed only if the claims were factual and not misleading. Thus it was implied that consumer choice could be accommodated through Canadian legislation (CFIA, 2006).

The first consultation took place in November 1993 at a workshop on 'Regulating Agricultural Products of Biotechnology', in which a range of viewpoints were expressed. Consensus was reached about the need to label GM products based on health and safety grounds, although it was realised that further consultation among interested parties was necessary. Consequently, a year later, all governmental departments responsible for the labelling of food in Canada convened a technical workshop on the 'Labelling of Novel Foods Derived through Genetic Engineering', in which producers, consumer groups, ENGOs, universities, and provincial governments also participated. By December 1995, a communiqué on 'Labelling of Novel Foods Derived through Genetic Engineering'[175] was published. Its purpose

[174] Positive and negative labelling refer to statements confirming or denying the GM status.
[175] Link: www.inspection.gc.ca/english/sci/biotech/tech/consulte.shtml. Retrieved on 16 March 2007.

was to make known the guidelines based on public consultations. The rationale of labels emphasised that the provision of information was to protect consumers and to allow them to choose between products. The responsibility for the regulation of labels was accepted by different governmental bodies according to safety and non-safety labelling policies and their requirements. The former were to be regulated by Health Canada, while the latter were to be established by Agriculture and Agri-Food Canada (AAFC). Subsequently, labelling for health and safety purposes, as in the case of the presence of allergens and when a significant change in food composition is detectable, became mandatory.

Consumers' right to information was also specified, but there were disagreements as to the extent to which information should be provided. Some concerned parties asserted that only full disclosure of all ingredients on labels, GM or not, would satisfy the right to know. Opponents, however, observed that providing such information on the label could be highly impractical (CFIA, 1995). They claimed that labels should be generally reserved for identifying health and safety concerns, and that there should be other means to provide non-safety additional information (i.e. internet, mass media, and centralised databases). CFIA argued that labelling the GM status of a product would eventually result in the majority of food labels bearing a statement about the GM origins of all ingredients, which in turn could result in health and safety information being overlooked.

Voluntary labelling was briefly mentioned as an option and it was deemed acceptable if it was truthful and if it focused only on giving information about the process used to obtain changes in food products. In addition, all these proposed mandatory and voluntary guidelines would need to conform to international standards, such as the Codex Alimentarius, and would also be required to achieve consistency with Canada's major trading partners.

In 1998, another conference addressed questions of consumer interpretation and understanding of voluntary labels as they could apply to GMF. The results found that

consumers indeed wanted to be informed about the origins of the products they acquire. However, it was observable that the wording of labelling phrases considerably affected the level of understanding and that, subsequently, consumers tended to react negatively to unknown scientific terminology. It was assumed, therefore, that it was better to avoid words such as 'genetically' or 'biotechnology', because participant consumers saw no reason for the provision of this type of information as it offered only ambiguous information. It was further recognised that there were implications in competition terms since labelling by a producer was viewed as 'putting down competitors' (as in the case of stating the lack of GMOs) or as being 'incompetent' for not knowing their own products better (as in the case of labelling through the 'may contain' phrase). Consequently, decisions taken on voluntary labelling seemed to obey market-based developments, where it was observed that consumers did not care about labels unless there were dramatic changes in a product's features. It was also noted that attempts to satisfy consumer choice could be granted by voluntary labelling and in any case, the level of awareness about the existence and implications of GMF was low. The general conclusion was that labelling was seen as important but not as a 'panacea' solution (CFIA, 1999), and that Canadians believed their government exercised control over this area in a fairly strict fashion. In fact, Canada's market approval procedures of GMF were considered superior to most others in the world (CFIA, 1999).

All the information gathered from these series of consultations led to the development, in 2004, of a 'National Standard on Voluntary Labelling and Advertising of Food'; that is to say, labelling guidelines for foods that were or were not, products of genetic engineering.[176] This was the achievement of discussions undertaken by a committee formed by representatives of diverse interest groups such as biotechnology companies, national and regional agricultural producers

[176] Published by the Canadian General Standards Board (CGSB).

associations, governmental ministries and agencies, consumer groups, health associations, academics and universities.

Thus, a regulatory framework for food and an environmental safety assessment of GMF was officially put in place, in which it was reiterated that there was the need for mandatory labelling for GMF with substantial nutritional and/or compositional changes. According to the Canadian General Standards Board (CGSB),[177] this national standard was aimed at providing consumer choice and information, although there were views that regarded this action as a design to divert attention away from GM regulators on the labelling issue (Andrée, 2007: 56). Then, the outcome was to focus on voluntary labelling. However, producers would not be able to voluntarily label their products until an acceptable verification process, which was underway at the time, was fully developed. The National Standard on voluntary labelling provided for an adventitious presence of less than 5 percent when claiming that food was not genetically engineered. This threshold was established because it was the lowest percentage that was achievable and verifiable.[178] Nevertheless, it was stated that foods derived from GM crops, like maize, might contain virtually undetectable amounts of GM material (CGSB, 2004); consequently it could be difficult to conform to the specified threshold level and, subsequently, to label this type of food.

Once voluntarily labelling of GMF became allowable, it would need to comply with additional required information that should be related to the method of producing genetic change, give details of why a particular method was used, and it would also have to provide further information and explanatory statements on GM ingredients. Furthermore, a verification process was created, which relied on the provision of detailed descriptions of the management system used to maintain the identity of the GM ingredient. Testing methods would have to be chosen for verification purposes, complicating even further the wish to voluntarily label GMF.

[177] Andrée (2007:56) comments that the CGSB committee was the result of a joint industry-government response, which aimed at developing a standard for food labelling.
[178] CAN/CGSB-32.315-2004, Appendix C.

6.3 The Mexican perspective

The inclusion of maize in the NAFTA is the result of many critical situations that Mexico was experiencing prior to signing the agreement. Due to the debt crisis of 1982, the Mexican government began a liberalisation strategy in an attempt to get mostly needed new sources of capital and investment. Crucial to this was reaching agreements with the IMF, the USA, and with the WTO, encouraging exports through plants on the US border, and amending investment rules (O'Brien, 1995: 707). All these went through jointly with a series of measures to liberalise Mexico's foreign economic relations. From then on, an agenda aimed at a series of liberalisations in Mexico was set up. As provided by the USA-Mexico Framework Agreement,[179] an acceleration of import liberalisation took place. In addition, the publication of Mexico's Foreign Investment Regulations,[180] allowing majority foreign ownership of companies, resulted in foreign capital moving to Mexico at a rapid rate in the form of loans, rather than direct investment. Under these circumstances it was that the Mexican government started to seek a free trade deal with the USA and Canada. In fact, Mexicans were well aware of the accomplishments of the Canada-USA Free Trade Agreement of 1989 and wanted to emulate a similar success. Nevertheless, the primary Mexican concern in NAFTA negotiations was not on trade matters; instead it was to create an institutional structure that would bolster investor confidence.

> Mexico desperately needed the return of capital to its country to maintain economic growth. Investors had to be assured that if they bought Mexican bonds, the peso [Mexican currency] would not be devalued and that if they bought Mexican assets, they would not lose value. NAFTA would cement the liberalisation process, reassuring investors that any future government would find it difficult to return to protectionist policies (O'Brien, 1995: 710).

[179] The USA-Mexico Framework Agreement was signed in November 1987.
[180] Published on 16 May 1989.

Thus, it looked like gaining access to the American market would foster investment in Mexico. At the end, investment was included in the NAFTA under the heading of Chapter 11.

All these liberal ideas and strategies were proposed by US-educated technocrats in the bureaucracy, which meant that the adoption of liberal economic principles was primarily state-led. This thus meant low participation of civil society in this type of decisions. Nevertheless, the society was aware of the proposals for a NAFTA, and they were initially resistant to this deal due, mainly, to the 1982 crisis and disenchantment on politicians. But it was the selling of the NAFTA as a chance to join the 'first world' when the agreement found popular resonance. This thus left the Mexican government with room to manoeuvre the free trade deal. However, civil society was not aware of the whole range of sectors to be included in the agreement. Sensitive crops, like maize, were negotiated carefully, as expressed below, while biotechnology or GMF were not even referred to in the agreement, perhaps as the implicit result of the consideration of equivalence between GMF and non-GMF as agreed under WTO rules, or because GM crops were not much of an issue in the early 1990s.

Prior to the NAFTA, policies on maize were dealt with carefully due to its cultural and social inferences. As this crop is an essential staple food for the country, on which the low-income stratum depends heavily,[181] the government was increasing its production for local consumption since 1970. In this regard, the commercialisation of maize was considered a strategic activity for the government: it embraced a network

[181] Prior to the drafting of the NAFTA, around 75 percent of the population was getting a large part of its caloric and nutritional needs from maize (Guerrero Andrade, 2005: 20). Besides which, roughly a third of the population lived in rural areas, from which up to 60 percent of workers were engaged in agriculture, and maize production accounted for the largest workforce (Levy and Van Wijnbergen, 1992: 15 – 17).

of different important social groups that had numerous members[182] (Guerrero Andrade, 2005: 33). The government adopted a policy directed to reduce and maintain low maize prices by increasing subsidies as a response to free market activities boosting prices worldwide (Brambila-Paz, 1987: 78). In order to achieve this, governmental agencies like CONASUPO, had to control an important share of the maize market.[183] This became extremely costly for the government, which argued that subsidisation was reaching not just the needy classes, but society as a whole. To complicate matters, Mexico was having difficulties paying its external debt and could no longer afford to allocate huge consumer subsidies to maize, particularly in an era of globalisation that was seeking liberalisation in a number of areas.[184] To cope with the situation, a series of short-term policies were implemented,[185] and these were followed until NAFTA negotiations began.

The subsequent adoption of a similar regulatory framework to that of North American trading partners, in terms of maize liberalisation, would result in a change in policy direction. Such a move would not pose a problem for Mexico, though, as the USA was selling 72 percent of its maize worldwide and could easily meet Mexican demands (Appendini, 2001: 218).

In spite of the vast economic disparity between Mexico and the United States and the relative size of their productive areas, contrary to what many people thought, Mexico did not have to take a subordinate role to the United States when negotiating terms.

[182] Guerrero Andrade lists agricultural peasants, farmers with deficit production, and urban workers as those whose alimentation is based on maize. Around 15 to 18 million Mexicans depend on maize production for their sustenance (2005: 33).
[183] For example, CONASUPO increased its share in 1970 from 15 to 33 percent, reaching 50 percent in 1980 (Brambila-Paz, 1987: 80, 211).
[184] At the time, the state-regulated maize market was co-existing with other agricultural crops already liberalised (Guerrero Andrade, 2005: 34).
[185] Examples are subsidised water for maize producers, guaranteed prices, subsidised credits, and the creation of a replacement for the traditional maize input.

Indeed, these inequalities were to favour Mexico.[186] However, the agricultural chapter proved to be one of the most polemic aspects with which to deal because the American agricultural sector was characterised by transnational companies producing big-scale processed food, as opposed to the Mexican sector, in which small-scale farmers were the main feature. This would presuppose that Mexico would be eager to protect its agricultural status quo. However, the Mexican government praised otherwise with the purpose to provide arguments to the American Congress on its viability by giving concessions to the American agricultural private sector. Such action was seen as an incentive to discourage the imposition of politically unacceptable conditions on Mexico (Lasana Blanco, 2003: 63 – 64). Despite Mexican eagerness to include maize in NAFTA,[187] the USA was expressing concerns about the issue due to potential social and political consequences. One of the worries of the American drafters was that their Congress would not accept inclusion since this might result in a reduction in the wages of American workers if a cheap Mexican labour force were to illegally migrate to the USA and take up employment (Weintraub, 1992: 46). The initial belief had been that the FTA would guarantee Mexico's economic growth while reducing illegal migration (White House, 1992). In this context, Mexican negotiators were questioned as to their intentions and their answer was that Mexican farmers would need to cultivate more profitable products[188] (Von Bertrab, 1997: 55). So the decision to include maize trade in the agreements was taken independently by Mexico. Trade barriers associated with maize would be completely eliminated, although grain would be dealt with in the category of 'sensible products'.[189] On a reciprocal basis, Mexico would request access to vegetables, fruits, and, mainly, sugar. This in turn would necessitate negotiations for a wider

[186] Indeed, Mexico was 'forced' to cede in many aspects of the agreement. However, this was not the case with maize, as has been explained.
[187] It is noticeable that the Mexican officials who pushed for the inclusion of maize and dealt with the agricultural chapter of the NAFTA were not officials of the Ministry of Agriculture, but came from the Ministry of Commerce (Lasana Blanco, 203: 67).
[188] The liberalisation of maize crops in Mexico started before NAFTA negotiations took place. It dates back to the late 1980s, and was aimed at reducing price subsidisation of the crop.
[189] The NAFTA has gradually eliminated tariffs over different periods of time: immediately it came into force, and then in periods of five, ten, and fourteen years. Agriculture is included in the latter period.

agricultural agreement, considered risky by the American delegation since it would go against the interests of influential American farmers lobbying the American Congress.

The inclusion of maize in NAFTA allowed the then Mexican government to reduce the political costs of liberalising the agricultural sector (Domínguez, 1998: 30). By arguing that it was a sacrifice imposed from the outside but that it would return benefits in medium and long terms, the government would gain greater manoeuvrability when reforming broader agricultural policies.[190] However, there was dissent from within the Mexican negotiating team. The argument was that linking maize to NAFTA would not just increase food dependency on the USA, but would also reduce governmental control over transnational companies controlling grain markets which were starting to operate in the country. In spite of these disagreements within the government, the final position was that maize was soon going to be included in the agreement and that full advantage should be taken out of it. (Lasana Blanco, 2003: 86, 89).

With the inclusion of maize in NAFTA, control over maize imports was transferred from the governmental sphere to a reduced number of companies that had nexuses with the administration of the time.[191] Some of them were working towards a transnational environment with biotechnology as its main purpose, and were also acquiring Mexican-owned factories producing maize flour.[192] This would mean that imported maize used to produce maize flour could contain GM maize. However, as

[190] The reforms comprised the reduction and cancellation of subsidies, the modification to the legal basis of land ownership and property, the approximation of national prices with international prices, credit selection and privatisation (Lasana Blanco, 2003: 79).

[191] Some of the companies that were importing maize were transnational like Anderson Clayton, Continental, Pilgrim's Pride, Purina, and Cargill. Subsequently (1998), the latter formed an association with Monsanto.

[192] For example, the company Archer Daniels Midland (ADM), which has links with Novartis, acquired 22 per cent of *Maseca* shares in 1994, *Maseca* being one of the two main maize flour producers in the country (Lasana Blanco, 2003: 96).

GM products were considered equal with others in the USA, there was no label to identify when, where, and how GM maize was being introduced into the country.

The Mexican government argued that maize needed to be liberalised due to its inefficient production in Mexico compared with that of the USA[193] and because of the comparative advantages Mexico had when cultivating other crops. At the same time, there was a counter-argument stating that maize imports were the result of a financial arrangement rather than as a strategy to level down maize prices or to counter reduced production[194] (De Ita, 2007). If the latter was the real reason behind opening up the sector, then it would be possible to speak of a business-influenced agricultural agreement instead of a competitive approach as used in the government rhetoric, stating, effectively, that competitiveness would be encouraged only for big companies working with industrialised maize. This was because the governmental elite gave priority to the interests of national and foreign companies, which would benefit from secured access to American corn, rather than to the interests of small farmers (Nadal, 2004: 156). However, as Lasana Blanco (2003: 126) points out, the inclusion of maize in FTA was also the result of the lack of organisation by small farmers when articulating their demands and trying to exert pressure.[195] As a consequence, there was no opposition to the consensus taken among the governmental elite and in influential businesses.

[193] Historically, production in Mexico reaches 2 tons per hectare, while production in the USA reaches an average of 11 tons per hectare, although the Mexican government did not relate such a disparity to the fact that American farmers use capital-based methods, sustained with heavy machinery, agro-chemical resources, and transgenic seeds (Nadal, 2004: 158 – 9). In addition, environmental conditions suitable for the cultivation of the crop are ideal in the American mid-west, as opposed to those in Mexico, where maize has mutated to adapt to diverse geographical conditions which have, in fact, become an advantage for Mexican farmers.

[194] The USA supports agricultural exports through the Commodity Credit Corporation (CCC) through which maize importers get credits with long-term payments (De Ita, 2007).

[195] The lack of organisation of small farmers was related to the political situation that Mexico was having at the time: the government was subsidising production and was promising to keep so doing in order to make it possible for the farmers to compete with their American counterparts (Appendini, 2001: 225).

It can be argued that a mix of technological disadvantages in Mexican farming and the financial interest of big companies were the determining factors in opening maize trade in Mexico. There is a common aspect here which relates to the specific features of Mexican maize. By deciding that it was better to import maize rather than to produce it, the Mexican government not only gave transnational companies control over the maize market, it also empowered the emerging biotech industry in the country because liberalisation would not only allow GM maize to access the Mexican market but also allow the possibility of taking over control of national maize production due to small farmers moving to urban centres.[196] The interest of the biotech industry in Mexican maize was stimulated by the maize's genetic characteristics,[197] which could offer new scientific insights for the development of new and different GM maize varieties.

Perhaps with an aim to ease concerns inherited from the previous Mexican administration,[198] the following one[199] launched two public programmes to support small farmers who wished to continue to produce maize, so that they could compensate for the American subsidies to the sector and to prepare them for the time when maize would be completely liberalised.[200] Running counter to this, and in the view of Guerrero Andrade (2005: 170, 182), governmental intervention was not aimed at improving small farmers' competitiveness,[201] but at administrating their exclusion from the market by negotiating the longest possible period for tariff

[196] Making small farmers move to cities was part of the strategy of liberalising the agricultural sector. Mexican officials thought this action could reduce rural poverty.
[197] Mexican maize has developed in several naturally-achieved genetic varieties that can overcome a number of agro-ecological obstacles posed by diverse regions, weather, altitudes, and soil characteristics (Naval, 2004: 159). This is the result of traditional farmers continually experimenting with their maize landraces, crossing them with other maize varieties to see if they can improve the quality of their maize crop (CIMMYT, 2002: 2).
[198] The NAFTA was conceived, drafted, and signed during the administration of former president Carlos Salinas (1988 – 1994).
[199] The administration of former president Ernesto Zedillo was in operation from 1994 to 2000.
[200] *Programa de Apoyos Directos al Campo* and the *Alianza para el Campo* (1994).
[201] He makes this point because there was a absence of support for research, technical assistance, and other types of aid needed to develop the maize industry.

reduction. The transition period, during which such tariffs and quotas would be completely phased out, would end by January 2008 (Morales-Moreno, 2004).

6.3.1 Position of the Mexican Government: Legal framework

When commercial GM maize was first released in the USA in 1995 (that is, a year after NAFTA was brought into force), the Mexican government took action on the matter. The Ministry for Agriculture, Livestock, Rural Development, Fisheries and Alimentation (SAGARPA) published a proposal[202] for an official norm[203] that would eventually enter into force the following year. Official norm NOM-056-FITO-1995 established the phytosanitary requirements for the handling, import, and experimental cultivation of GMOs at a time when, according to SAGARPA, no other regulation or international recommendation existed. It was commented in such norm that one of the requirements was that any person, institution or company aiming to release into the environment or to import a transgenic product would need to hand in a phytosanitary certificate. Moreover, any move of the GM product from within Mexico would entail notifying in writing to the General Direction for Vegetal Health.[204] Certificate information had to include the scientific name and the commercial name so as to identify the organisms modified in a given product. In addition, the packing methods, travelling routes and location maps, reasons for importing and moving the GM product, destruction process, description of biotechnology process to use, and impact assessments were compulsory issues to include in the certificate. With respect to labelling, the official norm stated that the GM product to be released, moved, and/or imported should be identified with visible labels containing information related to the nature and quantity of the product, country of origin, contact details of importer,

[202] The proposal for an official norm was published in the *Diario Oficial de la Federación* on 20 November 1995.
[203] An official norm is the name of each of a series of official, compulsory standards and regulations for diverse activities.
[204] The General Direction for Vegetal Health is part of the structure of the Ministry for Agriculture, Livestock, Rural Development, Fisheries and Alimentation (SAGARPA).

transporter, and receiver, and phytosanitary certificate number. Therefore, it is assumed that by filling in and handing in this certificate the product in question was of GM origin. In fact, additional information, in the form of a document stating the phytosanitary requirements covered and biosecurity measures taken for the import of transgenic products into the compilation of documents, was compulsorily adjoined to the certificate.

In 1997, the General Law on Health was amended with the addition of a Chapter regulating biotechnology products.[205] In such, there was the need to inform the Ministry of Health about these products when destined for human consumption. Labelling was contemplated as according to official norm NOM-056-FITO-1995. This action was agreed as stated in the Regulation of the General Law of Health with respect to Marketing,[206] which contains specific legal outlooks on the marketing of GMOs in its Chapter 10. In reference to this, it was stated that GM products cannot be advertised under three assumptions: firstly, as having attributes different to those for which they were evaluated; secondly, as being indispensable for human life; or thirdly, as being of a quality higher than conventional products (Art. 70). Moreover, this Regulation allowed the Ministry of Health to determine the cases when it was deemed necessary to advertise precautionary or warning messages that a given GM product recipient may need to contain (Art. 71).

There are other laws that also relate to biotechnology, although they cover the issue from different perspectives. About this, the Federal Law on Vegetal Health[207] establishes that the use of GM material for experimental purposes is subject to a

[205] *Ley General de Salud*, published on 5 January, 2009 in the *Diario Oficial de la Federación*.
[206] *Reglamento de la Ley General de Salud en materia de Publicidad*, published on 31 May 2009 in the *Diario Oficial de la Federación.*
[207] *Ley Federal de Sanidad Vegetal*, published on 26 July 2007 in the *Diario Oficial de la Federación*.

phytosanitary certificate. The Law on Production, Certification and Trade of Seeds[208] states the duty to request authorisation for researching GM material, the requirements for importing seeds, and the respective verification methods. The General Law on Ecological Balance and Environmental Protection[209] is another legislation that contains multiple references to GM material under the scope of 'genetic resource', and sets the general legislative framework with respect to environmental regulation. The Federal Law of Vegetal Varieties[210] focuses on the intellectual properties of vegetal GMOs. The Regulation on Health Control of Products and Services[211] points at regulating foods, ingredients, and additives derived from any biotechnology method. This is done with the aim of ensuring health and stability of such products.

Despite these legislations, doubts resided on the quantities of GM maize being introduced to Mexico, rather than on whether it was introduced.

> Sources at the US Department of Agriculture report that 34% of the US maize area was planted to transgenic maize in 2002, and it is quite possible that some of the maize imported into Mexico was transgenic (CIMMYT, 2002: 2).

Despite this report being from 2002, a previous statement explained that GM maize was potentially being imported to Mexico, although the quantities have been unknown. Information from previous years corroborates this by stating that Cargill was importing around 40 percent of maize to Mexico in 1999 (Guerrero Andrade, 2005: 195).

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[208] *Ley sobre Producción, Certificación y Comercio de Semillas*, published on 15 June 2007 in the *Diario Oficial de la Federación.*
[209] *Ley General del Equilibrio Ecológico y la Protección al Ambiente*, published on 16 May 2008 in the *Diario Oficial de la Federación.*
[210] *Ley Federal de Variedades Vegetales*, published on 25 October 1996 in the *Diario Oficial de la Federación.*
[211] *Reglamento de Control Sanitario de Productos y Servicios*, published on 10 January 1988 in the *Diario Oficial de la Federación.*

With regard to research, there have been funds allocated on plant biotechnology, which would come from both public and private resources (CIMMYT, 2004). This has been the case of CIMMYT, which considers the development of GM maize and GM wheat varieties as essential contributors to its main goals (CIMMYT, 2004). Importantly however, public funding has been reduced, and private funds have been adjusted according to the situation pertaining at the time and according to expected future market conditions (Matus Gardea et al, 1990: 44). Despite this, interest in the GMF sector has been increasing due to the vast natural resources and varieties of maize that Mexico possesses. Thus, despite the late approach to GMF in terms of research in the country, developments parallel to the founding and implementation of NAFTA resulted in an increasing number of scientific assessments in biotechnology, which either support or oppose GMF. One example about this was the assessment of potential effects on the diversity of maize. Biologists discovered in 2001 that transgenic DNA had been discovered in native maize (Quist and Chapela, 2001). Almost simultaneously to this development, in 1998, the Mexican government was decreeing a moratorium[212] on the introduction of GM maize seed into the country[213] (Ostroff, 2004). This was made with the argument of Mexico being the centre of maize diversity, and that the introduction of GM seeds would exacerbate losing such diversity. Another argument was the concern that at least 30 percent of maize imported from the USA by 1998 would be transgenic, of which a great chance existed of being used for cultivation in open areas (SAGARPA, 2005).

[212] The moratorium was the result of a study made by the National Council of Science and Technology (CONACYT), and was suggested to SAGARPA by the National Committee on Agricultural Biosecurity. The General Direction of Vegetal Health established the moratorium through an official document sent to people interested in requesting authorisation for experimental release of GM maize under the scope of official norm NOM-056-FITO-1995 (SAGARPA, 2005).

[213] Between 1993 and 1998, 22 trials were permitted under conditions of extreme environmental security, but from 1999 no other request was granted. This was because phytosanitary certificates were temporarily suspended (SAGARPA, 2005).

By January 2002, the Mexican government further reported higher percentages of GM maize in communities where the crop had been found previously, as well as in Diconsa stores, the government's food distribution agency, where 37 percent of the grains were found to be transgenic (ENS, 2004). In this context, the CIBIOGEM[214] considered adequate lifting the moratorium as it was posing limits to scientific research, and thus stopping biotechnology benefits from offering substantial improvement in the cultivation of maize.[215] Thus, lifting the moratorium would imply to admit new requests for environmental release of GM maize with research purposes[216] (CIBIOGEM, 2004). However, the Commission for Agriculture and Livestock of the Mexican Congress exhorted the Executive Government to instruct the Ministries conforming CIBIOGEM to preserve the moratorium status on the experimental cultivation of maize until a federal law was set up (*Senado de la República*, 2004/d).

In this context, three legislative initiatives to deal with GMF were presented to the Mexican Congress but did not become law because the congressmen who proposed them failed to raise enough support from their parties or the rest of Congress to discuss such initiatives. The first one dates back to 4 April 2001, and it relates to the inclusion of a paragraph in Article 282 of the General Law on Health to make compulsory the labelling of all GM products destined for human consumption. Also without success was the initiative suggested for a law on the production, distribution, commercialisation, control and encouragement of GM products proposed on 2 October of the same year. Finally, by 23 October, 2001, three articles were proposed for inclusion in the Federal Law of Consumer Protection, which sought to inform consumers on the existence and characteristics of GM products.

[214] CIBIOGEM is the Inter-Ministry Commission of Biosecurity of Genetically Modified Organisms. It is formed by SAGARPA, SEMARNAT, Health, Education, Treasury, and Economy.
[215] Agreement 06.02.03, Meeting 02.03 of CIBIOGEM, dated 13 August 2003.
[216] Comments made by Dr. Víctor Villalobos Arámbula, who was Executive Secretary of CIBIOGEM at the time. Retrieved from CIBIOGEM (2004).

It was not until March, 2005, that a Law on Bio-security and Genetically Modified Organisms (LBOGM)[217] was established. Its main purpose has been to regulate the research and commercial activities of GMOs with an aim to prevent, avoid and reduce potential risks to human health, to the environment, and to biodiversity (LBOGM, 2005). To achieve this, it established the role that the following Ministries would have in the applicability of the law: the Ministry for Agriculture, Livestock, Rural Development, Fisheries and Alimentation (SAGARPA); the Ministry of Health (SSA), and the Ministry for the Environment and Natural Resources (SEMARNAT). The latter would participate in case of potential release of GMOs into the environment. Furthermore, it established the National System of Information on Biodiversity, and the National Registry of Biodiversity of GMOs. The general public, the private and social sectors, as well as the producers, would be consulted when releasing GMOs into the environment. Security measures would be based on technical and scientific grounds, with the lack of scientific evidence not considered an indicator of a potential risk or its absence. This was because LBOGM would focus clearly on the experimental release into the environment as well as on research with educational, scientific, commercial and industrial purposes.

A key development of LBOGM was the protection of certain territories against scientific research and the release of GMOs since they were considered centres of origin and biodiversity for specific crops. This was the case with maize, for which warranties were provided after genetically modified DNA was found in those centres of origin. This aspect was developed from the position on the moratorium that was issued in 1998.

With regard to labelling, the LBOGM listed two articles. The first Article (101) states that GMF should be labelled without prejudice to the usual labelling requirements

[217] The abbreviation LBOGM responds to the Spanish name of the law. Published in the *Diario Oficial de la Federación* on 18 March 2005.

issued by SSA, when its characteristics are significantly different from those of conventional food. This was not the case in seeds destined for agricultural production, for which a compulsory labelling system indicating the features of the genetic modification and their implications for cultivation was established. The requirements for this type of labelling would be agreed upon following national standards and international treaties of which Mexico was a signatory. The second Article (102) established that labels should state the reason behind using any GM seed.

After the LBOGM was issued, on 30 October 2006, there was another proposal from within the Senate calling for an amendment to the General Law on Health.[218] This law already considered the existence of GM products (Art. 282 bis), as well as the necessary notifications when these products were destined for human consumption (Art. 282 bis 1). However, in order to improve settings of this law, the initiative aimed at labelling all GM products and respective derivatives. This was due to what the legislator proposing it considered as a handicap for world agriculture. The Senate ruled that, despite GMF being controversial and that there could be long term consequences, there was no need to rule on the matter. The reason for this ruling was that the issue was already contemplated in the LBOGM, in which it is stated that GMF should be labelled according to the official norms issued by the Ministry of Health, informing of the GM status only if the characteristics of the products were significantly different to those of conventional products.

Three years after the LBOGM was published, additional regulations supporting the LBOGM were set up (RLBOGM).[219] In such, detailed steps of the processes to

[218] Proposal amending Article 282 bis 3 of the General Law of Health. It was sent by Senator Mr. Manuel Velasco Coello, from the Green Party, to the Joint Commission for Health and Legislative Studies of the Mexican Senate.

[219] *Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados* was published on 19 March 2008 in the *Diario Oficial de la Federación*.

follow, jointly with the required documentation, were included for cases when importing GMOs and releasing them with either agricultural or commercial purposes. License requests for environmental release, monitoring measures for GMO cultivation and human protection, equivalence studies in case of consumption, as well as legal assurances that the GMO in question has already been released in the country of origin were also set up. However, no explicit mention was granted for labels as they would be established by official norms.[220] Overall, RLBOGM became controversial among NGOs and civil society because they established the possibility to cultivate and import GM maize, although this would be granted on a case by case basis and under strict assessment procedures (CIBIOGEM, 2010). For this, authorisation requests for releasing GM maize into the environment would be evaluated, once they fulfil the appropriate law requirements to be developed by SAGARPA and SEMARNAT in the future.

By 2009, official norm NOM-056-FITO-1995, which set up the requirements to which GM products should adhere to was cancelled.[221] The argument behind this decision was that the LBOGM was of a higher hierarchical level,[222] and that its additional regulations foresaw the elaboration of newer official norms. This was necessary so as to adequate new norms to the issues that prevail in the LBOGM.[223]

Further to cancelling official norm NOM-056-FITO-1995, the moratorium on GM maize was lifted by September of 2009. In this respect, CIBIOGEM (2010) commented that the conditions in which Mexico was a decade earlier were very different to those at the time of issuing the RLBOGM. This was because the moratorium was established at a time when Mexico was not part of an international

[220] Referred to official norm NOM-056-FITO-1995.
[221] Cancellation announcement (*Aviso de cancelación de la Norma Oficial Mexicana NOM-056-FITO-1995, por la que se establecen los requisitos fitosanitarios para la movilización nacional, importación, y establecimiento de pruebas de campo de organismos manipulados mediante la aplicación de ingeniería genética*) was made on 22 June 2009 in the *Diario Oficial de la Federación*.
[222] While LBOGM is a law, NOM-056-FITO-1995 is merely a norm.
[223] At present, no new official norms have been issued to replace NOM-056-FITO-1995 (SENASICA, 2010).

agreement regulating cross-boundary transfer of GMOs, and did not have a national law regulating them. But the LBOGM and its respective RLBOGM were now providing legal instruments that assured appropriate and secure use of biotechnology methods. Thus, lifting the moratorium would allow generating information that would assist in answering scientific questions on the transgenic sequences of maize, while assuring the protection of centres of origin and of genetic diversity. Weeks after, SAGARPA and SEMARNAT granted 15 approvals for experimental cultivation in some regions of the country.[224]

6.4 Development of the NAFTA's regulatory framework on GM maize labelling

By analysing the GMO context of each NAFTA nation-state, some observations are drawn. First, labelling is compulsory when indicating potential health risks, like the presence of allergens, and not for indicating GM status. Secondly, labelling is an option in Canada and the USA if producers want their GM product to be labelled, whereas Mexican law does not provide for voluntary labelling. Thirdly, Mexico requires compulsory labelling for all maize seeds due to specific internal features.

Despite not being explicitly included in the NAFTA, biotechnological production and commercialisation of maize has been handled through two bilateral agreements in which the USA appears as the signatory on both. The first one dates from 4 December 1998, and is a 'Comprehension Action Plan' between Canada and the USA regarding areas of agricultural trade. This mainly reaffirmed American and Canadian commitments to market-oriented agricultural policies, which could be achieved by encouraging their industry associations to work together, as long as it would be consistent with international trade agreements. They also pledged to use a science-

[224] Of the 15 approvals, 9 were granted to Monsanto, while Dow AgroScience obtained 6.

based approach to regulate biotechnology products, including GM maize, where the regulation related to the product itself, and not to the process used to develop it. Following a 1998 'Technical Agreement on the Regulatory Requirements for the Assessment of Specific Aspects of Transgenic Plants', both nation-states committed themselves to compare and conjoin, where possible, their regulatory review processes. In addition, they made a commitment to discuss and prioritise future areas of cooperation and information exchange, which would facilitate the safe incorporation of GM crops into agricultural production and trade (USFDA, 1998). To achieve this, they would need to consider their international contractual obligations and the 1998 Technical Agreement therefore complied with the UN Biosafety Protocol. It also meant that both the USA and Canada shared common views on biotechnology in the context of the SPS and TBT Agreements. These aspects would in turn be observed in the context of OECD, the Codex Alimentarius and APEC, in which the use of a science-based approach would be encouraged. Labelling issues were also included in the Comprehension Action Plan, although focus was related to that of 'country of origin' requirements as stated under NAFTA and WTO, and not on the potential GM status of any given product, given the method of product homologation regardless of the process employed. In fact, there was a statement rejecting the unjustified use of measures as barriers to legitimate trade. Among others, labels may have been considered as such measures.

Within the bilateral context, the USA also signed a 'Cooperative Agreement' with Mexico in 2001 to enhance activities of mutual interest on the safety of foods for human consumption. Such an agreement would include the involvement of the Agriculture and Health Ministries of both nations. It would also commend the participation of non-governmental actors such as consumer groups, industry representatives, and academia. In the Agreement, it was 'affirmed' that the intention was to strengthen scientific and public health protection activities, including biotechnology and labelling. By exchanging information and developing joint programmes, the identification of regulatory and scientific standards was proposed

wherever there was potential for immediate and future harmonisation (USDA, 2001). In addition, emphasis was placed on a commitment to confidentiality on the information they would exchange, but which would need to take into account the information that should be accessible to the public.

These two bilateral agreements have allowed the setting up of a regulatory framework that has had implications in the context of NAFTA, despite the FTA not implicitly mentioning matters on biotechnology. For example, environmental concerns on the development of GM maize in the USA and Mexico have led interest groups to direct their efforts towards a regional institution created in the context of NAFTA through an auxiliary environmental agreement. This is the case with Mexican farmers and ENGOs, who, supported by more than ninety organisations and institutions within the three nation-states, filed a legal request in April 2002 to the North American Commission for Environmental Cooperation (CEC)[225] for an investigation into the reasons and implications of transgenics found in conventional maize varieties (ENS, 2004).

Pursuant to Article 13 of the North American Agreement on Environmental Cooperation (NAAEC), which authorises CEC to conduct studies on environmental-related matters affecting North America, CEC submitted a report on issues related to the protection of plant genetic diversity for maize, in which the assessment of both risks and benefits would constitute the greater part. Following standard procedures, an advisory group, formed by experts on ecology, biotechnology, law, economics and public policy was designated to compile the report, which had to include an input

[225] The role of the CEC has been that of ensuring the enforcement of environmental laws in the three nation-states, while addressing environmental challenges and opportunities presented by continent-wide free trade. Nevertheless, it enjoys only limited enforcement power, as it is an intergovernmental institution established by an auxiliary environmental agreement with the NAFTA, the North American Agreement on Environmental Cooperation (NAAEC).

from international and national groups and organisations, the private sector, interested members of the public, as well as from the governments of the three nations (CEC, 2002).

The CEC report issued a series of recommendations starting with the preservation and enforcement of the 1998 moratorium on maize seeds imports. To begin with, it advised the labelling of all maize imported from the USA as either containing GM maize or else certified as GM-free. This would not include Canada, though, as she did not export bulk maize to Mexico. In case American or Canadian maize was not certified as GM-free, it was suggested that it should be milled into flour at the American border so as to prevent transgenic seeds from being planted in Mexico. Another recommendation was that the Mexican government should notify local farmers that maize distributed by Diconsa was likely to contain GM maize and that grain bags should be labelled accordingly. This stipulation was based on the argument that the introgression of traditional maize could not be considered simply a national problem because the effect on the genetic biodiversity of Mexican maize could have direct repercussions on the biodiversity of maize and ecosystems in all of North America (ENS, 2004). For this purpose, it was suggested that the assessment and management of bio-safety risks should be approached through greater coordination of research and regulatory policies in all three countries, such as proposed under the North American Biotechnology Initiative (NABI). This would entail that proponents of GM products would have to make coordinated applications for regulatory reviews in all three markets, although the commercial release of a GM product simultaneously in all markets was a matter of concern.

> To ensure complete regulatory oversight, there should be greater information exchange among regulators in the three countries in order that no products are released without the knowledge of all three governments. Ideally, harmonisation

> should address risks both specific to individual countries and those common to one or more of the countries (CEC, 2004: 31).

There were other aspects that CEC brought into focus which were related to the exclusion of GM maize from Mexican territory. Listed among them were programmes with the aim of educating farmers in the avoidance of planting transgenic seeds and even of not planting American seeds at all.

The report provoked strong protests from the USA and Canada. Their governments claimed that the report was fundamentally flawed and unscientific (CEC, 2004), because key recommendations were not based on sound science and were contradicted by the report's own scientific findings. They contended that the report failed to consider the potential benefits of biotechnology. They complained, too, that the report lacked economic analysis, while too much emphasis was placed on socio-cultural considerations. In this regard, USA officials, through the EPA (Environmental Protection Agency) and the USTR (U.S. Trade Representative), considered that following the report's recommendations would cause economic harm to farmers and consumers across the three NAFTA nations and restrict international trade because of the portrayed equivalence between GM and conventional products. Canada encouraged the development of a Mexican regulatory framework to deal with this matter with Environment Canada, the agency in charge of commenting on the report, arguing that the level of protection should be consistent with Mexico's international obligations. The Canadian representative considered that recommendations should take full account of commitments reached under the Convention on Biological Diversity (CBD), the Cartagena Protocol on Biodiversity (CPB), NAFTA, and WTO guidelines such as the SPS Agreement and the TBT Agreement. Emphasis was placed on the latter two, since Environment Canada considered that risk assessment and the regulation of GM products should be science-based and no more trade restrictive than necessary. In case there was insufficient

information upon which to take a protective decision, there was the possibility of adopting provisional measures within a reasonable period of time. Even so, Environment Canada stated that such measures should be adopted according to relevant international standards.

The proposal by the CEC to rely on the work and objectives of NABI was welcomed by the national governments. In March 2005, it was formally established under the Prosperity Agenda of the Security and Prosperity Partnership (SPP) of North America. The necessity for increased cooperation between each nation's regulatory policy on agricultural biotechnology was observed. This would partially achieve the aim of maintaining high standards of health and safety for North American citizens, while enhancing the competitive position of North American industries throughout the world. A proposal was tabled for the elimination of 'redundant testing and certification requirements' (White House, 2005). To cope with these duties a Food and Agriculture Regulatory Systems Working Group (FARS) was created, and three initiatives were put into place. The first was designed to support NABI in the initiation, coordination and prioritisation of various biotech activities: it was proposed that by March 2006, Mexican regulators would be included in the technical regulatory exchanges between Canada and the USA, leading to the formalisation of trilateral regulatory exchanges. The second initiative, working towards developing common approaches for regulatory policies, was realised by establishing training workshops in Mexico for risk assessors, also in March 2006. The third initiative would place its emphasis on the cooperation and sharing of information on international biotechnology activities. A proposal for a NABI intercessional conference to discuss biotechnology issues in international organisations, such as Codex, OECD, and CBD, was submitted for March 2007 (FAITC, 2005). According to data from SSP, in 2006 the first initiative was in operation and on an ongoing basis; the second was delayed until August of 2006, and the third initiative was considered to be fulfilling its brief. To date, little is known about the progress of NABI and the efforts of FARS to realise the initiatives because this information is for official use only and not open to the

public.[226] Therefore, it could be understood that the ministries with access to this confidential information are CFIA and AAFC from Canada; SAGARPA, SSA, and SECON from Mexico; and USDA, USFDA and EPA from the USA.

Beyond its biotechnological involvement, the FARS Working Group is concerned with pursuing a standardised guideline for food safety and labelling, although this is undertaken outside its biotechnology remit. By so doing it is reinforcing the criteria adopted by the three nation-states in their wish to avoid linking GMF and labels. There is also the prospect of coordination between the respective laboratories to build confidence regarding testing procedures and results.

6.4.1 GMF developments outside the remit of the NAFTA text

Besides these issues obtained through the NAFTA – CEC context, there have been aspects about labelling agreed at the trilateral level. In this sense, the Agreement establishing the Documentation Requirements for Living Modified Organisms for Food, Feed, or Processing[227] basically envisaged that documentation for living GMOs (may contain) was only triggered in transboundary movements of living GMOs that were authorised in or sold from an exporting nation-state. The exception would be when an exporter or importer would have contractually defined, in accordance with the regulatory requirements of the importing nation-state, that a shipment of 95 percent of non-GMO content was a non-GMO shipment (Lin and Ching, 2004). That is, only shipments that contain over 5 percent of GMOs need to be labelled as 'may contain GMOs'. And as long as adventitious presence is unintentional, labelling is unnecessary. Thus, this trilateral agreement between the USA, Canada, and Mexico spelt out its own terms for labelling transboundary GM shipments intended for food, feed, and processing.

[226] According to an international trade specialist from the Office of Scientific and Technical Affairs, Foreign Agricultural Service, the NABI only develops an internal website as a vehicle for information exchange among the three nation-states.
[227] This trilateral agreement was signed on 29 October 2003.

Furthermore, it was agreed that information on shipments containing GMOs should be stated in commercial invoices, rather than on 'stand-alone documents'[228], since Customs officials would be the people most likely to view the papers. In this sense, monitoring or enforcement of the trilateral agreement would be left to commercial buyers and sellers.

The trilateral agreement was seen as an American strategy by American officials. According to John Pitchford (USDA, 2003), the USA would develop a 'bilateral agreement' template, consult with fellow exporters to reach a consensus approach, hold bilateral consultations with key markets, and influence others as they gain implementation experience. The arrangements were designed to provide clear definitions of when documentation was needed, clarify exporter versus importer obligations, and not to affect any party's liability to develop its own policies based on risk assessments.

With regard to the Mexican side, this trilateral agreement raised concerns within the Congress. Ten months after its signing, the Senate called the Mexican official who signed the agreement on behalf of the country to appear before them.[229] The reasons for this were that the signing was done under the auspices of no legislative body, and that Mexico had already signed the CPB.[230] The official's appearance did little to appease the Senate's concerns. Instead, there were more doubts and questions regarding the juridical nature of the agreement, its aims, its functioning, as well as its operational matters (*Senado de la República*, 2004/a). In addition, the Senate called

[228] In CPB discussions, the stand-alone document was opposed by commodity traders because of worries it could stigmatise those shipments (Andreé, 2007: 260).
[229] The Mexican Senate called up Dr. Víctor Villalobos Arámbula to appear before it on 11 August 2004 (*Senado de la República*, 2004).
[230] According to Article 133 of the Mexican Federal Constitution, an international agreement that is signed by the Executive Government and ratified by the Senate becomes a national law with the highest hierarchical level. The CPB was signed by Mexico on 29 January 2000, and ratified by the Senate on 30 April 2002. It entered into force on 11 September 2003.

the Minister of SAGARPA[231] to explain the reasons and conditions by which the trilateral agreement was signed. In his appearance, he affirmed that the CPB allowed for bilateral or multilateral agreements on the transboundary movement of living GMOs to take place. These would include non-signatories of such protocol, like the cases of the USA and Canada. In this context, he commented that CIBIOGEM worked on defining guidelines to suppress unnecessary trade barriers with NAFTA partners (*Senado de la República*, 2004/b). In fact, he added, the outcome was an inter-institutional arrangement among the three North American nation-states, which included a working plan to comply with the CPB and to have access to American and Canadian information.

In the views of Congressmen from the left-wing party,[232] his appearance before the Senate merely showed the lack of knowledge that the Minister of SAGARPA had over the nature of the trilateral agreement, calling it 'arrangement', 'inter-institutional document', and 'working plan' (*Senado de la República*, 2004/b). Resulting from this, left-wing Congressmen proposed to the Senate to promote a Constitutional controversy before the Mexican Supreme Court of Justice against the Mexican Executive Government for signing the trilateral agreement, which was regarded to violate the Mexican Federal Constitution (*Senado de la República*, 2004/c). The arguments behind this were many. Firstly, an official from SAGARPA is not legally permitted to sustain an international agreement that oblige all citizens from the country. He/she can do so only on administrative matters of the ministry in question. Secondly, the trilateral agreement should have been registered in the Ministry of Foreign Affairs,[233] so it could have 'agreement' status under international law. Nonetheless, this was never done. Thirdly, the trilateral agreement contravened the Federal Constitution because the former was directly affecting basic interests such as health, alimentation, and the assurance of a healthy environment. Fourthly, the trilateral agreement was regarded as illicit because it was infringing citizens' rights

[231] Mr. Javier Usabiaga Arroyo was the Minister of SAGARPA at the time.
[232] *Partido de la Revolución Democrática* (PRD), led by Mr. Omar Ortega Álvarez.
[233] As established in the Law on Treaty Signing (*Ley sobre la Celebración de Tratados*) signed on 2 January 1992.

by obliging them to include a 'may contain' label in the invoice of the imported / exported product (*Cámara de Diputados*, 2004/a: 222 – 6; *Senado de la República*, 2004/b). Despite these arguments and the insistence of the left-wing party, the proposal for the Constitutional controversy was postponed,[234] with no update at present.

Then, it is observable that the context, in which the Mexican approach to the trilateral agreement was made, implied merely the Executive Government point of view, without taking into account the legislative body's perspective. Assessing each other's opinion confirms this, as both executive and legislative institutions disagreed on the existence of the trilateral agreement.

6.5 Observations

The USA, Canada, and Mexico have developed their own national approaches to GMF and labelling. By examining the evolution of their legislations on GMF labelling, it is observable that they developed their own initial views on the issue. Although similar between Canada and the USA in terms of voluntary labelling, their legislations featured one key element in the form of the threshold allowed for a product deemed as GM or not. Mexico established a consistent strict approach to GM products, in which commercial labels were not mentioned. Nonetheless, compulsory documentation requiring the identification of the GM status of a given product when imported allows speaking of a type of label.

With time, the three nation-states started to develop common approaches that would include not only labelling, but also biotechnology-related aspects like risk assessment and scientific measures. These took place via bilateral agreements and trilateral

[234] It was postponed as detailed in Session 10 of First Period of Ordinary Sessions, LIX *Legislatura*, 5, 7 – 12 October 2004 (*Cámara de Diputados*, 2004/b)

initiatives, both relying on features established at the international level. With this, a regional approach to labels has arguably been reached. But this refers on food produced through biotechnology means. A different case has been GM seeds, which have been treated in a dissimilar manner by Mexico. Labelling of GM seeds comes as the result of specific environmental, consumption, societal, and legislative issues that characterise this nation-state with respect to its northern neighbours. Nonetheless, it is noticeable that Mexico has aligned its legislation on GMF labelling. Lifting the moratorium and establishing national laws that changed the approach followed previously have meant that Mexico has renounced to its own initial views on the matter. This could have been done for the sake of the regional market, thus making convergent policies at the regional level. In fact, Mexico is regarded to be so adjoined to American and Canadian views that, at present, the CEC is awaiting feedback from the Mexican government after it received a complaint submitted by different NGOs[235] claiming that the Mexican government has failed to effectively enforce its environmental law with regard to control, inspection, investigation, and risk assessment of transgenic maize in the north of the country[236] (CEC, 2010).

[235] Concerned NGOs are from peasantry, agricultural, services, environmental, and human rights remits: *Frente Democrático Campesino, Unión Nacional de Productores Agropecuarios, Comerciantes, Industriales, y prestadore de Servicios El Barzón, A.C., Centro de Derechos Humanos de las Mujeres, A.C.,* and Greenpeace Mexico, A.C.

[236] Northern state of Chihuahua, Mexico.

CHAPTER 7: A COMPARATIVE ASSESSMENT OF GM MAIZE LABELLING POLICIES BETWEEN THE EU AND THE NAFTA REGION

The EU and the NAFTA region present features that show convergent features within them. They take the form of pieces of legislation that develop into different policies according to their policy legacies, policy problems, cultural approaches and, above all, the level of integration. However, it is due to these integrative processes, including features like institutional settings and legislative procedures, that striking differences are observed between them.

The EU has been developing a wide range of labelling policies, ranging from products containing GMOs, to products produced from GMOs that may not be present once they are marketed, and to GMO seeds. Its institutions have been dealing constantly with different matters with the attempt to upgrade policies as they are developed. Labelling thresholds exemplify this regard. Products containing GMOs in the final product or under processes using GMOs have already an established limit of 1 percent. However, there is the eagerness to reduce even further such threshold, as legislative debates demonstrate. A different case is that of seeds, which is being defined at present.

North America has developed a series of much less complex policies. By establishing regional agreements, labelling policies have been kept at a minimum. National policies homologating GMF to conventional products simplify the approach that labelling policies have in this region. However, Mexico's position about labelling imported GM seeds casts doubts on a potentially strong convergence in North America.

Maize is no exemption. In both the EU and the NAFTA region, this crop has been at the core of the regulatory processes. This is no surprise as maize is one of the most cultivated crops using biotechnology means, one of the crops with the most

authorization requests in the EU, and one of the most important food staples. In this sense, GM maize has experienced the same, if not more delicate, labelling rules as the rest of GMF.

7.1 Participation of regional and national institutions

The different levels of integration infer in the manner in which regional institutions participate in policy-making. In Chapter 2, the institutional structures of both the EU and the NAFTA were detailed. After assessing the development of GMF and GM maize labelling policies, it is observable that EU institutions have been at the core of policy evolution and upgrade. The EP, the Commission, the Council of Ministers, the ESC, and the CoR have all been involved in such developments according to their own positions and to the type of activities they were conferred to by EU treaties. On a different stance are NAFTA institutions, like the Free Trade Commission, Working Groups, and the NAFTA Secretariat, who do not appear to influence any development about GMF labelling. At best, the CEC exhorts member nation-states to label maize, as it was the case with the report the CEC published on finding GM maize in the Mexican environment. Nevertheless, the CEC's views were considered merely of an advisory character and no action resulted as a consequence.

This thus leaves it to national governments to take a prominent role. In North America, American, Canadian, and Mexican positions on labelling GM maize have been developed according to their own national policy legacies, policy preferences, and cultural backgrounds. In the EU, member nation-states have also played a leading role in the developments of this policy area; as their own cultural backgrounds, legacies and preferences have set the direction to which policies are developed at the regional level. Their representation at EU level via the Council of Ministers confirms this from a liberal intergovernmental viewpoint. In both regions, individual actions from nation-states have affected the manner in which GMF labelling policies have evolved. Historical developments about policy-making explained in Chapter 5 detail

the context in which many member nation-states' policies were prior to the introduction of the current regional GMF labelling policies. An implicit consensus on the labelling issue was observable; this was regardless of whether national governments were for or against the use of biotechnology on food. That is, there were supportive views for biotech from the Netherlands and Finland; while opposing views coming from France, and Greece. Despite this difference, labels on GM products found support from both sides. Chapter 5 also exemplified Austria, Italy, and Germany, among others, as nation-states unilaterally banning the introduction of GM maize to their territories. Furthermore, information about France, Ireland, the UK, and Hungary has assisted in setting the context in which not only labels, but also national approaches towards GMOs in general, have developed. These comments in turn allow recognising the level of influence that national governments have in developments on this policy area at the regional level. Chapter 6 also exemplifies the relevance of national governments as it lists Mexico imposing restrictions to the import of GM maize seeds for cultivation purposes.

Hence, the involvement of regional institutions and national governments vary according to the level of integration of the region in question. The more integrated a region is, like in the case of the EU, the greater the role that regional institutions play in policy-making. Nevertheless, nation-states remain at the core of policy-making across different stages. North America is a clear example of this aspect, while the EU offers an interesting insight about the manner in which member nation-states have dealt with labelling and related matters, such as bans on approvals of new GM products.[237] However, doubts remain on whether national governments have acted

[237] Despite not being the area assessed in this study, bans on already authorised GM maize varieties and approvals of new ones also mirror the different positions that national governments have with respect to GMOs and labels. The majority of them have taken anti-GMO positions. One example dates back to a 2005 Council meeting, when, except for the UK, the Netherlands, the Czech Republic, and Sweden, 21 member nation-states sided with Austria when the Commission attempted to overturn two bans on GM maize. A similar outcome followed in 2007, when 22 member governments rallied around Hungary's right to retain bans on specific GM varieties. Only Finland, the UK, the Netherlands, and Sweden supported otherwise, while Romania abstained. Subsequent meetings denote an increase of member nation-states abstaining at the expense of anti-GMO views; while the UK, Sweden and the Netherlands remain as the only governments supportive of the Commission's proposals (Pollack and Shaffer, 2009: 259, 367).

either out of opposition to GMOs, or because of a belief that member nation-states' positions should be respected.

On a different approach, the existence of trade agreements, like NAFTA, set national governments to remain as key actors, both individually and collectively through intergovernmental institutions created to oversee the implementation of the agreement.

Regardless of whether regional institutions or national governments take the lead in GMF policy-making, certain similarities appear in each region with regard to area-specific bodies. The process by which Regulation 1830/2003 was created shows that focus in the EU has been given to views on environment, health, and consumer information. The CEPHCP was responsible for presenting the EP's position on the proposal at first and second readings. The Commissioners for Environment and for Health and Consumer Protection were representing the Commission in the debates held with the EP. Also, the Council of Ministers involved in making this policy gathered those in charge of the Environment in their respective countries. A wider scope of national ministries has been taken into account, but only for assessing the implementation of regulation, as it was the case when the Commission requested information for issuing two reports in 2006 and 2008.

As for North America, different bodies have participated in creating national policy frameworks of GMF labelling. The USFDA, the USDA, and the EPA have delimited the scientific grounds for which equivalence between GMF and its conventional counterpart has been taken for granted. In Canada, the CFIA, Health Canada, and the AAFC have driven the processes by which voluntary labelling has been established. However, the CGSB is the body responsible for publishing the latest standard on voluntary labelling. Mexico has followed a similar way in the sense of setting an official standard, although it refers to phytosanitary documentation requirements. In this regard, SAGARPA took the lead on this policy area. With time, other ministries became involved. The Ministry of Health and SEMARNAT have been heavily

involved in the evolution of Mexican legislation. Furthermore, the Ministries of Education, of Economy, and Treasury have been taken into account in the formation of CIBIOGEM. Hence, it is noticeable that food, agriculture, and environment have been the core areas considered for developing each of the North American national approaches. However, Mexico has encouraged the participation of a wider scope of ministries. This would suggest that Mexico has had a more complete perspective and assessment on GMF and the implications for labelling. Nonetheless, Mexican policy output has not differed greatly from the Canadian and the American ones.[238]

In both the EU and the NAFTA region, policy-making of GMF labelling has been put in hands of environment and health related institutional bodies.[239] Nevertheless, from this point there is a divergence as to which other institutional body is sharing policy-making powers, or merely performing advisory roles. Consumer protection is an area that has been hugely involved in EU developments within both the EP and the Commission. This is not the case with North America. The USFDA and the CFIA consulted the opinion of the citizenry, who were regarded as consumers. Mexico shows a similar approach in that LBGOM states the potential consultation to the general public when GMOs are released into the environment. However, in none of the three countries an official approach to protect consumers' rights exists; at least, not in the way the EU does. This certainly relates to the equivalence of GM and conventional products taken for granted in North America. In turn, such equivalence allows speaking of agriculture as a relevant area for GMF policies in North America. The USDA has regarded biotechnology as a promising technology, and has been keen to show the benefits of these products. AAFC was also involved in labelling matters in Canada, while Mexico's SAGARPA would direct the policy approach to the point that a senior member of staff was in charge of representing Mexico when the Trilateral Agreement on Documentation Requirements for Living GMOs was signed.

[238] Depth on this thought is developed further in this chapter.
[239] This is regardless of whether they are classified as Ministries, Directorate General, Agencies, or Departments.

In spite of the European focus on consumer protection and the North American focus on agriculture, there is an interesting aspect regarding trade-related institutional bodies. They seem to be absent in the development of regional (EU) and national (NAFTA) policy-making processes. At most, the EP relied on the CIETRE to merely express a position on policy proposals, which would not be definitive. In this absence, it is fair to mention that the trade sector has participated in two different ways. One refers to the lobbying efforts that transnational companies have made before agricultural and governmental bodies. The second is implicitly stated when producers have proven that GMF is safe for the environment and consumers' health; and have proven so to the point that GMF has been authorised for release and consumption. Examples of this are Commission Decisions 97/98/EC, 98/292/EC, and 98/294/EC authorising placing different GM maize varieties in the market

Then, it could be assumed that each region's GMF labelling policy output develops from views of institutions in charge of commenting and deciding on environmental, health, consumer protection, and agricultural matters. Following this assumption, different policies could have been made if trade-related bodies would have been in charge of developing them, if consumers would have influenced North American developments, or if agriculture would have influenced EU policy outputs.

Besides area specific institutional bodies influencing policy outputs, the stance that political parties have with regard to developments of GMF can also affect the approach to label them. Mexico represents a good case in this sense. The example of left-wing congressmen attempting to change the direction of legislation and to propose compulsory labels for GMF demonstrates this aspect. EU policy also shows instances of political parties' involvement both at the national and regional levels. With regard to the national level, some member nation-states have provided insights about the manner in which the party in power affected the development of national legislation prior to the establishment of the labelling regime, as well as with other

GMO-related issues. Denmark and France have clearly exemplified this regard, as shown in Chapter 5. Regarding the regional level, negotiations from within the EP at first and second readings, when making Regulation 1830/2003, have shown the influence of political parties. In this case, parties on the left and on the centre of the political spectrum have tended to support issuing labels. Right-wing parties have also expressed their views by adopting industry-supportive approaches. In the EU, debates that led to Regulation 1830/2003 corroborate this. Nonetheless, this position is less clear in the NAFTA region. One example are the links made of members of the Bush Administration, coming from the Republican Party, participating and having high-ranked positions within different biotechnology companies.[240]

Then, when comparing policy outputs in each region, jointly with the position of political parties, two issues are recognisable. Firstly, the Left have influenced more in the EU than in North America. This could be attributed to the support they have received from the citizenry as the result of problems that the biotechnology sector has suffered in the past, like the BSE crisis and dioxin-contaminated feed. In fact, such problems led to the development of stringent laws for GMF. Secondly, right-wing support for industry and science has been the pattern followed in each of the North American nation-states. It has found less support in the EU not because of reliance on scientific grounds, but because what is perceived as the omission to consider social and consumer perspectives. Hence, a stronger cultural tradition in Europe of questioning claims of big corporations is observed.

[240] During a debate sustained at the EP on the 1st July 2003, Mr. Jean-Claude Martínez, an Independent MEP for France, exemplified this by mentioning that the senatorial campaign in Missouri of John Ashcroft, the then US Attorney General, was partly funded by Monsanto. Another example was Donald Rumsfeld, US Secretary of Defence, who also performed as the President of a laboratory that Monsanto bought in 1985. In addition, Ann Vaneman, former US Secretary of Agriculture, was member of the Board of Directors of Calgene, the multinational that created the first transgenic tomato. Linda Fisher, former Deputy Administrator of the EPA, was also responsible for the Monsanto lobbying bureau at Washington. Lastly, there is Clarence Thomas, a judge of the US Supreme Court, who used to be a lawyer at Monsanto (European Parliament, 2003/c).

7.2 Relevance of different policy processes

Each region has shown different processes through which they develop GMF labelling policies. The EU has reached present policy outputs through co-decision, in which the EP and the Council of Ministers decide together. This aspect resembles that of a nation-state's legislative process, where legislative and executive bodies reach consensus on a given policy area. However, the existence of the Commission is a peculiar feature for the policy process. Its initiator role means that it can drive policy-making in a particular direction. Nonetheless, the Commission is not the ultimate decider. Debates held between Commissioners and MEPs when discussing Regulation 1830/2003 thus were intended to only deal with aspects on proposals for legislation.

The NAFTA region shows features of a different kind. Policies are adopted through contractual obligations that emphasise the application of policies adopted elsewhere through international agreements. This is the case of SPS measures, TBT measures, and national treatment to goods of another nation-state. The NAFTA text corroborates the relevance of these WTO agreements and precepts. In fact, such is the intergovernmental character of the NAFTA that it has created a dispute settlement panel, just as in the WTO context. Two bilateral agreements have been signed regarding scientific, public health, environmental, and labelling matters of GMF. Both agreements have relied on approaches observed in the Codex Alimentarius and the WTO. The trilateral agreement on documentation requirements for living GMOs slightly moves away from the common pattern of adopting international agreements. Actually, this trilateral agreement was created with the purpose of preventing CPB accords that would potentially harm international trade due to requirements to label.

The EU's co-decision and NAFTA's international trade-related policies link with their respective levels of integration. As a political and monetary union, the EU has developed strong policy processes entailing the participation of different regional

institutions that develop strict and compulsory rules. This contrasts with the dominant intergovernmental character of the North American region, where policies are based according to developments made at the international level. Nonetheless, a qualification must be made that only one policy area has been analysed.

7.3 Features on labelling GM maize

This study has shown that different views on labelling exist. Voluntary and compulsory labelling of GM products, as well as GM-free labelling, were discussed by authorities when current policies took place. In the EU, the establishment of compulsory labels was the output of negotiations and debates that derived in issuing Regulation 1830/2003. North America shows two labelling approaches: one followed at the national level and another followed at the regional level. At the national level, Canada and the USA have developed a voluntary approach to labels based on the equivalence between GMF and its conventional counterpart. As with the case of Mexico, both of them deem labelling as necessary when characteristics of the modified product diverge to an extent that the name of the traditional product could no longer apply. Nonetheless, Mexico makes no comment on the option to voluntarily label. As a special case, Mexico requires compulsory labels for GM maize seeds due to specific features inner to its environment. At the regional level, the three countries have established that they require details on documentation of shipments that contain a specific percentage of GMOs.

7.3.1 Labelling thresholds for GMF

A threshold relates to how strict is a law with respect to the allowance of adventitious presence of GMOs in a given product. In this sense, the EU has developed stricter approaches to those of North America. Here, some issues need to be accounted for.

To begin with, the threshold established by the EU was the result of a series of discussions and debates both between and within the EP and the Commission. Different positions were expressed, but it was agreed that a threshold of 0.9 percent was adequate after the Council of Ministers reached a compromise in this matter. Despite this, there have been views regarding such a percentage as either too high or too low. There are expectations to move in either direction; although lowering the threshold seems more approachable, as Regulation 298/2008 allows the Commission to do so.

With regard to the NAFTA region, a threshold of 5 percent has been established in case of cross-boundary shipments. This thus means that a shipment can contain grain that is 95 percent pure; that is, free of GMOs. And this can be defined as a non-GMO shipment. Therefore, a shipment need not be labelled, even if it has a large amount of GMO content, so long as it is unintentional adventitious presence.

The percentage at which a threshold is established can pose queries about the manner in which a given threshold is calculated. However, the outcome in the EU relates more to a political agreement than to any scientific basis. Different reasons were provided when different thresholds were proposed: Market access, simplification of procedures, and scientific bases.[241] At the end, the majority of MEPs voted according to the position presented by their respective political parties. Subsequently, the EPP, which was the only party against a low threshold, was outvoted despite it including a significant number of MEPs. The threshold adopted in the NAFTA region appears more as a response to the CPB than to own concerns about adventitious presence. The exemption has been the Mexican position about labelling GM maize seeds, which appears to have influenced the establishment of such a threshold. That is, the CPB and Mexican views would impose documentation requirements to GMOs. This thus

[241] Industry and research community affirmed that certain thresholds could be met.

would affect trade of non-signatories of the protocol; therefore, pre-emptive action was required.

Another example refers to bulk products sold in containers. For example, a given consignment containing several tons of maize would mean that some tons of the crops are of GM origin according to the authorised adventitious presence. In this case, thresholds are needed for explanation.

7.3.2 Regional and national laws on GM maize

As observed in Chapters 5 and 6, different laws have been developed between the EU and the NAFTA region. On one side, the EU has developed specific legislation in a constant manner; to the point that, at present, legislation proposals have appeared with the aim of strengthening current regulations. GM maize is the main object of Regulation 1813/97, which establishes rules for labelling when this crop is commercialised. From then on, other Regulations have been developed with the aim of deepening the context of not only GM maize, but also general GM food and feed. Nonetheless, maize has continued to be at the core of the European approach to GMF labelling. The Commission's Decisions authorising the introduction of different GM maize varieties to the EU, despite some member nation-states' refusal, corroborates this. In fact, questionnaires from which information was retrieved to elaborate the two reports on the implementation of Regulation 1830/2003 asked governmental bodies their views on the adventitious presence of GMOs in commercialised maize. However, regulating GM products in the EU is still in process. For example, laws on labelling of GM seeds, where those of maize would be included, are on pending status. Moreover, further legislation may be required to address shortcomings observed when implementing existing Regulations. This is the case of documentation requirements, as it has been difficult for operators and competent authorities to track

GMOs that have been labelled because national documents differ from each other. The reason is that there is no Europe-wide standard document available. Nonetheless, as commented by stakeholders, existing labelling policy has helped member nation-states in recognising any potential contamination of products sold within the EU.

In the NAFTA region, there is no labelling of GM maize for trading purposes, as neither national policy requires it so. Hence, an implicit regional approach has been developed across the region. However, initial national views on labelling differed. This was because Mexico previously required listing the GM status of crops in documentation to provide to authorities prior to their introduction to the country. But, with time, this changed as the result of the introduction of LBOGM and its complementary regulations. In addition, the signing of the Trilateral Agreement on Documentation Requirements for Living GMOs further strengthened similarities across nation-states by finally establishing a procedure by which a certain threshold was delimited.

However, there are signs that allow speaking of diverging developments with respect to maize. For example, Mexico's approach to compulsorily label GM seeds influences trade and cultivation parameters among the three countries. Furthermore, American maize producers have been keen on identifying and labelling their grains so as to obtain the approval status of the event they went through (NCGA, 2010/b). With this, they aim to satisfy EU requirements on the issue. Nonetheless, they support the American government's position in that it should be voluntary labelling the adequate option indicating whether food has been developed using biotechnology.

Differences between the EU and North America with regard to labelling GMF refer to the use given to two concepts that have been approached oppositely: consumer information and sound science. On one side, consumer information has been at the core of GMF labelling policies in the EU. For this reason, labels were established

across the whole food chain, be it as food, feed and products derived from them. Labels would, in turn, not only provide information on the content of the product, but also on the methods used to produce them. This would impose a traceability system that would allow tracking products that could carry unforeseen damages to consumers' health and the environment. This position would assume that the precautionary principle is included in the legislation, despite it not being explicitly mentioned. Its exclusion from legislation was because the Commission and the Council of Ministers were eager to omit any wording related to risk assessment since scientific proof would corroborate labelled products were safe from the beginning, as stated in their respective positions and statements during negotiations that led to issuing Regulation 1830/2003.

By contrast, sound science has been at the core of North American policy developments. Equivalence between GMF and conventional products is the proof about this. However, while this consideration has been made to traded products, products for cultivation purposes have experienced another fate. Mexico's requirement to label GM maize seeds and the 5 percent threshold established in the Trilateral Agreement on Documentation Requirements suggest that sound science is approached differently. Mexico requires labels because she considers that some of its territories are deemed as centres of origin for biodiversity and she wants to preserve them as such. The trilateral agreement suggests that the threshold established was aimed at relaxing CPB's measures on transboundary movement. The USA and Canada, as main GMO producers, would make this taking into account that the CPB is applicable to trade between signatories and non-signatories, that they were not members, that Mexico was already signatory, and that they could become members in the foreseeable future.

North America established a threshold of 5 percent adventitious presence for the transboundary movement of GMOs with the firm purpose to gain access to markets

of signatory nation-states. The trilateral agreement was set up with the purpose to be used as a template for subsequent agreements under the same context (USDA, 2003). On the opposite hand, the USA and Canada have regarded the threshold of 0.9 percent that the EU established as inadequate, unreachable, and imposing costs on producers. Hence, two different juxtaposed approaches to GMF labelling have been developed by, if not Mexico, the USA and Canada. Nevertheless, it is necessary to point out that the supported threshold only applies for transboundary movements and not for final product at marketplaces, which is the stage at which the EU is requiring GM products to be labelled. Subsequently, it can be concluded that the USA and Canada are eager to notify the potential existence of GMOs only in invoices, and not precisely on labels.

7.3.3 Views on the implementation of GM maize labelling policies

The systems developed by each region have different tolerances, diverging application, and different levels of enforcement. This refers to different perceptions on the ways to label. One refers to the stage in which labels should be developed. In this regard, labels can take place across the whole process of production and commercialisation, or can appear only in the final product.

Another perception relates to the appreciation of thresholds. In this sense, there were comments in the EU that an arbitrary threshold of 0.9 percent or lower would automatically lead to an obligation not to label a product as GMF. However, there were comments refuting this, stating that thresholds can only be applied provided that the detected presence of GM material is adventitious and technically unavoidable, and that the operator is in a position to supply evidence that this presence is adventitious and technically unavoidable. [242] For this, concepts such as 'adventitious' and 'technically unavoidable' should be clearly stated. Still referring to thresholds, a

[242] Comments made by Mr. Peter Loosen, who was Head of the Brussels Office of the German Federation for Food Law and Food Science.

further issue refers to the documentation of shipments when it states that 'this lot contains GM material under 0.9 percent.' Specifically, if larger lots were divided over and over again, and if GM material did not mix evenly through the lot, concentration of the GM material exceeding the threshold level in some sub-lots could happen.[243]

A third perception refers to labels on feed. About this, conclusions that the 0.9 threshold value should be based on the final product have been suggested. Also, that feed should be labelled either by listing GM feed material as an ingredient or by labelling the product collectively as containing GM material. If the latter was the case, additional labelling rules were recommended, since present legislation only prescribes labelling of GM ingredients.[244]

The fourth perception relates to the operational way in which the threshold percentage should be calculated. That is, whether threshold calculation should be in weight percent or in DNA percent,[245] or whether labels should refer to each independent GMO or to the total sum of a partial percentage of every detected GMO.[246]

A fifth perception is that disagreements exist about the different contexts in which labels should take place. This refers on whether labels should take place with regard to the product intended for food, for feed, or even in the manner in which it is sold; that is, as either individually, or in bulk consignments.

The last perception refers to different interpretations of the legislation adopted. For example, to specify what is the necessary 'evidence to satisfy the competent

[243] Different contact people from Finland addressed this view: Mrs. Leena Mannonen (Ministry of Trade and Industry), Mrs.Sari Sippola, Mrs. Sanna Viljakainen, Mrs. Tiina Seppälä, and Mr. Erkki Vesanto (Finnish Food Safety Authority Evira), and Anna-Riita Savolainen (Cutoms Laboratory).
[244] Comments made by Mr. Gorm Lunn, from the Danish Plant Directorate, in the Ministry of Food, Agriculture and Fisheries.
[245] This refers only to the description of analytical testing, hence describing the result of qualitative analysis expressed as the percentage of GM. This comment was made by Mr. Lars Korsholm and Mrs. Hanne Boskov Hansen, of the Danish Veterinary and Food Administration.
[246] Views from Ms. Ana Fresno, of the Spanish Ministry of Environment.

authorities that [operators] have taken the appropriate steps to avoid the presence of [GM] material'.[247]

Besides suggestions from national authorities regarding the depth that GMO labelling legislation should reach, there have been views expressed from European authorities. For example, once labelling threshold for GM products has been set up at 0.9 percent, there have been requests from the Commission about assessing the possibility of meeting such threshold in the final product, when sowing conventional seeds with a GMO content of up to 0.3 percent for cross-pollinating species and 0.5 percent for self-pollinating species.[248]

Thus, as it is observed, all these examples from the EU demonstrate that implementing regulation on GMF labelling has proven difficult despite legislation being adopted at the regional level. This thus suggests the need to further converge the policy in a manner that establishes a clear framework to adopt. When comparing this to North America's approach to label, it is understood that labels could be converged in the simplest possible way.

With all the above, two comments need to be made. First, labelling can stigmatise GMF by leading consumers to conclude that food is unsafe. Therefore, if governments establish mandatory labelling requirements, they should provide standards, testing methods, certification, and enforcement. Second, labelling of complex, unclear information may be of little value and may not reduce information costs. In addition, labelling can act as an implicit market ban on GMF (Gruère, 2006: 159). On the other hand, a simple label can quickly become ubiquitous and hence uninformative. However, if this is the case and GMF labels are everywhere and

[247] Mrs. María de Lourdes Camilo, of the Portuguese Directorate of Planning and Politics.

[248] In 2001, the Commission asked the Scientific Committee on Plants to assess this aspect. This Committee estimated levels of adventitious presence at different stages in the production cycle for maize, as well as oilseed rape and sugar beet. It concluded that it would be possible to meet the 0.9 percent threshold for the final product (European Parliament, 2006).

become unnoticed, it will prove that products are effectively meeting consumers' expectations.

North America has not received this type of perceptions. This is due to the level of integration that this region entails and the position it has about labelling GMF. With no labels, no perceptions arise on procedures to do so. The only issue that has arisen refers to clarifying responsibility on documentation requirements when shipments with over 5 percent of adventitious presence are imported. In this sense, it was controversial to regard the importer as the sole responsible for the requirements. That is, while shipments being introduced with a 5 percent threshold of GMO adventitious presence were documented in the invoice, it would be the importer who would be responsible for verifying the shipment and assessing whether the product fulfilled the needed requirements.

7.4 Observations

GMF labelling policies have been developed consistently in both the EU and in North America. Each region has followed a convergent approach from within its borders, which has resulted from different perspectives on biotechnology. Sound science and risk assessment have been at the core of policy developments. That is, any GMF to be authorised for human consumption or to be released into the environment have gone through risk assessment procedures that focus on obtaining scientific proof about the safety of GMF. From this perspective, labelling is not deemed necessary since authorised GMF in both regions have been under scientific scrutiny. Nevertheless, the EU has also focused its legislation on the right of consumers to be informed with respect to the content of a product and the process by which it was produced. This has entailed the appearance of a strict labelling approach that does not find enough support on the other side of the Atlantic Ocean. However, irrespective of the policy

output, both regions have shown that convergent procedures within both regions have been developed. In fact, by observing comments from national institutions in the EU on the implementation of the policy output, it is noticeable that the policy on GMF labelling is in constant development. On the other hand, policy developments in North America seem stagnant. The explanation for this is that the aim, for which GMF labelling policies were established, has been reached despite Mexico's position with regard to seeds.

The case of GM maize shows slightly different changes according to findings discovered in each region's legislation. The EU has deepened legislation with respect to GM maize in terms of legislation such as Regulations and Decisions. However, North American nation-states have held divergent views about this. Mexico becomes the country affecting the environment in which GM maize is developed in North America. Labelling GM seeds prior to import and the creation of the trilateral agreement have redirected a policy that has established the approximation of GMF and conventional products.

Agreements reached on legislation thus demonstrate that nation-states remain at the core of policy developments. Because of the level of integration, this is more apparent in North America. But when assessing the manner in which co-decision is carried out, it is noticeable that the Council of Ministers remain at the core of EU policy-making, despite of the Commission and the EP being heavily involved. That is, the Commission initiates policy proposals, while the EP has increased its participation in policy-making under co-decision. Nonetheless, findings have proven that both institutions shaped their positions at the second reading according to views of the Council of Ministers. This was arranged so as to make Regulation 1830/2003 pass smoothly at the later stages of its making.

It is important to remember that the policy output responds to the perspective and aims that the institution in charge of developing it has. That is despite the fact that, in both regions the environmental and health sectors have been at the core of legislation. However, North America emphasises agriculture, as it refers to two of the greatest GM producers. And, if maize is cultivated by biotechnology means, the outcome is a type of maize that has similar or improved characteristics to maize grown under traditional circumstances. The EU focuses on consumer information, which in turn means that labels providing such information are deemed as necessary.

CHAPTER 8: OVERVIEW ON POLICY CONVERGENCE AND TRADING UP IN THE EU AND THE NAFTA REGION

The analysis of the development of GM maize labelling policies in the two regions provides a deep insight about how policy convergence takes place. Each region's approach to this policy area has shown signs of convergence, although towards different directions, at different degrees and with different scopes.

Reminding Knill's (2005: 768) concept of policy convergence, there should be an increase in the similarity between characteristics of a given policy at a specific political jurisdiction over a certain time period. With this in mind, this study has aimed at examining one policy area and at comparing it in two different regional settings. The time period of the policy assessment happens to be similar due to features existing at the international level at the time of developing such policies. Explanations about these issues have been given in Chapters 5 and 6.

In the former, details about the EU developing policies not only on GM maize labelling, but also on general GM food, feed, and seeds suggest that convergence is taking place constantly. Since 1990, European legislation has evolved with the appearance of Directives and Regulations of compulsory application across the territories of member nation-states. During this time, specific legislation on labelling GM maize has been issued,[249] amended twice, [250] and complemented;[251] to the point of reaching its actual legislative framework,[252] which has also been modified and complemented by recent developments.[253] Further developments may appear in the time to come with respect to legislating on labelling GM seeds. Hence, an evolving regulatory framework allows us to speak of the development of a policy convergence.

[249] Regulation 1813/97.
[250] Regulation 1139/98 and Regulation 49/2000.
[251] Directive 2001/18/EC.
[252] Regulation 1829/2003 and Regulation 1830/2003.
[253] Regulation 298/2008.

Chapter 6 has explained the context in which national policies on labelling GM products are found. Both American and Canadian policies on GMF have had close approaches from their beginnings[254] by establishing voluntary labels based on equivalence of GM products. On the other side, Mexico has moved from its own national standard[255] towards a homologating position on equivalence with its North American counterparts. To this point, convergence is observable. However, Mexico has implemented labelling requirements for GM maize seeds when entering her territory. This is an issue that does not match the others' views. At the regional level, NAFTA nation-states have reached consensus on identifying potential GMO adventitious presence in shipments when imported; thus reinforcing the notion that policy convergence has taken place.

8.1 Assessment of indicators of policy convergence

There is a decrease in variation of policies among nation-states in each region. Hence, following Holzinger and Knill's (2005) perception, the use of σ-convergence becomes relevant. In this regard, the degree, the scope, and the direction of convergence need to be pointed out. The degree of convergence is observed in the similarity of policy outputs and policy outcomes. For the EU, the creation of legislation at the regional level denotes not only similarity in policy outputs, but full convergence in areas covered in Regulations and Directives. As for policy outcomes, views of some national authorities on the implementation of Regulation 1830/2003 denoted that, although convergence has been positive in that GMF and GM maize should be labelled, different formats have been used to express the inclusion of GMOs in such products. This in turn has posed difficulties among the interaction of member nation-states' authorities when interpreting information. As for North America, the idea of 'similarity' applies adequately since no regional approach has

[254] Initial policies date back to 1992 and 1993 respectively.
[255] Official norm NOM 056-FITO-1995.

been developed on voluntarily GM maize labelling in the marketplace. Each of the national approaches has focused on the equivalence between GM maize and its conventional counterpart. Nevertheless, this region has also reached convergence in the sense that a policy output; that is, the trilateral agreement, established the documentation requirement that they need to follow when importing shipments with potential adventitious presence of GMOs.

The scope of convergence differs greatly between the two regions. It is acknowledged that the scope is greater in the EU due to the number of its member nation-states and the amount of issues covered in the policies developed.[256] On a lesser scope is found the NAFTA region. This is because only three nation-states form it, the trilateral agreement focuses only on documentation requirements, and the approximation of national policies centre at the equivalence of products. Another factor needs to be taken into account. This study has proven that a deeper degree of convergence results from the commitment that nation-states acquire through international agreements, regardless of the number of participant members. In this view, EU legislation and the North American trilateral agreement prove a high degree of convergence in as much as they oblige their member nation-states to follow GMF labelling rules and documentation requirements.

The most relevant way to assess σ-convergence in the present study, just as Holzinger and Knill (2005: 776) point out, is the direction of convergence. This is because a movement upward or downward of a converged policy assists in delimiting whether 'trading up' takes place. In this sense, it is usually assumed that the extent of state intervention relates to the strictness of legislation adopted. If the resulting policies are lax or laissez-faire, they are identified with the bottom, while strict or interventionist standards with the top (Drezner, 2001: 59 – 64). Nevertheless, different value

[256] Besides GM maize labelling, policy development in the EU has entailed issues on GM food, feed, products derived from them, the potential presence of GMOs in organic food, and seeds.

judgements may exist about what the top and the bottom are in a policy (Botcheva and Martin, 2001: 4). This aspect becomes relevant when comparing the approaches to policy and the direction they have taken. Both the EU and the NAFTA region have their respective policies on GM maize labelling converged. However, this has been done towards dissimilar directions. This refers to the establishment of regional policies that delimit the type of labels that GMF and GM maize should receive. Europe-wide Regulations requiring labels on GMF and GM maize have been established with the aim to make the internal market in this area work efficiently, as different perceptions and approaches towards these products previously existed. The harmonised policy output has been regarded as tough in that GM producers have found it difficult to allocate their products in the European market. Therefore, the process by which GMF is introduced in the EU implies that policy convergence has been achieved by setting up strict rules.

North American nation-states have also delimited their own national policies on GMF and labelling, with the aims of furthering free trade and getting rid of technical trade barriers. The direction of convergence has gone towards approximating national views on the equivalence of GM products to traditional counterparts. In addition, the trilateral approach has developed harmonised documentation requirements on shipments. However, North American policy outputs do not show signs of 'trading up'. Both approximation and harmonisation of policies merely affirm the position that each government has had from within their national boundaries. For this, the role of Mexico has been crucial. National laws were approximated at the regional level when Mexico changed the direction of its initial policy of requiring documentation stating the GM origin of imported products. Otherwise, only the USA and Canada would have kept their approach to equivalence and voluntary labelling. Whether Mexico was pressured to move in this direction remains to be seen; however, the existence of the North American integration process and Mexican aims to liberalise trade have facilitated a change of direction, which deepened with the introduction of the LBOGM. On an opposite stand was the development of the trilateral agreement. In this case, Mexico's membership to the CPB has forced its signing so as to overcome

the potential indication of the GM status of products imported to Mexican soil. The outcome was the establishment of a threshold that allows adventitious presence of GMOs.

Analysis of degree, scope, and direction of σ-convergence has shown that the EU has achieved higher convergence than the NAFTA region. The harmonisation of rules, the number of participant member nation-states, and how upward policy outputs have taken place demonstrate that European developments on GMF and GM maize are in constant evolution that seeks to preserve the strictness of legislation. North America looks different. National approaches approximating GM products refer to a laxer view on green biotechnology, while the trilateral agreement imposes detailed requirements that set hurdles on a CPB's simplified process implementing the identification of any amount of GMOs. However, these actions do not include GM maize seeds, for which Mexico has established that labels are mandatory. Hence, convergence in North America has depended on Mexico's actions towards different contexts of biotechnology.

8.2 Assessment of 'trading up' in the EU and in the NAFTA region

As commented earlier, the direction of convergence relates to whether 'trading up' or a 'race to the bottom' takes place. Nation-states in the EU and in North America have agreed the extent and the direction to which their policies should be converged. To some extent, convergence has been achieved because they share views on the approaches to label GM maize at the regional level: To make it compulsory in the EU, and to consider it equivalent to conventional maize in the NAFTA region. With these outcomes and by considering initial positions on the issue, it is observable that 'trading up' has taken place in the EU, while North America has preserved the status quo. The basis of these arguments lies on the level of strictness that each region has

developed. As time went by, the EU raised its standards by developing harmonised policies about labelling GMF and GM maize. On an opposite stance remains the NAFTA region, where the approximation of policies has implied no change towards a stricter common approach; instead, each national government has moved its own national policies at the regional level. In fact, Mexico's position on labelling GM maize seeds, and American and Canadian reluctance to label these products can corroborate this regard.

Policy convergence can happen through different mechanisms (Bennett, 1991: 220 – 9; Drezner, 2005: 841; Holzinger and Knill, 2005: 779 – 86). This study has shown two of them. It is through the mechanism of international agreement that policy convergence has taken place in the EU. This is confirmed with the scope of increasing Regulations and Directives that result in strengthened standards established by the EP and the Council of Ministers, and supervised in its implementation by the Commission.

North America also portrays an international agreement as the mechanism through which the threshold on adventitious presence is converged. A regional institution may not exist to oversee the implementation; nonetheless, a legally binding standard has been set up. North America also denotes the terms of market access as the mechanism behind the approximation of national policies stating the equivalence of products. In this sense, equivalence appears after scientific assessments have proven GMF as safe. With this, in addition to the positive attributes that GMF entails, North American governments perceive to offer protective policies producing benefits for consumers. American and Canadian statements used when retrieving information on consumers' views through public hearings, besides the wording of the Mexican LBOGM, corroborate this aspect.

The 'trading up' mechanism that refers to terms of market access (Princen, 2004) seemed to appear in the relationship existing between both regions; specifically between the EU and the USA. Because there is no international agreement between

both of them when dealing with labelling on GM products, American producers have felt obliged to comply with EU legislation in an attempt to cover the necessary requirements to introduce and sell their GM products in the EU. However, these producers have been adamant to introduce labels other than voluntary. Hence, no further developments that might lead to think of 'trading up' taking place have appeared so far.

The existence of 'trading up' in the EU implies that a change in policy has taken place. Here, the approach has meant that benefits have outweighed the costs of preserving the status quo. In this sense, perceptions on benefits and costs differ between this region and North America. The EU has established compulsory labelling requirements with the aim to provide consumers with information on the origin and ingredients of the products they buy. It seems that EU institutions were obliged to develop this approach due to the discontent that the citizenry had on how GM products were handled across Europe. Avoiding doing anything to overcome such displeasure may have had negative implications not only for the biotechnology industry, but also for general food industry. Then, the compulsory labelling approach appeared as an attempt to regain credibility and confidence of consumers after a series of food scandals.

North America's approach on equivalent products has benefited producers, who also have the option to label their products. Nonetheless, some of them have been keen to adapt their businesses so as to enter the European market, where consumers have been wary about these products. However, no mandatory labels have been supported by these producers. Hence, no 'trading up' appears beyond the mere intention to gain or preserve access to the European market. This comes in addition to producers trusting regulatory agencies in the field.[257] Mexico shows a slightly different case in that it has adopted the approach on equivalence, perhaps as the result of trade pressures by her North American counterparts. However, it is more remarkable that

[257] For the cases of Canada and the USA.

no change was made on the approach to cultivate maize. In this sense, Mexico imposed a moratorium, which subsequently was lifted; but was changed for a policy stating the adoption of labels for GM maize seeds. Mexico's position affects the extent to which policy convergence takes place.

8.3 Policy change and causes of convergence

It is noticeable that labelling policies have evolved differently in the two regions. This is according to factors (Schmidt and Radaelli, 2004) that are perceived differently in each region. For example, policy problems have influenced diversely on the policy output adopted. The EU experienced a greater set of troubles and crises derived from the unprecedented adoption of biotechnology-based products. In North America, troubles surrounded on finding GM maize unauthorised for cultivation within Mexico. Both problems drove policy outputs, although in different contexts and at different degrees. Resulting Europe-wide labels have focused on a wider set of applications, which includes trade, environment, and consumer information. North America, instead, has approached labels only on agricultural terms, while suffered problems do not seem to have influenced the adopted policy output, since Mexican views about the relevance of maize were kept regardless of GM maize findings.

Consequently, the manner in which problems have been approached mirrors the policy preferences and policy legacies arisen in each region when developing problem solutions. In this sense, policies have converged according to preferences on consumer information and on furthering free trade. They differ in terms of how influential they are. That is, the EU developed the approach to inform consumers due to their wariness towards GM products. This approach took the form of compulsory regulations, which meant that some national preferences may have been sidelined. On the opposite stand, the NAFTA region has continued to focus on trade and equivalence of products. Here, national preferences are shared; hence, adopting a region-wide preference has proven adequate. Nonetheless, key issues for Mexico

have proven that her maize legacy and her preference to keep this crop outside the realm of biotechnology influence have resulted in a lesser extent of convergence.

The adoption of such preferences and legacies has been possible due to the influence that consumer and environment-supporting political parties exerted during debates leading to tailor-made regulations in the EU. Information retrieved in this study has also suggested that trade perspectives of political parties in power have driven the position of North American governments. In fact, it could be suggested that it is under this context that the trilateral agreement was signed.

With regard to discourse, the voluntary labelling approach in North America represents a good example of the discursive power of equivalency (Andrée, 2007: 97). These governments do not directly challenge the notion of choice. Perhaps they do this as it would be a tough argument to win. Instead, they state that there is no scientifically justifiable reason for singling out GMF and GM maize from their conventional counterparts. This thus can exemplify the way that an issue that may be perceived to be political is ostensibly decided on the basis of a scientific judgement.

However, the Mexican Law on Biodiversity and GMOs, and the Trilateral Agreement on the Documentation Requirements for Living Modified Organisms for Food or Feed infer that there is a deeper perspective on labelling as opposed to the generally assumed equivalence between GM and non-GM food.

National policies have converged due to own views for and against labelling GMF and GM maize. The existence of EU regulations, the North American trilateral agreement, and the establishment of similar North American national policies have allowed proving this aspect. In this regard, the identification of causal mechanisms leading to convergence is as follows. It can be suggested that harmonisation is the causal mechanism through which labelling policies are converged in both regions. This is because nation-states have found it compulsory to adopt such common labelling policies, which are shaped under the influence of EU institutions and the Codex Alimentarius Committee in North America. Furthermore, regulatory competition also appears as a causal mechanism (Holzinger and Knill, 2005) in North

America. The implementation of similar policies due to competitive pressures to mutually adjust them for the sake of free trade confirms this regard.

However, regardless of whether international harmonisation or regulatory competition appears as causal mechanisms of policy convergence, σ-convergence may not necessarily move in a given direction. This study has shown that European GMF policies have become stricter over time, while North American GMF policies remain partially stagnant. This comes despite of each region's policy makers' differing views on the level of strictness that their respective policies imply.

At the end, thus, convergence has taken place. However, it has come towards a presumed different direction, at different speeds and at diverse degrees. The policy outputs have exemplified cases when nation-states remain at the core of policy-making at the regional level. Although some policy-making powers have been conferred at EU level, national governments remain focused on preserving their sovereign rights when they consider it convenient. Mexico has done so when imposing compulsory labels to GM maize seeds, while European countries, like Austria, France, Germany and Hungary, have reacted to developments proposed and implemented by the Commission on authorising the introduction of GM maize.

8.4 Observations

This study has contributed to explain the manner in which policy convergence appears and develops by assessing the establishment of GMF and GM maize labelling policies in the EU and in the NAFTA region. Such an assessment has made plausible the opinion that convergence has taken place. This comes with different degrees, scopes, and directions. In this sense, it is the latter that has provided an insight about

the potential existence of ‘trading up’ with respect to policy outputs. Harmonised and approximated policies in each region have resulted from similar previous national preferences and legacies. This in turn implies that regional policies have not experienced major direction changes in comparison to national views. In fact, it is all the opposite since it is due to this that policies have been deepened to cover related areas. Nevertheless, European developments have become stricter while widening the scope of GMF policies.

The assessment of legal measures adopted in each region has allowed observing ‘trading up’ in only one region. This refers to a constant improvement and development of strict policies in the EU. In an opposite stance is found North America, since the observed convergence has remained similar to the positions adopted previously at the national level. No ‘trading up’ has appeared in the US approval process with regard to what has been achieved in the EU. With regard to labelling, there seems to be a refusal from American authorities to comply with mandatory labelling in its own region. In addition, other features appear when considering the context of North America as a whole. For example, the evolution of Mexican labelling policies shows a downgrading movement through time. That is, initial accounts of this policy demonstrate that the Mexican government aimed at identifying GM crops when setting up a phytosanitary certificate and the moratorium of GM maize seeds; thus setting a tough stance towards these products. However, the trilateral agreement and the new national approach have implied a redirection of the policy. Hence Mexico’s performance appears likely to fit in within the concept of race to the bottom. The recent authorisations granted to transnational biotechnology companies to experimentally cultivate maize, the lifting of the moratorium, and Mexico’s position in CPB meetings can corroborate this.

The EU seems to experience a different stance. An approach developed to adjust policies with the purpose to satisfy consumers’ demands has being developed at the regional level, where views from different actors have been taken into account.

Tightening up GMF labelling policies shows that the EU has not been heavily influenced by external developments. Nonetheless, the EU is keen on following labelling approaches that better suit the European view on GM products, like those established in the CPB.

Gathered information has shown that there is a general approach between GMF and GM maize in the EU, despite the latter receiving special consideration in legislation about labels. North America presents a different position, where maize entails a series of factors that affect the position that Mexico has had on the topic. In fact, it is Mexico's position the cause of the greatest difference between both regions when determining convergent policies in both regions. That is, the EU has developed a policy stating compulsory labels for GM maize, where GM maize seeds look heading towards a similar approach. The NAFTA region has embraced a policy suggesting only voluntary labels on this crop. However, compulsory labels on GM maize seeds at Mexico's request have blocked any increase on the extent to which North America could have developed a full common approach.

Then, North American approaches to sound science and the EU's perception on the relevance of consumers' right to be informed imply that no profound coincidences can be reached between both regions. In this sense, the wider the divergence, the more complicated and costly it is for change to take place.

Policy convergence has been examined and linked up with the concept of trading up. The results shown in this study demonstrate that they can appear with time, and only if nation-states agree to take part on them. This comes regardless of the position that regional institutions have, although they may influence to some extent. In fact, it is through international agreements that convergence seems more approachable. Subsequently, signatory countries are committed and obliged to follow the resulting policies. Nonetheless, this study has focused only on the position that national

governments and regional institutions have on GM maize labelling policies. In this regard, the present study could be complemented by assessing the roles that civil society and the biotechnology industry perform in the evolution of such policies. Otherwise, the cases analysed in this study refer to only one dimension of the different policies that take place at the regional level. Also, different outcomes may appear when other policies are examined.

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