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HACCP plan fresh fish processing Marituna

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Table of Contents:

Table of Contents: 2

1. HACCP plan fresh fish processing in Marituna 3

1.1 Introduction and regulatory needs/laws for Hazard Analysis of Critical Control Points 3

1.2 Scope 4

1.3 HACCP step by step 4

1.3.1 Commitment 4

1.3.2 HACCP team 4

1.3.3 Terms of reference 5

1.3.4 Product information 5

1.3.5 Identify the intended use 5

1.3.6 Process overview 6

1.3.7 Hazards-analysis of each processing step 6

1.3.8 Identify critical control points 8

1.3.9 Target levels and tolerance 9

1.3.10 Monitoring procedures 9

1.3.11 Corrective actions 10

1.3.12 Verification 10

1.3.13 Documentation 10

1.3.14 Review and update the HACCP plan 11

2. HACCP plan for frozen Sardines 12

2.1 HACCP-team 12

2.2 Description of the product 12

2.3 Intended use of the product 12

2.4 Flow diagram 12

2.5 Identification of potential hazards 13

2.6 Verification program 18

2.7 Documents needed to be used within the HACCP plan 18

2.8 Additional information 19

Annexes 19

References 19

1. HACCP plan fresh fish processing in Marituna

1.1 Introduction and regulatory needs/laws for Hazard Analysis of Critical Control Points

In the past regulatory authorities for food products had a duty to ensure that foods offered to the consumer are at least safe to eat. The authorities required a positive approach of using Good Manufacturing Practices (GMP), producing food in a hygienic manner, and by inspection of finished product. It is now realised that inspection of finished product gives a poor control over the safety of foods. Therefore, since 1 January 1993, regulatory authorities in Europe required that companies take a preventative approach to safety based on the principles of Hazard Analysis and Critical Control Points (HACCP). European Countries have food legislations which are placing full responsibility for food quality on the producer (EEC Council Directive 91/493/EEC (EEC 1991b)). These requirements might be incorporated in primary legislation on food control, or be applied by executive action of the regulatory authority. The management of the company must then be able to produce for the regulatory authority a documented HACCP plan, and be able to demonstrate that the plan is being effectively implemented.

HACCP is therefore a major change for companies as it is a food safety management system, which concentrates prevention strategies on known hazards, occurring at specific points in the food chain, rather then end product testing with the chance of rejecting complete production lots. The major difference of this quality system, compared with final product check systems, is that by using HACCP a company is able to prevent problems before they occur. It controls all production steps and prevents food safety problems, which can occur. There will however, always be a need for some end product testing particularly for verification purposes.

Anyone exporting fish products to Europe or North America will have to implement a programme based on HACCP. If a company cannot demonstrate to the satisfaction of regulating agencies in importing countries that it has an effective programme operating in their processing plant, importers will not be permitted to accept the products.
The United Nations food standard group Codex Alimentarius Commission has recommended HACCP's adoption as a system for ensuring the safety of foods (including finfish and shellfish) and the prevention of foodborne diseases (ref: http://www.fao.org/DOCREP/005/Y1579E/y1579e00.htm#Contents)

1.2 Scope

HACCP is a powerful system, which can be applied to a wide range of simple and complex operations. For manufacturers to implement HACCP they must investigate not only their own production methods, but must also apply HACCP to their raw material supplies and to final product storage, and must consider distribution and retail operations up to and including the point of consumption.
It can be concluded that HACCP is not a 'stand alone' process control system but may be a part of a larger system, of viz. integral quality assurance.

1.3 HACCP step by step

1.3.1 Commitment

First of all the management of the companies must be committed to provide all the necessary resources for the study for implementation of HACCP. This includes appointing team members, provide time for HACCP analysis, writing the HACCP plan, implementation of the system, training and instruction of personnel, reviews and updates. Without such commitment there is no point in beginning the study. Everybody in the organisation must be aware of the needs of the company to comply with HACCP regulation.

1.3.2 HACCP team

It is important that a multi-disciplinary team, with knowledge and expertise required for the specific product line being considered carries out the study. The use of such team is known to improve greatly the quality of data considered and, therefore, the quality of decisions reached. The team can for example consist of:

- A chairman who has knowledge of HACCP and should be responsible for managing the study.
- A quality assurance/quality control specialist: an individual who understands the microbiological and/or chemical hazards and associated with a particular product group (fish).
- A production specialist: an individual who has responsibility for, or is closely involved with the process under study. It is essential that this individual is able to contribute details of what actually happens on the production line throughout all shift patterns.
- An engineer: an individual who has a working knowledge of the hygienic design and engineering operation/performance of the process equipment under study.
- Others with special knowledge e.g. microbiology, hygiene, food technology, plant construction/maintenance, operations, market requirements etc.
- Sales representative: to consider quality expectations of the end product.

1.3.3 Terms of reference

The HACCP study should be carried out on a specific product- or process-line, for instance manufacture of Individual Quick (IQF) whole round fish. In order for the study to proceed quickly it is essential that the terms of reference be outlined clearly at the start. It is necessary to decide upon the process line, product and whether physical, chemical and microbiological hazards (or any combination of these) and whether product safety and/or microbiological quality aspects (i.e. spoilage) are to be considered with respect to food legislation. It may be necessary to also take into account demands of buyers of manufactured products. It is also to be considered when the product is judged as safe: the point of consumption or the point of manufacture with clear storage and use instructions.
It is to advise to keep it simple when you start to make it a successful operation; when a system is working, it can be further developed.

1.3.4 Product information

A full description of the product under study, or intermediate product if only part of the process is to be looked at, should be prepared.
Product information should contain:

- Composition
- Structure and physical characteristics
- Description of the processing (whether the product has been heated and to what extent)
- Packaging
- Storage and distribution conditions
- Required shelflife
- Instructions for use.

1.3.5 Identify the intended use

The intended use of the product by the consumer and the consumer target groups should be defined. This can be done in combination with the other product information you just made. Some groups of the population, elderly very young, sick or immune compromised are much more susceptible to some hazards. For instance, it might be necessary to label the products with the text: 'not recommended to be eaten during pregnancy' when there is a risk of *Listeria monocytogenes* being present. The intended consumer group may affect your 'level of concern'. Are there specific requirements imposed by the importer or the importing country?

1.3.6 Process overview

Show all specific steps in the manufacturing process, from the time raw materials are received until the end product is on the market; receiving, preparation, processing, packaging, storage, distribution.
The more specific the flow-chart, the easier to understand the possible source of hazards. Take into account the delays that may occur during the process. Include sufficient technical data for the study to proceed.

Examples of information that might include:
- All raw materials and ingredients and packaging used (microbiological, chemical, Physical data)
- Floor plans and equipment layout
- Sequence of all process steps (including raw material addition)
- Time/temperature history of all raw materials, intermediate and final products. Including potential for delay
- Product recycle/rework loops
- Equipment design features (including presence of void spaces)
- Efficiency of cleaning and disinfecting procedures
- Environmental hygiene
- Personnel routes
- Routes of potential cross-contamination
- High (dirty)/low (clean) risk area segregation
- Personal hygiene practices
- Storage and distribution conditions
- Consumer use instructions.

Confirm the flow chart and all recorded details during operating hours to verify that it is accurate and that all recorded details show what actually happens rather than what is wished to be happened by the HACCP-team.

1.3.7 Hazards-analysis of each processing step

The flow chart, which was prepared, can now be used for assessment of hazard at each processing step.
Hazards have been defined as the unacceptable contamination, growth or survival of bacteria in food that may affect food safety or quality (spoilage) or the unacceptable production or persistence in foods of substances such as toxins, enzymes or products of microbial metabolism.

The team may decide in its terms of reference to include only particular groups of hazards, e.g. infectious pathogens or toxin forming pathogens. Equally the team may decide to study all potential microbiological, chemical, physical and economical hazards.
Hazard analysis requires two essential ingredients. The first is an appreciation of the pathogenic organisms or any disease agent that could harm the consumer or cause spoilage of the product, and the second is a detailed understanding of how these hazards could arise. Thus the hazard analysis requires thorough microbiological knowledge in combination with epidemiological and technological information.
In order to be meaningful, hazard analysis must be quantitative to assess both severity and risk. Severity means the seriousness of the consequences when a hazard occurs, while risk is an estimate of the probability or likelihood of a hazard occurring. It is only the risk, which can be controlled. It is however difficult to estimate risk, as it cannot be predicted what the chances are that an employer makes a mistake during processing. Therefore, we will not estimate chances for a hazard to occur.
Hazard Analyses:
a) Identify hazards
b) Identify contamination point
c) Determine the probability
d) Asses severity
e) Determine preventative measures.

A Identify hazards:

Identification and classification of hazards should be carried out. Different classifications (e.g. Food Safety, Other legislation, Other Quality aspects, Commercial aspects) are set, and in the terms of reference decide whether these hazards are considered in this study or not.

B Identify contamination points:

Identify contamination points by a so called 'cause -> effect' analysis.
The principal causes are:

Man power (skills, training, attitudes, and knowledge)
Method (procedures, inspections),
Machines (processing, engineering)
Materials (attributes of the product and its components)

C Determine probability:

It is to advise to determine the probability by using historical data from quality controls or failures that occurred in the past.

The potential for cross-contamination in food preparation is built by: food raw materials, cleaning methods, raw material preparation, equipment, environment, post cooking handling, people and personal hygiene.

D Asses severity:

Within the context of HACCP, risk can be defined as the likelihood that a hazard will occur. Within food safety it is helpful to consider food-risk-categories being high, medium or low.
Products of high risk: product not heated prior to consumption, containing fish, egg, vegetable, cereal and/or dairy ingredients, which need to be refrigerated. Raw meat, fish and dairy products. Infant feed.
Products of medium risk: dried or frozen products containing fish, meat, egg, vegetable or cereal and/or dairy ingredients or any substitutes for these and other products excluded in the food hygiene regulations and heated prior to consumption.
Products of low risk: not relevant for fish products.
The rationale behind the allocation of foods to these groups is a consideration of: Is the fish likely to contain and/or support the growth of potential pathogens. Will the product undergo any additional heat processing? Will future storage conditions provide opportunities for the growth of pathogens or further contamination? Is the population consuming the fish especially susceptible?

E Preventative measures:

Control measures are actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specific control measure.

1.3.8 Identify critical control points

A CCP is identified as a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to an acceptable level. Thus for every step, location or procedure identified as a CCP, a detailed description of the preventative measures to be taken at that point must be provided. Those CCP's highlight for the manufacturer where particular care has to be concentrated in the implementation of preventative measures. There are two levels of control, and therefore two kinds of CCP's: CCP1 is a Critical Control point where a food safety hazard is eliminated (for example sterilisation), where as CCP2 is a Critical Control Point where a food safety hazard is reduced to an acceptable level (for example pasteurisation).

In any operation many control points (CP) could be necessary but not critical due to low risk or low severity of the hazard involved. Some of these control points are there as a result of company rules for good manufacturing practice, product reputation, company policy or aesthetics. Such distinction between CP's and CCP's is one of the unique aspects of the HACCP-concept, which set priorities on risks and emphasises operations that offer the greatest potential for control. Thus the HACCP points out what is necessary while further control may be nice.

It is not always easy to determine if a certain processing step is a CCP.
Examples of CCP's are: a specified heat process, chilling, specific sanitation procedures, prevention of cross contamination, adjustment to food to a given pH or NaCl content. When considering a possible increase in levels of the hazard, the team should be aware that it is possible that a single process step will not allow development of the hazard to unacceptable levels, but that over a number of process steps the amount of increase may reach unacceptable levels, due to the cumulative time and temperature of holding the product during processing. The team must therefore take account not only of the specific process step under discussion, but also the accumulated effect of subsequent process steps when answering the question.

1.3.9 Target levels and tolerance

Proceed the HACCP system by identifying target levels (and specified tolerance) for the control measures at each CCP. The specific target levels and tolerance set for each CCP/control measure must represent some measurable parameter related to the CCP.

1.3.10 Monitoring procedures

Monitoring is the series of observations or measurements to ensure that the preventative measures being implemented correctly. The CCP's are 'in control'. Monitoring should provide this information in time for corrective action to be taken to regain control of the process before there is a need to segregate or reject the product. Therefore those that can be measured relatively easy and quickly are preferred. Examples of these measurements suitable for monitoring are temperature, time, moisture level, metal detection, pH, aw, in some cases chemical analysis, visual assessments of product and management/operational practices. Unfortunately this is not always possible. Microbiological monitoring systems have the disadvantage of having to interpret the results in the light of the known distribution of organisms in the product and are therefore only suitable for verification of CCP's.

1.3.11 Corrective actions

The HACCP plan should contain written details of:

- Immediate action to be taken when there is (a trend to) loss of control.
- Who is to be informed and the type of report to be produced.
- What to do with the product that has been produced.
- Investigations of how loss of control has occurred (prevention of recurrence should be an essential element of any HACCP plan).
- Who is responsible for decision making.

1.3.12 Verification

How to verify that the HACCP-system is working effectively:
- Methods that might be used to verify random sampling and analysing (microbiological analysis and chemical analysis (for example TVB-N) and trend analysis. Reinforced analysis or tests at selected critical control points. Intensified analysis of intermediate or final products. Take surveys on actual conditions during storage, distribution, sale and use of products.
- Verification procedures: Inspection of operations, validation of critical limits, with specialists, experts and standards setting organisations. Review of deviations from the set critical limits and of corrective actions. Audits by consulting agencies or government inspection authorities.

1.3.13 Documentation

In a HACCP system all activities from production to safety and quality control are described in procedures and instructions, so it will be clear what action is needed at every step of processing and when problems occur. Operating instructions (OI) cover working activities, whereas Control Instructions (CI) explain which controls have to be carried out, how they are to be carried out and by whom, what to do when control limits are exceeded, what to record. As production data is important for control of production, so is quality and safety data important for control of safe processing. These data are recorded on Registration forms (RF). Production and quality aspects of raw material, intermediary products, end products, and any material needed for processing (packaging, ingredients) need to be specified in Product Specifications (PS). Documents are identified by an abbreviation of the type of document (OI, CI, RF, PS) and a number, referring to a specific topic. Table 2 shows at which point, which documents are in use.

Operating instructions and Control Instructions have to be available to the persons responsible for the tasks in those instructions. They should be present and accessible at the point where the tasks take place, so they serve as quick reference. Registration forms have to be collected and managed by the Quality Manager.

1.3.14 Review and update the HACCP plan

When HACCP is completed, it is necessary to review the plan.
It is essential that change to any of the following should automatically act as a trigger for a HACCP review and update:
Change in raw material/product formulation.
Change in processing system.
Change in factory layout and environment.
Modification to process equipment.
Change in cleaning and disinfecting programme.
Change in packaging, storage and distribution system.
Change in staff levels and /or responsibilities.
Anticipated change in consumer use.
Receipt of information from the market place indicating a health or spoilage risk associated with the product.
etc.

2. HACCP plan for frozen Sardines

2.1 HACCP-team

Quality and Operation manager:	J. Grzunov
Technical manager:	M. Stohera
Operations manager:	M. Mirkovic
Sales manager:	K. Marinovic
External specialist:	C. Aalberts, Netherlands Institute for Fisheries Research (RIVO)

2.2 Description of the product

See Final product specification PS 02

2.3 Intended use of the product

To be eaten cooked, fried or grilled.
Product will not be sold directly to end users/consumers but to wholesale companies or institutions.

2.4 Flow diagram

To be used in combination with layout of the plant. In the flow diagram all processing steps are included. It shows the raw materials, ingredients, packaging materials and equipment (boxes, tubs and water) as input into the process. Furthermore the unknown delays are given. Other process delays are not specified. The rooms where processes take place divide processes. Not included but important to know in daily practice:
Product recycle/waste material routes. Waste material has to be taken out from the production area as soon as possible, with minimum spilling and no possibilities for cross-contaminating the product. This is included in the layout and route of the plant. Similar conditions are taken for the personnel route in the plant. These are not included in the HACCP plan but belong to a total quality plan for the plant.
Consumer instructions/information is not included in the HACCP plan as the product has to be processed again by the client.
The complete flow-chart is given in Annex 1.

2.5 Identification of potential hazards

Chemical residues

- pesticides
- antibiotics
- growth hormones
- toxic heavy metals
- PCB's

Physical hazards

- bones
- glass
- wood
- metal
- insects
- plastics
- jewellery
- paper/cardboard
- cigarette ends
- flaked paint
- string
- hair

Biological hazards

- Pathogenic micro-organisms, indigenous as well as non-indigenous
- Biotoxins
- Pathogenic viruses,
- Parasites
- Formation of biogenic amines like histamine.

These potential hazards are identified in the production process of this product. They are classified as Food safety hazards (FS), Other legislations hazards (OL), Other quality hazards (OQ) (internal standards IS or client standards CS), and Commercial hazards (CA). Only the Food Safety hazards and the Other Legislation hazards are within the scope of this HACCP plan. Table 1 shows the result of the Hazard Analysis for processing of IQF Sardines from fresh Sardines. There is one CCP level 1 are: Microbiological contamination

Table 1: Hazard Analysis Worksheet.

Regarding food safety the following CCP1 and CCP2 are identified

CCP1: **Water quality: microbial contamination**

CCP1: **Hygiene Control: microbial contamination**

CCP1: **Time and Temperature Control: microbial contamination**

CCP2: Government monitoring programme on sanitary quality of the fishing environment: chemical residues, biotoxins

CCP2: Sensory evaluation and time and temperature control of raw material: risk on formation of biogenic amines

CCP2: Operating instruction control of metal and foreign bodies

CCP2: Time-temperature control during freezing: risk of chemical/autolytic spoilage.

An overview of CCP's and related hazards, preventive measures, monitoring and control, corrective actions, registration records and verification activities are presented in Table 2.

Table 2.

<insert table 2> page 1

table 2 page 2

2.6 Verification program

Internal and external auditing system.
For a good verification of the HACCP plan, every 12 months an internal audit is performed. The quality manager is checking if the HACCP plan is still working as it was described, if processing or equipment or ingredients or suppliers etc. has been changed and whether it affects the HACCP plan. It is recommended to have a bi-annual external audit, performed by an inspection body, to check if the HACCP plan is still appropriate.

Continuously internal verification of each critical control point is layed out in Table 2.

2.7 Documents needed to be used within the HACCP plan

Documents printed in bold are presented in this manual. See Annex 3 for documents

Control instructions (CI)

CI 01: Control instructions reception of fresh fish
CI 02: Control instructions time and temperature registration
CI 03: Control instructions water quality
CI 04: Control instructions packaging material
CI 05: Control instructions hygiene control

Operating instructions (OI)

OI 01: Operation instructions cleaning and desinfecting
OI 02: Operation instruction offal, waste materials, and waste water**:** *not included in this HACCP plan, present in Croatian*
OI 03: Operation instructions reception of fresh fish
OI 04: Operation instructions cleaning of fish, deheading and gutting
OI 05: Operation instructions temporally storage 0°C
OI 06: Operation instructions packaging into 10-kg boxes
OI 07: Operation instructions tunnel freezer
OI 08: Operation instructions on frozen storage.

Registration forms (RF)

RF 01: Registration form reception of fresh fish

RF 02: Registration form time/temperature control

RF 03: Registration form water quality

RF 04: Registration form hygiene control

RF 06: Registration form weight control

RF 07: Registration form control packaging materials

Product specifications (PS)

PS 01: Product specifications incoming sardines

PS 02: Product specifications final product

PS 03: Product specifications packaging materials

PS 04: Product specification water quality

2.8 Additional information

Annexes

1. Factory layout
2. Process flow chart
3. HACCP documents
4. EEC directive water quality EC 778/1980
5. EEC directive food processing EC 178/2002
6. Recent analysis reports of water quality, hygiene of the workplace, end product quality

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Dillon, M. and Griffith, Ch. How to HACCP an illustrated guide. ISBN 1 900134004 (1995).

Codex Alimentarius: Recommended International Code of Practice for frozen fish.

Annex 1: Factory Layout

Annex 2: Process Flow chart

Annex 3: HACCP documents

Annex 4: EEC water quality directive

Annex 5: EEC food

Annex 6: Recent analysis reports of water quality, hygiene of the workplace, end product quality

CI 01 Control instruction reception of fresh fish

Aim: To control the incoming fish according to specifications as mentioned in PS 01
Who: The person responsible for the reception of the incoming fresh fish/quality manager
When: Every batch
How: Following the checklist/registration form RF 01
Registration: Registration form: RF 01

Every batch of fresh fish that is presented at the reception room must be inspected and registered according to specifications in PS 01 and form RF 01. Information about the fishing grounds together with the government-monitoring programme for chemical contaminants in the aquatic environment should prove control of chemical contaminants.

Checklist evaluation incoming fish. CI 01/RF/ PS01

Subject	Description	Critical limits	Corrective action
Identification	Fishing grounds, name of ship, date of catch.	Available	Put batch on hold until identification is completed
Properties	Batch containing fresh sardines. Fish is stored in containers 8kg of fish, covered with ice	Others species (mackerel, anchovies) not more than 30%.	Reject batch
Freshness	Odour:	Fresh, seawater	Reject batch
	Appearance:	Firm smooth skin, bright black eyes, bright colour pattern No bruises, cuts or other injuries. No excessive blood, no debris	
	Texture: firm (possible in rigor mortis)		
	Gills:	fresh dark red, no slime	
Size		Within 25-45 fish per kg	Reject batch
Temperature		0-2°Celsius and covered with ice	Apply ice

Annually check one batch on chemical residues and biotoxins. If concentrations exceed government regulations, respective fishing grounds are excluded from fishing sardines for human consumption, until new analysis show that concentrations are within limits.

CI 02 Control instruction time and temperature registration

Aim:	To control the time and the temperature according to process specifications.
Who:	The person responsible for the specific process (operation manager, line manager, machine operator).
When:	According to description following hereafter
How:	According to description following hereafter
Registration:	Follow the registration form: RF 02

At each process step the time and temperature must be controlled to prevent microbiological growth. There are time/temperature limits available for each process.

Reception of fish and temporary storage

When fresh fish is presented to the reception room check for temperature or presence of ice on the fish. If the temperature is above 5°Celsius reject the batch for processing and direct it to cold store for Tuna feed. Use the registration form RF 002 and fill in per batch: date and time of reception, date, time and temperature of temporary storage, and if fish is covered by ice.
Corrective action. If fish temperature is above 5°Celsius degrees or there is no ice visible, cover the fish with ice.

Cleaning, deheading and gutting

If the process is delayed, check if fish is covered with ice. If not, apply fresh ice. If there is a delay, use registration form RF 002 and fill in per batch: date and time of start of the delay, date and time of end of the delay, and result of checks every 20 minutes.
Corrective action. If the delay exceeds 20 minutes, apply fresh ice.

Washing

Check washing machine every 20 minutes: make sure conveyor belt is running and nozzles are spraying water. As long as the machine is running, there is no need to check temperature.

Freezing

Check temperature and speed of tunnel freezer. Fish should be 17 minutes inside the tunnel at –35 to -45°Celsius air temperature. Check temperature of tunnel freezer every 30 minutes.

Glazing

Fish should be coming directly from freezer when it is put into the glazing machine. Water temperature may not be higher than 5°Celsius. Check visually by checking if there is ice in the reservoir AND if the conveyor belt of the glazing machine is moving (this guarantees homogenous temperature of the glazing water).
Corrective action: add ice and/or start conveyor belt.

Packaging

If this processing step is running correctly, no problems are to be expected. If the process is delayed by technical problems, the time temperature registration must be performed. Use the registration form RF 002 and fill in per batch: date and time of start of the delay, date and time of end of the delay, temperature of the fish every 15 minutes.
Corrective action: If the delay exceeds 15 minutes, return melted fish to the conveyor belt to the freezing. Pallet with boxes containing fish should not stand longer than 1 hour in packaging room. If there is a delay, put pallet with filled boxes in freezer and return after resuming processing.

CI 03 Control instruction water quality

Aim:	To control the water quality according to specifications as mentioned in PS 04
Who:	Quality manager
When:	4 times per year
How:	conducted by public health authorities. Bacteriological control as set in standards.
Registration:	Use registration form RF 03.

CI 04 Control instruction packaging material

Aim: To control the incoming packaging materials according to specifications as mentioned in PS 03
Who: The person responsible for the reception of the packaging materials.
When: Every batch of packaging material
How: Following the checklist/registration form RF 07

Checklist control of packaging material. CI 04

Date	Date of reception of packaging materials.		
Time	Time of inspection		
Item	Name of the packaging materials.		
Supplier	Name or number of the supplier.		
Origin	Place of origin.		
Code marks	Code marks used by the supplier.		
Quantity	Quantity of packaging materials (number of boxes, etc.).		
Specification	Specification of the batch		
Damages	Is the packaging material damaged at arrival?	No ✍ OK	Yes ✍ determine the % of damage
How much damage	How much is damaged (number or %)	If more than 10% is damaged reject the batch. If between 5 and 10%, warn the supplier	
Remarks	General remarks concerning quality of the packaging materials.		

OI 01 Operation instructions cleaning and disinfecting of plant and equipment.

One of the most important actions in controlling the food safety of fish products is a good hygiene plan. Factors like housekeeping, personal hygiene, training and education, plant layout, design of equipment and machines, characteristics of materials selected, the maintenance and general condition of the plant can easily become more important than actual cleaning and disinfecting. But this instruction is only dealing with cleaning and disinfecting as a regularly task to prevent bacterial contamination throughout the whole production process.

Who is responsible for the cleaning?
Everyone in the plant is responsible for good hygiene keeping during the production shift! For the daily hygiene and disinfecting procedure one person (not the quality manager) is responsible but more persons have to work together and must get education in hygiene procedures.

The frequency of cleaning and disinfecting.
a) Every break. Minor cleaning of the workplace
b) After every shift or production day. Major cleaning of the whole plant.

Working method.
A: Clean every workplace. Remove all fish into the chill rooms. Remove all other materials like boxes, tubs, waste materials etc. and place them in the designated areas. Use hoses for cleaning workplaces and high-pressure water to clean machines.

B: Clean the whole plant.
- Remove all fish into the chill rooms.
- Clear the area for bins, containers, packaging material and all other equipment what is not to be cleaned.
- Dismantle equipment and machines to expose surfaces to be cleaned.
- Remove small equipment parts and fittings to be cleaned in a specified area.
- Cover sensitive installations to protect them against water.
- Clear the area, machines and equipment for food residues by flushing with cold water and by using brushes and brooms.
- Apply the cleaning agent and use mechanical energy (high pressure and brushes) as required.
- Rinse thoroughly with water to completely remove the cleaning agent after the appropriate contact time (residues of cleaning detergent may completely inhibit the effect of disinfecting).
- Check the cleaning.
- Sterilisation by chemical disinfecting.
- Rinse the sterilant off with water after the appropriate contact time. This final rinse is not needed for some sterilants e.g. H_2O_2 based formulations that decompose rapidly.
- After the final rinse, the equipment is allowed to dry.
- Visual control of cleaning and disinfecting as described in CI 05.

OI 03 Operation instructions reception of fresh fish

Reception of fish

When a batch of fresh fish is presented at the reception room, identify the batch with registration form RF 01.
If there is more than one batch in the reception room or at temporary storage awaiting processing or removal to Tuna feed coldstore, label the batch with a unique code which is also registered on RF 01.
Perform evaluation of the raw material with CI 01 and decide whether the batch is acceptable for further processing.
If so, make sure the fish is properly iced and store the fish in Temporary storage at 0 Celsius. If not, label the batch clearly with a label TUNA FEED and transport it to the Tuna feed collecting freezer.

Temporary storage

During temporary storage fish should be checked regularly (minimum of two times a day) to check if ice is still present on the fish. If not reapply ice. Temporary storage should not exceed 48 hours.

RF 01 RF 01 Registration forms reception of fresh fish

Date and time of reception		Date: Time:
Date and time of inspection		Date: Time:
Batch identification		
Fish inspector		
Government inspection report available		Yes/no
Batch size	Number of boxes: Weight:	
Identification	Fishing grounds: Name of ship: Date of catch: Time of catch:	
Properties	Batch containing fresh sardines. Others species (mackerel, anchovies) not more than 30%	% of other species:
Freshness	Odour: fresh, seawater: Appearance: little bit of slime on the skin, bright black eyes, bright colour pattern Texture: firm (possible in rigor mortis) Gills: fresh dark red, no slime Skin: No bruises, cuts or other injuries. No excessive blood, no debris.	Good/acceptable/unacceptable Good/acceptable/unacceptable Good/acceptable/unacceptable Good/acceptable/unacceptable Good/acceptable/unacceptable
Size	Number per kg:	
Temperature	Temperature Covered with ice	°Celsius Yes/no
Evaluation result		Accepted/Not accepted
Destination		Processing/Tuna feed

RF-02 Registration forms time/temperature control

Check temperature visually (by presence/absence of ice) or with a thermometer.

Date	
Assistant Name	
Batch number	
Start production time of batch	
End production time of batch	
Product delay	
	1. time: duration: temperature check: 2. time: duration: temperature check: 3. time: duration: temperature check: 4. time: duration: temperature check: 5. time: duration: temperature check: 6. time: duration: temperature check:

RF-03 Registration forms water quality control

Name	Quality Manager	
Year		
Inspection reports		
Date of analysis	**Analysis result**	**Corrective action**
	Good/unacceptable	Yes/no
	Good/unacceptable	Yes/no
	Good/unacceptable	Yes/no
	Good/unacceptable	Yes/no

Corrective action:

Contact water supplier to ask for remedial actions.

PS-01 Product specification of fresh fish

Identification	Fishing grounds, name of ship, date of catch.
Properties	Batch containing fresh sardines. Others species (mackerel, anchovies) not more than 50%
Freshness	Odour: fresh, seawater Appearance: little bit of slime on the skin, bright black eyes, bright colour pattern Texture: firm (possible in rigor mortis) Gills: fresh dark red, no slime No bruises, cuts or other injuries. No excessive blood, no debris.
Size	25-45 fish per kg
Temperature	0-2°Celsius and covered with ice.

PS 02 Product specification final product

Product description	**Sardines Individually Quick Frozen** whole-round or headed/gutted
Process description	Fresh caught sardines properly handled, well iced and kept at ±2°C untill start of processing, frozen at –35 to 45°C for 17 –20 minutes, glazed and packed in plastic bags and carton boxes. Glazing: 5%
Physical product specifications	Size 25-45 pieces/kg (depending on season), whole-round or headed and gutted
Microbiological specifications	Salmonella spp: absent in 25g Staphylococcus aureus: <1000cfu/g Enterobacteriaceae: <1000/g Sulphite reducing Clostridiae: <1000/g Listeria monocytogenes: =< 10/g
Storage conditions Storage packaging Storage temperatures	Product is delivered packed in plastic bags of 0.5, 1 and 10kg in carton boxes of 10 kg at –18°C.
Minimal shelflife Shelflife at –18°C	12 months
Distribution to consumer/client	Freezer trucks –20°C
Preperation before use/consumption	Product is produced for wholesale and retail, intended to be eaten whole: cooked, fried or grilled.

PS 04 Water quality

See Council directive (80/778/EEC) Annex 2 and Croatian legislation.

CI-05 Control instruction Hygiene Control

Aim: To control the cleaning and disinfecting of plant and equipment.
Who: The quality manager.
When: Every day before the start of the shift.
How: Following the checklist/registration form for visual inspection. Every month microbiological analysis of surfaces and equipment and tools is carried out by Public Health inspection.

Checklist hygiene control. CI 05

		Good	Unacceptable: improve cleaning	Attention next time
Date	Date of control.			
Time	Time of control.			
Production area's	Reception area			
	Cold store ice K 3			
	Processing area			
	Storage room K 2			
	Packaging area			
	Cold store for temporary storage K 5			
	Cold store for long term storage			
Equipment/tools	Transport boxes			
	Cleaning, deheading and gutting table (including conveyor belt)			
	Knifes			
	Tubs			
	Boxes			
	Aprons			
	Washing tunnel			
	Conveyor 1			
	Conveyor to freezing tunnels			
	Loading table of freezing tunnel 1			
	Loading table of freezing tunnel 2			
	Loading table of freezing tunnel 3			
	Conveyor belt to glazing machine			
	Glazing machine			
	Conveyor belt packing machine			
Concentration chemicals	Cleaning foam			
	Disinfecting			

Good: No dirty surfaces with fish or other product rests. Also check the 'not directly in sight' surfaces like the undersides of the tables, the corners and the difficult to clean places.
Unacceptable: Larger dirty surfaces in direct contact with fish.
Needs attention next cleaning: Smaller dirty surfaces, not in direct contact with fish.

Corrective actions:

- Visual inspection: unacceptable cleaning: clean before start of production.
- Bacteriological inspection: unacceptable hygiene: clean respective item.

I

(Acts whose publication is obligatory)

REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95, 133 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4],

Whereas:

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be assured in the pursuit of Community policies.

(3) The free movement of food and feed within the Community can be achieved only if food and feed safety requirements do not differ significantly from Member State to Member State.

(4) There are important differences in relation to concepts, principles and procedures between the food laws of the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market.

(5) Accordingly, it is necessary to approximate these concepts, principles and procedures so as to form a common basis for measures governing food and feed taken in the Member States and at Community level. It is however necessary to provide for sufficient time for the adaptation of any conflicting provisions in existing legislation, both at national and Community level, and to provide that, pending such adaptation, the relevant legislation be applied in the light of the principles set out in the present Regulation.

(6) Water is ingested directly or indirectly like other foods, thereby contributing to the overall exposure of a consumer to ingested substances, including chemical and microbiological contaminants. However, as the quality of water intended for human consumption is already controlled by Council Directives 80/778/EEC [5] and 98/83/EC [6], it suffices to consider water after the point of compliance referred to in Article 6 of Directive 98/83/EC.

(7) Within the context of food law it is appropriate to include requirements for feed, including its production and use where that feed is intended for food-producing animals. This is without prejudice to the similar requirements which have been applied so far and which will be applied in the future in feed legislation applicable to all animals, including pets.

(8) The Community has chosen a high level of health protection as appropriate in the development of food law, which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally.

[1] OJ C 96 E, 27.3.2001, p. 247.
[2] OJ C 155, 29.5.2001, p. 32.
[3] Opinion delivered on 14 June 2001 (not yet published in the Official Journal).
[4] Opinion of the European Parliament of 12 June 2001 (not yet published in the Official Journal), Council Common Position of 17 September 2001 (not yet published in the Official Journal) and Decision of the European Parliament of 11 December 2001 (not yet published in the Official Journal). Council Decision of 21 January 2002.
[5] OJ L 229, 30.8.1980, p. 11. Directive repealed by Directive 98/83/EC.
[6] OJ L 330, 5.12.1998, p. 32.

(9) It is necessary to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law, its scientific basis and the structures and independence of the institutions protecting health and other interests.

(10) Experience has shown that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not placed on the market and at ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health. Similar issues relating to feed safety should be addressed.

(11) In order to take a sufficiently comprehensive and integrated approach to food safety, there should be a broad definition of food law covering a wide range of provisions with a direct or indirect effect on the safety of food and feed, including provisions on materials and articles in contact with food, animal feed and other agricultural inputs at the level of primary production.

(12) In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety.

(13) Experience has shown that for this reason it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals, including the production of animals which may be used as feed on fish farms, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety.

(14) For the same reason, it is necessary to consider other practices and agricultural inputs at the level of primary production and their potential effect on the overall safety of food.

(15) Networking of laboratories of excellence, at regional and/or interregional level, with the aim of ensuring continuous monitoring of food safety, could play an important role in the prevention of potential health risks for citizens.

(16) Measures adopted by the Member States and the Community governing food and feed should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. Recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.

(17) Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis — risk assessment, risk management, and risk communication — provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.

(18) In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.

(19) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

(20) The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle.

(21) In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community.

(22) Food safety and the protection of consumer's interests is of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. It is necessary to ensure that consumer confidence and the confidence of trading partners is secured through the open and transparent development of food law and through public authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health.

(23) The safety and confidence of consumers within the Community, and in third countries, are of paramount importance. The Community is a major global trader in food and feed and, in this context, it has entered into international trade agreements, it contributes to the development of international standards which underpin food law, and it supports the principles of free trade in safe feed and safe, wholesome food in a non-discriminatory manner, following fair and ethical trading practices.

(24) It is necessary to ensure that food and feed exported or re-exported from the Community complies with Community law or the requirements set up by the importing country. In other circumstances, food and feed can only be exported or re-exported if the importing country has expressly agreed. However, it is necessary to ensure that even where there is agreement of the importing country, food injurious to health or unsafe feed is not exported or re-exported.

(25) It is necessary to establish the general principles upon which food and feed may be traded and the objectives and principles for the contribution of the Community to developing international standards and trade agreements.

(26) Some Member States have adopted horizontal legislation on food safety imposing, in particular, a general obligation on economic operators to market only food that is safe. However, these Member States apply different basic criteria for establishing whether a food is safe. Given these different approaches, and in the absence of horizontal legislation in other Member States, barriers to trade in foods are liable to arise. Similarly such barriers may arise to trade in feed.

(27) It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the internal market in such products functions effectively.

(28) Experience has shown that the functioning of the internal market in food or feed can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.

(29) It is necessary to ensure that a food or feed business including an importer can identify at least the business from which the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.

(30) A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety. Although this principle exists in some Member States and areas of food law, in other areas this is either not explicit or else responsibility is assumed by the competent authorities of the Member State through the control activities they carry out. Such disparities are liable to create barriers to trade and distort competition between food business operators in different Member States.

(31) Similar requirements should apply to feed and feed business operators.

(32) The scientific and technical basis of Community legislation relating to the safety of food and feed should contribute to the achievement of a high level of health protection within the Community. The Community should have access to high-quality, independent and efficient scientific and technical support.

(33) The scientific and technical issues in relation to food and feed safety are becoming increasingly important and complex. The establishment of a European Food Safety Authority, hereinafter referred to as 'the Authority', should reinforce the present system of scientific and technical support which is no longer able to respond to increasing demands on it.

(34) Pursuant to the general principles of food law, the Authority should take on the role of an independent scientific point of reference in risk assessment and in so doing should assist in ensuring the smooth functioning of the internal market. It may be called upon to give opinions on contentious scientific issues, thereby enabling the Community institutions and Member States to take informed risk management decisions necessary to ensure food and feed safety whilst helping avoid the fragmentation of the internal market through the adoption of unjustified or unnecessary obstacles to the free movement of food and feed.

(35) The Authority should be an independent scientific source of advice, information and risk communication in order to improve consumer confidence; nevertheless, in order to promote coherence between the risk assessment, risk management and risk communication functions, the link between risk assessors and risk managers should be strengthened.

(36) The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food and feed supply chains, which implies wide-ranging responsibilities for the Authority. These should include issues having a direct or indirect impact on the safety of the food and feed supply chains, animal health and welfare, and plant health. However, it is necessary to ensure that the Authority focuses on food safety, so its mission in relation to animal health, animal welfare and plant health issues that are not linked to the safety of the food supply chain should be limited to the provision of scientific opinions. The Authority's mission should also cover scientific advice and scientific and technical support on human nutrition in relation to Community legislation and assistance to the Commission at its request on communication linked to Community health programmes.

(37) Since some products authorised under food law such as pesticides or additives in animal feed may involve risks to the environment or to the safety of workers, some environmental and worker protection aspects should also be assessed by the Authority in accordance with the relevant legislation.

(38) In order to avoid duplicated scientific assessments and related scientific opinions on genetically modified organisms (GMOs), the Authority should also provide scientific opinions on products other than food and feed relating to GMOs as defined by Directive 2001/18/EC [1] and without prejudice to the procedures established therein.

(39) The Authority should contribute through the provision of support on scientific matters, to the Community's and Member States' role in the development and establishment of international food safety standards and trade agreements.

(40) The confidence of the Community institutions, the general public and interested parties in the Authority is essential. For this reason, it is vital to ensure its independence, high scientific quality, transparency and efficiency. Cooperation with Member States is also indispensable.

(41) To that effect the Management Board should be appointed in such a way as to secure the highest standard of competence, a broad range of relevant expertise, for instance in management and in public administration, and the broadest possible geographic distribution within the Union. This should be facilitated by a rotation of the different countries of origin of the members of the Management Board without any post being reserved for nationals of any specific Member State.

(42) The Authority should have the means to perform all the tasks required to enable it to carry out its role.

(43) The Management Board should have the necessary powers to establish the budget, check its implementation, draw up internal rules, adopt financial regulations, appoint members of the Scientific Committee and Scientific Panels and appoint the Executive Director.

(44) The Authority should cooperate closely with competent bodies in the Member States if it is to operate effectively. An Advisory Forum should be created in order to advise the Executive Director, to constitute a mechanism of exchange of information, and to ensure close cooperation in particular with regard to the networking system. Cooperation and appropriate exchange of information should also minimise the potential for diverging scientific opinions.

(45) The Authority should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence. It is necessary to reorganise these Committees to ensure greater scientific consistency in relation to the food supply chain and to enable them to work more effectively. A Scientific Committee and Permanent Scientific Panels should therefore be set up within the Authority to provide these opinions.

(46) In order to guarantee independence, members of the Scientific Committee and Panels should be independent scientists recruited on the basis of an open application procedure.

(47) The Authority's role as an independent scientific point of reference means that a scientific opinion may be requested not only by the Commission, but also by the European Parliament and the Member States. In order to ensure the manageability and consistency of the process of scientific advice, the Authority should be able to refuse or amend a request providing justification for this and on the basis of predetermined criteria. Steps should also be taken to help avoid diverging scientific opinions and, in the event of diverging scientific opinions between scientific bodies, procedures should be in place to resolve the divergence or provide the risk managers with a transparent basis of scientific information.

[1] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

(48) The Authority should also be able to commission scientific studies necessary for the accomplishment of its duties, while ensuring that the links established by it with the Commission and the Member States prevent duplication of effort. It should be done in an open and transparent fashion and the Authority should take into account existing Community expertise and structures.

(49) The lack of an effective system of collection and analysis at Community level of data on the food supply chain is recognised as a major shortcoming. A system for the collection and analysis of relevant data in the fields covered by the Authority should therefore be set up, in the form of a network coordinated by the Authority. A review of Community data collection networks already existing in the fields covered by the Authority is called for.

(50) Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of the Member States and the Community in the exercise of its policies. It is therefore necessary to assign to the Authority an anticipatory task of collecting information and exercising vigilance and providing evaluation of and information on emerging risks with a view to their prevention.

(51) The establishment of the Authority should enable Member States to become more closely involved in scientific procedures. There should therefore be close cooperation between the Authority and the Member States for this purpose. In particular, the Authority should be able to assign certain tasks to organisations in the Member States.

(52) It is necessary to ensure that a balance is struck between the need to use national organisations to carry out tasks for the Authority and the need to ensure for the purposes of overall consistency that such tasks are carried out in line with the criteria established for such tasks. Existing procedures for the allocation of scientific tasks to the Member States, in particular with regard to the evaluation of dossiers presented by industry for the authorisation of certain substances, products or procedures, should be re-examined within a year with the objective of taking into account the establishment of the Authority and the new facilities it offers, the evaluation procedures remaining at least as stringent as before.

(53) The Commission remains fully responsible for communicating risk management measures. The appropriate information should therefore be exchanged between the Authority and the Commission. Close cooperation between the Authority, the Commission and the Member States is also necessary to ensure the coherence of the global communication process.

(54) The independence of the Authority and its role in informing the public mean that it should be able to communicate autonomously in the fields falling within its competence, its purpose being to provide objective, reliable and easily understandable information.

(55) Appropriate cooperation with the Member States and other interested parties is necessary in the specific field of public information campaigns to take into account any regional parameters and any correlation with health policy.

(56) In addition to its operating principles based on independence and transparency, the Authority should be an organisation open to contacts with consumers and other interested groups.

(57) The Authority should be financed by the general budget of the European Union. However, in the light of experience acquired, in particular with regard to the processing of authorisation dossiers presented by industry, the possibility of fees should be examined within three years following the entry into force of this Regulation. The Community budgetary procedure remains applicable as far as any subsidies chargeable to the general budget of the European Union are concerned. Moreover, the auditing of accounts should be undertaken by the Court of Auditors.

(58) It is necessary to allow for the participation of European countries which are not members of the European Union and which have concluded agreements obliging them to transpose and implement the body of Community law in the field covered by this Regulation.

(59) A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992 on general product safety [1]. The scope of the existing system includes food and industrial products but not feed. Recent food crises have demonstrated the need to set up an improved and broadened rapid alert system covering food and feed. This revised system should be managed by the Commission and include as members of the network the Member States, the Commission and the Authority. The system should not cover the Community arrangements for the early exchange of information in the event of a radiological emergency as defined in Council Decision 87/600/Euratom [2].

(60) Recent food safety incidents have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to common measures in the event of a serious risk to human health, animal health or the environment. Such a comprehensive approach to emergency food safety measures should allow effective action to be taken and avoid artificial disparities in the treatment of a serious risk in relation to food or feed.

[1] OJ L 228, 11.8.1992, p. 24.
[2] OJ L 371, 30.12.1987, p. 76.

(61) Recent food crises have also shown the benefits to the Commission of having properly adapted, more rapid procedures for crisis management. These organisational procedures should make it possible to improve coordination of effort and to determine the most effective measures on the basis of the best scientific information. Therefore, revised procedures should take into account the Authority's responsibilities and should provide for its scientific and technical assistance in the form of advice in the event of a food crisis.

(62) In order to ensure a more effective, comprehensive approach to the food chain, a Committee on the Food Chain and Animal Health should be established to replace the Standing Veterinary Committee, the Standing Committee for Foodstuffs and the Standing Committee for Feedingstuffs. Accordingly, Council Decisions 68/361/EEC ([1]), 69/414/EEC ([2]), and 70/372/EEC ([3]), should be repealed. For the same reason the Committee on the Food Chain and Animal Health should also replace the Standing Committee on Plant Health in relation to its competence (for Directives 76/895/EEC ([4]), 86/362/EEC ([5]), 86/363/EEC ([6]), 90/642/EEC ([7]) and 91/414/EEC ([8])) on plant protection products and the setting of maximum residue levels.

(63) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([9]).

(64) It is necessary that operators should have sufficient time to adapt to some of the requirements established by the present Regulation and that the European Food Safety Authority should commence its operations on 1 January 2002.

(65) It is important to avoid confusion between the missions of the Authority and the European Agency for the Evaluation of Medicinal Products (EMEA) established by Council Regulation (EEC) No 2309/93 ([10]). Consequently, it is necessary to establish that this Regulation is without prejudice to the competence conferred on the EMEA by Community legislation, including powers conferred by Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin ([11]).

(66) It is necessary and appropriate for the achievement of the basic objectives of this Regulation to provide for the approximation of the concepts, principles and procedures forming a common basis for food law in the Community and to establish a European Food Safety Authority. In accordance with the principle of proportionality as set out in Article 5 of the Treaty, this Regulation does not go beyond what is necessary in order to achieve the objectives pursued,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Aim and scope

1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market.

It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.

It establishes the European Food Safety Authority.

It lays down procedures for matters with a direct or indirect impact on food and feed safety.

([1]) OJ L 255, 18.10.1968, p. 23.
([2]) OJ L 291, 19.11.1969, p. 9.
([3]) OJ L 170, 3.8.1970, p. 1.
([4]) OJ L 340, 9.12.1976, p. 26. Directive as last amended by Commission Directive 2000/57/EC (OJ L 244, 29.9.2000, p. 76).
([5]) OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2001/57/EC (OJ L 208, 1.8.2001, p. 36).
([6]) OJ L 221, 7.8.1986, p. 43. Directive as last amended by Commission Directive 2001/57/EC.
([7]) OJ L 350, 14.12.1990, p. 71. Directive as last amended by Commission Directive 2001/57/EC.
([8]) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2001/49/EC (OJ L 176, 29.6.2001, p. 61).
([9]) OJ L 184, 17.7.1999, p. 23.
([10]) OJ L 214, 24.8.1993, p. 1. Regulation amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).
([11]) OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1553/2001 (OJ L 205, 31.7.2001, p. 16).

3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

Article 2

Definition of 'food'

For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

(a) feed;

(b) live animals unless they are prepared for placing on the market for human consumption;

(c) plants prior to harvesting;

(d) medicinal products within the meaning of Council Directives 65/65/EEC [1] and 92/73/EEC [2];

(e) cosmetics within the meaning of Council Directive 76/768/EEC [3];

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC [4];

(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;

(h) residues and contaminants.

Article 3

Other definitions

For the purposes of this Regulation:

1. 'food law' means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals;

2. 'food business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;

3. 'food business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;

4. 'feed' (or 'feedingstuff') means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

5. 'feed business' means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;

6. 'feed business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;

7. 'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;

8. 'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;

9. 'risk' means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

10. 'risk analysis' means a process consisting of three interconnected components: risk assessment, risk management and risk communication;

11. 'risk assessment' means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

12. 'risk management' means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

[1] OJ 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).
[2] OJ L 297, 13.10.1992, p. 8.
[3] OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2000/41/EC (OJ L 145, 20.6.2000, p. 25).
[4] OJ L 359, 8.12.1989, p. 1. Directive as last amended by Directive 92/41/EEC) (OJ L 158, 11.6.1992, p. 30).

13. 'risk communication' means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

14. 'hazard' means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;

15. 'traceability' means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;

16. 'stages of production, processing and distribution' means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;

17. 'primary production' means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;

18. 'final consumer' means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.

CHAPTER II

GENERAL FOOD LAW

Article 4

Scope

1. This Chapter relates to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.

2. The principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature to be followed when measures are taken.

3. Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10.

4. Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 5 to 10.

SECTION 1

GENERAL PRINCIPLES OF FOOD LAW

Article 5

General objectives

1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.

3. Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community.

Article 6

Risk analysis

1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.

Article 7

Precautionary principle

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Article 8

Protection of consumers' interests

1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:

(a) fraudulent or deceptive practices;

(b) the adulteration of food; and

(c) any other practices which may mislead the consumer.

SECTION 2

PRINCIPLES OF TRANSPARENCY

Article 9

Public consultation

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.

Article 10

Public information

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

SECTION 3

GENERAL OBLIGATIONS OF FOOD TRADE

Article 11

Food and feed imported into the Community

Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

Article 12

Food and feed exported from the Community

1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.

2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.

Article 13

International standards

Without prejudice to their rights and obligations, the Community and the Member States shall:

(a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;

(b) promote the coordination of work on food and feed standards undertaken by international governmental and non-governmental organisations;

(c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures;

(d) give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries;

(e) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced.

SECTION 4

GENERAL REQUIREMENTS OF FOOD LAW

Article 14

Food safety requirements

1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be:

(a) injurious to health;

(b) unfit for human consumption.

3. In determining whether any food is unsafe, regard shall be had:

(a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4. In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;

(b) to the probable cumulative toxic effects;

(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Article 15

Feed safety requirements

1. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.

2. Feed shall be deemed to be unsafe for its intended use if it is considered to:

— have an adverse effect on human or animal health;

— make the food derived from food-producing animals unsafe for human consumption.

3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.

4. Feed that complies with specific Community provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.

6. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Article 16

Presentation

Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

Article 17

Responsibilities

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

Article 18

Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

Article 19

Responsibilities for food: food business operators

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

Article 20

Responsibilities for feed: feed business operators

1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

2. A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.

4. Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied.

Article 21

Liability

The provisions of this Chapter shall be without prejudice to Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products ([1]).

CHAPTER III

EUROPEAN FOOD SAFETY AUTHORITY

SECTION 1

MISSION AND TASKS

Article 22

Mission of the Authority

1. A European Food Safety Authority, hereinafter referred to as the 'Authority', is hereby established.

2. The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks.

3. The Authority shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market.

([1]) OJ L 210, 7.8.1985, p. 29. Directive as last amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20).

4. The Authority shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.

5. The mission of the Authority shall also include the provision of:

(a) scientific advice and scientific and technical support on human nutrition in relation to Community legislation and, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme;

(b) scientific opinions on other matters relating to animal health and welfare and plant health;

(c) scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC and without prejudice to the procedures established therein.

6. The Authority shall provide scientific opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission.

7. The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.

It shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of the Authority.

8. The Authority, Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.

9. The Member States shall cooperate with the Authority to ensure the accomplishment of its mission.

Article 23

Tasks of the Authority

The tasks of the Authority shall be the following:

(a) to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission;

(b) to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission;

(c) to provide scientific and technical support to the Commission in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions;

(d) to commission scientific studies necessary for the accomplishment of its mission;

(e) to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission;

(f) to undertake action to identify and characterise emerging risks, in the fields within its mission;

(g) to establish a system of networks of organisations operating in the fields within its mission and be responsible for their operation;

(h) to provide scientific and technical assistance, when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed;

(i) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Community, applicant countries, international organisations and third countries, in the fields within its mission;

(j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;

(k) to express independently its own conclusions and orientations on matters within its mission;

(l) to undertake any other task assigned to it by the Commission within its mission.

SECTION 2

ORGANISATION

Article 24

Bodies of the Authority

The Authority shall comprise:

(a) a Management Board;

(b) an Executive Director and his staff;

(c) an Advisory Forum;

(d) a Scientific Committee and Scientific Panels.

Article 25

Management Board

1. The Management Board shall be composed of 14 members appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission which includes a number of candidates substantially higher than the number of members to be appointed, plus a representative of the Commission. Four of the members shall have their background in organisations representing consumers and other interests in the food chain.

The list drawn up by the Commission, accompanied by the relevant documentation, shall be forwarded to the European Parliament. As soon as possible and within three months of such communication, the European Parliament may make its views available for consideration by the Council, which will then appoint the Management Board.

The members of the Board shall be appointed in such a way as to secure the highest standards of competence, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution within the Union.

2. Members' term of office shall be four years, and may be renewed once. However, for the first mandate, this period shall be six years for half of the members.

3. The Management Board shall adopt the Authority's internal rules on the basis of a proposal by the Executive Director. These rules shall be made public.

4. The Management Board shall elect one of its members as its Chair for a two-year period, which shall be renewable.

5. The Management Board shall adopt its rules of procedure.

Unless otherwise provided, the Management Board shall act by a majority of its members.

6. The Management Board shall meet at the invitation of the Chair or at the request of at least a third of its members.

7. The Management Board shall ensure that the Authority carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation.

8. Before 31 January each year, the Management Board shall adopt the Authority's programme of work for the coming year. It shall also adopt a revisable multi-annual programme. The Management Board shall ensure that these programmes are consistent with the Community's legislative and policy priorities in the area of food safety.

Before 30 March each year, the Management Board shall adopt the general report on the Authority's activities for the previous year.

9. The Management Board, having received the Commission's approval and the opinion of the Court of Auditors, shall adopt the Authority's financial regulation which specifies in particular the procedure for drawing up and implementing the Authority's budget, in accordance with Article 142 of the Financial Regulation of 21 December 1977 applicable to the general budget of the European Communities ([1]) and with the legislative requirements concerning investigations conducted by the European Anti-Fraud Office.

10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat. The Management Board shall invite the Chair of the Scientific Committee to attend its meetings without voting rights.

([1]) OJ L 356, 31.12.1977, p. 1. Regulation as last amended by Regulation (EC, ECSC, Euratom) No 762/2001 (OJ L 111, 20.4.2001, p. 1).

Article 26

Executive Director

1. The Executive Director shall be appointed by the Management Board, on the basis of a list of candidates proposed by the Commission after an open competition, following publication in the *Official Journal of the European Communities* and elsewhere of a call for expressions of interest, for a period of five years which shall be renewable. Before appointment the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and answer questions put by members of this institution. The Executive Director may be removed from office by a majority of the Management Board.

2. The Executive Director shall be the legal representative of the Authority and shall be responsible for:

(a) the day-to-day administration of the Authority;

(b) drawing up a proposal for the Authority's work programmes in consultation with the Commission;

(c) implementing the work programmes and the decisions adopted by the Management Board;

(d) ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee and the Scientific Panels;

(e) ensuring that the Authority carries out its tasks in accordance with the requirements of its users, in particular with regard to the adequacy of the services provided and the time taken;

(f) the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority;

(g) all staff matters;

(h) developing and maintaining contact with the European Parliament, and for ensuring a regular dialogue with its relevant committees.

3. Each year, the Executive Director shall submit to the Management Board for approval:

(a) a draft general report covering all the activities of the Authority in the previous year;

(b) draft programmes of work;

(c) the draft annual accounts for the previous year;

(d) the draft budget for the coming year.

The Executive Director shall, following adoption by the Management Board, forward the general report and the programmes to the European Parliament, the Council, the Commission and the Member States, and shall have them published.

4. The Executive Director shall approve all financial expenditure of the Authority and report on the Authority's activities to the Management Board.

Article 27

Advisory Forum

1. The Advisory Forum shall be composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority, on the basis of one representative designated by each Member State. Representatives may be replaced by alternates, appointed at the same time.

2. Members of the Advisory Forum may not be members of the Management Board.

3. The Advisory Forum shall advise the Executive Director in the performance of his duties under this Regulation, in particular in drawing up a proposal for the Authority's work programme. The Executive Director may also ask the Advisory Forum for advice on the prioritisation of requests for scientific opinions.

4. The Advisory Forum shall constitute a mechanism for an exchange of information on potential risks and the pooling of knowledge. It shall ensure close cooperation between the Authority and the competent bodies in the Member States in particular on the following items:

(a) avoidance of duplication of the Authority's scientific studies with Member States, in accordance with Article 32;

(b) in those circumstances identified in Article 30(4), where the Authority and a national body are obliged to cooperate;

(c) in the promoting of the European networking of organisations operating within the fields of the Authority's mission, in accordance with Article 36(1);

(d) where the Authority or a Member State identifies an emerging risk.

5. The Advisory Forum shall be chaired by the Executive Director. It shall meet regularly at the invitation of the Chair or at the request of at least a third of its members, and not less than four times per year. Its operational procedures shall be specified in the Authority's internal rules and shall be made public.

6. The Authority shall provide the technical and logistic support necessary for the Advisory Forum and provide the Secretariat for its meetings.

7. Representatives of the Commission's departments may participate in the work of the Advisory Forum. The Executive Director may invite representatives of the European Parliament and from other relevant bodies to take part.

Where the Advisory Forum discusses the matters referred to in Article 22(5)(b), representatives from competent bodies in the Member States which undertake tasks similar to those referred to in Article 22(5)(b) may participate in the work of the Advisory Forum, on the basis of one representative designated by each Member State.

Article 28

Scientific Committee and Scientific Panels

1. The Scientific Committee and permanent Scientific Panels shall be responsible for providing the scientific opinions of the Authority, each within their own spheres of competence, and shall have the possibility, where necessary, of organising public hearings.

2. The Scientific Committee shall be responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonisation of working methods. It shall provide opinions on multisectoral issues falling within the competence of more than one Scientific Panel, and on issues which do not fall within the competence of any of the Scientific Panels.

Where necessary, and particularly in the case of subjects which do not fall within the competence of any of the Scientific Panels, the Scientific Committee shall set up working groups. In such cases, it shall draw on the expertise of those working groups when establishing scientific opinions.

3. The Scientific Committee shall be composed of the Chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the Scientific Panels.

4. The Scientific Panels shall be composed of independent scientific experts. When the Authority is established, the following Scientific Panels shall be set up:

(a) the Panel on food additives, flavourings, processing aids and materials in contact with food;

(b) the Panel on additives and products or substances used in animal feed;

(c) the Panel on plant health, plant protection products and their residues;

(d) the Panel on genetically modified organisms;

(e) the Panel on dietetic products, nutrition and allergies;

(f) the Panel on biological hazards;

(g) the Panel on contaminants in the food chain;

(h) the Panel on animal health and welfare.

The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request, in accordance with the procedure referred to in Article 58(2).

5. The members of the Scientific Committee who are not members of Scientific Panels and the members of the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a three-year term of office, which shall be renewable, following publication in the *Official Journal of the European Communities*, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest.

6. The Scientific Committee and the Scientific Panels shall each choose a Chair and two Vice-Chairs from among their members.

7. The Scientific Committee and the Scientific Panels shall act by a majority of their members. Minority opinions shall be recorded.

8. The representatives of the Commission's departments shall be entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.

9. The procedures for the operation and cooperation of the Scientific Committee and the Scientific Panels shall be laid down in the Authority's internal rules.

These procedures shall relate in particular to:

(a) the number of times that a member can serve consecutively on a Scientific Committee or Scientific Panel;

(b) the number of members in each Scientific Panel;

(c) the procedure for reimbursing the expenses of members of the Scientific Committee and the Scientific Panels;

(d) the manner in which tasks and requests for scientific opinions are assigned to the Scientific Committee and the Scientific Panels;

(e) the creation and organisation of the working groups of the Scientific Committee and the Scientific Panels, and the possibility of external experts being included in those working groups;

(f) the possibility of observers being invited to meetings of the Scientific Committee and the Scientific Panels;

(g) the possibility of organising public hearings.

SECTION 3

OPERATION

Article 29

Scientific opinions

1. The Authority shall issue a scientific opinion:

(a) at the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Authority to be consulted;

(b) on its own initiative, on matters falling within its mission.

The European Parliament or a Member State may request the Authority to issue a scientific opinion on matters falling within its mission.

2. Requests referred to in paragraph 1 shall be accompanied by background information explaining the scientific issue to be addressed and the Community interest.

3. Where Community legislation does not already specify a time limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time limit specified in the requests for opinions, except in duly justified circumstances.

4. Where different requests are made on the same issues or where the request is not in accordance with paragraph 2, or is unclear, the Authority may either refuse, or propose amendments to a request for an opinion in consultation with the institution or Member State(s) that made the request. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

5. Where the Authority has already delivered a scientific opinion on the specific topic in a request, it may refuse the request if it concludes there are no new scientific elements justifying the re-examination. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure provided for in Article 58(2). These rules shall specify in particular:

(a) the procedure to be applied by the Authority to the requests referred to it;

(b) the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

7. The Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

Article 30

Diverging scientific opinions

1. The Authority shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

2. Where the Authority identifies a potential source of divergence, it shall contact the body in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.

3. Where a substantive divergence over scientific issues has been identified and the body in question is a Community agency or one of the Commission's Scientific Committees, the Authority and the body concerned shall be obliged to co-operate with a view to either resolving the divergence or presenting a joint document to the Commission clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

4. Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

Article 31

Scientific and technical assistance

1. The Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles which does not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular assistance to the Commission for the establishment or evaluation of technical criteria and also assistance to the Commission in the development of technical guidelines.

2. Where the Commission refers a request for scientific or technical assistance to the Authority, it shall specify, in agreement with the Authority, the time limit within which the task must be completed.

Article 32

Scientific studies

1. Using the best independent scientific resources available, the Authority shall commission scientific studies necessary for the performance of its mission. Such studies shall be commissioned in an open and transparent fashion. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.

2. The Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.

Article 33

Collection of data

1. The Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission. This shall involve in particular the collection of data relating to:

(a) food consumption and the exposure of individuals to risks related to the consumption of food;

(b) incidence and prevalence of biological risk;

(c) contaminants in food and feed;

(d) residues.

2. For the purposes of paragraph 1, the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries or international bodies.

3. The Member States shall take the necessary measures to enable the data they collect in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority.

4. The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at Community level.

5. Within one year following the date of entry into force of this Regulation, the Commission shall publish an inventory of data collection systems existing at Community level in the fields within the mission of the Authority.

The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular:

(a) for each system, the role which should be assigned to the Authority, and any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States;

(b) the shortcomings which should be remedied to enable the Authority to collect and summarise at Community level relevant scientific and technical data in the fields within its mission.

6. The Authority shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States.

Article 34

Identification of emerging risks

1. The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission.

2. Where the Authority has information leading it to suspect an emerging serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as a matter of urgency and forward any relevant information in their possession.

3. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.

4. The Authority shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.

Article 35

Rapid alert system

To enable it to perform its task of monitoring the health and nutritional risks of foods as effectively as possible, the Authority shall be the recipient of any messages forwarded via the rapid alert system. It shall analyse the content of such messages with a view to providing the Commission and the Member States with any information required for the purposes of risk analysis.

Article 36

Networking of organisations operating in the fields within the Authority's mission

1. The Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.

2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of competent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.

3. The implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 58(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.

4. Within one year following the entry into force of this Regulation, the Commission shall publish an inventory of Community systems existing in the fields within the mission of the Authority which make provision for Member States to carry out certain tasks in the field of scientific evaluation, in particular the examination of authorisation dossiers. The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular, for each system, any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States.

SECTION 4

INDEPENDENCE, TRANSPARENCY, CONFIDENTIALITY AND COMMUNICATION

Article 37

Independence

1. The members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

2. The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

3. The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda.

Article 38

Transparency

1. The Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay:

(a) agendas and minutes of the Scientific Committee and the Scientific Panels;

(b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included;

(c) without prejudice to Articles 39 and 41, the information on which its opinions are based;

(d) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings;

(e) the results of its scientific studies;

(f) the annual report of its activities;

(g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

2. The Management Board shall hold its meetings in public unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda, and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.

3. The Authority shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred to in paragraphs 1 and 2.

Article 39

Confidentiality

1. By way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health.

2. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of confidentiality pursuant to Article 287 of the Treaty.

3. The conclusions of the scientific opinions delivered by the Authority relating to foreseeable health effects shall on no account be kept confidential.

4. The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

Article 40

Communications from the Authority

1. The Authority shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions.

2. The Authority shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Authority shall develop and disseminate information material for the general public.

3. The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.

The Authority shall publish all opinions issued by it in accordance with Article 38.

4. The Authority shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

Article 41

Access to documents

1. The Authority shall ensure wide access to the documents which it possesses.

2. The Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents referred to in paragraph 1, taking full account of the general principles and conditions governing the right of access to the Community institutions' documents.

Article 42

Consumers, producers and other interested parties

The Authority shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties.

SECTION 5

FINANCIAL PROVISIONS

Article 43

Adoption of the Authority's budget

1. The revenues of the Authority shall consist of a contribution from the Community and, from any State with which the Community has concluded the agreements referred to in Article 49, and charges for publications, conferences, training and any other similar activities provided by the Authority.

2. The expenditure of the Authority shall include the staff, administrative, infrastructure and operational expenses, and expenses resulting from contracts entered into with third parties or resulting from the financial support referred to in Article 36.

3. In good time, before the date referred to in paragraph 5, the Executive Director shall draw up an estimate of the Authority's revenue and expenditure for the coming financial year, and shall forward it to the Management Board, accompanied by a provisional list of posts.

4. Revenue and expenditure shall be in balance.

5. By 31 March each year at the latest, the Management Board shall adopt the draft estimates including the provisional list of posts accompanied by the preliminary work programme and forward them to the Commission, and the States with which the Community has concluded the agreements referred to in Article 49. On the basis of that draft, the Commission shall enter the relevant estimates in the preliminary draft general budget of the European Union to be put before the Council pursuant to Article 272 of the Treaty.

6. After the adoption of the general budget of the European Union by the budgetary authority, the Management Board shall adopt the Authority's final budget and work programme, adjusting them where necessary to the Community's contribution. It shall forward them without delay to the Commission and the budgetary authority.

Article 44

Implementation of the Authority's budget

1. The Executive Director shall implement the Authority's budget.

2. Control of commitment and payment of all expenditure and control of the existence and recovery of all the Authority's revenue shall be carried out by the Commission's financial controller.

3. By 31 March each year at the latest, the Executive Director shall forward to the Commission, the Management Board and the Court of Auditors the detailed accounts for all the revenue and expenditure in respect of the previous financial year.

The Court of Auditors shall examine the accounts in accordance with Article 248 of the Treaty. It shall publish each year a report on the Authority's activities.

4. The European Parliament, acting on a recommendation from the Council, shall give a discharge to the Authority's Executive Director in respect of the implementation of the budget.

Article 45

Fees received by the Authority

Within three years following the date of entry into force of this Regulation and after consulting the Authority, the Member States and the interested parties, the Commission shall publish a report on the feasibility and advisability of presenting a legislative proposal under the co-decision procedure and in accordance with the Treaty and for other services provided by the Authority.

SECTION 6

GENERAL PROVISIONS

Article 46

Legal personality and privileges

1. The Authority shall have legal personality. In all Member States it shall enjoy the widest powers granted by law to legal persons. In particular, it may acquire and dispose of movable and immovable property and institute legal proceedings.

2. The Protocol on the privileges and immunities of the European Communities shall apply to the Authority.

Article 47

Liability

1. The contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority.

2. In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.

3. The personal liability of its servants towards the Authority shall be governed by the relevant provisions applying to the staff of the Authority.

Article 48

Staff

1. The staff of the Authority shall be subject to the rules and regulations applicable to officials and other staff of the European Communities.

2. In respect of its staff, the Authority shall exercise the powers which have been devolved to the appointing authority.

Article 49

Participation of third countries

The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation.

Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries will participate in the Authority's work, including provisions relating to participation in the networks operated by the Authority, inclusion in the list of competent organisations to which certain tasks may be entrusted by the Authority, financial contributions and staff.

CHAPTER IV

RAPID ALERT SYSTEM, CRISIS MANAGEMENT AND EMERGENCIES

SECTION 1

RAPID ALERT SYSTEM

Article 50

Rapid alert system

1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network. The Commission shall be responsible for managing the network.

2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network.

The Authority may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States.

3. Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:

(a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;

(b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;

(c) any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.

The Commission shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs.

Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin.

4. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information.

5. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network.

6. Participation in the rapid alert system may be opened up to applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.

Article 51

Implementing measures

The measures for implementing Article 50 shall be adopted by the Commission, after discussion with the Authority, in accordance with the procedure referred to in Article 58(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information.

Article 52

Confidentiality rules for the rapid alert system

1. Information, available to the members of the network, relating to a risk to human health posed by food and feed shall in general be available to the public in accordance with the information principle provided for in Article 10. In general, the public shall have access to information on product identification, the nature of the risk and the measure taken.

However, the members of the network shall take steps to ensure that members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public, if circumstances so require, in order to protect human health.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.

SECTION 2

EMERGENCIES

Article 53

Emergency measures for food and feed of Community origin or imported from a third country

1. Where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, acting in accordance with the procedure provided for in Article 58(2) on its own initiative or at the request of a Member State, shall immediately adopt one or more of the following measures, depending on the gravity of the situation:

(a) in the case of food or feed of Community origin:

(i) suspension of the placing on the market or use of the food in question;

(ii) suspension of the placing on the market or use of the feed in question;

(iii) laying down special conditions for the food or feed in question;

(iv) any other appropriate interim measure;

(b) in the case of food or feed imported from a third country:

(i) suspension of imports of the food or feed in question from all or part of the third country concerned and, where applicable, from the third country of transit;

(ii) laying down special conditions for the food or feed in question from all or part of the third country concerned;

(iii) any other appropriate interim measure.

2. However, in eMERGENCIES, the Commission may provisionally adopt the measures referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.

As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 58(2), and the reasons for the Commission's decision shall be made public without delay.

Article 54

Other emergency measures

1. Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.

2. Within 10 working days, the Commission shall put the matter before the Committee set up in Article 58(1) in accordance with the procedure provided for in Article 58(2) with a view to the extension, amendment or abrogation of the national interim protective measures.

3. The Member State may maintain its national interim protective measures until the Community measures have been adopted.

SECTION 3

CRISIS MANAGEMENT

Article 55

General plan for crisis management

1. The Commission shall draw up, in close cooperation with the Authority and the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as 'the general plan').

2. The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54.

The general plan shall also specify the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.

Article 56

Crisis unit

1. Without prejudice to its role of ensuring the application of Community law, where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 53 and 54, it shall immediately notify the Member States and the Authority.

2. The Commission shall set up a crisis unit immediately, in which the Authority shall participate, and provide scientific and technical assistance if necessary.

Article 57

Tasks of the crisis unit

1. The crisis unit shall be responsible for collecting and evaluating all relevant information and identifying the options available to prevent, eliminate or reduce to an acceptable level the risk to human health as effectively and rapidly as possible.

2. The crisis unit may request the assistance of any public or private person whose expertise it deems necessary to manage the crisis effectively.

3. The crisis unit shall keep the public informed of the risks involved and the measures taken.

CHAPTER V

PROCEDURES AND FINAL PROVISIONS

SECTION 1

COMMITTEE AND MEDIATION PROCEDURES

Article 58

Committee

1. The Commission shall be assisted by a Standing Committee on the Food Chain and Animal Health, hereinafter referred to as the 'Committee', composed of representatives of the Member States and chaired by the representative of the Commission. The Committee shall be organised in sections to deal with all relevant matters.

2. Where reference is made to this paragraph, the procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Articles 7 and 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 59

Functions assigned to the Committee

The Committee shall carry out the functions assigned to it by this Regulation and by other relevant Community provisions, in the cases and conditions provided for in those provisions. It may also examine any issue falling under those provisions, either at the initiative of the Chairman or at the written request of one of its members.

Article 60

Mediation procedure

1. Without prejudice to the application of other Community provisions, where a Member State is of the opinion that a measure taken by another Member State in the field of food safety is either incompatible with this Regulation or is likely to affect the functioning of the internal market, it shall refer the matter to the Commission, which will immediately inform the other Member State concerned.

2. The two Member States concerned and the Commission shall make every effort to solve the problem. If agreement cannot be reached, the Commission may request an opinion on any relevant contentious scientific issue from the Authority. The terms of that request and the time limit within which the Authority is requested to give its opinion shall be established by mutual agreement between the Commission and the Authority, after consulting the two Member States concerned.

SECTION 2

FINAL PROVISIONS

Article 61

Review clause

1. Before 1 January 2005 and every six years thereafter, the Authority, in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices and the impact of the Authority. The evaluation will take into account the views of the stakeholders, at both Community and national level.

The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices. The evaluation and the recommendations shall be made public.

2. Before 1 January 2005, the Commission shall publish a report on the experience acquired from implementing Sections 1 and 2 of Chapter IV.

3. The reports and recommendations referred to in paragraphs 1 and 2 shall be forwarded to the Council and the European Parliament.

Article 62

References to the European Food Safety Authority and to the Standing Committee on the Food Chain and Animal Health

1. Every reference in Community legislation to the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Veterinary Committee, the Scientific Committee on Pesticides, the Scientific Committee on Plants and the Scientific Steering Committee shall be replaced by a reference to the European Food Safety Authority.

2. Every reference in Community legislation to the Standing Committee on Foodstuffs, the Standing Committee for Feedingstuffs and the Standing Veterinary Committee shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

Every reference to the Standing Committee on Plant Health in Community legislation based upon and including Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC and 91/414/EEC relating to plant protection products and the setting of maximum residue levels shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

3. For the purpose of paragraphs 1 and 2, 'Community legislation' shall mean all Community Regulations, Directives and Decisions.

4. Decisions 68/361/EEC, 69/414/EEC and 70/372/EEC are hereby repealed.

Article 63

Competence of the European Agency for the Evaluation of Medicinal Products

This Regulation shall be without prejudice to the competence conferred on the European Agency for the Evaluation of Medicinal Products by Regulation (EEC) No 2309/93, Regulation (EEC) No 2377/90, Council Directive 75/319/EEC [1] and Council Directive 81/851/EEC [2].

Article 64

Commencement of the Authority's operation

The Authority shall commence its operations on 1 January 2002.

Article 65

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Articles 11 and 12 and Articles 14 to 20 shall apply from 1 January 2005.

Articles 29, 56, 57 and 60 and Article 62(1) shall apply as from the date of appointment of the members of the Scientific Committee and of the Scientific Panels which shall be announced by means of a notice in the 'C' series of the Official Journal.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 January 2002.

For the European Parliament
The President
P. COX

For the Council
The President
J. PIQUÉ I CAMPS

[1] OJ L 147, 9.6.1975, p. 13. Directive amended by Directive 2001/83/EC of the European Parliament and of the Council (OJ L 311, 28.11.2001, p. 67).

[2] OJ L 317, 6.11.1981, p. 1. Directive amended by Directive 2001/82/EC of the European Parliament and of the Council (OJ L 311, 28.11.2001, p. 1).