

Task Order 2.2 – Free Trade Activity

**Lessons learned from the EU harmonization process,
giving special emphasis to SPS relevant issues**

**Submitted by:
Andreas Bocker and Claus Brodersen
Chemonics International, Inc.**

**Submitted to:
Regional Center for Southern Africa,
U.S. Agency for International Development**

Gaborone, Botswana

October, 2001

Contract No. 690-I-00-00-00149-00

Contents

1	<i>Introduction</i>	5
2	<i>Overview of EU harmonization toward the Common Market</i>	6
3	<i>Organizational structure dealing with food safety issues</i>	9
3.1	The services of DG Health and Consumer Protection	10
3.1.1	The Food and Veterinary Office	11
3.1.2	Scientific Committees	13
3.2	The Standing Committees	18
4	<i>The process of harmonization at EU level</i>	19
4.1	Authorization of active substances in plant protection products	19
4.1.1	The legal framework: Directive 91/414/EEC	20
4.1.2	Organizational entities involved	21
4.1.3	The decision process and measures taken	22
4.1.4	Relation to other Community legislation	28
4.1.5	Activities at international fora	30
4.1.6	Concluding remarks	33
4.2	EU food law	34
4.2.1	Development, principles and impacts of establishing the Common Market in the area of food law	34
4.2.2	The principle of mutual recognition	36
4.2.3	Vertical legislation	37
4.2.4	Reform of EU food law: The 2000 EU White Paper on Food Safety	39
4.3	National provisions beyond EU legislation: The case of creosote	43
4.3.1	Background information on creosote and legislation concerned	44
4.3.2	The procedure	45
4.3.3	The Assessment	47

5	<i>Selected case studies concerning the SPS agreement</i>	50
5.1	Players	50
5.2	List of Cases analyzed:	50
5.3	Case 1 Glyphosate: Inclusion of Glyphosate and other active substances to Annex 1 to Council Directive 91/414/EEC	50
5.4	Case 2 Potatoes from Cuba: Request by the Netherlands to introduce early potatoes from Cuba	52
5.5	Case 3 Egypt potatoes: Emergency measures against dissemination of <i>Pseudomonas solanacearum</i>, the cause of brown rot	54
5.6	Case 4 Fish: Sardines from Peru	54
5.7	Case 5 Requirement for control of Infectious Bursal Virus (IBDV) in cooked chicken meat	57
5.8	Case 6 Citrus imports from Israel, South America and South Africa	57
5.9	Case 7 New Maximum Levels for certain Contaminants: Aflatoxin	58
5.10	Concluding comments	61
6	<i>References</i>	62
7	<i>Appendix: List of pdf documents attached to the report</i>	63

List of Tables and Figures

Table 1: Food and Veterinary Office inspection activities in 1999 and 2000	12
Table 2: Opinions adopted by EU scientific committees since 1998	14
Table 3: International fora touching upon EU Directive 91/414/EEC	32
Figure 1: Co-Decision Procedure.....	8
Figure 2: Procedure to reach evaluation decision on first priority list of 90 substances.	24
Figure 3: The changing procedure for ECCO review in decision process on authorizing existing active substances.	26
Figure 4: The evaluation procedure(s) for new active substances	27

1 Introduction

The European Union is one of the world's main producers, importers and exporters of food and agricultural products. In international trade negotiations the EU has developed a particular standpoint and increasingly taken an active role in the development of international standards. Important aspects of its position are:

- a) the **precautionary principle**: The European Commission has recently delivered an additional negotiating proposal on food safety to the WTO, in which it proposes criteria for the application of precaution under the SPS agreement¹.
- b) the **support of developing countries**: In the same negotiating proposal the EU stresses the importance of supporting the developing countries in their attempts to meet SPS standards.
- c) the **EU position papers for the Codex Alimentarius**: While the Member States of the EU are all Codex members, the European Commission is an observer. The European Commission and the Member States attempt to present joint comments on issues discussed in Codex Committees in these position papers. The Directorate-General "Consumer and Health Protection" acts as the contact point and coordinates this work.
- d) **bilateral trade agreements**: Over the years, the EU has signed a rather great number of bilateral trade agreements and associations with third countries or groups thereof².
- e) the **Single Market**: The internal harmonization of legislation in the Community toward the establishment of the EU Common Market is paramount to understanding the EU position in external relations, because, in principle, the rules for internal trade shall also apply to external trade.

This paper, as part of a series of 'lessons learned' papers commissioned by RAPID addresses aspects of EU organization, legislation and decision processes that are relevant with respect to SPS provisions. Due to the importance of the internal harmonization process, the report starts with a brief account of the development process toward the EU Common Market. This section is intended for demonstrating the complexity of both the task of

¹ The proposal, which is available online, is provided in the annex.

² A complete list of these agreements, which is available online, is provided in the annex.

harmonization and the procedure involved in legislation in order to take full account of the different national approaches and interests.

In the third section the organizational structure dealing with matters of food safety and plant and animal health is described. As the European Commission, and therein the Directorate-General (DG) "Health and Consumer Protection" is mainly in charge for these matters, chapter three is in essence an overview of the monitoring, regulatory and scientific units in this DG.

The working and involvement of these units in specific areas of the EU harmonization and in SPS matters are described in chapters four and five. First, chapter four deals with selected aspects of the European Integration. These are the harmonization of the authorization of active substances in plant protection products in the community, the continuous reform of EU food law and the possibility of derogation in national legislation from EU wide legislation, the so called horizontal legislation. While the first two aspects cover fairly broad and basic activities in the harmonization process, the third is presented through a specific case that is well suited for illustrating the procedures of requesting for derogation and assessing such a request by the Commission.

Second, in chapter five, seven short case studies of SPS relevant issues are presented to give a more detailed account of the processes behind EU decision making in this area. While the preceding sections are mainly based on official EU documents and secondary literature, information on chapter five was gathered through personal interviews with EU officials.

2 Overview of EU harmonization toward the Common Market

The EU has a broad body of legislation relating to food safety, veterinary and phytosanitary issues. The legislation has evolved over the past 40 years and aims to ensure minimum standards of food safety, animal welfare and animal and plant health across the EU. It reflects a blend of scientific, societal, political and economic forces, especially in the effort towards creating the European Common Market since the 1960ies. For two main reasons, this development has not been guided by an overall coherence:

- At a given point in time, the member states differed greatly in their approach toward regulating matters of food safety and plant and animal health.
- In the course of time, accession of new Member States demanded adaptations in order to account for still more different approaches and experiences. As accessing states were rather small relative to the existing group of Member States (e.g., 1987: Portugal and Spain vs. EC(10); 1995:

Austria, Finland, Sweden vs. EC(12)), the adaptation procedure chosen was piece-meal in nature, rather than discrete and comprehensive.

Due to the heterogeneity of Member States and the piece-meal adjustment process, legislation in this field has not been clearly structured so that there has been and still is great need for consolidating and streamlining the body of legislation in the process of harmonization. This need has been recognized and expressed in the various areas at different points in time. Partly triggered by the BSE crisis in 1996, the Green Paper³ on The General Principles of Food Law of 1997 particularly addressed this for food safety hygiene rules. The new regulations will, as proposed in the subsequent White Paper⁴ on Food Safety (2000), merge, harmonize and simplify the detailed and complex hygiene requirements previously scattered over 17 (!) existing directives. The objective of this White Paper is to install one European Food Authority responsible for all matters in this area by mid 2002. A time period of only five years from the first envision in a Green Paper toward complete implementation is exceptional by EU standards, documenting that this topic is of top priority. Other regulation, e.g. concerning the evaluation of active substances in plant protection products, have met much harder resistance in the process of harmonization. The corresponding directive took 15 years from the first Commission proposal in August 1976 to the final adoption by the Council in July 1991 – plus a further six years until implementation at the national level was completed.

The harmonization process is complex, as the different national interests, legal systems and administrative traditions have to be taken into account. Furthermore, for major decisions a long list of steps prior to putting legislation into force are required, as e.g. for the co-decision procedure (Figure 1).

³ Green Papers are communications published by the Commission on a specific policy area. Primarily they are documents addressed to interested parties, organisations and individuals, who are invited to participate in a process of consultation and debate. In some cases they provide an impetus for subsequent legislation.

⁴ White Papers are documents containing proposals for Community action in a specific area. They often follow a Green Paper published to launch a consultation process at European level. While Green Papers set out a range of ideas presented for public discussion and debate, White Papers contain an official set of proposals in specific policy areas and are used as vehicles for their development.

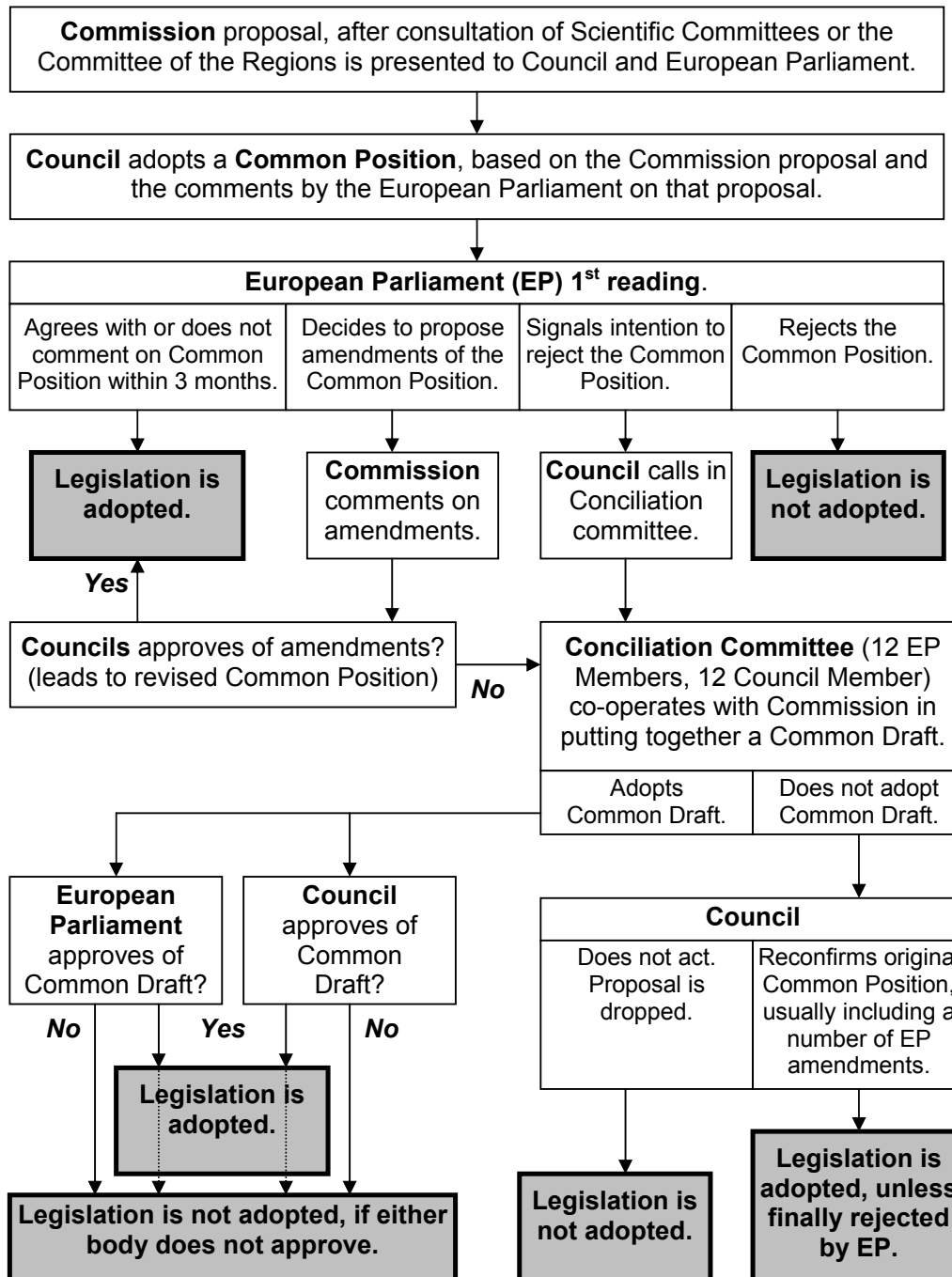


Figure 1: Co-Decision Procedure (Source: Amended from BLL 1998, p.19)

At EU level the basic approach to harmonization of consumer protection legislation is to apply the same rules across all Member States, while implementation at national level has to consider the different legal backgrounds. Typical examples for such horizontal legislation would be positive lists of approved food additives, active substances in plant protection measures or

maximum residue levels that are valid for the entire Community. The equivalency of the national legislation and its monitoring procedures with EU legislation is then monitored by the corresponding EU authorities, e.g. the Food and Veterinary Office.

Where such horizontal legislation is not feasible or not meaningful, the approach switches to the principle of mutual recognition, which is well accepted in EU food law since 1985. Under this principle, a Member State must not block imports of a good that is processed and marketed in another Member State. Derogations are possible, however, when concern is justified that the product may be harmful to consumers or the corresponding trading practices may interfere with long established fair trading practices in that market. So, if compatible with the Treaty of Maastricht, national governments may apply stricter rules than the EU.

Prior to 1985 the EU also tried to establish a system of so called vertical legislation, which had far reaching consequences in food law. That system was intended to prescribe the composition of specified food products so that these defined recipes would be valid across all Member States. But since the early 1980ies it was recognized that such a system was too restrictive and would reduce the large variety of traditional food in Europe when fully applied. Furthermore, such a restrictive legal system was found to be detrimental to innovation in the food industry (BLL 1998, p. 7). Although the vertical approach of food legislation has by now been largely replaced by the principle of mutual recognition, part of it is still in function. These matters will be addressed in more detail under 4.2 below.

3 Organizational structure dealing with food safety issues

The BSE crisis of 1996 triggered a major reorganization of the EU administration dealing with food safety issues. This process has mainly concentrated responsibility for such matters under the Directorate-General DG "Health and Consumer Protection." Major changes were initiated in 1997. First, the *Food and Veterinary Office* as a service unit of DG "Health and consumer Protection" was founded in April, replacing the former *Office for Veterinary and Phytosanitary Inspection and Control* under DG "Agriculture." Second, the system of scientific advice was restructured by creating the Scientific Steering Committee (SSC) and eight specialized Scientific Committees, six of which are

relevant for queries concerning food safety and animal and plant health⁵. The functioning and role of these organizational units will be described in more detail in the following subsection, while the regulatory committees, which provide the ultimate opinion prior to a Commission decision, are described in the final subsection. These committees were not affected by reorganization of the administration since 1997.

3.1 The services of DG Health and Consumer Protection

In response to a number of severe food safety and animal health crises, the European Commission has rated food safety as of top priority. The White Paper on Food Safety (2000), that has now nearly been transferred into legislation, sets out the plans for a new food policy: modernizing legislation into a coherent and transparent set of rules, reinforcing controls from the farm to the table and increasing the capability of the scientific advice system. For achieving the goal to guarantee a high level of human health and consumer protection, DG “Health and Consumer Protection” is active in the following main subject areas:

- Animal Health / Prevention and Control of Animal diseases
- Animal Welfare
- Plant Health / Pesticides Safety
- Animal Feed Safety
- Safety of Food Products
- Food Labeling
- International Food safety Issues
- EU Enlargement

⁵ As pointed out above, the processes of reform and reorganisation continue toward general principles of food law and establishing the European Food Authority. In November 2000 the European Commission put forward a proposal for a corresponding Regulation. The European Parliament adopted its report in first reading on June 12, 2001. The Council of Ministers reached political agreement on the proposal on June 28, 2001, and adopted a common position on 17 September 2001. The Commission adopted an amended proposal on 7th August which reflects the Commission’s orientations on the discussions in the Council and Parliament during the first reading. The Second Reading started on 20 September. A final political agreement can be expected by the end of 2001, with a formal adoption of the Regulation potentially early in 2002. A decision on the final location of the European Food Authority is due to be taken before the end of 2001.

The Commission, mainly through DG "Health and Consumer Protection," implements the new policy in the above subject areas by undertaking three specific tasks:

- Organization of independent scientific advice and development and application of risk assessment procedures to determine the risks to consumer health (*conducted and coordinated through scientific committees and SSC, respectively*).
- Preparing and implementing legislation to protect the consumer against identified risks (*conducted through regulatory or standing committees*).
- Inspections and controls in EU Member States and third countries to monitor the implementation of EU legislation or determine its equivalency with third countries' legislation (*conducted through Food and Veterinary Office*).

3.1.1 The Food and Veterinary Office

The Food and Veterinary Office (FVO) is located in Dublin, Ireland. After a reorganization in 1999/2000 there are five units in the Office with the following responsibilities:

- Unit F1: Quality, planning, follow-up and development
- Unit F2: Foods of animal origin: mammals
- Unit F3: Foods of animal origins: birds and fish
- Unit F4: Food of plant origin, plant health, processing and distribution
- Unit F5: Animal nutrition, import controls, residues

By the end of 2000, the FVO had a total staff of around 160, 92 of whom were inspectors. In total, 250 inspection missions had been completed, an increase by 60 as compared to 1999 (Table 1). The inspection activities, which are based on specific legislation, can be divided into six broad categories:

- Food of animal origin,
- Food of plant origin,
- Unauthorized substances and residues,
- Animal health,
- Animal welfare and zootechnics,
- Plant health.

The first three categories constitute the general category of food safety, which is of key importance to the EU and thus receives most attention by the FVO. This can be seen from Table 1, where the distribution of missions across categories and across Member States and 3rd countries are shown.

Table 1: Food and Veterinary Office inspection activities in 1999 and 2000

	1999		2000	
	Absolute	Share in %	Absolute	Share in %
Total	190	(100)	250	(100)
EU	122	(64)	145	(58)
3rd Countries	68	(34)	105	(42)
Food Safety ^a	122	(64)	200	(80)
Animal Health	25	(13)	24	(10)
Plant Health	21	(11)	15	(6)
Animal Welfare	7	(4)	11	(4)
Import controls	15	(8)	n.m.	n.m.

Source: Food and Veterinary Office, Annual Report 1999 and 2000; n.m. = not mentioned

Concerning harmonization within the EU, there is a large variation as to how and how far single Member States have implemented EU legislation. The FVO therefore investigates in co-operation with the national competent authorities concerned the adequacy and performance of national legislation and administration. This also includes inspection of border controls. For monitoring food safety and animal and plant health of imports, about 250 Border Inspection Points have been designated. Only through these points are food, feed, animal and plant imports allowed to enter the EU.

Inspections in third countries are carried mainly for one reason. Before exporting animals, animal products, food of animal origin, organic food and a number of plant products into the EU, third countries must apply to be put on a list of approved exporters. After this application has been forwarded – via a Member State – the FVO inspects the competent authorities, a sample of production and processing premises and, where applicable, analytical facilities and certification bodies. After a country has been approved, it must supply a complete list of bodies and premises involved in producing, processing and trading the product(s) or commodity(ies) concerned.

The large increase of abroad inspections from 1999 to 2000 is partly due to intensified efforts by EU accession candidates in central and eastern Europe to prepare for EU membership.

3.1.2 Scientific Committees

In November 1997 the Scientific Steering Committee and the eight new scientific committees had been constituted and began their work. In 1998, their first year of functioning, the tasks for all the scientific committees were twofold:

First, they had to develop their identity and working methods based on the principles established in the Commission Communication of April 1997 on Consumer Health and Food Safety. These principles are: scientific eminence, independence of the members and transparency in the work of the committees. To fulfil these tasks:

- The committees' members are selected for a three year period. The selection process starts with a call for interest for the position of committee member, which is widely publicized. Members are then appointed in their individual capacity. For the latest round of renewing the committees membership, 151 scientists were selected from 483 applicants in total.
- Each year the members inform the Commission in writing of any interest which could be regarded as prejudicial to their independence. At each meeting the members declare any particular interest which could be regarded as prejudicial to their independence in the light of the topics on the agenda of the meeting.
- The scientific opinions as well as the minutes of the plenary meetings are published on the Internet shortly after their adoption by the Committees. The committees' members' names and affiliations are also freely available online.

Second, in addition to these procedures, reflecting and specifying the main principles of independence and transparency they had to fulfill their role of providing the scientific basis for Commission initiatives. For that purpose, the committees had established a methodological approach on the evaluation of risks which not only strengthens the scientific basis of the Committees' Opinions but also makes them clearer and easier to understand due to the common structure. Carrying out this original mandate of the scientific committees lead to the adoption of numerous Opinions by the committees which entered the EU political decision process as independent input at various stages. Table 2

provides an overview of the number of Opinions adopted by the committees from 1998 to date (October 2001).

Table 2: Opinions adopted by EU scientific committees since 1998

Committee	2001	2000	1999	1998
Scientific Steering Committee	44	18	8	15
SC on Food	20	24	24	16
SC on Animal Nutrition	6	11	5	5
SC on Animal Health and Animal Welfare	3	7	8	7
SC on Veterinary Measures relating to Public Health	4	4	5	7
SC on Plants	19	27	17	23
SC Toxicity, Ecotoxicity and the Environment	34	23	11	16
Subtotal relating to Food Safety	130	114	78	89
SC on Cosmetic Products and Non-Food Products	13	28	50	36
SC on Medicinal Products and Medical Devices	2	4	8	7
Total	145	146	136	132

Source: Counts from committees' official Internet websites, under http://europa.eu.int/comm/food/fs/sc/index_en.html

The process of harmonizing procedures across the single scientific committees is, however, still ongoing. Two major points, the Scientific Steering Committee has to deal with, relate to creating a generally applicable risk assessment procedure and to laying down for which matters consultation of the Scientific Committees ought to be made mandatory.

3.1.2.1 The Scientific Steering Committee (SSC)

The SSC has 16 members. Eight are appointed directly after having undergone the official application process described above, while the remaining eight are the chairpersons of the specialized Scientific Committees elected separately by the members of each committee.

When founded in 1997, the SSC replaced the Multidisciplinary Scientific Committee (MDSC), which had been established in 1996 for addressing the multi-disciplinary aspects of the Bovine Spongiform Encephalopathy (BSE) epidemic.

High quality and independent scientific advice for the drafting and amendment of Community rules regarding consumer protection in general and consumer

health in particular is of utmost importance. Here, the Commission defines consumer health as including matters on consumer health in its strictest sense, thus including animal health and welfare, plant health and environmental health. Many issues relating to consumer health are of a multidisciplinary nature and require input from various scientific disciplines. The main role of the SSC is to coordinate scientific advice from the eight specialized scientific committees. Because of the urgency of the matter and its potential major effects on public health, most efforts by the SSC have concentrated on addressing the risks for humans and animals related to transmissible spongiform encephalopathies, especially bovine spongiform encephalopathy (BSE). Topics addressed by the SSC in its scientific opinions included BSE risk in general, specified risk materials (SRMs), the UK Date Based Export Scheme, BSE in sheep, the safety of gelatine, meat-and-bone meal, tallow, dicalcium-phosphate, hydrolysed proteins and organic fertilisers, the impact of stunning methods on BSE risk, and possible links between organo-phosphates used as pesticides and BSE.

Major efforts have been initiated with the objective of identifying relevant criteria and development of a methodology for the evaluation of the geographical BSE risk. A "Handbook" for the assessment of the geographical BSE risk of member states and third countries was developed in a series of four scientific opinions⁶. In addition to the focus on BSE, the following tasks were among those that have received most attention by the SSC.

a) A further initiative aims at the introduction in all Committees of harmonized procedures for risk assessment, based on current practice within each Committee. The objectives are to establish common ways of approaching risk assessment issues, to introduce, where possible and relevant, standardization of threshold and reference values, to adopt common principles for the development and use of models for assessment of human exposure risk. This initiative has produced a comprehensive report on the "Harmonization of Risk Assessment Procedures in the Scientific Committees advising the European Commission in the area of human and environmental health," which was published in October 2000 and made available on the Internet in December 2000⁷. Furthermore, an opinion was also adopted by the SSC in October 2000⁸,

⁶ These Opinions were adopted in January 1998, April 1999, January 2001 and July 2001 (s. appendix) and are attached as pdf files.

⁷ The report (173 pages) and the appendices (261 pages) are listed in the appendix and attached as pdf files.

⁸ Available online at: http://europa.eu.int/comm/food/fs/sc/ssc/out82_en.html .

in which it commented on the suggestions made by the working group and stressed the importance of such a harmonization process for:

- enhancing the quality of the risk assessment procedures,
- achieving greater consistency when the same or very similar risk sources are assessed by different scientific Committees,
- improving transparency and risk communication,
- enabling the EU to demonstrate **externally** a consistent high quality scientific approach for all risk assessments conducted on its behalf pertaining to the protection of human health and the environment.

b) The SSC established a specific working group for investigating the multidisciplinary aspects of the use of antimicrobials. The working group is composed of experts from each of the Scientific Committees and has a wide ranging mandate aimed at providing an overall frame and common basic principles to serve as the scientific basis for policy making in this complex field. Two Opinions have so far been issued⁹. More specific aspects of the use of antimicrobials e.g. in animal feed, in plant protection or for therapeutical use are managed by the relevant specialized Committee.

c) Also through establishing a working group work was initiated on the development of scientific approaches to emerging health issues, including the application of the precautionary principle, ways and means to address perceived, but not scientifically verified, risks and to address uncertainties related to a scientific Opinion, e.g. insufficient data, and thus possible assumptions made. From that initiative an Opinion has evolved that envisions future strategies by the EU¹⁰.

3.1.2.2 Specialized Scientific Committees

The eight scientific committees usually give advice in an early stage of the political decision process, i.e. after the first legislation proposal by the Commission. This advice, however, is not mandatory in every case. Each piece of legislation clearly sets out which directorates-general are (co-)responsible for managing the legislation. It also defines which scientific committees are

⁹ These opinions were adopted in May 1999 and May 2001 and are attached as pdf files (s. appendix).

¹⁰ This strategic opinion was adopted in October 2000 and is attached as a pdf file (s. appendix).

required to give advice and at what stage of the decision process. At present, work by the SSC continues to define on a general basis under which conditions it shall be mandatory to consult the scientific committees for advice, i.e. when to request an Opinion. In the following the specialized committees will be shortly described in their fields of competence. A more detailed account of their involvement in decision making will be given in chapter 4 and chapter 5.

- **Scientific Committee on Food**

Scientific and technical questions concerning consumer health and food safety associated with the consumption of food products and in particular questions relating to toxicology and hygiene in the entire food production chain, nutrition, and applications of agrifood technologies, as well as those relating to materials coming into contact with foodstuffs, such as packaging.

- **Scientific Committee on Animal Nutrition**

Scientific and technical questions concerning animal nutrition, its effect on animal health, on the quality and health of products of animal origin, and concerning the technologies applied to animal nutrition.

- **Scientific Committee on Animal Health and Animal Welfare**

- **Sub-committee Animal Health:**

Scientific and technical questions concerning all aspects of animal health, hygiene, animal diseases and therapies, including zoonoses of non-food origin and zootechnics.

- **Sub-committee Animal Welfare:**

Scientific and technical questions concerning the protection of animals, notably in regard to animal husbandry, herd management, transport, slaughter and experimentation.

- **Scientific Committee on Veterinary Measures relating to Public Health:**

Scientific and technical questions concerning consumer health and food safety, and relating to zoonotic, toxicological, veterinary and notably hygiene measures applicable to the production, processing, and supply of food of animal origin.

- **Scientific Committee on Plants**

Scientific and technical questions relating to plants intended for human or animal consumption, production or processing of non-food products as regards characteristics liable to affect human or animal health or the environment, including the use of pesticides.

- **Scientific Committee for Cosmetic Products, and Non-food Products intended for Consumers**

Scientific and technical questions concerning consumer health relating to cosmetic products and non-food products intended for the consumer especially substances used in the preparation of these products, their composition, use as well as their types of packaging.

- **Scientific Committee on Medicinal Products and Medical Devices**

Scientific and technical questions relating to Community legislation concerning medicaments for human and veterinary use, without prejudice to the specific competences given to the Committee for Proprietary Medicinal Products and the Committee on Veterinary Medicinal Products¹¹ in the context of the evaluation of medicaments. Scientific and technical questions relating to Community legislation concerning medical materials and equipment.

- **Scientific Committee for Toxicity, Ecotoxicity and the Environment**

Scientific and technical questions relating to examination of the toxicity and ecotoxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment.

In order to increase transparency, the members of each committee and their affiliations are available online¹². Furthermore, the Health and Consumer Protection Directorate-General publishes the dates of the committees' plenary meetings on a quarterly basis on the committees' homepage¹³. The pages of the scientific committees provide more detailed up-to-date information. Finally, opposite to the SSC or the regulatory or standing committees described below, not every single Member State is represented in each scientific committee. Especially smaller countries, which simply lack the required scientific expertise in some areas are not represented in every committee.

3.2 The Standing Committees

The standing committees take a central role in preparing legislation, as the measures on which the committees have delivered an opinion are formally adopted by the Commission in accordance with an appropriate procedure, as set out by the legislation concerned. In each committee every single Member

¹¹ Committees established in the European Agency for the Evaluation of Medicinal Products.

¹² http://europa.eu.int/comm/food/fs/sc/index_en.html

¹³ http://europa.eu.int/comm/food/fs/sc/agenda_en.html

State is represented so that national interests can best be articulated here in a very early stage of decision making.

The standing or regulatory committees hold their meetings about four times a year. Short reports on these meetings are available online¹⁴. In total, there are nine standing committees in the area of food safety, animal and plant health, and animal welfare:

- The Standing Committee on Foodstuffs
- The Standing Committee on Propagating Material and Ornamental Plants
- The Standing Committee on Propagating Material and Plants of Fruit Genera and Species
- The Standing Committee on Agricultural, Horticultural and Forestry Seeds and Plants
- The Standing Committee on Community Plant Variety Rights
- The Standing Committee on Plant Health
- The Standing Committee for Animal Nutrition
- The Standing Veterinary Committee
- The Standing Committee on Zootechnics

The involvement of these committees in the harmonization and decision making processes at EU level is illustrated in specific areas and with examples in the remaining chapters.

4 The process of harmonization at EU level

4.1 Authorization of active substances in plant protection products¹⁵

Regulation concerning active substances does not stand on its own. It touches upon national and international interests of great relevance to political decision makers, such as health, worker safety, environment, agriculture and trade. Furthermore, it is a very complex matter in a dynamic economic and technological environment. Lending itself to a shared approach for these two

¹⁴ http://europa.eu.int/comm/food/fs/rc/index_en.html

¹⁵ This section is mainly based on the DOCUMENT SANCO/2692/2001 of July 25, 2001. This working report by DG "Health and Consumer Protection" (SANCO) technical annex services evaluates the process of internal harmonisation concerning active substances in plant protection products.

reasons, Community harmonization on plant protection products was therefore recognized as necessary early on in the process toward the Common Market. The first Commission proposal to the Council and the European Parliament was issued in August 1976. The final version of the directive, however, was not adopted until July 1991, documenting the enormous difficulties during harmonization.

4.1.1 The legal framework: Directive 91/414/EEC

Council Directive 91/414/EEC¹⁶ sets out a work program in three stages with detailed measures and time schedules for harmonizing across all EU Member States the procedures for placing plant protection products on the market. Prior to this regulation, there was great disparity among the administration, procedures, requirements and standards prevailing in the Community. Community legislation was restricted to four directives on maximum residue levels in agricultural produce and food, and one directive on banned substances. Furthermore, until establishment of the OECD Pesticide Forum in 1992, there was no international forum on pesticides. The lack of such international constraints may explain the long time it took from the first proposal to the final adoption, because each Member State's national interests had to be considered in full. Therefore, also the necessary regulation for implementing the first stage of the work program set out in Directive 91/414/EEC took one and a half years to be adopted. It was not until 1997 that implementation was completed at the national level and the requirements were met for a regulation on implementing the second and third stages. But it took another three years until this regulation was adopted in February 2000. The great friction in this particular piece of EU harmonization is further documented by the fact that 14 (!) directives amending Directive 91/414/EEC and the two implementation regulations have been adopted since July 1991.

Directive 91/414/EEC addresses in detail the applicability of the legislation (Art. 1), product and substance definitions (Art. 2), general provisions (Art. 3), authorization requirements (Art's. 4-6), transitional measures and derogations by Member States (Art. 8), the application for and mutual recognition of authorizations (Art's. 9 and 10), the possibility of applying stricter rules (Art. 11), the exchange of information (Art's. 7 and 12), data requirements and confidentiality (Art's. 13 and 14), packaging and labeling (Art's. 15 and 16), control and monitoring (Art. 17), administrative provisions and involvement of

¹⁶ Including the subsequent Commission Regulations (EEC) No 3600/92 of 11 December 1992 and (EC) No 451/2000 of 28 February 2000 for detailed implementation procedures.

regulatory committees (Art's 18 – 21), research and development in the plant protection products industry (Art. 22) and the time schedule for compliance at the national level.

4.1.2 Organizational entities involved

For dealing with the complicated task of harmonizing authorization procedures across Member States, both existing organizational units were referred to and new ones were established.

4.1.2.1 Inter-service Group on Pesticides

Within the Commission, DG "Health and Consumer Protection" and DG "Agriculture" are co-responsible for managing Directive 91/414/EEC. Due to this co-responsibility an inter-service group was established to improve communication and co-operation between the two DGs. This group also involves DGs "Environment," "Industry," "Trade," "Development" and "Research & Development" in order to help solve problems of a wider nature in matters of practical implementation.

4.1.2.2 Standing Committee on Plant Health (SCPH)

The Standing Committee on Plant Health was established in 1976. Its opinion is required under Article 19 of Directive 91/414/EEC, before the Commission may adopt a decision, directive or regulation. For the specific task of dealing with this directive, an Evaluation Working Group was established.

4.1.2.3 Scientific Committee on Plants (SCP)

The scientific Committee on Plants was established in 1997 in the course of reforming the EU system of scientific advice. Compared to its predecessor, the Scientific Committee on Pesticides (set up in 1978), its mandate was enlarged and now covers scientific and technical matters relating to plant products for consumption as well as non-food products with respect to potential harm to humans or the environment, including the use of pesticides.

In case of plant protection products, the Committee is consulted at the end of a process involving detailed examination of the dossiers by a Rapporteur Member State, peer review in ECCO (s. below) and examination in the Evaluation Working Group of the SCPH. The majority of cases referred to the SCP involved specific questions of unresolved issues. In the minority of cases, further reassurance were considered necessary. But generally, the SCP drew

the Commission's attention regularly to matters of concern on which it had not been consulted before.

4.1.2.4 European Commission Co-ordination (ECCO)

Due to the complexity of the task, systematic high quality evaluation of the dossiers on active substances in plant protection products that are required as a first step in the application for authorization, is required. As the resources single Member States could provide for that purpose varied substantially both in amount and quality, the Commission established ECCO (European Commission Co-ordination) in 1996 to provide the institutional base and the necessary resources for co-ordination. Its secretariat is based in the Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA) in Braunschweig, Germany, and in the Pesticide Safety Directorate (PSD) in York, UK. The initial tasks to be performed by ECCO were to organize a series of small meetings of experts from up to seven Member States to peer-review the initial assessments of substances. Up to 10 substances have been on the agenda of a single meeting, and so far more than 120 have been conducted, indicating the substantive workload to be handled by ECCO. ECCO's scope of work has been extended recently. It now also assists the Commission in the development of guidance documents and in managing the extensive documentation required for evaluating active substances.

4.1.3 The decision process and measures taken

Prior to the harmonization, producers of active substances had to apply for authorization in every Member State, where they wanted to place the product on the market. That meant that a single company had to deal with a number of fairly different requirements in the application procedure, if it wanted to market its product in more than one Member State. The ultimate goal of the harmonization legislation is to reduce the efforts associated with application, evaluation and authorization both for manufacturers on the one hand and EU and national authorities on the other. The first part of the work program was on existing substances, the second part on new substances.

4.1.3.1 Evaluation of existing active substances

Existing substances have been divided in four groups or so called priority lists. Assignment to one of these lists determined the urgency with which manufacturers had to notify their support of the substance, i.e. their willingness to keep it on the market. If neither the producer nor a Member State expresses

interest to support the substance, it is withdrawn. The basic sequence in the evaluation process is shown in Figure 2. Commission Regulation N° 933/94 allocated the existing substances among Member States with each acting as the Rapporteur for those substances allocated to him. The Rapporteur Member State plays a central role in the evaluation process, because it is the first organizational entity addressed and has to deliver the first draft assessment report within a year. Its performance in this role may thus determine the overall performance of the evaluation to a great extent.

The many steps of the complex process that follow the notification reflect the depth of the evaluation but also the breadth of consultations and feedback procedures involved. This complexity and the fact that new information was allowed to enter at any stage of the process in the first years of the working program may explain why it often took several years to evaluate single substances – a reason for massive industry complaints.

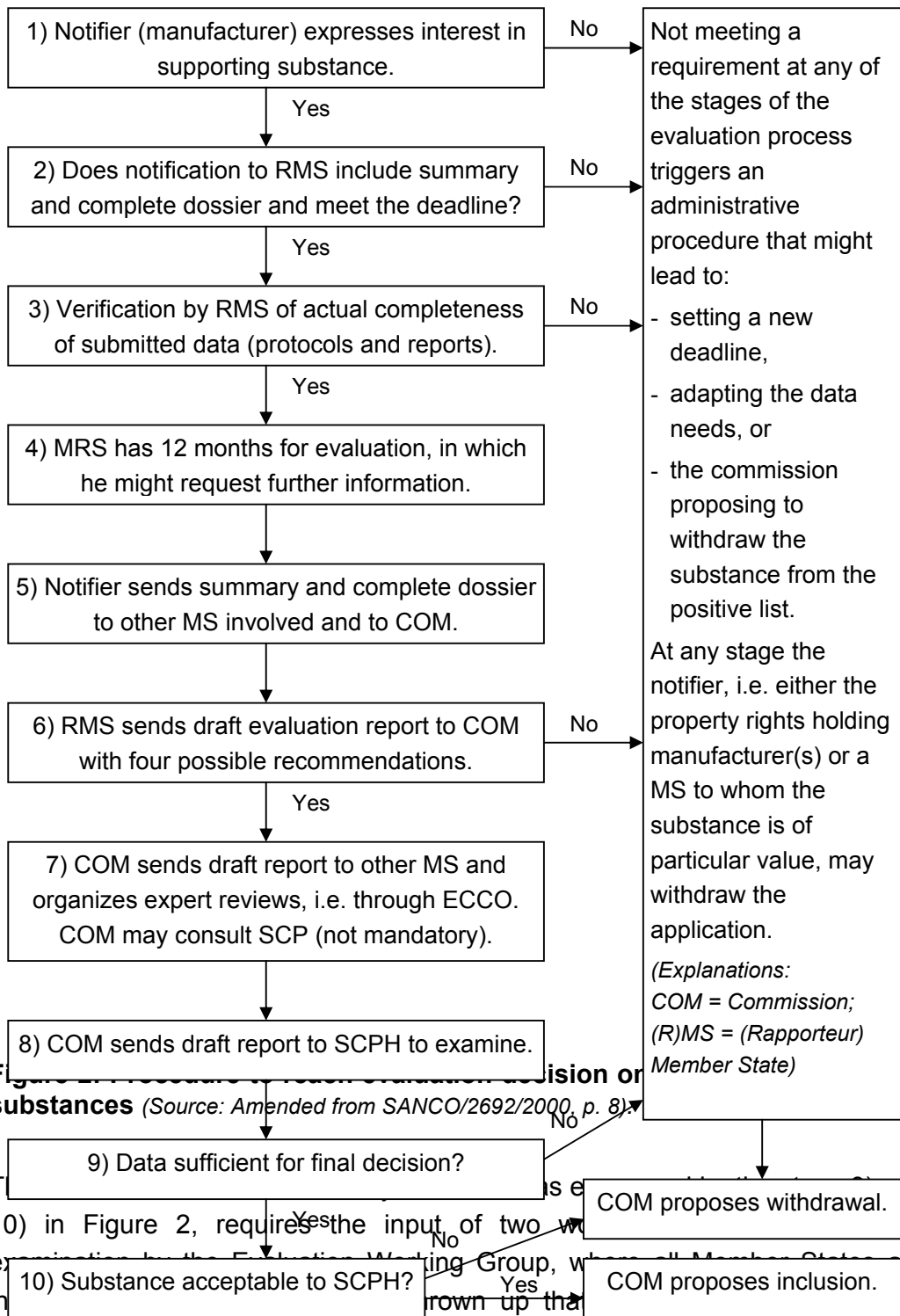


Figure 2: Evaluation process for substances (Source: Amended from SANCO/2692/2000, p. 8)

The evaluation process for substances is a complex administrative procedure. It begins with a manufacturer expressing interest in supporting a substance. The process then moves through several stages: notification to the Rapporteur Member State (RMS), verification of the dossier's completeness, a 12-month evaluation period where further information may be requested, and the submission of a complete dossier to the Commission (COM) and other Member States (MS). The RMS provides a draft evaluation report to the COM, which then organizes expert reviews through the European Chemicals Council (ECCO) and consults the Scientific Committee on Health, Environmental and Consumer Protection (SCPH). The COM sends a draft report to the SCPH for examination. A key decision point is whether the data is sufficient for a final decision. If not, the COM proposes withdrawal. If yes, the substance's acceptability to the SCPH is determined. If acceptable, the COM proposes inclusion; otherwise, the process loops back to the data sufficiency check. This process can be lengthy, as technical or political issues may arise, requiring new research and potentially taking one to two years before proceeding to the next step. Once evaluation is complete, the SCPH Legislation Working Group provides a final orientation to guide the Commission's draft proposal.

Due to the lack of experience in the beginning of the process, the peer-review process mentioned in box 7) of Figure 2 was also quite cumbersome and prone to delays. Following the receipt of the draft assessment report from the Rapporteur Member State, an ECCO peer review is organized. The early ECCO reviews involved 7 to 8 Member States and were followed by another review involving 10 Member States. As experience was gained and the quality of dossiers and reports improved, the system moved to a 5 Member State review before going directly to the 15 Member States. As the procedure is being improved for the second, third and fourth priority lists, the ultimate goal is to have a single Member State review going directly to all 15 Member States, as shown in Figure 3.

4.1.3.2 Evaluation of new active substances

The evaluation of a new active substance can be triggered at any time by an application from industry to a Rapporteur Member State of its choice. Figure 4 depicts the procedures for new active substances. A major difference to the procedures for existing substance is that special provisions to be followed for the evaluation of new substances are set out – the most important being the administrative checks of completeness of the dossiers. The intention is to avoid delays in evaluation due to the lack of key studies hampering a full assessment of the substance's safety properties. The completeness check has been useful in assuring a uniform high standard of the dossiers.

Caused by the negative experience of massive delays in the authorization of existing substances and the consequent pressure from industry, the option of an accelerated evaluation procedure was introduced, which consists of three phases, each being limited to 30 days. This incentive of time saving gradually moves the evaluation practice away from the "Normal ECCO review" on the left hand side toward the accelerated procedure on the right hand side of Figure 4.

A further procedural innovation aimed at avoiding delays in the introduction of substances to the market was to allow for provisional authorization by individual Member States. An important condition to be met is that the Member State has to establish that the substance can meet the requirements of Article 5(1) and can be expected to meet the requirements of Article 4(1)(b) to (f) of the Directive. The rationale behind this flexibility was that new substances would be more targeted in their mode of action and, therefore, be generally of less concern than existing substances. To date, all Member States have utilized this option.

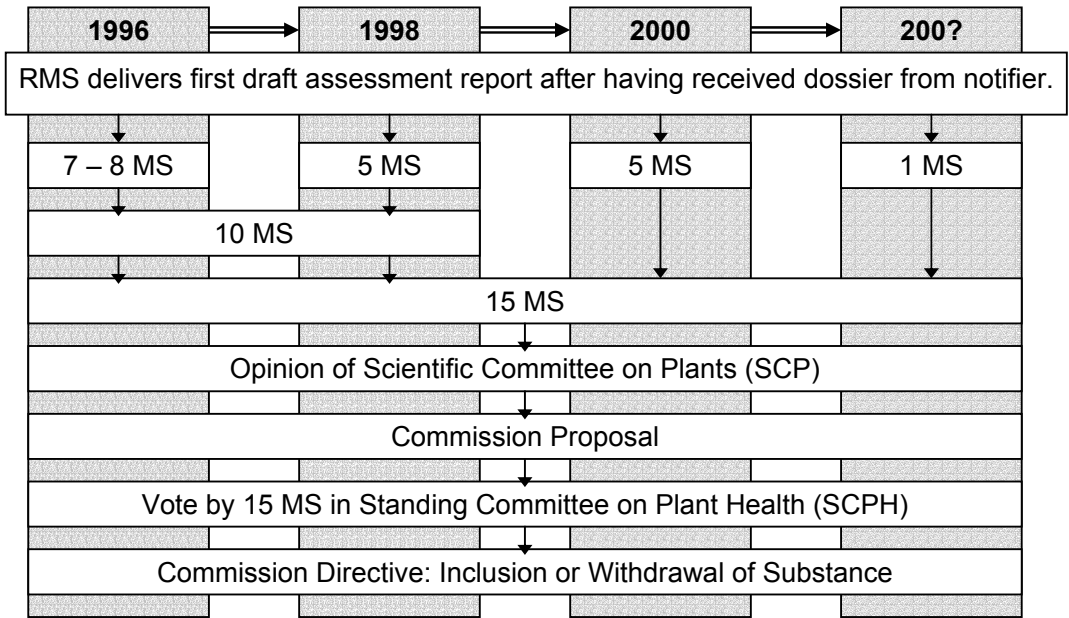


Figure 3: The changing procedure for ECCO review in decision process on authorizing existing active substances (Source: SANCO/2692/2000, p. 9).

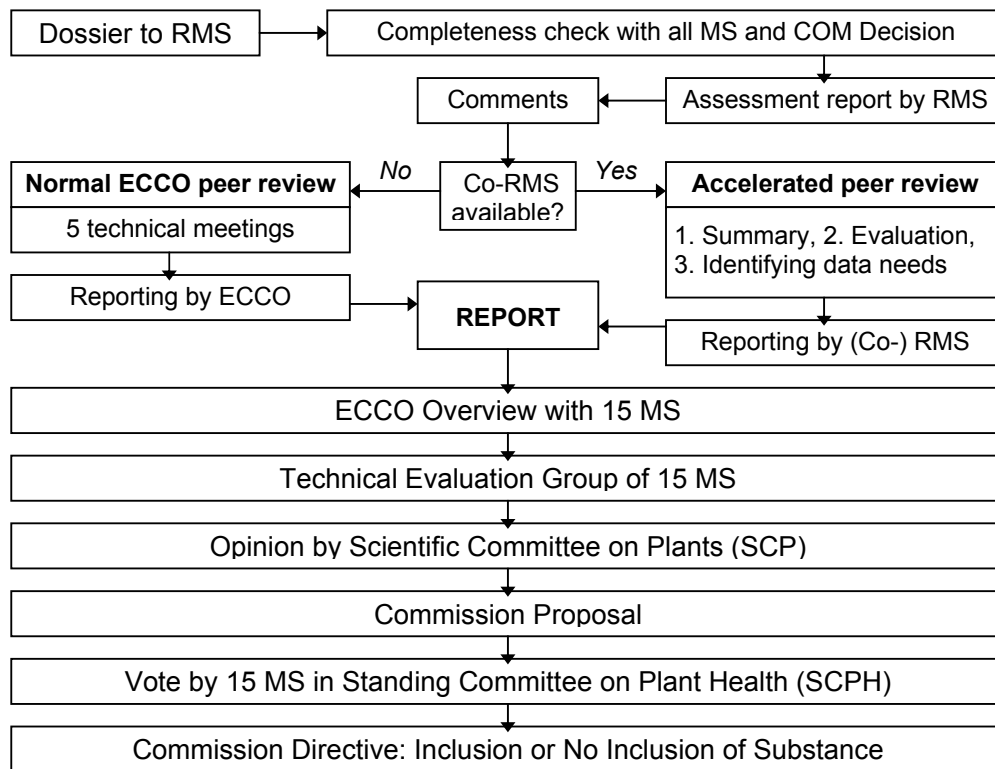


Figure 4: The evaluation procedure(s) for new active substances

(Source: SANCO/2692/2000, p. 14).

The first measure taken after adoption of Directive 91/414, but still before it entered into force, was an inventory of all active substances in the Community. Based on this inventory, broad consultations with Member States and other stakeholders followed in order to select the 90 substances to be put on the first priority list for review under Regulation 3600/92. Also in 1992 a pilot project on three substances was launched in order to have some experience for developing detailed guidance legislation. The results of a meeting with all Member States at the conclusion of the pilot project in 1994 then formed the basis for further developing the evaluation procedures for existing and new active substances and the co-ordination of the review activities by the (Rapporteur) Member States.

The legislative measures taken by the EU can be divided in three groups. First, a group of measures and guidance documents setting out data requirements and assessment and decision making criteria were adopted in the period 1993 to 1996. These laid the groundwork for applying Uniform Principles across Member States.

Second, a number of amendments of the original legislation were required to take account of Austria's, Finland's and Sweden's accession and of new experience from previous authorization cases. And third, since 2000, legislation was targeted at the later phases of the review working program.

Defining data requirements also touched upon the establishment of electronic databases, archiving and communication. Guidance documents were targeted at establishing a general framework for the assessment and quantification of potential groundwater contamination, at issues of ecotoxicology, the assessment of operator exposure and worker safety, and consumer exposure. In all areas substantial demand for further research to improve the performance of the evaluation procedure has been identified.

4.1.4 Relation to other Community legislation

The Directive 91/414/EC is intertwined with a number of other EU directives and regulations. Co-operation between the organizational entities managing the different pieces of legislation is thus not only desirable but necessary. In the remaining part of this subsection the various pieces of legislation concerned are mentioned and the way in which the tasks of co-ordination and co-operation are addressed outlined.

There are four directives under which **maximum residues levels (MRLs)** may be set for pesticides. These concern fruits and vegetables, products of animal origin, cereals and products of plant origin. Although these directives are managed by the same services within the Commission, the Commission has put forward a proposal to consolidate and amend them for better clarity. The task of co-ordination of activities is tackled in two ways. First, wherever possible, the same Rapporteur Member State is nominated under both sets of directives. Second, the evaluations of existing and new substances under Directive 91/414/EC are used in the preparation of MRL proposals.

Many active substances in plant protection products may also be used in **biocidal products**, e.g. against household pests, in wood conservation or anti-fouling agents in paints. Such products are regulated under Directive 98/8. The borderlines between the two product groups need to be continuously defined and further clarified in amendments and guidance documents. It is estimated that about 100 products need to be assessed under both directives. To avoid inconsistencies as much as possible, assessment reports on plant protection products are made available at an early stage to the biocidal "counterpart." Furthermore, the relevant Commission services co-operate closely at the

working level. And finally it was agreed that, where possible and meaningful, the dossier of an active substances may be used under both directives.

Water legislation touches upon or better extends Directive 91/414/EC in numerous ways. First, it is required that potential contamination by plant protection products be measured against the high standard concerning water for human consumption. Second, while the Directive 91/414/EC restricts risk assessment to areas directly adjacent to areas of application of plant protection products, the Water Framework Directive addresses the wider regional context of the use of plant protection products in areas such as the setting of quality standards for surface, transitional and coastal waters.

Two directives¹⁷ that govern the classification and labeling of **dangerous chemical substances and preparations** also apply to active substances in plant protection products and preparations. As plant protection products are thus classified and labeled in the same way as any other dangerous chemical preparation, they are a coherent part of the more general legislative system on classification and labeling of dangerous chemical substances. Directive 91/414/EEC, however, complements the provisions of the above mentioned directives with respect to protection of users, consumers and the environment.

In May 2001 a Progress Report by the Commission on the Community Strategy for dealing with **endocrine disruptors** established a list of 553 substances to be evaluated on their potential for endocrine disruption. 38 of these substances were used in plant protection products. Three of these have been decided not to be included in Annex 1 of the Directive, while the remaining 28 are currently under review. Regulation 451/2000 for implementation of Directive 91/414/EEC considerably improved the situation, as all substances bound to be withdrawn were identified. Notifiers became known for those substances intended to remain on the market and, more particularly, notifiers expressed their intention to defend their substances. Therefore, the Commission can now require a specific data call-in for review of a substance's endocrine potency.

Finally, Directive 91/414/EEC touches upon two international conventions dealing with the production, export and import of dangerous chemical substances. In the first case, relating to the **Rotterdam Convention**, substances on which negative decisions have been taken under the Directive become subject to an export notification procedure, as laid down in the Convention, demanding prior informed consent (PIC) by the importing country. In the second case, the **Stockholm Convention on Persistent Organic Pollutants** (POPs) requires the EU to regulate in order to prevent the

¹⁷ These are Council Directive 67/548/EEC and Directive 1999/45/EC.

production and use of new pesticides that exhibit POP characteristics¹⁸. The Directive will have to be amended in order to fully meet the requirements of the convention.

4.1.5 Activities at international fora

For EU legislation on plant protection products the development of standards at the international level has to be considered. This may require the EU to play an active part in this process or simply follow the standards provided. Here, seven areas or international fora are relevant, which are listed and briefly described with respect to relevance and EU activities in these platforms in Table 3.

¹⁸ At present a total of 12 existing substances have been banned, 9 of which are substances used in pesticides.

Area/Forum	Relevance to EU (Directive 91/414/EEC) and role played by EU
OECD	<ul style="list-style-type: none"> - simultaneous embarking of the EU and the USA on pesticide evaluation programs spurred establishment of the OECD Pesticide Forum in 1992 (renamed Pesticides Working Group in 2000), - EU dossier and data requirements (with minor amendments) adopted as the agreed OECD dossier system in 2000, - annexes of the Directive setting up the requirements for microorganisms developed in full co-operation with the OECD, - EU major driving force behind development of one global dossier and evaluation system.
WTO	<ul style="list-style-type: none"> - adoption of the Directive preceded creation of the WTO, subsequent obligation to notify in advance decisions to withdraw substances has added unforeseen delay of 6 months to evaluation process, - WTO seen as a forum to disseminate EU protection levels globally.
Codex Alimentarius Commission	<ul style="list-style-type: none"> - EU, not a Codex member itself, requested that Codex procedural manual be amended so that EU can supply input to the Codex decision making process, - high relevance, because WTO recognizes Codex standards to be the basis for national standards, - EU questions the practice of Codex Commission on Pesticide Residues to base its decisions on the evaluations by the FAO-WHO Joint Meeting on Pesticide Residues (JMPR), because JMPR resource and capacities are rated as insufficient, its decision process as intransparent and the dossiers used as not up to date, - trade conflicts arise because Codex assessments do not consider factors such as worker and environmental safety or efficacy of active substances, - EU tries to resolve these issues by (a) seeking Codex membership, (b) requesting access to JMPR meetings, (c) insisting on higher and broader standards, and (d) requesting that WHO-FAO improve the JMPR working procedures.
ACP-EC Partnership Agreement	<ul style="list-style-type: none"> - agreement provides that EU notifies to ACP countries technical measures relating to plant protection products that likely affect the interests of one or more ACP country, - many ACP countries likely to be affected by Directive 91/414/EEC, because it bans many old generic and cheap substances that are mainly used in less developed countries, thus effectively blocking imports from countries where such banned substances are still used, - EU has launched two development programs in anticipation of these negative impacts: the first promotes Integrated Crop Management, the second, named "Pesticide Initiative" promotes better co-ordination and information gathering in the ACP area.
Accession countries	<ul style="list-style-type: none"> - intensive contacts between Commission services and the accession countries in all areas of the <i>acquis</i> to prepare accession, - analyses of the current situation in accession countries and their plans to implement national legislation did not reveal specific problems.
European Plant Protection Organization (EPPO)	<ul style="list-style-type: none"> - EPPO is a regional FAO inter-governmental organization for co-operation in plant protection in the European and Mediterranean Region, - more than 200 EPPO guidelines on efficacy evaluation and environmental risk assessment are referred to in Directive 91/414/EEC - Commission and Council are closely involved in EPPO activities (joint panel).
CIPAC	<ul style="list-style-type: none"> - = Collaborative International Pesticides Analytical Council, - produces analytical methods for pesticides and their impurities and physical methods for testing the physical properties of formulations, - organizes and evaluates international trials carried out according to ISO and IUPAC guidelines, - Commission services follow this work closely and accept its methodologies.

Table 3: International fora touching upon EU Directive 91/414/EEC

(Source : Information extracted from SANCO/2692/2000, p. 33-37)

4.1.6 Concluding remarks

The above description of the harmonization process towards a unified procedure for authorization of active substances in plant protection measures are based on official EU documents. These are – of necessity – intended to provide an overview of the progress in that matter without giving too much attention to procedural details and routines that have developed in the course of time. In order to gain insight into these interesting but hidden features of the harmonization process, an interview was conducted with the German representative in the Standing Committee on Plant Health (SCPH) (Bruno 2001), which revealed the following interesting aspects:

- For reaching a decision on an Opinion to the Commission, a qualified majority, i.e. according to the weights of single Member States, is required. To achieve this or, if possible, even unanimity, guidance papers have proven to be an effective support. If a democratic decision can still not be reached, the matter is transferred directly to the Council, where a decision will be reached that is usually politically motivated.
- At present there are two areas, in which a democratic decision is not in sight. The first is the assessment of Antrazit, a herbicide that is predominantly used in maize production. Here, the northern Member States have already banned the substance, while the southern Member States are not willing to follow. The second concerns the question whether metabolites of active substances are to be included in the risk assessment. Some countries, e.g. Germany, are fairly indifferent, while others, e.g. Denmark, are very strict on that matter and stress the importance of including them in the assessment.
- The review system is not free of political influences. Especially the fact that the first report by the Rapporteur Member State may influence the decision process considerably has to be rated as problematic. Experience shows that these reports are particularly prone to political opinions rather than subjected to mere scientific criteria. According to Mr. Bruno (2001) an independent authority would be better suited for providing the first assessment report.

4.2 EU food law

4.2.1 Development, principles and impacts of establishing the Common Market in the area of food law

In 1957 the Treaty of Rome provided that in order to create a common market, the Community should, according to Article 3, focus its activities on (O' Rourke 1999, p. 2 ff.):

- the elimination of customs duties and quantitative trade restrictions between Member States,
- the abolition of obstacles to the free movement of goods, persons, services and capital, and
- the approximation of national legislations to the extent necessary for the functioning of the Common Market.

The goals of consumer protection and public health were not explicitly considered at these times, but subsequently added as amendments to Article 3 through the Single European Act and the Maastricht Treaty. Opposite to the legislation of most Member States, development of EU food law was piecemeal in nature. The progress towards creating a body of food law started with a directive on food coloring agents in 1962 but lacked a central unifying text setting out fundamental and consistent principles of EU food law in order to clearly define the obligations of the players at every stage of the food supply chain. It took a number of major court cases to cause the commission to re-orientate its approach to Community food law in 1985. Further reform of the EU food law and monitoring system was triggered by the BSE crisis of 1996, which led to the formulation of a EU Green Paper on Food Law in 1997 and a White Paper on Food Safety in 2000. Despite the continuous progress in establishing the Common Market, progress in food law has only been piece-meal; where Community legislation is not in force, national law remains valid (BLL 2001, p. 16).

4.2.1.1 Approximation and harmonization of food law up to 1985

Beginning in 1960, the establishment of a Common Market for food products was mainly driven through law approximation procedures until the mid 1980ies. There was no distinction between horizontal areas, as e.g. food additives, and vertical provisions on the composition of individual foods, so called "recipe prescriptions." It was intended to put Community legislation in force in both areas. Overall, however, these attempts were not successful for three main reasons (BLL 2001, p. 16). First, it was recognized that the goal to regulate food

issues entirely at the Community level was far too ambitious, while concrete implementation was characterized by a tendency toward perfectionism.

Second, there was increasing resistance against a – necessarily – very restrictive Community legislation prescribing food composition and recipes. It was recognized that such restrictions would threaten the traditional variety of European food production and processing as well as hamper innovation in the food industry.

Third, the fact that Article 100 of the EU Treaty was the basis for such legislation required unanimity in Council decisions for adoption. So every Member State that felt its interests would be negatively affected by a specific legislation proposal could effectively block the adoption of that piece of legislation.

4.2.1.2 The new approach to harmonization since 1985

The Commission introduced its new approach in a Communication entitled “Completion of the Internal Market: Community Legislation on Foodstuffs.” It stated that such legislation should be limited to provisions justified by the need to:

- protect public health;
- provide consumers with information and protection in matters other than health;
- ensure fair trading;
- provide for the adequate and necessary official controls of foodstuffs.¹⁹

Since 1985 the following areas have been identified as qualifying for inclusion in EU legislation: (BLL 2001, p. 18)

- Food labeling and advertising claims
- Food additives and aromas
- “Novel Foods” and genetically modified foods
- Contaminants and pesticide residues
- Food hygiene, general and product specific
- Food irradiation
- Foodstuffs for particular nutritional uses
- Control and monitoring

¹⁹ Commission Communication on Completion of the Internal Market: Community Legislation on Foodstuffs (1985) Com (85) 603, as cited in O’ Rourke (1999, p. 3).

- Quality of specified foodstuffs (vertical regulation)

Generally, Council or Commission Directives relating to these areas have to be transferred into national law before coming into force. Only in cases when a Member State has not met the deadline for implementation, such directives can come into force directly under certain conditions. In contrast, EEC Regulations always come into force directly.

4.2.2 The principle of mutual recognition

In those areas where Community Legislation is not in place yet or principally not desired, the principle of mutual recognition is applied. It provides that any product that has been legally produced and marketed in one Member State must be allowed to be marketed in any other Member State. Derogations from this principle can only be justified on the grounds of major needs, as e.g. public health, consumer protection or fair trading practices (BLL 2001, p. 19).

To date, the principle of mutual recognition is generally recognized as a major pillar of the Common Market, in particular for foodstuffs. In a Communication from 1999²⁰ the Commission stresses the importance of the principle for establishing the Common Market and proposes a number of initiatives aimed at improving the application of the principle within the Community. The proposals address both businesses and their professional associations on the one hand and Member States on the other. While the final responsibility for implementation remains with the Member States, the Commission commits itself to increase efforts to monitor the effective application of the principle.

In the context of international or extra-EU trade, especially with respect to the European Economic Area²¹ (EEA), the principle also applies. This means that a Member State may not block imports of foodstuffs from third countries, if one of the following conditions holds:

- The product is legally produced in a third country and legally marketed in a Member State of the EU.
- The product is legally produced in a third country and legally marketed in a Member State of the EEA.

²⁰ „Die gegenseitige Annerkennung im Rahmen der Folgemaßnahmen zum Aktionsplan für den Binnenmarkt“ (European Commission Document CA15-0136/03/01/99)

²¹ The European Economic Area was established on January 1st, 1994 and comprises of all EU Member States and the EFTA (European Free Trade Association) Member States Iceland, Liechtenstein and Norway.

Effectively, this means that stricter national food law does not apply to such imports. Although legislation does not address further processing of such imported products, ruling of the European Court indicates that mutual recognition does not only apply to foodstuffs ready for final consumption but also to foodstuffs intended for further processing (BLL 2001, p. 22). EU Legislation, however, grants the single Member the right to temporarily ban or restrict imports for reasons of public health or consumer protection.

In summary, the principle of mutual recognition facilitates the free movement of goods that are legally produced in any EU Member State – and to some extent of goods legally produced in third countries. But in contrast to these imports, national food law of a Member State still applies to domestic producers and processors. As national legislation may still be stricter than Community legislation in some respects, domestic producers or processors may be put at a considerable competitive disadvantage.

Therefore, the principle of mutual recognition is often seen as leading to the discrimination of domestic suppliers. How national governments respond to such a situation depends on a number of factors, of which consumer preferences and the opinion of the sector or industry affected are of key importance. E.g., in Germany, national law on dairy products was amended to completely abolish the strict imitation prohibition, as it was recognized that it imposed far reaching restrictions on product design and innovation without being appreciated by German consumers. In contrast, German brewers still have to produce according to the strict compositional or purity standards of the German beer regulation. Here, industry rated the disadvantages due to higher costs considerably less than the benefits of higher consumer loyalty due to preferences for purity or compositional characteristics.

4.2.3 Vertical legislation

From generally accepting the principle of mutual recognition follows, in principle, the rejection of vertical legislation regulating compositional standards or other specific quality dimensions of foodstuffs. The basic assumption behind this consequence is that providing adequate information to customers on type, composition and other quality dimensions of a food item, renders definitions of these criteria obsolete. Replacement of the vertical harmonization approach by the principle of mutual recognition, however, has not been completed yet. Partly for reasons of national interests, partly for lack of a comprehensive and clear system of labeling, product design and advertising required by complete mutual

recognition, many Member States continue to have compositional, quality or marketing related standards legislation on their statute books for a whole range of foodstuffs (O' Rourke 1999, p. 56).

Furthermore, there are still quite a few product categories for which specific vertical EU legislation exists. The particular pieces of legislation regulate the following foodstuffs with respect to different quality and marketing aspects: (BLL 2001, p. 178 ff.; O'Rourke 1999, p. 56 ff.)

- Chocolate and cocoa products;
- Specific sugar types;
- Honey;
- Fruit juices;
- Coffee and zichoria extracts;
- Jams, marmalades and jellies;
- Certain types of soured milk and dried milk;
- Natural mineral water;
- Spirit drinks;
- Aromatized wines and cocktails containing aromatized wines;
- Marketing of eggs;
- Spreadable fats.

Some of these pieces of legislation are hotly debated, as some Member States whose traditional product definitions or marketing practices are not in line with the corresponding directives or regulations feel to be put at a disadvantage because of adaptation costs. Furthermore, the cost of legislation amendments in response to technological change or alterations in the socio-economic framework is high, as are the costs of monitoring. For a critical view on selected pieces of legislation see O' Rourke (1999, p. 57 ff.).

Finally, there exist three pieces of vertical legislation that have their roots both in food law and in the common agricultural policy. These are: (O' Rourke, 1999, p. 72)

- Regulation 2092/91 on organic production;
- Regulation 2082/92 on agricultural certificates of specific character;
- Regulation 2081/92 on agricultural geographical indications, differentiating between "Protected Designations of Origin" (PDO) and "Protected Geographical Indication" (PGI).

These instruments are voluntary, and companies or regional bodies have to apply for such certificates. Therefore, there is no problem of their co-existing with general legislation, provided that they do not interfere with the correct application of the basic principles regarding the free movement of goods within the Internal Market.

4.2.4 Reform of EU food law: The 2000 EU White Paper on Food Safety

With publication of the White Paper on Food Safety²² on January 12th, 2000 the Commission proposed a “radically new concept” for food legislation. The guiding motive is that the policy of food safety shall be based on a comprehensive and unified concept that covers all stages of value added chain from farm input production to the consumer and takes into account all who are involved at the various stages. The following basic principles are rated necessary for such a concept:

- Definition of responsibilities for all parties involved at the single stages of the value added chain;
- Traceability of feedstuffs, foods and their ingredients;
- Risk analysis as the fundament on which food safety policy be based;
- Application of the Precautionary Principle;
- Consideration of further factors relevant to public health, consumer protection and fair competition.

Corresponding proposals for legislation have been made by the Commission in a draft Framework Regulation on Food Law. The following subsections address the main features of this proposal. They are of necessity formulated at a general level, because the corresponding legislation is at a very early stage of progress and, therefore, subject to amendments before being implemented.

4.2.4.1 EU Framework Regulation on Food Law in preparation

The Framework Regulation on Food Law from November 29th, 2000 consists of three parts: (BLL 2001, p. 30)

²² The White Paper, as well as the subsequent Commission Communication from February 2000 and the comments by the Scientific Steering Committee are available online and are attached to this report (see Annex).

- General Principles of Food Law
- Establishment of a European Food Agency
- Rapid Alert System for Foodstuffs

The general principles touch upon definitions, rules for legislative bodies and specific food law. First, definitions concern the term food as well as many other terms. But no attempt is made to propose definitions that shall apply to the entire European food law. Furthermore, as the definition of food is rather general it is not well suited for regulating the problematic area of distinguishing food from pharmaceuticals – a matter highly relevant for the production and marketing of so called “novel foods.”

Second, articles 5 to 8 of the Regulation set out general objectives and principles, which translate into rules to be followed in legislation activities.

These rules relate to:

- Protection of the free movement of goods;
- Application of international standards;
- Health protection based on the principles of risk analysis, precaution and protection of consumer interests.

Third, articles 9 to 18 regulate specific aspects of food law. Responsibilities are defined and the obligation of traceability established. Requirements concerning the safety of foods and feedstuffs are set out, as well as principles in food trade relating to import and export restrictions. The Community, however, commits itself to furthering international food standards in the EU.

Finally, the principles of transparency shall guarantee the information and consultation of the public.

Article 64, however, states that the above mentioned principles shall not apply directly and immediately. Instead, existing legislation shall remain in force until it is amended in order to conform with the corresponding parts of the Regulation.

4.2.4.2 European Food Agency

The objective is to establish an independent, scientific European authority that shall provide scientific advice to EU legislative and executive bodies. The agency is supposed to be responsible for risk assessment in the areas of:

- Food safety;
- Animal health;

- Animal welfare;
- Plant health;
- Nutrition;
- Genetic engineering.

Furthermore, it is supposed to deal with data generation and analysis, official monitoring and running the rapid alert system for foodstuffs. While risk communication will also be one of the agency's tasks, the agency will have no responsibilities in the area of risk management, which will remain the central task of the legislative bodies of the EU, i.e. primarily Council and Parliament with the Commission being involved in adopting directives and initiating proposals for primary legislation.

In Council negotiations on the White Paper and in particular on the Food Agency it has been stressed that the scope of the Agency's tasks shall be limited to risk assessment and evaluation. Of further particular interest to the Member States are questions concerning:

- the adequate representation in the Agency's monitoring boards, and
- the scientific co-operation with the national authorities and institutes.

4.2.4.3 Rapid Alert System for Foodstuffs

Chapter 4 of the EU White Paper on Food Safety deals with the establishment of a rapid alert system for foodstuffs and the shared obligation of Commission and Food Agency to develop a general plan for crisis management. Furthermore, rules are defined for an immediate call-in of staff for managing an urgency. To date, discussions in the Council and the Parliament on the Food Agency and the rapid alert system in particular have shown the concern that the rapid alert system might be misused by the Agency to expand its activities to include tasks in the area of risk management. Therefore, amendments have focused on establishing rules and procedures that effectively rule out any such expansion attempts.

At present such a rapid alert system is already in function. It is operated by the Commission under DG "Health and Consumer Protection". In its scope, however, the system is limited to those food products that pose a risk to health that goes beyond the territory of a single Member State. The responsibility of establishing and maintaining a well functioning alert system at national level, remains with the single Member States. The alert systems legal basis is Council Directive 92/59/EEC on general product safety.

The basic criteria for notification to the Commission by a Member State are knowledge or suspicion that:

- a foodstuff poses a serious risk to consumers, and
- the foodstuff is likely to be on the market in another Member State.

The system clearly defines the type of hazards that qualify for notification to the EU in Annex 6. The notification procedure then has to meet three requirements:

- Information shall be communicated to the official contact point of the Commission (Annex II) by the official national contact point (Annex III).
- Information shall be communicated on the official notification form (Annex IV).
- Information must be as complete as possible.

The system then sets out the immediate action to be taken by the notifying country and the competent EU authorities. Furthermore, it also provides guidelines for follow-up reaction relating to out of hours service, press release and company recalls. The EU has to be informed about these matter on an official form provided in Annex V of the Document.

4.2.4.4 Precautionary Principle

With the Communication of February 2nd, 2000 the Commission clarifies its standpoint on the application of the precautionary principle, which has been hotly debated for many years at the international level concerning the work of Codex Alimentarius. In this communication the Commission provides an inventory of the principle, as it describes the characteristic features and the measures that may be taken on the basis of this principle. Furthermore it defines guidelines for its application:

- The precautionary principle shall be applied, when scientific evaluation, i.e. risk assessment, has not yet produced sufficient results and a threat to the environment or consumers cannot be ruled out.
- Prior to applying the precautionary principle, the proportionality of measures, the general prohibition of discrimination and the requirement of coherence have to be considered.
- Eventually, advantages and disadvantages of both taking measures and not taking measures have to be compared to reach a decision.

According to the Commission the precautionary principle is part of risk management, i.e. shall be applied in political decisions. The European Parliament has further stressed that the principle shall be applied in those situations, when the risks associated with a product or a production process are unknown. From this follows that the application of the principle is always temporary in nature, i.e. it may only be applied until sufficient information has been gathered. Furthermore, the Parliament criticizes that the proposed criteria on which to base the decision, i.e. proportionality, coherence and non-discrimination, are difficult to apply. Finally, the Parliament suggests to make the entire procedure of applying the precautionary principle as transparent as possible (BLL, 2001, p. 30).

4.2.4.5 Conclusion

The EU White Paper is seen as a milestone for the goal of increasing consumer trust in food supply. The success of subsequent implementation measures remains to be seen at this stage of progress. Although the EU food supply chain is among the safest in the world, there is still room for improvement in a number of areas. These improvements are necessary in order to modernize existing Community food law and to make it more coherent, more transparent, more flexible and safer. The establishment of a European Food Agency is only one, albeit important, step towards a modern Community food law.

In summary, despite its generally positive reception, the White Paper does not provide answers to many questions that have been raised in the 1997 Green Paper on the principles of Community food law and in the subsequent discussions this Green Paper has triggered. This calls for broadening the discussion in the future.

With respect to international trade, the White Paper and subsequent Commission Communications have however fulfilled a main purpose. By making the precautionary principle one of the guiding motives for EU legislation and thus for food production and trade in the Community, it clarifies that industry and consumers in the EU are willing to bear the additional cost caused by adhering to the principle. Furthermore, the Commission signaled to its international trading partners that it is not going to use the principle as a justification for protectionist measures.

4.3 National provisions beyond EU legislation: The case of creosote

As has been stated a number of times above, national legislation still applies in many instances, although horizontal EU legislation is in force, if certain

conditions are met. A main justification for stricter national legislation and thus different production and marketing standards within the Community being accepted are public health and consumer concerns. A particular well documented and illustrative case is presented in this section. In October 1999 national provisions of four Member States, Netherlands, Germany, Sweden and Denmark, effectively limiting the marketing and use of the wood treatment creosote were approved by the Commission. The following subsections provide the details for the case of Germany²³.

4.3.1 Background information on creosote and legislation concerned

Council Directive 94/60/EC harmonizes the use and marketing of creosote, as well as preparations containing it, by limiting the content of one specific component, Benzo-[a]-pyrene (B[a]P), and water extractable phenols when used for wood treatment. The limit for B[a]P is fixed at a maximum of 50 ppm by mass and the limit for water extractable phenols is fixed at a maximum of 3 % by mass. Wood treated with creosote or preparations containing creosote not respecting those limits may not be placed on the market. However, by derogation, the Directive allows for the use of creosote with up to 500 ppm B[a]P by mass for wood treatment in industrial installations. Such products may not be sold to the general public and containers have to be labeled with the phrase "For use in industrial installations only". Wood treated this way and placed on the market for the first time can only be used in industrial and professional applications. But its use is generally excluded:

- inside buildings,
- in contact with products intended for human or animal consumption,
- in playgrounds and in other outdoor places for public pleasure, or
- where there is a risk of contact with skin.

Old treated wood commercialized for a second time can be used irrespective of the creosote-type applied except in the cases mentioned before.

In summary, the German provisions, that are based on an ordinance of 1991 with amendments in 1994, are more restrictive in several aspects:

²³ A complete account of the case is given in the Commission Decision of 26 October 1999 on the national provisions notified by the Federal Republic of Germany concerning the limitations of the marketing and use of creosote, notified under document number C(1999) 3425 and published in the Official Journal L 329 , 22/12/1999 p. 0043 – 0062.

- creosote and preparations containing creosote may not be sold to the private consumer irrespective of their B[a]P content,
- placing on the market of creosote and preparations containing creosote with a B[a]P content up to 500 ppm is only possible for export to countries with climatic conditions requiring enhanced wood preservation and, domestically, for industrial use. Furthermore, specific obligations for the use of creosote and preparations containing creosote with regards to process technology have been established depending on the B[a]P content (up to 5, 5 to 50, and 50 to 500 ppm),
- newly treated wood may not be placed on the market unless certain obligations with regards to the treatment process have been met. Additional restrictions apply for the use of wood treated with creosote containing less than 50 ppm. Wood treated with creosote containing B[a]P in the range 50 to 500 ppm may only be used for two specific applications (railway sleepers, electricity poles for export),
- placing on the market and use of previously treated wood are further restricted in comparison to the EC Directive.

4.3.2 The procedure

4.3.2.1 Legal basis

The German Tar-Oil Ordinance contains the national provisions concerning creosote, was notified to the Commission in 1990 and entered into force on October 1st, 1991. As part of the general reorganization of the legislation, the provisions of the Tar-Oil Ordinance were included in two ordinances, the Banned Chemicals Ordinance and the Hazardous Substances Ordinance, on November 1st, 1993 without changing the substantive contents. The provisions of the two ordinances concerning tar-oils were amended in September 1994.

Directive 94/60/EC was adopted on December 20th, 1994 and had to be transposed into the national law of the Member States by December 20th, 1995. The national provisions had to be applied as from June 20th, 1996.

On May 1st, 1999, the Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, signed at Amsterdam, October 2nd, 1997, entered into force. By letter of August 24th, 1999 the General Secretariat of the Commission informed Germany of the fact that their notification regarding the placing on the market and use of creosote would be treated in the framework of the new provisions of the Treaty.

4.3.2.2 Activities and opinions by Member States

By letter of July 4th, 1995 Germany informed the European Commission that, on grounds of health protection, Germany deemed it necessary to continue to apply the legislation on "tar-oils", and requested a derogation on the basis of the former Article 100a(4) of the EC Treaty from Directive 94/60/EC with regards to creosote. It was also stated that some amendments would be made in order to incorporate a part of the provisions of the Community Directive into the national legislation. These amendments were notified on 8 July 1996.

By letter of 6 December 1995, the Commission invited the other Member States to present their observations on the German request under the former Article 100a(4). The Commission received comments from Denmark, Sweden, The Netherlands, Austria, and the United Kingdom:

- Denmark recalls that in its opinion, creosote is a dangerous substance to both human beings and the environment, and its use should be restricted as far as possible, or banned completely. Denmark therefore fully supports Germany's request.
- Sweden shares the German views regarding the risks posed by creosote and has no objections to the notified German provisions. Sweden underscores that creosote has adverse environmental impacts as it is highly toxic to certain aquatic organisms and certain components are bio-accumulating. Sweden recalls that it had also notified its intention to maintain its national provisions on creosote in view of special circumstances applying in its territory.
- The Netherlands had made a statement in the Council that the level of protection for public health, the workplace, and the environment set by the Directive was insufficient, and therefore had already notified a request for derogation under the former Article 100a(4). The Netherlands consider that the German measures meet a major need and therefore support their confirmation by the Commission.
- According to Austria, the primary objective of the German provisions is the protection of consumer health, which is the objective of the former Article 100a(3). Austria agrees to the position that the cancer risk to consumers from direct dermal exposure to B[a]P containing tar-oils or wood treated with such tar-oils is considerable. Austria therefore considers the continuous application of the national provisions as justified.
- The United Kingdom objects to the request from Germany and considers that it is based on a disagreement with scientific consensus, which was

reached at Community level during the adoption of Directive 94/60/EC. Following the UK opinion, all Member States should accept the standards imposed by single market measures, unless there are special circumstances which would lead to an increase of risk in one Member State. The UK is not aware of any special circumstances in Germany, which would justify the application of more stringent measures.

The fact that only five Member States submitted an opinion clearly shows one deficit of the procedure: A real incentive to become active exists only for those countries whose national interests are likely to be touched upon by the Commission decision on a particular notification. And in fact, concerning this case, three of the countries commenting had already issued or were going to issue a notification on the same matter to the Commission. The Member State objecting to the German request was the United Kingdom, which next to Germany is the major producer of creosote in the EU. Political motives of national interests may thus have a greater impact than strict scientific evidence and reasoning.

4.3.3 The Assessment

Before the actual assessment the Commission first has to decide which pieces of Community legislation apply to a specific case. Then it decides whether the request for derogation by a Member State is at all admissible under EU legislation. Only if this question is answered in the positive, the procedure will start with the assessment of merits.

4.3.3.1 The assessment of merits

In accordance with the provisions of Article 95 of the Treaty, the Commission has to assure that all the conditions enabling a Member State to avail itself of the possibilities of derogation provided for in this Article are met. The Commission has, in particular, to verify whether:

- the provisions notified by the Member State are justified by the major needs of protection referred to in Article 30, or relating to the environment or working environment;
- the measures it has to assess are a means of arbitrary discrimination or a disguised restriction on trade between the Member States,
- these measures constitute an obstacle to the operation of the internal market.

Germany based its request on the major need for protection of human health. Germany submitted a brief justification for the more restrictive national measures which was substantiated by three scientific documents.

However, it was not possible to examine the merits of the request based exclusively on this information. Therefore, the Commission mandated a study to an external consultant to assess the situation of environmental contamination by creosote in Germany. In addition, the findings of three further studies, which were mandated by the Commission in the framework of similar requests from other countries, have been used in this assessment²⁴.

None of the studies was completely conclusive with regards to the effects of creosote on human health, in particular concerning its carcinogenic potential, as a specifically designed long-term carcinogenicity study was still ongoing. This study was made available to the Commission at the beginning of 1998. In addition, all studies have been made available to the Scientific Committee on Toxicity, Ecotoxicity, and the Environment, which expressed a first opinion on the cancer risk to consumers from creosote in November 1998, which was revised in March 1999.

The assessment then proceeds to check the justification on the grounds of major needs. A first step is to assess the toxicity of creosote. The Commission Decision discusses in great detail the existing scientific information on human health effects and environmental effects.

The next step in the procedure is to elaborate on the position of Germany, the notifying Member State, which justifies its request exclusively on the claim that the level of health protection guaranteed by the Community provisions is in general insufficient, especially with regards to health hazards to consumers.

The Commission then evaluates the position of Germany with respect to the available information on human exposure and exposure of the environment. Additionally, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) has been consulted. In the overall evaluation by the Commission three aspects are stressed:

²⁴ The Commission stresses, however, that these substantial efforts of the Commission to find the elements necessary for the justification of the maintenance of the German national provisions cannot constitute a precedent for the future. When examining whether the national measures notified under Article 95(4) are justified by a major need, the Commission has to take as a basis "the reasons" put forward by the Member State. This means that the responsibility of proving that these measures are justified, lays with the requesting Member State.

- The Opinion by the SCTEE is interpreted under application of the precautionary principle. In this light measures aiming at reducing the probability of prolonged dermal exposure to creosote are seen as justified.
- It is established whether the measures taken by Germany take account of the principle of proportionality. This requirement was rated to be met by the German legislation.
- The Commission points to ongoing scientific studies relevant for this case and to the demand for further research in that area.

4.3.3.2 The evaluation of impacts on trade

Three further criteria have to enter the Commission decision process prior to reaching the final conclusion on that case. These are:

- the absence (or presence) of arbitrary discrimination,
- the absence (or presence) of a disguised restriction on trade,
- the absence (or presence) of obstacles to the functioning of the internal market.

For all three additional criteria, the Commission considered that there was no evidence that the German regulations can be used as a means to protect German producers effectively by restricting trade.

Therefore, the Commission concludes that the provisions regarding the use of creosote under German national law:

- fulfill the formal requirements of the relevant EU legislation provisions and are to be admitted,
- can be considered justified on grounds of major need of protection of human health,
- do not constitute either a means of arbitrary discrimination, a disguised restriction on trade between Member States, or a disproportionate obstacle to the functioning of the internal market.

Eventually, the Commission approved the provisions of the stricter German legislation in 1999.

5 Selected case studies concerning the SPS agreement

5.1 Players

The case study analyses focus on the:

- Behavior of the EU and its Member States,
- Behavior of Third Countries,
- The role of the Standing Committees, Specialized Scientific Committees and the Scientific Steering Committee

5.2 List of Cases analyzed:

1. Glyphosate, Cyflanilide and other pesticides inclusion or not-inclusion in Annex I of Directive 91/414/EEC, a case of internal harmonization
2. Potatoes from Cuba: Request by the Netherlands to introduce early potatoes – potato tubers other than those officially certified as seed potatoes may in principle not be introduced to the Community, same Directive 2000/29/EC
3. Member states emergency measures against dissemination of *Pseudomonas solanacearum* as regards Egypt
4. Fish and Pesticides/Residues
5. Requirement for control of Infectious Bursal Virus (IBDV) in cooked chicken meat
6. Citrus imports from Israel, South America and South Africa
7. New maximum levels for contaminations and food additives

5.3 Case 1 Glyphosate: Inclusion of Glyphosate and other active substances to Annex 1 to Council Directive 91/414/EEC

Council Directive 91/414/EEC of July 1991 concerning the placing of plant protection products on the market sets out a Community harmonized framework for authorization, use and control of plant protection products.

Annex I of Directive 91/414 contains a list of active substances authorized for incorporation in Plant Protection Products.

Annex II describes the data requirements active substances.

Annex III describes the requirement for the dossier to be submitted for the authorization of a plant protection product introduction into the EU.

The problem with Glyphosate is that many “free rider” companies use public information to describe their source product and to commercialize preparations. The competition today drives some notifiers – mainly the companies that have developed the active substances – to legal action concerning the national and European data regulation. France and many other MS would prefer an updating of Annex III as soon as possible.

The Commission ensures to update the Annex III and invites the Standing Committee on Plant Health to take note of an updated Annex III.

While Germany supports the Commission in updating the preparation of the Annex III other countries still do not allow glyphosate in preharvest application and aquatic use (Sweden) and are willing to maintain these restriction on a national level. The Netherlands want to include new results of dermal penetration studies of glyphosate and glyphosate trimesium. The Commission will include these interests in a special amendment for workers protection.

An interesting fact is that Greece has announced it was not possible to proper evaluate the correctness of the proposed Commission Directive and the appended Review Report related to the inclusion of *Paecilomyces fumosoroseus* a microbial pesticide to Annex I (short report of SCPH from 27 April 2001).²⁵ It asked for assistance from EU and Member States.

Another interesting case is esfenvalerate, which has finally been included to Annex I of Directive 91/414/EEC in October 2000. Denmark always voted against the inclusion and it had good arguments from the Scientific Committee on Plants (SCP) with its non-favorable opinion.

In June 2001 Denmark notified the Commission that Denmark intends to withdraw esfenvalerate by July 2001. Denmark reached the decision on national rules in absence of Community legislation in force. The decision is based on higher tier studies, for which no strict guidance is provided in the uniform principles.

The SCPH has decided to include glyphosate in Annex I, the Commission has to bring it into force now, which can be considered as a formal act.

Comment

²⁵ See for example short reports of the Standing Committee on Plant Health of 29 June 2001 and 19 October 2000 etc.

WTO/SPS obligations have delayed the process of pesticide legislation by about six month.

Relevant Documents and References:

EC: Council Directive 91/414/EEC, Report from the Commission to the European Parliament and the Council "Evaluation of the Active Substances of Plant Protection Products (Sanco822/2001/rev.3)

Reports of the Standing Committee on Plant Health: ra07_en .. rap37_en

Interviews with:

Prof. Unger, BBA,

Dr. Bruno, German representative in the SCPH,

Mr. Spinti, BBA

5.4 Case 2 Potatoes from Cuba: Request by the Netherlands to introduce early potatoes from Cuba

Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction of organisms harmful to plants or plant products and against their spread does in principle not allow third countries to introduce potato tubers other than those officially certified as seed potatoes into the Community. Exceptions, mentioned in Annex III, Part A, Nr. 12 are the countries Algeria, Cyprus, Egypt, Israel, Libya, Malta, Morocco, Syria, Switzerland, Tunisia, and Turkey, as well as countries which have are either recognized as being free from diseases (*clavibacter michiganensis* ssp. *sepedonicus*) or in accordance with the procedure in Article 18 (where it is described how and who can trigger measures against harmful organisms) or provisions equivalent to the Community provisions.

It is argued that there is a risk of introducing exotic harmful organisms from Cuba which would present a health risk to the Community.

By several decisions the Commission authorized derogations under special technical conditions in respect of potatoes for human consumption. During the seasons 1987 to 1996 it has been allowed to import potatoes for human consumption from the province of Pinar Del Rio in Cuba. From 1997 to 2000 it has been allowed to introduce potatoes from the same province other than intended for planting.

Several samples have been drawn from imports, without finding any harmful organisms.

Information supplied by Cuba and collected during a mission in 1999 by the Food and Veterinary Office (FVO), has shown that potatoes from three other provinces can be imported without danger.

There has been communication and agreement with the Standing Committee of Plant Health.

The Decision from 18 January 2001

With regard to Annex III of Directive 2000/29/EC member states may permit the introduction into their territory of potatoes. The potatoes shall satisfy several conditions: be immature, or treated for the suppression of their faculty of germination, must be grown in the regions that are free of the relevant diseases etc.

Comments

Bert Justus, potato broker Cologne:

There is no economic reason for importing potatoes from Cuba, neither for European nor for Cuban Dealers. It seems that the permission for imports is recognized as a fall back position in case Egypt potatoes have brown rot and import is forbidden.

5.5 Case 3 Egypt potatoes: Emergency measures against dissemination of *Pseudomonas solanacearum*, the cause of brown rot

The framework is the same as in case 2.

France already adopted in March 1996 measures to implement a ban on potatoes from Egypt, after having detected infections of *Pseudomonas solanacearum* in potatoes originating in Egypt.

Finland followed with similar measures in early April 1996, Spain and Denmark in late April 1996.

The measures include testing for presence of the organism in Egypt potatoes intended for export to the Community. All measures will be assessed continually in the import season 1997/98.

Decision of 28 January 1998

The Decision is in accordance with the opinion of the standing Committee on Plant Health.

The entry into the territory of the Community of tubers of *Solanum tuberosum* L. (potatoes) is prohibited with effect of 1 February 1998 unless with reference to certain areas in Egypt (which are officially declared as qualified area with no outbreak of *Pseudomonas* s. A detailed scheme of testing and rules is adopted.

Comment

Egypt managed it virtually every year to export almost all potatoes to the EU with one exception. It can be seen as a process of education of the Egypt producers and authorities to reach European standards.

5.6 Case 4 Fish: Sardines from Peru

Regulation (EEC) No 3796/81 provides for the possibility of adopting common marketing standards for fishery products in the Community, particularly in order to keep products of unsatisfactory quality off the market and to facilitate trade relations based on fair competition;

The adoption of such standards for preserved sardines is likely to improve the profitability of sardine production in the Community, and the market outlets therefore, and to facilitate disposal of the products;

The EC specifies in this context, particularly in order to ensure market transparency, that the products concerned must be prepared exclusively with

fish of the species 'Sardina pilchardus Walbaum' and must contain a minimum quantity of fish.

To prevent the marketing of unsatisfactory products, certain criteria which preserved sardines must satisfy in order to be marketed in the Community for human consumption should be defined.

In March 2001 Peru requested consultations with the European Communities under Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes, Article XXII of the General Agreement on Tariffs and Trade 1994, and Article 14 of the Agreement on Technical Barriers to Trade, with respect to the implementation of Council Regulation (EEC) No. 2136/89 which prevents Peruvian exporters from continuing to use the trade description "sardines" for their products.

According to the Codex Alimentarius standards (STAN 94-181 Rev. 1995), the species "sardinops sagax sagax" is included among those which may be described as "sardines".

Peru therefore considered that the mentioned European Regulation constitutes an unjustified barrier to trade and is contrary to Articles 2 and 12 of the Agreement on Technical Barriers to Trade and Article XI:1 of the GATT 1994. Moreover, it appears to violate the principle of non-discrimination, causing prejudice to our export product and infringing Articles I and III of the GATT 1994.

On 20 March 2001, Peru formally requested consultations with the European Communities with a view to reaching a mutually satisfactory solution to this dispute. This request was distributed to WTO Members in document WT/DS231/1. The consultations were held in Geneva, Switzerland, on 31 May 2001, but unfortunately, they failed to settle the dispute.

Peru considered that Council Regulation (EEC) No. 2136/89 of 21 June 1989 laying down common marketing standards for preserved sardines creates an unnecessary obstacle to international trade. At the same time, these marketing standards cause discriminatory treatment of preserved sardines from Peru. Indeed, Article 2 of the Community Regulation stipulates that only preserved sardines that are "prepared exclusively from fish of the species *Sardina pilchardus* Walbaum" may be marketed as preserved sardines.

It should be mentioned that Peruvian preserved sardines prepared from *Sardinops sagax sagax* entered the German market without any problem under the description "Pacific Sardines" until June 1999, when their entry was prohibited through the application of Council Regulation (EEC) No. 2136/89.

Consequently, the application of the said Community Regulation is causing injury to Peruvian exporters and affecting their legitimate expectations under the Agreements of the World Trade Organization (WTO).

Peru therefore considered the said Community Regulation to be an unnecessary obstacle to international trade which infringes Articles 2 and 12 of the Agreement on Technical Barriers to Trade and Article XI.1 of the GATT 1994. Moreover, it appears to violate the principle of non-discrimination, causing injury to the Peruvian export product, contrary to Articles I and III of the GATT 1994.

Peru requested the establishment of a panel with the standard terms of reference set out in Article 7 of the Dispute Settlement Unit.

Comments

The dispute still ongoing and the influence of southern European Countries within the EC might be large enough to keep this regulation. Their interest in exporting sardines to Germany is the driving force of their behaviour within the EC Institutions. Northern European Countries tend to behave not so strict in this case. The outcome can not be foreseen as a member of the German Agricultural Ministry stated. A political decision can be expected.

Eco-Fish

Production of "Eco-Fish" is a point where the EU is discussing how to implement it. Problems arise when defining the methods of fishing which can be considered as "eco". For example dynamite fishing will be excluded from the allowed methods. A major point of discussion is the stock management of the fish. If high levels methods are requested this induces high costs that may cause a trade barrier.

A topic of interest is the purpose to create a complete list of wholesale and retail fish product names with the intension of informing consumers. These lists are at the moment quite static. The process of introducing new species into the market and has yet not been considered properly.

Relevant Documents and References

EC: Trade description of sardines contained in Council Regulation (EEC) No. 2136/89.

Interviews with:

Mr. Plettau, EC-Commission,

Mrs. Römerscheid, German Ministry of Consumer Protection, Nutrition and Agriculture,

Mr. Hinrichs, FAL

Mr. Schlapper, Ministry of Consumer Protection, Nutrition and Agriculture, responsible for Fisheries.

5.7 Case 5: Requirement for control of Infectious Bursal Virus (IBDV) in cooked chicken meat

EC raises trade concerns about the behavior of Australia with regard to Quarantine Requirements for the importation of cooked chicken meat (Sept. 1998).

Answer is given to ECEP (European Community Enquiry Point) and is under evaluation.

On 11, and 12 January 2000 the Animal Health Code Commission of the Office International des Epizooties (OIE) called in an Ad hoc Group on IBDV. The WTO/SPS have been informed about the process, especially about the expert replies to several questions.

The main topic today is the "Procedure to monitor the process of international harmonization".

5.8 Case 6 Citrus imports from Israel, South America and South Africa

South Africa presented a risk assessment document. The EC is still discussing it. In July 1997, Argentina requested bilateral consultations with EC experts on the proposed measure on citrus canker, and that the measure be suspended during these consultations. South Africa requested that the European Communities reassess its measures in light of the fact that South Africa was free from citrus canker. The European Communities noted that it was preparing a response to the Argentine concern, and was open to consultations with interested parties. The European Communities was moving from a system with internal restrictions in the production areas of Italy, Greece and Corsica to a truly single market with free movement of goods. With no restriction on internal movement of fruit, and considering the risk of introduction and the related economic consequences, alternative protection for the main producing areas had to be considered. This included monitoring requirements in the exporting

country, treatment and certification. The European Communities considered that its measures were based on science and minimized trade effects.

In March 1998, the European Communities reported that, in response to constructive consultations organized by the Chairman and involving Argentina, Chile, Uruguay, Brazil and South Africa, the measure had been revised and subsequently adopted. The revised text included the possibility for recognition of equivalent certification systems. Argentina agreed, but noted that negotiations on equivalence were not yet finished.

In June 1998, the European Communities indicated that it had come to the conclusion that, for the time being, Argentina could not objectively demonstrate the equivalence of its control measures with EC requirements. Argentina requested information on the risk assessment undertaken by the European Communities.

Comments

With the South European Countries having own trade interests, it seems that in this case SPS provisions have been heavily determined by trade policy.

Relevant Documents

WTO: G/SPS/N/EEC/46, G/SPS/N/EEC/47, G/SPS/GEN/21, G/SPS/GEN/26

5.9 Case 7 New Maximum Levels for certain Contaminants: Aflatoxin

The Commission Regulation No. 194/97 of 31 January 1997 is setting maximum levels for certain contaminants (covering aflatoxin) in foodstuffs.

In March 1998, a number of countries argued that the EC proposal to set new maximum levels for aflatoxins would impose severe restrictions on trade while not resulting in a significant reduction in health risk to consumers. The proposal did not seem to be based on a proper risk assessment.

There was no consensus between EC and the Codex Committee on Food Additives and Contaminants (CCFAC) on that issue. Many Countries did support the CCFAC norm – there has been no international standard – the EC did not.

Another point of discussion was the sampling procedure, which had to be adjusted to a small percentage of contamination. The proposed methods were

already used by some Member States. The EC planned to evaluate comments received until May 1988 and formalize the proposal in June 1988.

A revised proposal has been forwarded to Member States in June 1988. The EC Standing Committee on Foodstuffs would consider the proposed modifications on End of June 1988 – some maximum levels had been revised.

Measures would enter into force not before January 1989 and transitional arrangements were considered.

In September 1988, Bolivia informed the Committee that the proposed EC measure would have severe effects on Bolivian exports of Brazil nuts. Bolivia requested to see the EC risk assessment, and indicated it was prepared to enter into bilateral discussions with the European Communities in order to find a mutually agreeable solution. The United States encouraged the European Communities to take into account the recommendations contained in the FAO/WHO risk assessments establishing maximum levels for aflatoxin in consumer-ready products. The ASEAN countries expressed concern with maximum levels in milk, which would affect developing countries' feed exports.

The European Communities noted that the deadline for comments had been extended to allow for further comments from Members. The European Communities had also revised its proposal, and was prepared to raise the proposed maximum levels in nuts. With regard to milk, the proposed EC levels were in line with the standards being discussed in Codex.

In November 1988 bilateral consultations between Bolivia and the European Communities took place which he had been requested to facilitate. The discussions had been very fruitful, and had helped Bolivia to better understand the rationale behind the EC measures, as well as the EC procedures followed. They had also helped the EC understanding of the potential effect of some of its measures on the Bolivian industry. Technical consultations were continuing.

In March 1989, Bolivia reported that it had presented a plan to improve its Brazil nuts, and consultations with the European Communities were ongoing. Bolivia considered that this was a good case for the application of special and differential treatment. Peru indicated that several countries had brought their problems with the new EC regulation on aflatoxins to the attention of the European Communities through their missions in Brussels, without having obtained a satisfactory response. In particular, the European Communities had not presented a risk assessment. The European Communities assured Bolivia

that their common examination of the problem would continue through a rapid procedure. In response to other Members, the European Communities indicated that there had been ample time for comments, and that the proposal had been revised in response to comments received. On cereals, the European Communities was prepared to continue accepting comments until 1 July 1999 and to modify the measure if there was scientific justification.

The EC has amended the relevant Commission Regulation No. 194/97 of 31 January 1997 four times, lately in March 2001.

The EC is aware of disparities between Member States and the consequent risk of distortion of competition and has therefore adopted measures to ensure market unity while abiding by the principle of proportionality.

It adopted the new maximum levels on July 1998, which entered into force 1 January 1999. The regulations were open for discussion if new scientific knowledge is available, especially for unprocessed cereals which are not directly used for human consumption. During the process of gathering additional information and scientific knowledge the – probably – lower levels of cereals for direct human consumption apply.

The measures are in accordance with the opinion of Scientific Committee on Food.

It is planned to introduce additional maximum levels for food intended for infants and young children. The SCF will be consulted and these levels shall be established as soon as possible.

A complicated case in this area is nitrates. In principle the same rules and maximum level regulations apply for nitrate, but it is realized that different regional and climatic conditions influence the levels of nitrates in certain vegetables. The aim is to fix different nitrate levels depending on the season. Because the corresponding conditions vary extremely within the EC Member States and the effect of good agricultural practice, which is recommended for farmers to reduce nitrate level, takes a while to have its effects, a transitional regulation is accepted. Member states are allowed to authorize the marketing of lettuce with higher levels of nitrate than those fixed in the Regulation (466/2001).

Relevant Documents

WTO Database: G/SPS/GEN/204, G/SPS/N/EEC/51, G/SPS/GEN/50,
G/SPS/GEN/52, G/SPS/GEN/54, ..., G/SPS/GEN/63, G/SPS/GEN/93

EC: Commission Regulation EC No. 194/97, Amendments 398R1525,
399R0864, 399R1566, and 301R0466

Reports of the Standing Committee on Foodstuffs: rap01_en .. rap07_en

5.10 Concluding comments

The EU is following a policy of “minimum trade distortion”. This seems to be a rather weak policy – at least for plant health.

WTO/SPS obligations have played a major role for setting up and amending the EU directives. They do not influence the operational work of the EU Member States as much, but rather serve as a guide for decision making.

The process of harmonization of plant health regulations among EU Member States is finished since 1993 and working on a legal basis. Implementation is still varying among member states. Inspectors from the Commission do visit member states and control implementation.

Today it is accepted to a certain degree that different levels of implementation are applied among the member states. But only if there is an official complaint by a Member State, the EU Commission starts working.

With respect to plant protection measures, an amendment or request to the relevant directives (2000/29/EC) has to be put through a member state. At the beginning (until 1993) all submissions/requests to the EU were directly forwarded to the Commission. This led to an enormous workload for the Commission, inefficiency and a de facto paralysis of the administration. Since a risk assessment on a scientific level has to be delivered, this procedure is more effective. The costs must not be or are not covered by the third country, but a member state. It is thereby guaranteed that only serious requests for derogations are placed. This has led to a reduction of requests.

6 References

BLL (1998): Das gemeinschaftliche Lebensmittelrecht – Eine Zwischenbilanz zum 31.12.1998, Bonn.

BLL (2001): Das gemeinschaftliche Lebensmittelrecht – Eine Zwischenbilanz zum 30.6.2001, Bonn.

O' Rourke, R. (1999): European Food Law – with 1999 update. Bembridge.

Interviews with:

Prof. Unger, BBA.

Dr. Bruno, German representative in the SCPH.

Mr. Hinrichs, FAL

Mr. Plettau, EC-Commission,

Mrs. Römerscheid, Federal Ministry of Consumer Protection, Nutrition and Agriculture,

Mr. Schlapper, Federal Ministry of Consumer Protection, Nutrition and Agriculture, responsible for Fisheries.

Mr. Spinti, BBA.

7 Appendix: List of pdf documents attached to the report

1 Introduction

- EU additional negotiating proposal on food safety.pdf
- The complete list of the EC regional trade agreements.pdf

3.1.2.1 The Scientific Steering Committee (SSC)

a) Risk assessment procedure for GBR:

- final opinion of SSC on geographical BSE risk (GBR).pdf
- third opinion of SSC on geographical BSE risk (GBR).pdf
- second opinion of SSC on geographical BSE risk (GBR).pdf
- first opinion of SSC on geographical BSE risk (GBR).pdf

b) Harmonization of risk procedures across scientific committees:

- harmonization of risk assessment procedures across SCs I.pdf
- harmonization of risk assessment procedures across SCs II.pdf
(appendices)

c) Antimicrobial resistance:

- Second Opinion of the Scientific Steering Committee on Antimicrobial Resistance.pdf
- Opinion of the Scientific Steering Committee on Antimicrobial Resistance.pdf

d) Strategies for dealing with future food safety and consumer protection issues:

- Strategies for dealing with emerging and re-emerging scientific issues that have the potential to impact human health.pdf

4.1 Authorization of active substances in plant protection products

- SANCO_2692_2000.pdf

4.2 EU food law

- EU White Paper on Food Safety.pdf
- Integrated Report and Comment of SSC on EU White Paper.pdf