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Integrating Scientific Expertise into Regulatory Decision-Making.

The Cases of Food and Pharmaceuticals

ROBERT HANKIN

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Hankin: *Integrating Scientific Expertise into Regulatory Decision-Making. The Cases of Food and Pharmaceuticals*

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ROBERT SCHUMAN CENTRE

Integrating Scientific Expertise into Regulatory Decision-Making

The Cases of Food and Pharmaceuticals

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Integrating Scientific Expertise into Regulatory Decision-Making

The Cases of Food and Pharmaceuticals

ROBERT HANKIN * / **

1. INTRODUCTION

Article 3 of the Treaty of Rome, as amended by the Treaty on European Union, provides that the activities of the European Community shall include, amongst others;

(a) the elimination, as between Member States, of customs duties and quantitative restrictions on the import and export of goods, and of all other measures having equivalent effect;

(c) an internal market characterized by the abolition, as between Member States, of obstacles to the free movement of goods, persons, services and capital;

(h) the approximation of laws of the Member States to the extent required for the proper functioning of the common market;

(o) a contribution to the attainment of a high level of health protection;

(s) a contribution to the strengthening of consumer protection.

The Treaty provides two major instruments for the removal of obstacles to the free movement of goods within the internal market:

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* Deputy Head of Unit, Foodstuffs, Legislative, Scientific and Technical Aspects, Directorate General for Industry (DG III), European Commission.

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- the prohibition of quantitative restrictions and measures having equivalent effect on imports and exports between the Member states (Articles 30-36 EC);

- the approximation of provisions laid down by law, regulation or administrative action in Member States.

2. THE TREATY RULES ON THE FREE MOVEMENT OF GOODS

Articles 30 and 34 EC prohibit quantitative restrictions and measures of equivalent effect on imports from and exports to the other Member States respectively. In its judgment in Case 8/74, *Dassonville*, the Court of Justice gave a broad interpretation to the concept of a measure having equivalent effect, holding that it covers any measure which is capable of hindering intra-Community trade directly or indirectly, actually or potentially. In the *Cassis de Dijon* judgment of 1979 the Court clearly implied that Articles 30-36 lay down a general principle that goods lawfully produced and marketed in one Member State have the right to move freely throughout the Community.

Nevertheless, the principle of mutual recognition, which is set out in the *Cassis de Dijon* judgment, is subject to certain exceptions, some of which derive from Article 36 of the EC Treaty, and others from the case law of the Court. In particular, in accordance with Article 36 of the Treaty, Articles 30-34 do not apply to national measures which are justified for the protection of the health or life of humans, animals or plants provided that these do not constitute a means of arbitrary discrimination or a disguised restriction on trade. The protection of public health has also repeatedly been mentioned by the Court as one of the mandatory requirements which may justify national legislation having restrictive effects on the free movement of goods. In addition, the Court has also identified the protection of consumer interests and the protection of the environment as mandatory requirements.

For practical reasons, it is not possible to analyse in detail here the extensive body of case law on the application of Articles 30-36 of the Treaty. Nevertheless, it is important to note certain general principles which have been laid down by the Court, and which have had a major influence on the development of Community legislation in areas such as food or pharmaceuticals.

Firstly, it is clear that not every national measure which is ostensibly for the protection of public health is protected by Article 36 of the Treaty, or by the

mandatory requirements laid down by the Court. Article 36 itself states that a measure must be '**justified**', and must not constitute a means of arbitrary discrimination or a disguised restriction on trade. It is for the Member State which has adopted the measure to show that these conditions are fulfilled. On the basis of these provisions, the Court has applied a test of proportionality to the national measures concerned. National measures which are ostensibly for the protection of, for example public health, or consumer protection, are only compatible with the Treaty to the extent that they are necessary for the effective protection of the relevant interest. If the relevant interest could be as effectively protected by measures which do not restrict intra-Community trade as much, then the measures concerned will not fall within the scope of the exemptions set out in Article 36.[1] This line of reasoning has been particularly important in the foodstuffs area. The Court has consistently held that national rules on the composition of products, which are intended for consumer protection, rather than the protection of public health, are to be considered as unnecessarily restrictive in so far as labelling provisions would constitute a sufficient means of consumer protection (e.g. *German Beer* case).

Concerning national measures for the protection of public health, it is clear that the burden of proof lies on the Member State concerned to demonstrate that the national measure is justified (or necessary, the terminology used varies) for the protection of public health. The Court has not hesitated to declare incompatible with the Treaty national legislation which imposed alleged health restrictions for protectionist motives (e.g. Case 40/82 *Commission v United Kingdom* (*Newcastle disease*) and Case 124/81 *Commission v United Kingdom (UHT milk)*).

However, in those cases the issues were clear cut, and there was at least some circumstantial evidence that the Member State concerned was mis-using public health legislation in order to block imports. In many cases, the public health issues are less clear. A series of cases concerning restrictions on the use of food additives or restrictions on the sale of vitamin preparations illustrate the Court's approach in such circumstances. In *Eyssen* (case 58/80) the Court was asked to rule on the compatibility with Articles 30-36 of a Dutch rule which prohibited the use of nisin as an additive in cheese sold in the Netherlands, although it permitted it in Dutch cheese produced for export. In its judgment, the Court acknowledged the difficulties which international organisations were having in assessing the risks inherent in the use of nisin as an additive, and felt that this might explain the diversity of the national rules. Because of the scientific uncertainties as to the maximum amount of nisin which should be permitted in

[1] E.g., Case 104/75, *De Peijper* [1976] ECR 613.

individual preserved products, and bearing in mind the different dietary habits in the different Member States, the Court concluded that the measure concerned could not be considered as a means of arbitrary discrimination or a disguised restriction on trade.

In *Sandoz* (case 174/82) the Court had to consider Dutch legislation which required the prior authorization of foodstuffs containing added vitamins. Although excessive consumption of certain vitamins may present a health risk, there was no dispute that the level of vitamins contained in the products concerned was nowhere near that level, nor was it suggested that excessive consumption of the products concerned would constitute a health risk. Nevertheless, since the overall intake of vitamins could not be controlled, a potential health risk could not be entirely excluded. The Court pointed out that in the absence of harmonization, Member States were free to determine the degree of protection of the health and life of humans which they wished to ensure, subject to the treaty provisions, and in particular the requirements of the free movement of goods. Given the uncertainties involved in the scientific assessment of safe levels of vitamins, a system of prior authorization would be justified, provided authorizations were granted where they are compatible with the need to protect public health. Moreover, despite the fact that Member States had a wide discretion, they must, in order to observe the principle of proportionality, authorise marketing when the addition of vitamins to foodstuffs meets a real need, especially a technical or nutritional need. Thus although a Member State could require an importer to provide all available information about the composition of a product and the technical or nutritional reasons for adding vitamins, it could not require the importer to demonstrate a market need for the product.

So far as the actual evaluation of the risk to health presented by a particular product is concerned, in Case 344/90 *Commission v. France* (nitrates in cheese) the Court emphasised that the existence of a health risk resulting from the use of a food additive must be evaluated by taking into account the results of international scientific research, in particular the work of the Scientific Committee for Food, and dietary habits in the Member States concerned. However, where there is genuine scientific doubt, the Court will rarely over-rule the judgement made by the Member State. Thus, where, as a result of differing interpretations of the scientific evidence Member States adopt differing decisions on the use of products, the harmonization of national legislation will become necessary in order to ensure the operation of the internal market.

3. The development of Community legislation in the foodstuffs sector

The detailed harmonization of the provisions of national legislation relating to foodstuffs, in order to secure free circulation, began in the earliest years following the establishment of the Community. From 1962 to 1985, two approaches were followed:

- horizontal harmonization covering all foodstuffs, either in order to protect public health (e.g. additives) or for the protection of the other interests of consumers, such as the provision of information or the prevention of deceptive trade practices (e.g. labelling)

- vertical harmonization laying down detailed specifications for a specific type of foodstuff; 8 directives were adopted covering cocoa and chocolate products, sugars, honey, fruit juices and similar products, jams, jellies and marmalades, preserved milk, coffee extracts and natural mineral waters.

After the *Cassis de Dijon* case, the Commission completely reviewed its policy on the harmonization of legislation in the foodstuffs sector, and in 1985 it presented a communication to the Council and the European Parliament on the completion of the internal market in the foodstuffs sector.[2]

In accordance with the Communication, Community food legislation would henceforth be limited to the harmonization of those national rules which are justified for the furtherance of the mandatory requirements identified by the Court, namely:
- the protection of public health;
- the protection of other interests of the consumer, notably consumer information;
- the fairness of commercial transactions;
- the need to ensure appropriate official controls.

On the other hand, the Commission indicated that it would no longer bring forward proposals for the harmonization of quality specifications for foodstuffs, such as rules relating to the composition or manufacture of foodstuffs which are not related to the protection of public health. Instead, the Commission considered that mutual recognition could be achieved by a reinforcement of the labelling rules in order to ensure the information of the consumer and the fairness of commercial transactions. In addition, the Commission encouraged

[2] COM (85) 603 final.

the industry to develop quality policies based on the use of voluntary instruments.

In a further communication of 1989 on the free movement of foodstuffs within the Community and in its 1991 interpretative communication on the names under which products are sold, the Commission specified the system for mutual recognition of foodstuffs in non-harmonised areas together with the possibility of adopting sectoral provisions which are considered necessary for the implementation of other Community policies, for example, compositional requirements, definition of organic production, quality marks for traditional foods, and designations of origin.

Virtually all the legislation set out in the Commission's 1985 programme has now been adopted, with the exception of the proposals relating to food irradiation and novel foods which are currently under consideration by the Council and the European Parliament. In addition, further measures have been adopted to take account of problems which were not foreseen in 1985, notably in respect of food hygiene, contaminants, and cooperation between the Commission and the Member States on the examination of scientific questions relating to food.

All the Community provisions relating to foodstuffs are published in a single volume.[3] A summary of the main provisions is set out below.

Food labelling; Community legislation lays down detailed rules on the labelling of foodstuffs, including detailed information about the nature and composition of the product. It also sets out a general principle that the presentation, labelling and advertising of foodstuffs must not be such as to mislead the consumer. Although many food labelling rules are primarily intended to protect the economic interests of consumers, the provision of adequate information for the consumer about the storage and use of food is obviously important to ensure food safety. EC labelling rules require that consumers must be provided with such information in a language they can understand. In particular, the labelling must include a best before date, or in the case of highly perishable foodstuffs, a use by date.

Nutritional labelling; within the EC, nutritional labelling is not mandatory. However, if producers do wish to provide nutritional information, they must present it in a specific manner.

[3] This volume currently runs to about 720 pages: European Commission, Foodstuffs, Co-ordinated Instruments, 1994.

Additives; in line with the Codex Alimentarius, the positive list principle applies. Thus no additive may be used in food unless it has been included in a positive list established at EC level. Two directives which were adopted by the EC Council on 16 June 1994 establish the detailed conditions of use of colours and sweeteners, including lists of the foodstuffs in which such additives can be used, and maximum permitted levels of use. Similar provisions relating to the other additives are set out in Directive 95/2/EC.

Flavours; existing legislation lays down general criteria for the safety of flavours. Further proposals for the establishment of positive lists of synthetic flavours are under consideration by the Council and the European Parliament.

Extraction solvents; a positive list of compounds which may be used as extraction solvents is provided for, together with MRLs for certain compounds.

Contaminants; a large number of maximum residue limits (MRLs) have been established for residues of pesticides and veterinary medicines. The Community may also establish maximum limits for the presence of environmental and agricultural contaminants in food, and consideration is currently being given to the establishment of limits for heavy metals, for nitrates in vegetables and for mycotoxins. Detailed rules relating to contamination by radio-activity were established following the Chernobyl accident.

Materials in contact; specific legislation has been adopted to ensure that no risk to public health may result from materials which are intended to come into contact with foodstuffs, notably packaging materials.

Foodstuffs for special nutritional purposes; general provisions have been laid down to ensure the safety of this class of product, together with specific rules on the composition of infant formulae and follow on formulae. Further rules relating to other baby foods, to foodstuffs for weight control purposes and foodstuffs for special medical purposes are in preparation.

Quick frozen foodstuffs; specific rules are laid down in respect of the safety of such products, notably in respect of temperature control and maintenance of the cold chain at -18°C, with a tolerance of + 3°C.

Hygiene; a Council directive of 1993 lays down general rules on food hygiene, based on the application of the principles of hazard analysis and critical control points (HACCP). In addition, EC veterinary legislation lays down detailed specific rules in respect of the hygiene of products of animal origin. This legislation also provides the EC institutions with powers to adopt emergency measures arising within the Community and in trade with third countries.

Novel foods; as a result of technological developments, consumers are increasingly being offered novel foods which have not previously been used for human consumption, and foods being produced by new technological processes, such as genetic technology. The EC institutions are currently considering proposals which would require all novel foods to be subject to a safety evaluation at the EC level before being placed on the market. The major question outstanding concerns the extent to which specific mandatory labelling requirements should be laid down for foodstuffs derived from biotechnology.

Food irradiation; at present, the use of food irradiation is regulated by the Member States. Proposals for a harmonized approach at EC level are currently under consideration.

Control and enforcement; in accordance with the EC Treaties, responsibility for control and enforcement of EC rules lies with the competent authorities of the individual Member States. The role of the EC Commission is limited to ensuring that Member States are indeed fulfilling their obligations under the Treaty and EC secondary legislation. Nevertheless, EC legislation has laid down the general principles of the official control of foodstuffs. Control consists of inspection, sampling and analysis, inspection of staff hygiene, examination of written and documentary material and examination of verification systems set up by undertakings. Inspections shall cover all stages of production, manufacture, import into the Community, processing, storage, transport, distribution and trade. In accordance with the EC rules, products which are intended for consignment to another EC Member State must be controlled with the same care as products intended for marketing in the Member State concerned, and a product must not be excluded from control simply because it is intended for export from the Community.

In addition, the EC is developing procedures for administrative cooperation between the Member States on matters relating to control and enforcement in order to ensure that the necessary controls are being carried out effectively and equivalently across the Community. Thus, each year the Commission establishes a co-ordinated programme for the control of foodstuffs. The Member States exchange statistical information about the operation of the control systems, the number of inspections carried out and the nature of the infringements found. In addition, steps are currently being taken to establish a small centralized Community food control unit which will be responsible for auditing the national control systems.

The objective of these activities is to facilitate the operation of the internal market by establishing mutual confidence between the national inspectors, thus

removing the need to repeat controls for products produced in other Member States.

4. The development of the Community rules relating to medicinal products

The first Community directive relating to pharmaceutical products was adopted in 1965, in the wake of the thalidomide tragedy. Directive 65/65/EEC set out the principle that no medicinal product may be paced on the market of a Member State unless an authorization has previously been granted by the competent authority of that Member State. The Directive further set out the three basic criteria which had to be considered before granting a marketing authorization, namely the quality, safety and efficacy of the medicinal product concerned. By limiting the evaluation process to these three essential criteria, the Directive implicitly rejected the consideration of economic factors, during the assessment of pharmaceuticals. Likewise, it is not necessary for the applicant to show a therapeutic need for a product; simply that the benefits outweigh the risks. The directive also set out procedural requirements for the authorization procedure (time limits, reasons for decisions etc) and harmonised the general criteria for labelling.

Further legislation in 1975 set out detailed requirements for the conduct of the various analytical, pharmaco-toxicological and clinical tests and trials which must be carried out in order to demonstrate that the requirements for quality, safety and efficacy of a product are satisfied. Tests and trials which were carried out in accordance with these requirements did not need to be repeated within the Community. In addition, Directive 75/319/EEC harmonised the conditions for granting manufacturing authorizations, based on the principle of mutual recognition of national authorizations. Medicinal products which are accompanied by the batch control reports established by the manufacturer should not be subject to retesting within the Community.

Subsequent legislation progressively updated the basic rules set out in the first two directives, and progressively extended their scope to cover veterinary medicines (Directives 81/851/EEC 81/852/EEC) immunological products (Directive 89/342/EEC), radio pharmaceuticals (Directive 89/343/EEC), medicinal products derived from human blood or plasma (Directive 89/381/EEC), homeopathic medicinal products (Directive 92/73/EEC), immunological veterinary medicinal products (Directive 90/677/EEC) and homeopathic veterinary medicinal products (Directive 92/74/EEC). In addition, specific legislation was adopted governing the use of colouring matters in medicinal products (Directive 78/25/EEC) and the principles of good

manufacturing practice of medicinal products for human use (Directive 91/356/EEC) and veterinary medicinal products (Directive 91/412/EEC).

In addition to issues directly concerned with the authorization of the manufacture and marketing of medicinal products, for medicinal products for human use other legislation was adopted concerning wholesale distribution (Directive 92/25/EEC), classification for the supply of products to patients (Directive 92/26/EEC), labelling and patient information leaflets (Directive 92/27/EEC) and advertising (Directive 92/28/EEC). Moreover account was also taken of the social and economic environment of medicinal products for human use with the adoption of a directive on the transparency of measures regulating the pricing of medicinal products and their inclusion within the scope of the national health insurance systems (Directive 89/105/EEC) and through the establishment of a supplementary protection certificate to allow manufacturers to recoup that part of the effective patent life of new products which is lost during the research and development process.

Despite this extensive harmonization of the substantive rules applicable to medicinal products, one fundamental problem remained unsolved. As noted above, Directive 65/65/EEC (or for veterinary medicines Directive 81/851/EEC) established the principle that no medicinal product could be placed on the market of a Member State unless it had received prior authorization from the competent authorities of the Member State concerned. For medicinal products for human use, this process entails the detailed evaluation of the quality, safety and efficacy of the product concerned on the basis of a detailed dossier which is supplied by the applicant setting out the results of the analytical, pharmacological and toxicological tests and clinical trials undertaken during the development of the product. Following that evaluation, the competent authorities have to balance the therapeutic benefits of the product and its potential risks and decide whether authorization may be granted, and if so, subject to what conditions of use. For veterinary medicinal products, the process is essentially similar, although the benefit/risk evaluation is sometimes more complex, because account has to be taken not only of the benefits and risks for the animals concerned, but also of risks for the human consumer of foodstuffs from treated animals, and sometimes also of the safety of farm workers and environmental issues.

At first it was generally thought that the harmonization of the detailed rules concerning the testing of medicines and the presentation of authorization dossiers would lead in practice to the similar decisions on marketing authorization. However, practice showed that this was not the case. Even with very detailed harmonization of the substantive rules, Member States were still

adopting conflicting decisions on the authorization of individual medicinal products. Even if the same product were authorized by several Member States, this would commonly be subject to different conditions of use etc.

Thus in addition to the harmonization of the legislative rules, consideration was given to a variety of procedural mechanisms to co-ordinate the evaluation of individual medicinal products. The first such mechanism, known as the Multi-State procedure was established by Directive 75/319/EEC, and amended in 1983 by Directive 83/570/EEC. In its amended form, the procedure enabled a company which had received a marketing authorization in one Member State to apply for the extension of that authorization to two or more of the other Member States. The Member States who received the application were obliged to take the original authorization into due consideration, and should normally issue a marketing authorization within 120 days of the receipt of the original application. In exceptional cases, however, the Member State concerned could lodge its reasoned objections to granting an authorization with the CPMP within the 120 day period. Where objections were received, the Committee was required to give its opinion on whether the product meets the criteria of quality, safety and efficacy for authorization. The opinion was communicated to Member States who were required to give an opinion within 60 days.

The second procedure, established by Directive 87/22/EEC was of a more centralized nature. Reserved for medicinal products derived from biotechnology, for which it was compulsory, and other categories of high technology medicinal products, the procedure required the competent authorities to consult with each other systematically within the framework of the CPMP, from the moment an application was received. At the end of the procedure, which was required to be conducted within the same time limits as purely national procedures, the CPMP or the CVMP issued an opinion on whether the product satisfied the criteria laid down in the directives. This opinion was communicated to the competent authorities of the Member States who were required to reach a definitive decision within a further period of 30 days.

In practice, neither procedure proved capable of meeting the needs of the single market in the pharmaceutical sector. The opinions of the committees at the conclusion of the procedure were not binding, and could not serve as a means of resolving strong disagreements between Member States about the acceptability of a product. While in some cases it was possible to arrive at a unanimous opinion, many opinions were divided. Even when unanimous, this unanimity was sometimes achieved by fudging central issues. Moreover, the work of the

two committees was greatly complicated by many minor technical objections from Member States which made it difficult to focus on the real issues.

For this reason, after very extensive consultations, in 1990 the Commission decided to propose the establishment of new Community centralized and decentralized authorization procedures leading to binding decisions at Community level. In order to provide the necessary infrastructure to support these procedures, the Commission also proposed the establishment of a European Medicines Evaluation Agency (EMEA). Regulation (EEC) 2309/93 was finally adopted by the Council on 22 July 1993, and the new Agency, based in London, took up its responsibilities on 1 January 1995.

The new centralized procedure is largely based on the experience acquired with the Directive 87/22/EEC procedure. Use of the centralized procedure is compulsory for the majority of medicinal products derived from biotechnology, and is available on an optional basis for other categories of medicinal products. The applicant forwards a complete dossier to the Agency. The evaluation of the application is undertaken by the CPMP or CVMP as appropriate. The Committee must give an opinion on the application within 210 days, unless the time limit is suspended to enable the applicant to respond to questions or objections. The opinion of the Committee is transmitted to the Commission which takes a final decision on the application.

At present, the new decentralized procedure may be used on an optional basis for all other medicinal products which are marketed in more than one Member State. However, from 1 January 1998 onwards, the use of the procedure will become compulsory for all products marketed in more than one Member State. In accordance with the procedure, the holder of a marketing authorization in one Member State may apply for the recognition of that authorization in one or more of the other Member States. To this end he forwards an identical complete dossier to each of the Member States concerned. The Member States concerned have 120 days to recognise the original authorization, possibly after bilateral consultations with the Member State which granted the initial authorization. If, however, the Member State concerned considers that authorization may present a risk to public health, it must refer the matter to CPMP or CVMP as appropriate for binding arbitration. The Committee has 90 days to consider the matter and give its opinion. The opinion is transmitted to the Commission, which adopts a decision on the conditions of authorization of the product.

5. The External Dimension

Concerns about the effects of detailed technical legislation, notably legislation for the protection of public health and consumer protection, on free trade have not been confined to the Community. Problems have also been observed at international level. This aspect featured prominently in the Uruguay Round of trade negotiations and two of the new GATT/WTO agreements specifically address the matter; the amended and reinforced Agreement on Technical Barriers to Trade (TBT) and the Agreement on Sanitary and Phyto-Sanitary measures (SPS). These two Agreements are designed to prevent unjustified barriers to international trade caused by technical legislation. They do this by laying down a number of principles: the regulations of the contracting countries should have a legitimate objective, measures should be appropriate or proportional to those objectives, there should be no alternatives which cause less disruption to international trade and there should be no discrimination. The Agreements also enshrine the principle that if a contracting country observes the standards, directives and recommendations prepared by the relevant international organizations when adopting a regulation, the regulation in question is in principle considered as complying with the TBT and SPS agreements.

The TBT Agreement applies to all goods and covers all measures which could affect international trade. It does not cover health and phyto-sanitary measures as defined in the SPS Agreement. The parties to the agreement, including the Community, are required to elaborate and apply their technical legislation in a non-discriminatory manner, and to ensure that such measures do not create unnecessary barriers to international trade. Technical regulations should be intended to fulfil a legitimate objective, such as the prevention of practices which might be misleading (misleading information), protection of human health or safety, protection of animal life or health, and protection of the environment. In order to evaluate such risks, account must be taken of scientific and technical data, related processing methods or the end-use of products. Where relevant international standards exist, Members are required to use such standards as the basis for their own technical legislation, unless such standards would be insufficient or inappropriate to fulfil the objectives sought, for example because of geographical factors, or fundamental technological problems.

The SPS Agreement applies to measures taken by the contracting parties in connection with sanitary or phyto-sanitary risks arising from materials of animal or plant origin. The agreement does not apply to all public health measures; its scope is limited to those which seek to

- protect animals or plants against hazards arising from the dissemination of parasites, transmissible diseases or pathogenic organisms;
- protect humans or animals from additives, contaminants, toxins and pathogenic organisms present in food;
- to protect humans against zoonotic diseases.

Other public health measures fall within the scope of the TBT agreement.

The SPS Agreement requires Members of the WTO to participate actively, within the limits of their resources, in relevant international harmonization activities. The Agreement explicitly refers to the Codex Alimentarius (foodstuffs), the International Office of Epizootic Diseases (animal health) and the International Convention on Plants (phyto-sanitary measures) as the relevant international bodies. Where national health regulations are consistent with the relevant international standards they are presumed to comply with SPS. However, Members are entitled to maintain stricter requirements where these are justified on scientific grounds, or where these are necessary to maintain the level of sanitary or phyto-sanitary protection which the Member considers appropriate.

Thus both agreements emphasise scientific information as the justification for measures which diverge from the relevant international standards. In particular, justification for measures to achieve a higher level of protection than that provided for by the international standards must be based on scientific evidence or the determination of an appropriate level of safety based on objective criteria. Moreover the measures designed to achieve this level of safety should be planned so as to minimise the negative impact on trade and should avoid arbitrary and unjustifiable distinctions between the levels of protection which the country considers appropriate in different circumstances if these distinctions result in disguised discrimination or restrictions.

WTO members failing to comply with the relevant international standards may be challenged in several ways:

- countries considering that the national measures notified to them under the WTO notification procedures conflict with the SPS and TBT Agreements may ask for justification;
- the national measures may be brought before the committees responsible for managing the Agreements; for example the SPS Agreement states that in the case of legislation having a major impact on international trade, a list of which is to be drawn up by the management committee, a State which fails to apply an international standard will have to explain its reasons to the committee; this may also happen under the TBT Agreement;

- disputes may be settled by special panels set up within the framework of the WTO, which apply more stringent procedures than the old GATT panels.

It follows that any country, or the Community, which chooses not to follow the international scientific consensus when elaborating its public health legislation, may find itself required to justify its position at the international level.

6. THE ROLE OF SCIENCE IN PUBLIC HEALTH REGULATION

It is clear that where the objective of the regulation of food or medicines is the protection of public health, that regulation is primarily based upon science. Scientific based regulation pre-supposes that appropriate scientific methods and models are available for risk assessment and risk management, and that appropriate structures are available to undertake such an assessment.

Since 1945 there has been a rapid development of scientific knowledge for the safety assessment of chemicals which are consumed by humans in food or medicines. All major developed countries have established scientific advisory bodies charged with undertaking safety evaluation, and have laid down procedures to ensure that the advice given by such bodies is independent and impartial.

Whenever efforts are undertaken towards harmonization of science based regulations, it may also become necessary to provide an appropriate independent scientific structure to undertake a safety assessment at international level. At Community level, various scientific committees have been established to evaluate certain categories of risk. The Committee for Proprietary Medicinal Products (CPMP) the Committee for Veterinary Medicinal Products (CVMP) and the Scientific Committee for Food are most relevant for the purposes of this paper. Other such committees include the Scientific Veterinary Committee, the Scientific Committee on Animal Nutrition, the Scientific Committee on Cosmetics and the Scientific Committee on Toxicology and Eco-toxicology.

Similarly, in order to promote global harmonization of foodstuffs legislation, within the Codex Alimentarius, two independent scientific committees have been established; the joint meeting on pesticide residues (JMPR) and the Codex Committee on Food Additives (JECFA), which also covers residues of veterinary medicines. These two Committees are responsible for evaluating the safety of individual chemicals used in food or which may be present in foods as residues. In the pharmaceutical sector, priority at global level is currently being

given to issues concerning the mutual acceptance of test and trial data, notably though the tripartite International Conference on Harmonization (ICH), and to issues concerning mutual acceptance of manufacturing authorizations. There is currently no global body with responsibility for evaluating individual medicinal products.

At the present time, there is a broad degree of global consensus on the principles of safety assessment. For chemicals entering into food a range of toxicological tests is undertaken in animals; single dose toxicity; repeat dose toxicity; carcinogenicity; mutagenicity; teratogenicity. The results of the animal studies are then extrapolated to man by taking the highest dose which did not cause any effect to animals in the most sensitive study (the study where effects were shown in animals at the lowest dose administered) and then applying a safety factor, which is usually in the range of 100 - 1000. For pharmaceuticals, the assessment is complicated by the need to balance the therapeutic benefits of the product against its risks, but again the principles of evaluation are well-established.

Of course, risk assessment is not an exact science. Differences in the interpretation of data can and do arise, which may lead to products being authorized in some countries and refused in others, or in different conditions of use being laid down. Such differences can lead to barriers to international trade. However, the WTO agreements accept that each country is entitled to take a conservative approach to the protection of public health, and lay down stricter standards than those recommended by the international bodies, provided that there is an objective scientific justification.

As scientific knowledge increases over time, so the basis of risk assessment evolves. New factors are identified which may lead to increasing emphasis on certain risk factors. On the other hand, other risk factors, which were previously regarded as significant, may become less important in the overall process of safety evaluation.

However, such factors can be taken into consideration only if the law allows. In the case of carcinogens, U.S. legislation adopted in 1960 (the so-called Delaney Clause; section 409(c)(3)(A) of the Federal Food and Drug Act) effectively provides that a food additive which has been found to cause cancer in laboratory animals may not be approved for use in food for any purpose at any level. Similar rules applies to pesticide residues and veterinary drug residues. Because of this legislation, the U.S. has been unable to accept a number of international standards which reflect more modern scientific knowledge. Within Europe, this problem is less acute because the legislation is usually drafted in

more general terms, and allows increased scientific knowledge to be reflected in regulatory decisions without changes to the primary legislation.

Although independent scientific advice is a crucially important factor in the decision-making process, it is not necessarily the only factor which needs to be considered. In recent years there has been increasing controversy as to the extent to which it is appropriate or legitimate to take other factors into consideration when regulating in the public health sector. Such factors may include ethical or moral concerns, consumer concerns and sometimes economic or social concerns. Official Commission policy on the consideration of non-scientific factors developed over several years in response to demands from the European Parliament for the introduction of a 4th hurdle in various sectors, in particular in the debate on the amendment of the veterinary medicines directives and the introduction of bovine somatotropin (BST). The policy was formalised in a Commission communication on the competitiveness of the Community's biotechnology industry. As a general rule, the Commission will follow scientific advice. However, in exceptional cases, the Commission reserves the right to take other factors into consideration when reaching a final decision. In the first case since the communication, BST, the Commission decided to take two further factors into consideration, the imperatives of the CAP and consumer reactions, and it proposed the prohibition of BST. The other Community institutions may also take such factors into consideration during their discussions of Commission proposals.

In practice, there are many instances where decisions to prohibit or restrict the import or use of products are taken for reasons other than scientific reasons relating to the protection of public health;

- religious; for example the restrictions on the import or consumption of alcohol or products derived from pork in many Moslem countries;
- ethical; for example, restrictions on the use of medicines as contraceptives or abortifacients;

Such examples are non-controversial, because virtually everyone understands the reasons for which they are imposed, which are manifestly non-protectionist. However, as the development of biotechnology may present new ethical dilemmas as to what is acceptable. It was in this context that the decision was taken by the Commission to establish a high level group of advisers to advise on the ethical aspects of the exploitation of biotechnology. The group, presided by Madame Lenoir of France, has produced opinions on a range of issues including bovine somatotropin; blood products and the labelling of foodstuffs produced using recombinant technology.

In addition to these broader questions, the issue of public perception of risk must also be addressed. In general, European consumers are relatively conservative about the introduction of new technology in food production, although less so in the pharmaceutical field. Thus although the introduction in Europe of genetically engineered vaccines passed virtually without comment, major controversy surrounds the use of biotechnology in food, not only because of ethical concerns, but also because of concerns about safety. The irradiation of foodstuffs is another example where public concerns about safety, although real, are not shared by the vast majority of the scientific community.

In Europe, decisions on the authorization of new products or new technologies are in general taken by the political authorities. Although scientific committees have been established to prepare independent and objective scientific advice, the final decision is usually taken by a minister, or at Community level by the Commission or the Council. These decision-makers have to address the concerns of society at large. Thus, it may be that in order to address public concerns, the final decisions will contain conditions or restrictions which are not strictly necessary from the scientific point of view. However the imposition of such restrictions almost always presents a dilemma. On the one hand, public acceptance of new technology is vital to its success. But on the other hand, it is important not to block the introduction of new technology because of ignorance or prejudice. The Community institutions also have other responsibilities under the Treaties to promote a regulatory environment which is favourable to innovation, and the competitiveness of European industry. Balancing these considerations is not always easy.

Whatever the reasons which may ultimately lead to restrictions being imposed on new products, one principle is clear; the procedures for scientific evaluation of the benefits and risks of a new product must be kept separate from the consideration of other factors. The scientific evaluation must be conducted objectively and independently of economic, political or other considerations. The following sections consider the mechanisms by which the Community has sought to attain these objectives in the cases of food and pharmaceuticals.

7. THE COMPOSITION AND ROLE OF SCIENTIFIC ADVISORY COMMITTEES

In both the food and pharmaceutical sectors, the consultation of scientific committees is a mandatory part of the process of preparing legislative acts or regulatory decisions which may have an effect on public health. Many of the legislative acts adopted in the foodstuffs sector require the Scientific Committee for Food to be consulted before the adoption of legislation which may have an

effect on public health. Consideration is currently being given to generalising this obligation to cover all foodstuffs legislation. In the pharmaceutical sector the evaluation of applications by the Committee for Proprietary Medicinal Products (for products for use in humans) or the Committee for Veterinary Medicinal products is an integral part of the process of authorising new medicines or of imposing restrictions on the conditions of use of existing medicines.

The **Scientific Committee for Food** was first established by Commission Decision 74/234/EEC of 16 April 1974. The statutes of the SCF have now been completely revised by Commission Decision 95/273/EEC of 6 July 1995. The Committee is composed of not more than 20 members. The members of the Committee are appointed by the Commission for a term of three years, renewable. They are chosen from highly qualified people in fields relating to questions of the protection of the health or safety of persons or questions concerning the consumption of food, in particular on nutritional, hygienic and toxicological issues. The Committee elects a chairman and two deputy chairmen from among its members. Secretarial services for the Committee are provided by the Commission.

The **Committee for Proprietary Medicinal Products** and the **Committee for Veterinary Medicinal Products** each consist of two members, nominated by each Member State for a term of three years, which is renewable. They are chosen by reason of their role and experience in the evaluation of medicinal products for human or veterinary use as appropriate. CPMP and CVMP both elect a Chairman and a Deputy Chairman from among their members. Secretarial support is provided by the European Agency for the Evaluation of Medicinal Products. The Commission does not nominate members of either Committee, but its representatives are entitled to participate in all meetings of the Committee or its working parties as of right.

In order for it to operate effectively, the statutes of any scientific committee must provide certain guarantees as to the independence and objectivity of its members, for a sufficient degree of transparency for its work, and provision must be made for the necessary technical and logistical support.

The independence and objectivity of the members of scientific committees in the face of industrial and commercial interests is particularly important when issues relating to the authorization or use of individual products are concerned. Ideally, the members of the scientific committees should have no interests whatsoever in the fields in which the committees work. However, this ideal is impossible to attain in practice. Food and pharmaceutical research are highly

specialised fields, and the number of experts available are strictly limited. Moreover, much of the research which is undertaken is actually paid for by industry, with a view to the development of commercial products. It is difficult, if not impossible, to find experts in any given field who have not at some stage undertaken research for industry. Thus both Committees have found it necessary to develop rules to identify and eliminate potential conflicts of interest of members. The rules of the SCF require members to notify to the Commission annually, and as they occur during the work of the Committee, and its working groups. The rules applying to the CPMP and the CVMP are more specific in this respect. The names of the members of the Committee and their qualifications are made public. Members of the Committee may not have any financial or other interests in the pharmaceutical industry which could affect their impartiality. All indirect interests which could relate to this industry must be entered in a register held by the Agency which is open to public inspection.

In addition to ensuring the independence of members of scientific committees from commercial pressures, it is also important to safeguard as far as possible their independence from various political pressures which may be brought to bear. In the case of the SCF, these safeguards reside principally in the procedures by which its members are appointed. As noted above, the SCF is appointed by the Commission. Its members serve the Commission alone and are not representatives of Member States. Prior to appointing the members of the Committee, it is normal practice for the Commission to consult Member States and to ask for names of suitably qualified persons who might be considered to serve on the Committee. However, the final choice of members is made by the Commission alone, in order to ensure an appropriate balance in the representation of the different scientific disciplines in the Committee. In order to ensure an appropriate balance in the nationalities of the members of the Committee, the Commission has for many years followed an informal working practice that the make up of the Committee reflects the composition of the college of Commissioners itself, with two members from Germany, France, Italy, Spain and the United Kingdom and one from each of the other Member States.

For the pharmaceutical sector, the composition of CPMP/CVMP was the subject of lengthy debates during the negotiations which led up to the establishment of the EMEA. Since their establishment in 1976 and 1983 respectively, CPMP and CVMP had consisted of representatives of Member States and Representatives of the Commission. In its proposals for the EMEA, the Commission proposed to sever this link between the Committees and Member States by providing for a more independent structure along the lines of the SCF. However, during the negotiations, several Member States argued

strenuously that the evaluation of pharmaceuticals is closely linked with questions of national health policy and national medical practice.

For this reason the final text of the Regulation represents an elaborate compromise. Members of CPMP/CVMP are nominated by the Member States. In addition to their tasks of providing objective scientific opinions to the Community and Member States on the questions which are referred to them, the members of each committee are required to ensure that their is appropriate co-ordination between the tasks of the Agency and the work of the competent national authorities, including the work of consultative bodies established at national level dealing with the authorization of pharmaceuticals. The members of the Committees and experts responsible for evaluating individual medicinal products shall rely on the scientific assessment and resources available to the national authorization bodies. Each Member State is required to monitor the scientific level of the evaluation carried out and to supervise the activities of members of the Committees and the experts it nominates, but it shall refrain from giving them any instruction which is incompatible with the tasks incumbent upon them.

A further issue concerns the transparency of the work of the scientific committees. Not only must the different committees provide independent advice of the highest possible quality, but they must be seen to do so. However the need for transparency must be balanced against the need for the committees to be able to work effectively, with each member being able to voice his honest opinion. In addition, account must be taken that much of the work of the committees involves consideration of commercially confidential data which is submitted for evaluation by individual firms and which cannot be disclosed to competitors. For these reasons, it is not possible for the committees to meet in public, nor is it possible for outside observers to participate in their work.

In the case of the SCF, all opinions of the committee are published by the Commission. Although it is not a formal requirement, the names of the members of the Committee are also published. In addition, an informal system of briefings of the specialist press ensure that interested parties are kept informed of the principal aspects of the Committee's work.

In the case of CPMP/CVMP, transparency is provided for in part by the provisions governing the workings of the Agency, and in part by the specific procedural rules relating to the marketing authorization procedure for individual products. Thus each year the Agency is required to publish an annual report summarising the work of the committees. In addition, where the committee prepares an opinion in favour of authorizing a medicinal product, it is also

required to prepare an assessment report, which must be made available upon request to any interested person. Before the establishment of the Agency, the CVMP experimented with a system of dividing its meetings into two parts. One part consisted of the evaluation of individual applications for authorization, and other issues relating to a single product. This part of the Committee's meeting was restricted to members and invited experts. The second part related to discussions of a more general nature on scientific issues relating to veterinary medicines, and observers from industry, consumers and the veterinary profession were invited to attend and participate. These arrangements were discontinued following the establishment of the Agency, although the Agency does hold regular briefing meetings for interested parties on the work of the committees.

Scientific committees make major demands on the resources of public administrations. In order for them to work effectively, their meetings must be carefully prepared. This is not just a question of the organisation of meetings and documents. An application for a major innovatory pharmaceutical product will comprise the results of a research programme lasting 8-10 years, and costing anything up to ECU 100 million. The file is likely to over a hundred volumes of detailed research results which must be carefully checked and evaluated before any judgement can be made on the overall benefits and risks of a product. Although less extensive, the data submitted in support of a new food additive is also voluminous and requires careful evaluation. An extensive scientific support staff is therefore required. The pharmaceutical and food sectors provide two different examples of how such an infrastructure can be created.

8. THE AGENCY MODEL FOR PHARMACEUTICALS

In accordance with Article 50 of Regulation 2309/93, the EMEA consists of the CPMP and the CVMP, a Secretariat, which shall provide technical and administrative support for the two Committees and ensure appropriate co-ordination between them, an Executive Director and a Management Board. The task of the Agency is to provide the best possible scientific advice on any question relating to the evaluation of the quality, safety or efficacy of medicinal products for human or veterinary use which is referred to it in accordance with Community legislation. To this end, the Agency is required to undertake the following tasks **within its Committees;**

- co-ordination of the scientific evaluation of the quality, safety and efficacy of medicinal products which are subject to Community authorization procedures;
- transmission of assessment reports, summaries of product characteristics, labels and package leaflets or inserts for these medicinal products;
- co-ordination of the supervision, under practical conditions of use of medicinal products which have been authorized within the Community (pharmacovigilance)
- advising on maximum residue limits for veterinary medicines
- co-ordinating the verification of compliance with good manufacturing practice, good laboratory practice and good clinical practice;
- upon request, providing technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the evaluation of medicinal products;
- recording the status of marketing authorizations of medicinal products granted in accordance with Community procedures
- providing technical assistance on a data base on medicinal products which is available for public use;
- assisting the Community and the Member States in the provision of information to health care professionals and the general public about medicinal products which have been evaluated within the Agency;
- where necessary, advising companies on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products.

These provisions clearly show that all the substantive scientific activities relating to medicinal products are to be undertaken within CPMP/CVMP. The role of the Agency itself is to provide the administrative infrastructure for such activities. However, the Agency is given no autonomous responsibilities on such matters; responsibility for the evaluation of all scientific matters is clearly vested within the Committees. The administrative structure of the Agency would also appear to reflect this. The Agency is divided into four units;

- human medicines evaluation unit, responsible for the management activities of relating to the acceptance and processing of registration dossiers for human medicinal products, and in particular for the centralised and decentralised procedures;
- veterinary medicines evaluation unit, responsible for management activities related to the acceptance and processing of registration dossiers for veterinary medicinal products as well as for maximum residue limits

- technical co-ordination unit responsible for management activities which involve co-ordination and/or information support for CPMP/CVMP e.g. pharmacovigilance, inspection, documentation and archives
- administrative and logistic unit, responsible for personnel, administration, budget, accountancy, informatics and telecommunications.

Moreover, the Agency's independence from the regulatory authorities of the Member States is also carefully circumscribed. The Agency is governed by a Management Board made up of two representatives from each Member State (one with specific responsibilities for medicinal products for human use, and one for veterinary medicines), two representatives of the Commission and two representatives of the Parliament. The Member States thus have the overwhelming say in the management of the Agency.

It was noted above that the provisions governing the membership of CPMP/CVMP represent a careful compromise which is designed to ensure that members co-operate closely with the competent national authorities while retaining their independence in the discussion of specific scientific issues. This careful balance is also reflected in the provisions dealing with the evaluation of specific dossiers by CPMP/CVMP. The Committees are required to appoint one of their members as rapporteur for the evaluation of each specific dossier. The Regulation also provides for the establishment of a network of working parties, and expert groups to assist the main Committees in their work. Since the members of the Committees are nominated by Member States and represent the competent authorities, it follows that the actual preparation of the scientific evaluations will continue, as before, to be undertaken by the competent authorities of Member States. The role of the Agency staff is to manage and co-ordinate the evaluation process, and the dialogue between different Member States. The Agency will have a limited staff. It is expected that it will have about 100 employees by the end of 1995, rising to 250 by the end of 1999. It is anticipated that the costs of running the Agency at Community level will be offset by the elimination of duplication of effort and inconsistencies at national level.

At the conclusion of the evaluation process, CPMP/CVMP are required to adopt an opinion. When preparing this opinion, each Committee is required to use its best endeavours to arrive at a scientific consensus. However, if this is not possible, the opinion consists of the position of the majority of members, and may, at the request of those concerned also include the divergent positions with their grounds. If the relevant Committee is not able to reach a consensus, then the Commission will have to decide itself what action may be most appropriate, subject to control by the Member States through the so-called regulatory

committee procedure. Each Committee therefore has a strong incentive to reach consensus in order to maintain its credibility.

9. THE SCIENTIFIC CO-OPERATION MODEL FOR FOOD

As noted above, many provisions of Community foodstuffs legislation require the opinion of the Scientific Committee for Food to be obtained before decisions are taken on questions relating to public health. This applies, in particular in the fields of additives, flavours, contaminants, materials in contact with foodstuffs, food hygiene, extraction solvents, and foodstuffs for particular nutritional purposes. The types of questions on which the SCF may be asked to give an opinion vary greatly. The Committee may be asked to advise on very specific questions, such as the acceptability of a particular additive. At a much more general level, the Committee has been asked to advise on recommended daily allowances for intake of vitamins and minerals. Because of the volume of work involved, the SCF has recently established 8 working groups with responsibilities in specific areas, such as additives, nutrition, materials in contact or novel foods. The establishment of such working groups has made it possible to reinforce the expertise available to the Committee by appointing additional experts to work in specific areas. Nevertheless, the resources available to the members of the Committee, who are not paid for their work, remain extremely limited, and there have been disturbing signs that a backlog of work was beginning to emerge. Moreover, there was also a feeling that the SCF should become much more involved in Community policies relating to food, diet and health.

Although some consideration was given to the possibility of establishing a European Food Agency, a political decision was taken towards the end of 1990 that this would not be an appropriate approach for the foodstuffs sector. Instead, the Commission decided to try an alternative approach, which was based on the improvement of scientific cooperation between the Member States and the Commission. Thus rather than establishing new bodies at Community level, the idea was that the Member States would use their own scientific resources to co-operate with the Commission and lend it the assistance it needs in the scientific examination of questions of public interest relating to food. The principles of this scientific cooperation process were formalised in Directive 93/5/EEC, adopted on 25 February 1993.

The Directive sets out the principle that Member States shall take the necessary measures to enable their competent authorities and bodies to co-operate with the Commission and lend it the assistance it needs in the scientific examination of

questions of public interest relating to food, particularly in the field of public health, through disciplines such as those associated with medicine, nutrition, toxicology, biology, hygiene, food technology, biotechnology, novel foods and processes, risk assessment techniques, physics and chemistry.

In order to enable the cooperation process to operate effectively, each Member State is required to designate a single authority which is responsible for cooperation with the Commission and distribution of work to the appropriate institute. The principal tasks to be carried out in the scientific cooperation process include matters relating to;

- the drawing up of protocols for the assessment of risks relating to food components and elaborating methods of nutritional evaluation;
- assessing the nutritional adequacy of the diet;
- examining test data submitted to the Community and the production of a monograph for the SCF
- carrying out food intake surveys;
- conducting investigations relating to the components of diets in various Member States or of biological or chemical food contaminants;
- helping the Commission honour the Community's international commitments by providing expertise on food safety questions.

On the basis of suggestions received from Member States, and of its own priorities, the Commission is required to prepare and update an inventory of tasks for scientific cooperation. The inventory includes a summary description of the task, the name of the co-ordinating country, the name of the other countries participating in the task and the time limit for its completion. The current inventory includes a series of tasks relating to the collection of information about chemical and microbiological contaminants of foods, flavours, dietary intake and exposure assessments and examination of scientific aspects of nutrition.

The management of each task is the responsibility of the co-ordinating institute. The Commission undertakes the overall management of the scientific co-operation process. The costs of the tasks are primarily met by the Member states concerned. However the Commission provides limited financial support to cover the extra costs of coordinating and convening meetings with experts from Member States. Although it is still too soon to make a definitive judgement, the preliminary results suggest that scientific cooperation is a useful and very cost effective method of pooling information and resources on certain issues.

On the other hand it is important to recognise the complementary nature of the role of the scientific cooperation process and the role of the SCF. In the area of

risk assessment, the role of scientific cooperation is to collect and collate the best available information available to Member States on a particular problem. This information is then transmitted to the SCF in order to provide a firm basis for the evaluation of risk by the SCF, which retains its role as the primary source of scientific advice to the Commission on questions relating to food.

10. FROM SCIENTIFIC OPINION TO REGULATORY DECISION

Following receipt of the scientific opinion, steps must be taken to implement that opinion through a regulatory decision. In accordance with the EC Treaty, only the Community institutions are allowed to adopt legally binding decisions. During the elaboration of the proposals for the EMEA, some thought was given to delegating the power to take the final decision on applications for authorization to the Agency. However, it appeared that such a measure would only be possible on the basis of a new international treaty between Member States. Thus a legislative act by the Community institutions is always required.

In the pharmaceuticals sector, all decisions relating to the authorization of medicinal products may be taken by the Commission in accordance with the so-called regulatory committee procedure. In the foodstuffs sector, the Council has also delegated important powers to the Commission in the fields of contaminants, materials in contact with foodstuffs and food hygiene, using the same procedure. Following receipt of the scientific opinion, the Commission prepares a draft of the measures to be taken. This draft is submitted to a standing committee of representatives of the Member States at least three weeks before it is due to be discussed. This Committee is quite different from a scientific committee. Its members are appointed by Member States and vote on behalf of Member States. The chairman is appointed by the Commission. In accordance with the 'modus vivendi' the draft is also transmitted to the European parliament for information. Following discussions of the draft, or by a written procedure, the Member States give their opinion on the draft by a weighted vote, in accordance with Article 148 of the Treaty. If a qualified majority of 62 votes is in favour the Commission adopts the measure. If no qualified majority is obtained, the matter is referred to the Council. The Council has three months to reach a decision, also by qualified majority. If the Council is unable to reach a decision within three months, the matter is referred back to the Commission, which then adopts its draft. However, in a variant of the procedure, which is widely used on matters relating to public health, the Commission may not adopt the draft if a simple majority of Member States has voted against it.

In the other areas, however, the Council has been less willing to delegate powers to the Commission. Thus, for example, a new food additive can only be authorized for use within the Community in accordance with the procedure laid down in Article 100a, following the completion of the co-decision procedure between Council and Parliament.

It was noted above that although the Community institutions normally follow the scientific advice they receive, they are not bound to do so, and they may in exceptional circumstances take other factors into consideration. In the foodstuffs sector, the legislative rules do not place any particular constraints on the Commission as to whether, how or when to follow the scientific advice received.

However, in the pharmaceutical sector, a number of provisions are included with a view to reinforcing the value of the opinion of the Agency. Thus, not only is the Agency charged with preparing the scientific opinion, but it is also given the responsibility of preparing the draft authorization documents for the medicinal product concerned, namely the summary of product characteristics, details of any conditions or restrictions which need to be imposed on the product, the text of the labelling and package insert, and the assessment report. The Commission is required to prepare a draft of the decision to be taken within 30 days. If the Commission chooses not to follow the advice of the Agency, it must explain its reasons in detail. Following circulation of the draft decision, Member States have 28 days to comment. If these comments raise important new scientific or technical questions which have not been addressed by the Agency, the Commission is required to suspend the procedure, and refer the matter back to the Agency for re-consideration. These provisions clearly represent an attempt to preserve the status of the Agency as the sole provider of scientific advice on medicinal products, and to prevent the re-opening of the scientific issues at a more political level.

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