

**TRANSATLANTIC CONSUMER DIALOGUE
WASHINGTON MEETING, 10-12 FEBRUARY 2000**

**TACD RECOMMENDATIONS ON FOOD
AND
EUROPEAN COMMISSION SERVICES' RESPONSES**

The European Commission services are pleased to provide the following response to the TACD recommendations and position papers. We remain willing to pursue our fruitful discussion and co-operation with the TACD on Food Safety.

Many of the issues raised during the last session of the TACD and the recommendations on food safety are currently matters under consideration by the Commission services.

- How to build a more effective and consistent approach to risk analysis, how to improve the decision making process dealing with food risks,
- how to establish a better independent, transparent and excellent system for scientific risk assessments,
- how to communicate on risk, in particular where science is unable to fully assess them, are very important issues for the European Commission.

The restructuring of the Directorate General in charge of Health and Consumer Protection in the European Commission, which is now a single body responsible for all aspects of food safety regulation, is a first step. The creation of a European Food Authority in charge of risk assessment and risk communication will be the second step, following which, will be the review and simplification of food legislation outlined in the White Paper on Food Safety.

The strategy that has been developed has some parallels with the US food safety and inspection system from farm to table. This strategy marks a degree of convergence of approaches, whilst retaining some differences. The Commission services are strongly committed to a policy of consultation with all interested parties and the TACD recommendations are a useful contribution.

Therefore, while the EU has already implemented several of the TACD recommendations, some of our responses, below, should be considered as provisional in light of the ongoing process of review of the food safety system within the EU.

TACD RECOMMENDATION ON RISK ANALYSIS AND THE ROLE OF OTHER FACTORS

The TACD urges the US and the EU to work towards a more effective, inclusive and more consistent approach to risk analysis, and to push for the adoption of such an approach when international food standards are developed, for example, by the Codex Alimentarius Commission and more generally within the context of the SPS Agreement's provisions relating to risk assessment. This approach should recognize the importance of public participation and dialogue throughout the process and the need for greater openness and transparency.

The TACD also urges the US and EU governments to commit themselves to completing a policy on 'other legitimate factors' besides 'science' in risk analysis a high priority within their Codex work and to acknowledge that 'other legitimate factors' have an essential role to play and are already implicit in risk decisions even if they are currently not openly acknowledged.

Every effort must be made to reach a consensus on these difficult but very important issues to improve the quality and transparency of decisions and to enhance consumer choice and protection.

EUROPEAN COMMISSION SERVICES' RESPONSE

During the TACD meeting, the US Government and the Commission representatives explained the current status of the decision making process based on scientific risk assessment and management of the risk.

The TACD stressed the need for consumers to be associated with the process from the beginning in order to have their point of view taken into account. The Commission representative explained the ongoing discussion about the creation of a European Food Authority in charge of risk assessment and risk communication. Concerning the other legitimate factors, which are still in discussion within the Codex Committee on General Principle, there are some differences between US and EU interpretation of this concept.

The EU proposes a wide scope of factors and the US a narrower one, limited only to scientific facts. However, both representatives agreed to make every effort to reach a consensus on this important issue. The European Commission welcomes the TACD recommendation to work towards a more effective, inclusive and more consistent approach to risk analysis. The Commission's White Paper on Food Safety, adopted on 12 January 2000, is clearly intended to build a more coherent, understandable and flexible system of decision-making, based on principles of risk analysis. Risk Assessment is the cornerstone of the process. The existing system of scientific advice needs to be strengthened, and the White Paper proposes to create a permanent and truly independent, excellent and transparent system of risk assessment. The establishment of a European Food Authority is clearly designed to achieve this goal. The key task of the Authority will be risk assessment in the area of food safety in a broader sense, covering consumer health, animal health and plant health. The Authority will also be much more proactive, including a comprehensive information gathering and surveillance function of emerging risks.

In order to enhance public participation, and recognising the need for greater openness and transparency, the Authority will have a major role in risk communication. Its task will be the dissemination of scientific information, evaluation and conclusion in a consumer-friendly way. The Authority should provide an indispensable link between the scientific community and consumers. Risk management, that is to say the responsibility for taking decisions based on the outcome of the risk assessment, will remain the preserve of the European Commission, Parliament and Council. The Commission, in exercising its risk management function, will take full account of the scientific advice of the Authority.

Concerning the role of "other legitimate factors" in risk analysis, the Commission is committed to continue efforts to reach a consensus within the Codex Alimentarius. The Commission acknowledges that "other legitimate factors" are already taken into account implicitly in many risk management decisions and that it is necessary to clarify how they can be used by the risk managers.

TACD RECOMMENDATION ON MISLEADING FOOD LABELLING

- 1. The EU should adopt rules for nutrition claims. This effort should include defining within legislation the conditions under which claims may be used on products. Rules for nutrition claims should be made consistent, where possible, between the EU and U.S.**
- 2. Food labels should include a list of all ingredients, including those used in compound ingredients, to ensure that consumers have complete information about all of the ingredients used in a particular food.**
- 3. Food labels should not highlight the presence of an ingredient unless the ingredient is present in an amount considered significant by the consumer. Food labels should not feature depictions of ingredients that are not present in the product, or present in the product in only trivial amounts. Food labels should include quantitative ingredient declarations and a consistent, comprehensive approach to their use should be adopted by the EU and U.S.**

Specifically, labels should state the percentage of all major ingredients, i.e., those that comprise 5% or more of the total weight. If any ingredient appears in the name of the food or is highlighted on the label through words or pictures, the percentage of this ingredient should also be listed in immediate conjunction to such statements or pictures.

- 4. Meaningless terms that can mislead as to the quality of a food (including, or example, terms that imply slimming effects, "Energy" claims, the term "natural") should not be used unless they can be clearly defined and consistently used.**

EUROPEAN COMMISSION SERVICES' RESPONSE

Under Community legislation (Article 2 of Council Directive 79/112/EEC), the labelling, presentation and advertising of foodstuffs, must not be such as to mislead the consumer to a material degree, in particular:

1. as to the characteristics of the food product,
2. by attributing to the foodstuff effects or properties which it does not possess, and
3. by suggesting that the foodstuff possesses special characteristics when in fact all similar products possess such characteristics.

In its White Paper on Food Safety adopted on 12 January 2000, the European Commission announced that future work (a proposal from the Commission is planned for July 2001) will be carried out in order to introduce specific provisions to govern "functional claims" (for example claims related to beneficial effects of a nutrient on certain normal bodily functions) and "nutritional claims" (such as claims which describe the presence, absence or the level of a nutrient contained in a foodstuff or its value compared to similar foodstuffs).

In its White Paper the European Commission (a proposal from the Commission is planned for December 2000) also announced its intention to revise the "25% rule" on compound ingredients. This revision would remove the current provision to allow components of compound ingredient, where they form less than 25% of the final product, not to be indicated

on a label. This would ensure that consumers are given more detailed and comprehensive information about the ingredients of the products they purchase.

As far as quantitative ingredient declarations are concerned, Directive 97/4/EC, amending Article 7 of Directive 79/112/EEC, provides for detailed rules for declaring the quantity of an ingredient or category of ingredients used in the manufacture of a foodstuff. This indication is compulsory:

- a) where the ingredient appears in the name under which a foodstuff is sold, or is usually associated with that name by the consumer; or
- b) where the ingredient is emphasised in words, pictures or graphics; or
- c) where the ingredient is essential to characterise a foodstuff and to distinguish it from products with which it might be confused because of its name or appearance.

This indication shall appear either in or immediately next to the name under which the foodstuff is sold or in the list of ingredients in connection with the ingredient in question.

All the above mentioned elements and announced policy correspond to the recommendations on misleading food labelling expressed by the TACD Working Group in February 2000.

TACD RECOMMENDATION ON THE IMPACT OF THE TBT AND SPS AGREEMENTS ON FOOD LABELLING

- 1. The EU and the US should announce they will not make any formal challenges at the WTO to each other's food labelling and safety requirements during which time;**
- 2. The TBT agreement and the SPS Agreements should be subjected to a public and transparent review, with the full involvement of all stakeholders including consumer non-governmental organizations. The WTO SPS and TBT Committees' process should be open to participation by observers from non-governmental organizations.**
- 3. During such review, the EU and the US should support the specific recommendations for reform of the SPS and TBT Agreements as previously recommended by the TACD.**
- 4. The review should seek to clarify the approach that should be adopted for risk assessment within the context of the agreements and how the precautionary principle as described in Article 5.7 of the SPS Agreement should be applied in practice; in particular, the word "provisional" in Article 5.7 should be stricken.**

EUROPEAN COMMISSION SERVICES' RESPONSE

As laid down in the EC Treaty, the EC policies for health and consumer protection shall aim at a high level of protection, while taking into account international trade rules. An open and frank dialogue on food safety issues, including labelling, could contribute to ensuring compatibility and balance between food safety considerations and international trade rules. The Commission's ideas set out in the White Paper on food safety have met with considerable approval by the EU Member States. Preliminary reactions from Member States on the Commission communication on the Precautionary Principle are also positive. These documents will serve to stimulate discussion within the Community and internationally.

Some of the strategies, such as the setting up of a food safety authority, have some parallels within the US, and, while retaining some differences, also indicate a degree of convergence of approaches. However, other issues, such as the approval of GMOs and the use of the Precautionary Principle (PP) as a risk management tool, are not viewed in the same way on both sides of the Atlantic, and we are working hard to explore our differences in these areas, which we hope could contribute to preventing future trade conflicts. A number of initiatives, including the EU-US Veterinary Agreement, the Early Warning System for exchange of information on legislative initiatives, and the EU-US dialogue on Biotechnology should help improve our common understanding in these areas. Discussions in the SPS Committee will also provide valuable opportunities to address these issues at the international level.

The Commission has presented its Communication on the Precautionary Principle to the SPS Committee. Article 5.7 of the SPS Agreement, in its view, provides a framework for measures to be taken in the face of scientific uncertainty. Any such measures must be provisional in the sense that it should be subject to review in the light of new scientific data.

The Commission has also presented its Communication to Codex, in order to contribute to the substantive discussion on the Precautionary Principle in that forum. The results of that discussion will be forwarded to WTO.

The TBT Agreement has worked well overall. However, there are a number of problems in its implementation and operation. The most effective way to review and resolve these issues would be through the inclusion of the TBT Agreement in a new WTO Round of multilateral trade negotiations, which could provide the strong political commitment needed in order to make substantive progress. The Commission Services are also fully committed to trying to resolve problems relating to the TBT Agreement in the ongoing WTO work programme – the TBT Triennial Review. This review will conclude at the end of this year.

TACD RECOMMENDATION ON HEALTH RELATED CLAIMS

In countries where claims related to health are not prohibited, claims must be approved, prior to market introduction in the United States by a government agency and in the European Union by a government agency or a government certified independent authority. Such determinations must be based on a finding of scientific consensus.

EUROPEAN COMMISSION SERVICES' RESPONSE

As regards Recommendations on Health Claims, the Commission services note that the TACD does not define those. Under current Community legislation (Article 2 of Council Directive 79/112/EEC¹ the attribution to any foodstuff of the property of preventing, treating or curing a human disease, or reference to such properties, is prohibited. As indicated in its White Paper on Food Safety, the Commission continues to consider that labelling and advertising of a foodstuff should not contain such claims. However, the Commission will carry out work on the “functional” and “nutritional” claims as indicated in the European Commission Services' Response on Misleading Food Labelling.

¹ OJ L33 of 8/2/1979

TACD RECOMMENDATION ON ENCEPHALOPATHY (BSE) AND OTHER TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (TSE)

TACD calls upon the EU and US institutions to allocate increased funding for independent research into the origin of TSE, in particular into whether and how it is transmitted to other animals and to humans

- **Research on BSE and V-CJD, as well as on the relation between them, should be intensified and extended to all prion diseases (TSE). Special attention should be paid to the question of how "exposure" might transmit the disease from cattle to humans, including stunning methods causing infective tissue to spread through an animal and contaminate meat. There is a real need for research into the nature of the agent, how it is transmitted, whether it is accumulative, infectivity of various tissues e.g. bone marrow, possibility of BSE passing to sheep flock.**
- **Research should be conducted on the epidemiology of the disease, the agents that transmit the disease, the mechanisms involved in the pathological process, as well as on the preventative and therapeutic possibilities for established prion diseases. Moreover, improved methods for CJD diagnosis in humans should be developed and the reporting of new cases should be improved.**
- **Several tests exist today, and these should be considered, accredited and utilised urgently in order to determine whether live animals are contaminated, and to determine the presence of BSE in animals after slaughter.**
- **Funds should also be allocated to effective surveillance and to the development of a reliable system of epidemiological monitoring of BSE and to the collection of reliable statistical data based on existing cases (as there is still no response on the procedure for the contamination of animals born after the EU animal meal ban).**

Decision making process

TACD considers that all measures taken to combat the risk of BSE must be implemented in a fully transparent way, and therefore calls for the following:

- **Full transparency on the scientific basis on which EU and US decisions are taken.**
- **Full information including all known facts regarding the relation between BSE and CJD must be made public.**
- **TACD calls for a multi-disciplinary approach that involves both veterinary and public health expertise, and experts representing civil society, with full transparency for the civil society.**

EUROPEAN COMMISSION SERVICES' RESPONSE

Concerns expressed in the TACD proposal on BSE and TSE are shared by the services of the Commission. TACD recommendations on BSE tests, on stunning, and on Specified Risk Materials removal are measures which have been already taken into account in the draft or adopted Community regulations.

With a view to introducing post mortem tests in BSE surveillance, the Commission formally adopted a Decision amending Decision 98/272/EC on epidemio-surveillance for TSE on 2 May 2000. The new Decision will enter into force on 1 January 2001. The Decision will be published shortly.

The Communication from the Commission concerning the European initiative on TSE agreed by the Council of 5.12.1996, included a TSE Action Plan which highlighted the research priorities in this field. The Action Plan comprised the launching of specific calls for proposals, which resulted in an excellent mobilisation of European expertise combining scientific disciplines, which could contribute to speed knowledge acquisition in this field. As a result 54 RTD projects are now running addressing among others the research priorities identified by the TACD proposal.

The provision of scientific advice to the Commission on multidisciplinary aspects of TSE (including BSE) is delivered by the Scientific Steering Committee (SSC), which was set up by Decision 97/404/EC¹, with the support of a specific ad-hoc group. The agenda, minutes and opinions of the SSC are made publicly available on the Health and Consumer Protection Directorate-General Web page without undue delay and with regard to the need to respect commercial confidentiality. Minority views are always included and are attributed to Members only at their request.

¹ OJ L169 of 27/06/1997

TACD RECOMMENDATION ON ORGANIC FOODS

TACD welcomes expanded consumer access to organic food and calls on the US and the EU to support programs including strong Codex Alimentarius standards that will enhance their availability to consumers. Such programs should be based on the expectations and needs of the consumer with the aim of environmental and social sustainability, healthy, high-quality goods, and optimum animal welfare. Organic foods are produced without pesticides or chemical fertilizers, and without the use of antibiotics for livestock (except to treat disease). These provisions make organic foods good both for the environment and for the public. TACD also calls on the US and the EU to enact strict controls and labelling to safeguard consumer confidence in organic products, a vital factor in the continued growth of this sector.

Organic farming is defined as self-sufficient and sustainable agri-environmental system in equilibrium. The system is based as far as possible on local, renewable resources. Organic farming builds on an integrated ethos which encompasses the environmental, economic and social aspects in agricultural production both from a local and from a global perspective. Thus, organic farming perceives nature as an entity which has value in its own right; human beings have a moral responsibility to steer the course of agriculture so that the cultivated landscape makes a positive contribution to the countryside. The US and the EU should help promote these goals by maintaining high standards for organic producers, encouraging organic production by farms and companies of all sizes, and helping consumers distinguish organic foods by the use of clear labelling.

Organic standards should permit free trade of organic products. For organic foods produced in other countries outside the US and the EU, control bodies should be accredited by IFOAM, the International Federation of Organic Agricultural Movements. Small or recently established control bodies may be acceptable, especially in Third World countries, if the body undertakes to join IFOAM's accreditation program as soon as possible.

Governments should allow higher standards such as Demeter Certification, which are already active in over 20 countries worldwide.

Specifically, TACD supports the incorporation of certain principles in the regulation and certification of organic agriculture and food production:

- **Organic standards should be established by government officials who have experience with and knowledge of traditional organic agricultural practices and in a close collaboration with organic farm organizations, like IFOAM. The USDA should incorporate the recommendations of the US National Organic Standards Board and not make it illegal to set standards higher than the USDA's.**
- **The US and EU should cooperate with the Codex Alimentarius Commission to rapidly adopt international standards that are acceptable under the TBT and SPS agreements of the World Trade Organization.**
- **Performance standards should be allowed to include considerations for Process and Production Methods, to allow countries to distinguish between products**

based on how they are made, even though the WTO agreement currently is ambiguous on this issue.

- **All organic products should be clearly and conspicuously labeled to allow consumers to make informed purchasing decisions.**
- **The country of origin must be stated on all organic foods.**
- **Genetically modified organisms and irradiation must not be used in organic production.**
- **Governments and regulatory agencies should prohibit all use of hormones and all routine use of antibiotics for organic livestock. Humane treatment requires that sick animals be treated as appropriate, but these animals should then be removed from organic production until the drugs have fully cleared their systems.**
- **To protect consumers from the dangers associated with the use of animal manure, general standards must be developed for pathogen control and elimination.**
- **Livestock feed should be from organic sources and should never contain rendered animal protein.**
- **Environmentally-contaminated land should not be used for organic agriculture.**

EUROPEAN COMMISSION SERVICES' RESPONSE

Within the E.U., organic production has been regulated since 1991 by Regulation (EEC) n° 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. The main aim of this Regulation is to ensure a market, throughout the E.U., of organic products which are credible for consumers and which permits fair competition between producers.

The Commission services can in general terms support the main conclusions of the TACD resolution on organic foods.

The Commission services would however like to make the following specific comments.

1. The Commission services support the need expressed by TACD for a strong Codex Alimentarius Guidelines. These should however not only ensure an increased availability of organic foods to consumers, but must in particular ensure that organic products satisfy the expectations consumers have of these products. Therefore, the Commission services feel that the codex Guidelines should in the first instance provide precise production standards which clearly differentiate organic production from conventional production methods and also from other production methods such as integrated farming. Moreover the Guidelines must provide for appropriate inspection requirements. The Commission and EU Member States have co-operated intensively in the discussions in the Codex Labelling Committee since these discussions were started in 1993, and was very satisfied with the successful adoption, as far as crop production is concerned, of the Guidelines on Organically Produced Food by the Codex Alimentarius Commission in June 1999. This active contribution will be continued with regard to the development of Codex standards for organic livestock and livestock products, which satisfy the expectations of E.U. consumers with regard to such products.

2. The Commission services are of the opinion that the concept of “free trade” of organic products which is advocated by TACD in its resolution (the Commission services would rather define this concept as “facilitation of trade”) should take account of the need to ensure that the organic products which are placed on the market, whether they originate from the E.U. itself or from other countries, are effectively from organic production. As it is not possible to check by analysis of the final product whether all requirements of the production method have been respected, it is necessary that production and trade be carried out under appropriate measures of inspection operated by reliable inspection organisations. Appropriate requirements in this respect are provided in Regulation (EEC) n° 2092/91 for products produced within the E.U. : inspection bodies must inter alia satisfy the requirements of Standard EN45011 (or ISO65) and in this respect have been approved by the competent authority or have been accredited by the official accreditation body in the Member State where they operate their inspection activity. Similar requirements are provided, under terms of equivalency and in accordance with the above mentioned Codex Alimentarius Guidelines, for inspection bodies in third countries which are in charge of inspection for products exported to the E.U. The E.U. can only accept organic products from third countries for which inspection has been carried out by inspection bodies which were accepted under the above mentioned requirements.

3. With regard to the specific principles which TACD proposes to be included in Regulations on organic agriculture and food, the services of the European Commission would like to make the following comments:
 - a system of dialogue has been in place for many years between the Commission and the producer and consumer organisations, including in particular the EU group of IFOAM ;
 - the above mentioned Regulation provides for detailed labelling rules for products from organic production ; it also provides for a prohibition of use of genetically modified organisms and of the use of ionising radiation techniques ; it provides for a period for conversion of land intended to be used for organic production ;
 - the above mentioned Regulation provides also for an overall prohibition of use of hormones and a routine use of antibiotics. It incorporates the principle that sick animals must be treated and that treated animals loose their organic status unless a doubled withdrawal period (with a minimum of 48 hours) has been respected.
 - the Commission services are of opinion that, currently, a 100 % requirement of organic feed would prevent the development of organic livestock production within the E.U., as such feed will not always be available in sufficient quantities on reasonable distance ; the prohibition of rendering animal protein should not concern milk products and products from fish or other marine animals.
 - the Commission services do not understand why on all organic foods the origin must be mentioned on the label, and how such requirement should be applied for foods with ingredients originating from several countries.

TACD RECOMMENDATION ON GENETICALLY MODIFIED ORGANISMS

TACD calls for the establishment of a system of mandatory human health evaluation that will screen all foods produced using genetic engineering including GM food processing aids and prevent commercialisation of any GM products that contain hazardous levels of natural toxins, reduced levels of important nutrients, or a known common allergen that can cause anaphalctic shock in a sensitive individual, or that causes any other significant health problem. International agreement should be reached on a suitable approach and the TACD considers that the Codex ad-hoc Intergovernmental Task Force on Biotechnology is the most appropriate place for this to take place. Such a system should be based on the principles of openness and transparency, and should enable effective public participation throughout the risk analysis process. (see TACD recommendations on risk analysis and the precautionary principle)

TACD calls for the development of strong methods for assessing GM foods, which unlike 'substantial equivalence' can help to give a clearer idea of the potential unintended consequences of genetic modification.'

TACD stresses the need to conduct consumer research to gain a clearer understanding of consumer attitudes towards the potential for future uses of biotechnology and the measures required if their acceptability is to be ensured.

TACD calls for the setting of a strong system of environmental safety evaluation that will screen GMOs and prevent release of any products that will have negative environmental effects, such as increasing toxic pollution, reducing the effectiveness of natural pesticides, harming wildlife or natural enemies of plants or animal pests, reducing biodiversity, increasing the vigour of weeds or insect pests, altering the genetic makeup of non-engineered living things, or disturbing important ecological balances. Such a system should include a requirement for long-term monitoring.

TACD calls for a ban on antibiotic resistance genes in genetically modified crops.

TACD requires labelling of all GM food sold in Europe and the US, including ingredients of processed food, and food where GM ingredients have been used in production even if they are no longer detectable in the final product. Labelling of animal feed that contains GM ingredients should also be required.

TACD stresses the need to establish a system of government to government notification that is shipment-specific when GMOs are shipped in international commerce.

TACD calls for the establishment of strict rules for corporate liability and mandatory insurance for companies that want to release GMOs into the environment. TACD underlines the importance of developing common standards for ensuring identity preserved supplies of non-GM ingredients should be developed so that consumers can have confidence that they are consistent. Mechanisms should be developed for monitoring the long-term consequences of consumption of genetically modified foods and ingredients.

EUROPEAN COMMISSION SERVICES' RESPONSE

1. In the food sector, Council Regulation (EC) No 258/97 on Novel Foods and Novel Foods Ingredients covers inter alia food and food ingredients containing, consisting of, or produced from GMOs and sets out a mandatory pre-marketing safety

assessment for such products. The Regulation clearly states that novel foods must not present a danger to the consumer.

The mandatory evaluation implies that foods or food containing, or consisting of, or produced from a GMO cannot be placed on the market unless their safety has been determined through the appropriate procedures foreseen by the Regulation either at Member State or Community level. Furthermore, the Scientific Committee for Food is consulted on any matter likely to have an effect on public health.

2. The Codex ad-hoc Intergovernmental Task Force on Foods Derived from Biotechnology held its first session in Japan in March 2000. In its submission to the Task Force, the European Community recommended that the Task Force focus its work on issues that are of high importance to the protection of consumer health such as:
 - develop a specific risk analysis guideline for a mandatory pre-market approval system for foods derived from biotechnology
 - develop a specific guideline in order to provide transparency and public involvement in the market approval system for foods derived from biotechnology
 - develop specific guidelines for the monitoring and traceability of foods derived from biotechnology
 - develop a specific guideline to take into account the issues identified as other legitimate factors by the Codex Committee on General Principles as well as the Code of Ethics established by the same Committee.

3. Substantial equivalence is used as a starting point in risk assessments of Novel Foods. The Novel Foods Regulation also provides that GMO derived foods which are considered to be "substantially equivalent" to existing foods can be put on the market on the basis of a notification. However, the companies have to submit scientific justification that a product is substantially equivalent.
The Commission is currently considering launching a review of the concept of substantial equivalence and its application in the Novel Foods Regulation.
The Commission is also actively participating in international fora such as OECD and Codex) where the concept of substantial equivalence is kept under review.

4. The additional labelling requirements set out in the Novel Foods Regulation ensure that the final consumer is informed of the following:
 - The presence of a genetically modified organism
 - Any characteristic which renders the food or food ingredient no longer equivalent to an existing food or food ingredient because of its composition, nutritional value or effects or intended use, together with the information about the method by which it was obtained. This non-equivalence must be based on a scientific assessment taking into account a comparison of the GMO-derived product with other similar conventional products.
 - The presence of material not normally present in equivalent foodstuffs and which may have implications for the health of certain parts of the population (e.g. allergies)
 - The presence of material not normally present in existing equivalent foodstuffs and which gives rise to ethical concerns.

In Regulation (EC) N° 1139/98 that currently serves as a model for labelling in the EU, the presence of DNA or protein resulting from genetic modification has been used as the criterion triggering labelling of food or food ingredients derived from GMOs.

The Commission is currently working on harmonising and completing its labelling rules. A proposal is foreseen for September this year.

Furthermore, the Commission is considering the development of a legislative framework for a GMO-free production line in order to enable the consumers to have a choice between GMO products and non-GMO products. A GMO-free production line would be based on producers' voluntary adherence to the scheme, as it happens in the case of the organic farming regime.

5. Directive 90/220/EEC on the deliberate release of GMOs into the environment harmonises the regulations and administrative provisions for the protection of human health and the environment when carrying out deliberate releases into the environment of GMOs. It provides a safety net covering all products containing GMOs including products for which no specific sector based legislation is yet in place. According to the Directive the notifier is obliged to provide a comprehensive assessment and an adequate labelling for the product he is asking approval for.

The Commission has proposed to revise this directive with the aim of increasing the efficiency, the efficacy and the transparency of the decision-making process whilst ensuring a high level of protection for human health and the environment. A Common Position based on the Commission proposal was agreed on 9 December 1999. The Common Position:

- clarifies a number of operational aspects including the scope, definitions and administrative procedures,
- provides a comprehensive environmental risk assessment based on common principles to be carried out before Part B (experimental releases) or Part C (placing on the market) authorisation procedures,
- introduces mandatory consultation of the Scientific Committees and time-limited authorisations,
- promotes mandatory consultation of the public for Part B and Part C releases,
- introduces mandatory monitoring and labelling requirements and the possibility of establishing threshold levels for products where adventitious or technically unavoidable traces cannot be excluded.

Furthermore, the Common Position delivers provisions for a phasing out of antibiotic resistance genes.

On 12 April 2000, the European Parliament adopted 29 amendments at its second reading on the Council Common Position on a revised Directive 90/220/EEC. Out of these 29 amendments, the Commission has accepted four amendments in full and nine amendments in principle. Sixteen amendments were not acceptable to the Commission.

The main changes to the legal text adopted by the Parliament concern:

- the phasing out of antibiotic resistance marker genes by 2005,
- the introduction of the general obligation to ensure that implications of gene transfer are accurately assessed in each individual case,

- more flexibility for the time limitation of consents by requesting that the registration of the final product should be the starting point for the 10-year period and
- the possibility to establish differentiated procedures for the placing on the market of GMOs.

Following the second reading of the European Parliament the Council now has to decide whether the amendments adopted by the Council are acceptable or whether a conciliation procedure will be necessary. The new regulatory system will be implemented eighteen months after the publication of the final text of the Directive in the Official Journal.

6. The question of environmental liability has a wider scope than biotechnology and relates to the whole field of environment protection liability. It has been integrated into the Commission White Paper on Environmental Liability published recently. At the second reading on the Council Common Position on a revised Directive 90/220/EEC the European Parliament also adopted a recital, which requires the Commission to submit a Proposal concerning general environmental liability rules before the end of 2001.
7. The Commission will later this year present a proposal for legislation on Novel Feed. It is foreseen that the proposal will include provisions on pre-market approval as well as labelling of GMO feed.
8. Provisions for a basic framework ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern technology that may have an adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health, are provided by the Cartagena Protocol on Biosafety that was adopted in Montreal on 29 January 2000 during the Extraordinary Conference of Parties to the Convention on Biological Diversity. At the second reading on the Council Common Position on a revised Directive 90/220/EEC the European Parliament also adopted a recital which stresses the need to submit the appropriate Proposals for the implementation of the Cartagena Protocol on Biosafety when ratified.

TACD RECOMMENDATION ON THE ROLE OF SCIENCE AND OTHER FACTORS

The TACD urges the US and EU governments to commit themselves to completing a policy on 'other legitimate factors' besides 'science' in risk analysis a high priority within their Codex work and to acknowledge that 'other legitimate factors' have an essential role to play and are already implicit in risk decisions even if they are currently not openly acknowledged. Every effort must be made to reach consensus on these difficult but very important issues to improve the quality and transparency of decisions and to enhance consumer choice and protection.

EUROPEAN COMMISSION SERVICES' RESPONSE

The Commission services share the views of TACD concerning the need to work actively in the framework of the Codex Alimentarius on the « Role of « Science » and « other Factors » in Risk Analysis.

As TACD stresses, the perspectives of the U.S. and the E.U. in the debate have been divergent. In this context, the Commission services would like to point out that factors other than food science, such as animal health and welfare, cultural aspects and consumer concerns as well as the environment, where relevant, could be taken into account in the Codex Decisions. For the moment, consensus on this subject is not yet reached among Member States. However, the Commission services believe that other factors which have been suggested by other Codex Committees are already integrated in the normal risk analysis procedure of the Codex.

The papers submitted by Consumers International for Codex Committees are valuable contributions to the current debate.

This issue will be examined in the next meeting of the Codex Committee on General Principles. The contributions of other Codex Committees on this matter are not complete and the EU is of the opinion that every Codex Committee should express their point of view before the Commission could adopt a position. For the time being, the reference to cultural aspects and consumer concerns remains a point of disagreement.