

# EUROPEAN COMMISSION SERVICES' RESPONSES TO TACD'S APRIL 1999 RECOMMENDATIONS ON FOOD

## RECOMMENDATIONS ON FOOD:

- Genetically Modified Organisms
- Antibiotics in Animal and Food Production
- BST (bovine growth hormone)
- Dietary Supplements
- Consumer Participation
- Inspection
- Microbial Safety
- Nutrition Labelling
- Precautionary Principle

## Genetically Modified Organisms

### TACD RECOMMENDATION

Since consumers are concerned about risks, the environment, socio-economic factors, ethical issues and the lack of benefit for consumers, the TACD calls upon the governments of the US and the EU to establish effective and mandatory government approval systems of human health, safety and environmental protection.

Genetically modified foods should provide a clear showing of consumer benefits and present no harm to human or animal health or the environment.

In order to ensure consumers' right to choose and to be informed, governments must require mandatory labelling of all genetically engineered foods and ingredients based on complete traceability of GMOs throughout the entire production, processing and distribution chain.

### EUROPEAN COMMISSION SERVICES' RESPONSE

Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (GMOs) establishes Community-wide provisions for a human health and environmental safety evaluation of releases of GMOs. No product containing GMOs has been or can be placed on the market without an evaluation under Directive 90/220/EEC or under sector-based legislation, which covers the specific evaluation, foreseen by Directive 90/220/EEC.

The European Commission has now proposed to amend this Directive in order to increase the efficiency, and the transparency of the decision-making process whilst ensuring a high level of protection for human health and the environment. With regard to the latter, time limited authorisations linked to monitoring have been introduced and long term effects must be considered in the safety evaluation.

Specifically in the food sector, Council Regulation (EC) No 258/97 on Novel Foods 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 European Commission level. Furthermore, the Scientific Committee for Food is consulted on any matter likely to have an effect on public health.

Consumer concerns have also been addressed in the general labelling framework laid down in the Novel Foods Regulation, which ensures that the final consumer is informed of the following:

- the presence of a genetically modified organism;
- any characteristic (including the method by which it was obtained) 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. 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.

The European Commission is now developing further detailed implementation rules on labelling.

The European Commission is currently considering the development of a legislative framework for a GMO-free production line in order to enable the consumers to have a clear 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.

The European Commission has also co-ordinated and/or financed studies in order to develop and validate qualitative and quantitative methods for the detection of GMOs.

Furthermore, the European Commission's independent adviser group, the "European Group on Ethical Questions relating to New Technologies", delivers opinions upon request from the European Commission, European Parliament or Council, or on its own initiative. This group has presented a series of opinions on key biotechnology issues over the last 7 years.

It should also be noted that, within the Fifth Framework Programme of Research and Technological development, the thematic programme "Quality of Life and Management of living Resources" includes the Key Action "Food, Nutrition and Health" which has the objectives to improve the understanding of consumer requirements and providing a healthy, safe and high quality food supply. In particular, research areas such as "development of food raw materials better adapted to consumer requirements; detection of specific GMOs in food including development and standardisation of methods to enable and assure traceability throughout the food chain and food network; rapid detection test for hormones along the food chain, development of new methodologies for assessing microbial, chemical and allergies risk and exposure; identification of beneficial effects of foods containing physiologically active components for defined target functions", are addressed by this Key action.

#### Antibiotics in Animal and Food Production

#### TACD RECOMMENDATION

Antibiotic resistance is a growing health problem. Because of the potential risks to human and animal health, the TACD calls on the governments of the US and the EU to institute a total ban on the non medical use (including use as growth promoters) of antibiotics in animal and food production, and a ban on the prophylactic use of antibiotics, except where disease has been identified in an animal or within a group of animals.

#### EUROPEAN COMMISSION SERVICES' RESPONSE

Being adopted by the working group on food, the recommendation only deals with the use of antibiotics in animals and food production.

However, the growing problem of antimicrobial resistance has been recognised in various ways within the EU.

Following discussions in several of the specialised Scientific Committees, the European Commission asked the Scientific Steering Committee (SSC) to establish a multidisciplinary working group to examine all aspects related to the use of antimicrobials and the development of resistance. The working group includes experts designated by the Scientific Committees having competence on the issue, as well as external experts.

The mandate of the group implies a multidisciplinary assessment of all aspects of the use of antimicrobials in human, animals and plants. On 28 May 1999 the SSC adopted its opinion on the matter "Opinion of the Scientific Steering Committee on Antimicrobial Resistance."

The opinion proposes four important areas of action:

- Prudent Use of Antimicrobials;
- Prevention of Infection and Containment of Resistant Organisms;
- New modalities of Prevention and Treatment for Infections;
- Monitoring the Effects of Interventions.

In September 1998 - on the initiative of the Health authorities of the European Union - an EU conference was held in Copenhagen on the "Microbial Threat", that is human health implications of the increasing resistance to antimicrobial agents.

The conference adopted a Recommendation on inter alia the need for surveillance, for collection of data, for encouraging good practice and for co-ordinated research.

The Council (Agriculture) endorsed these recommendations at its meeting on 17 May 1999 and the Council (Health) at its meeting on 8 June 1999 adopted a resolution encouraging the European Commission to continue its work on reducing the emergence and spread of anti-micro-organisms.

Specifically concerning surveillance including the use of antimicrobials can be mentioned: The Community Network for the Epidemiological Surveillance and Control of Communicable Diseases, and The European Antimicrobial Resistance Surveillance System (EARSS).

Among European Commission initiatives with special reference to the recommendation from the TACD working group, as quoted above, can be mentioned the suspension - as a precautionary measure - as from 1 July 1999 (at the latest) of the use of 4 antibiotics (bacitracin zinc, spiramycin, virginamycin and tylosin phosphate) as feed additives. Carbadox and oliquinox for growth promotion purposes in pigs have been banned as from 1 September 1999.

BST (bovine growth hormone)

#### TACD RECOMMENDATION

The TACD recommends that the government of the US follows the lead of Canada (which has prohibited the use of BST (also called bGH or bovine growth hormone) on the basis of animal health and welfare) and that the EU institutes a permanent ban on BST. In the interim, the US and EU should promptly require mandatory labelling of all milk and dairy products from cows treated with BST.

#### EUROPEAN COMMISSION SERVICES' RESPONSE

The moratorium prohibiting the use of BST in the European Community will end on 31st of December 1999. On the basis of the conclusions of the reports of the two Scientific Committees, the European Commission is studying the follow up to give to these scientific opinions. A prolongation of the moratorium may be proposed to the Council and the European

Parliament.

The moratorium would apply to use of BST within the EU. No mandatory labelling is currently foreseen, in particular because such an option would be enforceable only if analysis of residues can be performed and can demonstrate that the milk comes from cows treated with BST. For the moment it is not clear whether it is possible.

The Codex Alimentarius Commission, during its session from 28 June till 3 July 1999 in Rome, decided to hold the MRLs for BST at step 8.

Dietary Supplements

#### TACD RECOMMENDATION

The TACD calls upon the governments of the European Union and the United States to require that dietary supplement ingredients be subjected to a government safety and efficacy review which shall include the establishment of safe upper limits.

#### EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission is preparing a preliminary draft directive to cover supplements marketed as foodstuffs. This draft is one of the measures to deal with the presence of certain nutrients in foodstuffs (a draft directive on the addition of nutrients to foods is also planned). As a first stage the draft will cover vitamin and mineral supplements.

Primary consideration will be given to:

- the definition of the products;
- ensuring correct and appropriate information of consumers (prohibition of making claims as to prevention, treatment or cure of a disease or of misleading statements);
- fixing upper limits for vitamins and minerals that will take into account scientific risk assessment (the Scientific Committee for Food is currently working on the establishment of upper safe limits for vitamins and minerals), intakes of these nutrients from all sources, and where necessary, recommended intakes;
- providing for a notification system of marketed products to the competent authorities in order to facilitate monitoring.

Consumer Participation

#### TACD RECOMMENDATION

The TACD recommends that the government of the US and the EU guarantee that consumers can fully participate in the setting of international food standards at the Codex Alimentarius and the World Trade Organisation (WTO). Furthermore, the decision-making process must be transparent, with full disclosure of documents. These requirements must also apply to decisions on equivalency by the US and the EU.

#### EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission Services welcome the request for participation, openness and transparency in the international fora.

The EU has sent to the Codex Commission its position on consumers' involvement in the work of the Codex Commission. The EU welcomes the document, which was drawn up by the Secretariat of the Codex in co-operation with Consumers International and considers that

it is a good document. As regards access to Codex documents, it should be the subject of close attention of the Secretariat that the consumer associations are allowed full participation in the work.

The EU supports a large part of the recommendations, but would underline that each Codex Member must keep freedom to organise the consumers' participation at national activities. The legal means and the methods by which governments improve the effective participation of consumer organisations in food standards and controls are matters for the Members. In the EU, Article 153 of the Amsterdam Treaty gives to the Community and its Member States shared responsibility in the protection of the consumers' interests and health.

The European Commission Services also note the request for full participation and disclosure of documents on equivalency decisions. The European Commission will continue to apply its policy of largest possible access to documents, based on the European Commission Decision of 8/2/1994, on the Access to Documents and will involve the stakeholders to the larger extent, according to the existing rules.

These rules are currently being reviewed, with a view to adopt the necessary Rules of Procedure to comply with art 255 of the Amsterdam Treaty, saying:

"1. Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have a right of access to European Parliament, Council and Commission documents, subject to the principles and the conditions to be defined in accordance with paragraphs 2 and 3.

2. General principles and limits on grounds of public or private interest governing this right of access to documents shall be determined by the Council, acting in accordance with the procedure referred to in Article 251 within two years of the entry into force of the Treaty of Amsterdam.

3. Each institution referred to above shall elaborate in its own Rules of Procedure specific provisions regarding access to its documents."

The European Commission Services will keep the TACD abreast of further developments in this respect.

## Inspections

### TACD RECOMMENDATION

There is a need for a coherent, hazard-based inspection program which covers food production from farm to table, consisting of the following items :

A general food inspection which follows and assesses the content of undesirable micro-organisms, chemicals and physical hazards in various foods-both presently and in the long term. This would provide a basis for both national and international decision making.

A system of industry self control in all stages of production from farm to table, based on HACCP (Hazard Analysis Critical Control Point System adopted by Codex) principles. The control system should be approved and regularly reviewed by authorities

Frequent and unannounced inspection by the authorities responsible for inspection of manufacturers and their control program to including sampling of manufactured goods; intensive control campaigns in susceptible areas; and screening tests.

### EUROPEAN COMMISSION SERVICES' RESPONSE

At Community level, the European Commission has reviewed the manner in which it carries out its statutory control and inspection responsibilities in the food, veterinary and phytosanitary sectors.

The Food and Veterinary Office (FVO) was established within DG XXIV (Consumer Policy

and Consumer Health Protection) on 2 April 1997 to undertake these responsibilities. It is governed by the three principles of transparency, independence and excellence, which have guided its progress in the last two years. In reviewing working practices and procedures within the FVO, certain key elements have been introduced:

- the use of audit techniques to focus control and inspection effort on the performance of competent authorities. This not only allows the best use of resources by the FVO, but also emphasises the central role of national authorities in ensuring adequate levels of consumer health protection.
- the development of a structured mission prioritisation system. This was intended to ensure that the FVO could identify and target production sectors and countries where particular risks to consumer health were considered to exist.
- the application of a "plough-to-plate" approach to the planning and performance of inspections, such that all parts of a production sector could be adequately assessed.

Responsibility for the implementation and operation of food safety controls rests with the national authorities. For this reason, the FVO's inspection effort is increasingly focussing upon the performance of the relevant competent authority, in particular the manner in which it organises, performs and responds to the results of food safety controls. This is supported by visits to individual farms, markets, processing establishments ("reality checks"). These are important both in providing a balanced picture of the health situation, and in reassuring consumers of the production standards being achieved. During these visits, the manner in which the competent authority implements and enforces EC (or equivalent) legislation is checked. This includes the operation and control of auto-control and HACCP systems within processing establishments.

The FVO will carry out audits of control systems in third countries with which agreements on sanitary measures applicable to trade have entered into force, following the operational procedures laid down in those agreements.

Reports of missions, which are published on the DG XXIV internet site, provide information on the findings and conclusions of the inspectors, as well as making recommendations as to the action required to improve standards.

At national level, the European Commission supports the principle that the "day-to-day" responsibility for the production of safe food rests with the food business and that this must be underpinned with effective official controls undertaken by competent and well-trained officials.

The European Commission Services welcome the recommendation of the TACD for the use of HACCP systems. It supports the principle that HACCP systems should be developed by food businesses to identify potential food safety hazards and apply controls at the most effective step in the production of the food to ensure that the food is safe and wholesome when it reaches the consumer. HACCP systems cannot be applied in isolation and the European Commission Services support the principle that businesses must ensure that good hygiene practices are in place in addition to HACCP.

The Commission in its review of hygiene legislation will be focusing on measures that require food businesses to apply good hygiene practices and overlay these with HACCP systems. Official controls are required at a frequency reflecting the risk in the food business and these should include frequent and where necessary unannounced visits.

The European Commission Services support the use of sampling of foods as an adjunct only to the assessment of compliance with food legislation as it is inherently unreliable as a tool for detecting contaminated foods. The European Commission through its Co-ordinated Control Programmes identifies annually areas of concern for more focussed controls. These may include sampling of foods for contaminants, for example, pesticide residues in fruit and vegetables and an assessment of other control activities in relation to ensuring compliance with Community legislation.

## Microbial Safety

### TACD RECOMMENDATION

The TACD calls upon the governments of the US and the EU to take the following steps to reduce food-borne illness caused by pathogen contamination of food products:

- Establish high performance standards to be implemented through HACCP (Hazard Analysis Critic Control Point System adopted by Codex) systems extending from farm to table;
- Collect and publish data on contamination levels;
- Expand sampling of products to include a wider range of pathogens;
- Encourage programs to minimise human pathogens in animal populations by eliminating infected flocks and other steps.

### EUROPEAN COMMISSION SERVICES' RESPONSE

The development of legislative and operational controls designed to ensure the microbial safety of foodstuffs intended for human consumption has a high priority within the European Commission and in Member States.

In line with the Codex Alimentarius Commission General Principles of Food Hygiene the European Commission supports the application of good hygiene practices in food establishments and in some sectors there are already Community requirements for the application of HACCP systems. The European Commission is committed to the extension of HACCP to other sectors. In its review of the community hygiene legislation the European Commission is considering the role of targets and performance standards for HACCP systems in ensuring the microbiological safety of foods.

This is reflected within Community legislation and in the approach adopted by the Food and Veterinary Office in its control and inspection activities. The development of auto-controls within food processing establishments, including HACCP systems, was emphasised in the European Commission's recent Green Paper on Food Safety. These principles form an integral part of the food safety controls in place in Member States, and will increasingly form the basis for Community legislation in this sector.

Member States have, in conformity with Community provisions, to collect and evaluate data on zoonotic diseases and zoonotic agents in animals and they have to report to the European Commission the trends and sources of these diseases and agents recorded. The European Commission evaluates these data and reports yearly to the Standing Veterinary Committee. Furthermore, EU legislation provides for monitoring data of human cases of zoonoses

As regards the zoonoses legislation, preparatory work is currently in hand to amend the existing Directive for the following reasons:

- the actual legislation is not adequately implemented in different Member States and the trends in food borne infections show that the current situation seems to be worsening ("new" pathogens are emerging and infections by "traditional" pathogens remain constantly high);
- the stable to table approach creates a new environment, which necessitates redefining the scope of the Directive as regards the responsibility of the primary producer;
- a clear policy should be created as regards placing on the market rules including imports and trade negotiations with third countries.

Taking into account the subsidiarity principle, future rules would allow a flexible, step by step approach, based on monitoring and surveillance results and focussing on an effective reduction in the prevalence of certain pathogens in livestock in the Member States.

Other actions undertaken include official checks at border inspection posts on imported foodstuffs, according to pre-set sampling frequencies, which reflect the perceived risk associated with the product and country concerned. Where certain pathogens are found, immediate action is taken to remove the product concerned from the human food chain.

A Rapid Alert System exists, which allows Member States and the European Commission quickly to notify all Member States of incidents where food-borne pathogens are identified, and for the appropriate control action to be initiated.

In respect of a number of zoonoses, including brucellosis, tuberculosis and rabies, Community-funded eradication programmes have been in operation for several years. In some Member States this applies for salmonellosis.

In most of the Member States, these have achieved considerable success in reducing the incidence of these diseases in the susceptible animal populations. Such programmes are subject of regular inspections by the Food and Veterinary Office, to ensure that their rules are being respected, and that the objectives are being achieved.

The Codex Alimentarius Commission, during its session from 28 June till 3 July 1999 in Rome, adopted principles and guidelines for the conduct of microbiological Risk Assessment.

#### Nutrition Labelling

#### TACD RECOMMENDATION

The TACD calls upon the governments of the EU to require mandatory nutrition labelling for food products, disclosed in a meaningful, consistent and easy to read format, regardless of whether nutrition claims are made. Both the EU and US should support mandatory nutrition labelling requirements at Codex Alimentarius.

#### EUROPEAN COMMISSION SERVICES' RESPONSE

A draft European Commission Communication on the follow-up to the "Green Paper on the General Principles of Food-Law in the European Union", adopted in 1997, is being drafted. Among the tasks to be undertaken, the Communication mentions the revision of Directive 90/496/CEE on nutritional labelling of foodstuffs. Among the options envisaged by the European Commission is to make such labelling compulsory. Currently, the EU is supporting in the Codex Alimentarius an enlargement of the number of nutritional elements that must appear on the label when a nutritional claim is made about them.

The Codex Alimentarius Commission, during its session from 28 June till 3 July 1999 in Rome, returned the proposed amendment on Nutrition Labelling to step 3 for further consideration.

#### Precautionary Principle

#### TACD RECOMMENDATION

The precautionary principle should apply in cases when the scientific evidence is not conclusive enough to determine a level of protection but there is a necessity to take measures for the purposes of protecting public health, safety, or the environment.

The TACD calls on the governments of the US and the EU to incorporate the precautionary principle in regulatory decisions involved in consumer health and safety and the environment.

In this perspective, the TACD calls on the Codex Alimentarius Commission to set a clear policy that includes the precautionary principle, along with science, social and ethical factors,



animal welfare and environmental protection within the decision making process.

We urge deletion of the word " provisional " in the first sentence of Article 5.7 of the SPS agreement. We call on the US and EU to seek to strengthen this article. In addition, we urge reconsideration of the current rules relating to the burden of proof to demonstrate that a product is safe.

#### EUROPEAN COMMISSION SERVICES' RESPONSE

The European Commission services welcome the TACD recommendation calling for the incorporation of the precautionary principle in regulatory decision.

In essence, it is the European Commission view that the Precautionary Principle may be invoked in order to determine appropriate protective action in those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary assessment, that the possible effects on health, safety or the environment may be inconsistent with the chosen level of protection. In these cases all efforts must be made to obtain more comprehensive information concerning the risk in order to review the basis and necessity for the measures taken.

Concerning the environmental protection, the European Commission applies the provisions of the Amsterdam treaty amended Article 130r(2) as follows:

"Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community: it shall be based on the precautionary principle and on the principles that preventive action should be taken that environmental damage should as a priority be rectified at source and that the polluter should pay".

The European Commission services also support the recommendation of TACD to consider the Precautionary Principle in its proposals for consumer health protection. In this respect the European Commission has already stated in its Communication of 30 April 1997 on consumer Health and Food Safety that:

"The Commission will be guided in its risk analysis by the precautionary principle, in cases where the scientific basis is insufficient or some uncertainty exists."

The European Commission makes this point again in its Green Paper on "The General Principles of Food Law in the European Union", reiterating the obligation imposed by the Treaty to take a high level of protection as a basis for action. The European Parliament has endorsed this approach.

In addition, the European Court of Justice has upheld the European Commission's decision banning the exportation of beef from the United Kingdom on the basis of the precautionary principle. The Court stated: "Where there is uncertainty as to the existence or extent of risks to human health, the Commission may take protective measures without having to wait until the reality and seriousness of those risks become apparent."

Finally on 13 April 1999, the Council adopted a resolution calling on the European Commission "to be, in the future, even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as a priority clear and effective guidelines for the application of this principle".

The institutions of the European Community therefore agree that application of the precautionary principle should not be restricted to the environment but should, on the contrary, be extended to all instances where there is an obvious need to protect the health of the public, animals or plants, without waiting for scientific uncertainty to be clarified.

The European Community will continue to support reference to the precautionary principle in the Working Principles for Risk Analysis in the Codex Alimentarius Commission Procedural

Manual, and to the development of guidelines for the application of this principle in the Codex Alimentarius decision making process.

Concerning the deletion of the word "provisional" in the first sentence of Article 5.7 of the SPS Agreement, the European Commission services believe that the provisional nature of measures taken on the basis of precaution pending further scientific data is desirable. The Article 5.7 does not specify how much time a provisional measure can be maintained in force. In fact, this duration depends on the acquisition of new scientific evidences and re-assessment of the risk. It could be years; in other words, the provisional nature of measures taken on the basis of the precautionary principle is not bound up with a time factor but with the development of scientific knowledge. The provisional nature of the measure is also linked to the obligation of searching new scientific data.

The European Commission services think that Article 5.7 needs clarification and explanation. With this objective in mind, the European Commission has proposed to the Council and the European Parliament, in the context of the new round of multilateral trade negotiations "to clarify and strengthen the existing WTO framework for the use of the precautionary principle in the area of food safety, in particular with a view to finding an agreed methodology for the scope of action under that principle."