COMMISSION OF THE EUROPEAN COMMUNITIES

SEC(92) 361 Brussels, 28 February 1992

COMMENTS OF THE EUROPEAN COMMUNITY ON THE ITEMS OF THE AGENDA CX/FAC 92/1 FOR THE TWENTY-FOURTH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

(THE HAGUE, 23-28 March 1992)

(Commission Staff Working Paper)

N.B. : The following items of the agenda will be discussed in a coordination meeting in The Hague : items 7, 8, 11, 12, 16.

Agenda Item 4

Matters of interest to the Committee arising from the Nineteenth Session of the Codex Alimentarius Commission and other Codex Committees (Doc. CX/FAC 92/2).

A. Horizontal Approach to Food Standardization

See general statement under agenda item 6-1

D. Risk Assessment

The Member States should bear in mind the fact that in its proposal COM (91) 525 final for a Council Directive on the Hygiene of foodstuffs (which is a framework Directive), the Commission of the European Community recognizes the importance of the principle of Risk Assessment.
Article 3 of this document obliges food business operators to identify any process undertaken which is critical to ensure food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed (HACCP).

E. Migrants from Packaging Materials

Also see point J

The Community's representative will support the view of the Executive Committee which has not approved the recommendation made by the FAO/WHO Conference regarding food standards, chemical substances in foods and the trade in foodstuffs, asking that high priority be given to the assessment, by the JECFA, of migrants from packaging materials. Indeed the JECFA should concern itself solely with substances causing major health problems.

F. *Implications of Biotechnology on International Food Standards and Codes of Practice*

The Member States should invite the Codex to take note of the Communication on promoting the competitive environment on biotechnology within the Community.

Products, including foodstuffs, are to be assessed on the basis of safety, quality and efficacy and a proposal for a regulation on novel foods, which includes novel foods arising from biotechnological techniques, is discussed in the EC.

The texts of the Communication and of the proposal of Regulation will be transmitted to the Secretariat of the Codex for information.

H. *Regional and National Programmes on Control of Mycotoxins in Food*

See general statement on Mycotoxins in Food and Feed under agenda item 14.

I. *Guideline Levels for Methylmercury in Fish*

See agenda item 15

J. Guideline Levels for Acrylonitrile in Food and Vinyl Chloride Monomer in Food and Food Packaging Materials

Also see point E.

The Community's Representative will take the stand in order to state that: the limits adopted are identical to those already in existence within the European Community and have been laid down in the Community Directive (78/142/EEC of 30 January 1978, O.J. L44 of 15 February 1978 in respect of vinyl chloride and Directive 90/128/EEC of 23 February 1990, O.J. L349 of 13 December 1990 in respect of acrylonitrile).

It must be stressed as regards the method of analysis used to determine the two relative VC limits, that the European Community has already adopted a method of analysis for each limit (Directive 80/766/EEC of 8 July 1980, O.J. L213 of 16 August 1980 and Directive 81/432/EEC of 29 April 1981, O.J. L167 of 24 June 1981).

A method standardized by the CEN is available, where appropriate, for the analysis used in order to determine acrylonitrile.

K. International Numbering System for Food Additives

See agenda item 9.

L. Proposed Draft Guideline Levels for Contaminants in Food

See agenda item 13.

N. Proposed Draft Codex General Standard for Food Additives

See agenda item 6.

O. Guideline Levels for Aflatoxins in Food and Feed
P. Methods of Analysis for Aflatoxins
Q. Sampling Plans for Aflatoxins

See under agenda item 14.

R. Guideline Levels for Radionuclides in Foods

Comments of the EC have been made on the 23rd session of the CCFAC.

The Community spokesman will make the following statement :
this question has been dealt with in Council Regulations Nos 2218/89 and 3954/87, which stipulate that "the (maximum permitted) level applicable to concentrated or dried products shall be calculated on the basis of the reconstituted product as ready for consumption".

The EC agrees that the note pertaining to the reconstituted product should be maintained and hence should not be subject to review.

The EC holds the view that with regard to foodstuffs of minor dietary importance the guideline levels are indeed unduly restrictive. Commission Regulation N° 944/89 (Euratom) lays down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency. This regulation contains a list of foodstuffs considered to be of minor importance. The maximum permitted contamination levels for these products are ten times higher than those applicable for "other foodstuffs except minor foodstuffs". The list only applies inside the European Community.

S. Establishment of Guideline Levels for Radionuclide Levels in Foods Subsequent to the Accident Year

The Community spokesman will take the floor to say that :
the EC agrees that the Codex levels should be considered on a permanent basis, although subject to regular revision. They should apply to the whole period during which contamination may exceed the guideline levels.

The EC regulation on foodstuffs contaminant levels subsequent to the Chernobyl accident, has been extended to 1995 (Council Regulation EEC 402219/89). However, an ad-hoc committee establishes and updates regularly a list of products which are excluded from the regulation.

The EC does not consider the Codex guideline levels to be too high. They compare quite well with the figures established for application in case of a future accident (Council Regulation Euratom N° 2218/89 for foodstuffs, and N° 770/90 for feedingstuffs). In fact these values are provisional and will be considered in case of an accident, taking into account the specific situation. The new recommendations of ICRP (International Commission on Radiological Protection) (Publication 60, 1990) offer guidance on the radiation protection principles pertaining to situations of intervention. It is important to note that in such situations dose limits do not apply.

T. Procedure for the Establishment of Guideline Levels for Contaminants

See agenda item 13.

Agenda Item 6

Consideration of the Proposed Draft Codex General Standard for Food Additives (Doc. CX/FAC 92/3).

The representative of the Community will make a general statement on the following lines :

1. General Comments

The general principles outlined in the so-called "Denner" paper (CX/FAC 89/16) have been accepted by the CCFAC as a basis for the establishment of a general standard on food additives. The Commission of the European Communities supports the horizontal approach recommended by Dr. Denner since EEC has adopted such an approach in its Council Directive 89/107/EEC (21st December 1988, JO L40, 11.2.1989, p. 27) on the approximation of the laws of Member States concerning food additives. This approach is the most effective way to protect human health, and enables to take into account the probable daily intake of the use of an additive from all sources. The continuous observation of food additives is also facilitated.

2. Criteria for the use of food additives

In the Community, the general criteria for the use of food additives is the protection of the consumer's health. To assess the possible harmful effects of a food addtitive, EC regulation foresees that the food additive must be subjected to appropriate toxicologial testing and evaluation and conditions of use established from this scientific basis. Thus all permitted additives should be regarded as equally "safe" under these conditions of use.
Therefore, the European Community disagrees with the classification of additives in the two categories "low" and "high priority" additives.

Furthermore the EC regulation foresees the following general criteria for the use of additives :

- there can be demonstrated a reasonable technological need and that the purpose cannot be achieved by other means which are economically and technologically practicable.

- they do not mislead the consumer.

- there is evidence that the use of the additive would be of benefit to the consumer.

- additives are continuously monitored and reevaluated whenever necessary.

3. *Use of "Quantum Satis" level*

Specific directives are in preparation inside the Community on the basis of the framework directive (colours, preservatives, antioxidants and other food additives) in which it is proposed that all food additives with a "not-specified" ADI will be allowed at "quantum satis" level, except in those foods where additives are forbidden. This rule should not apply to those additives for which a specified ADI has been allocated. It does not mean that some additives with a specified ADI cannot exceptionally be subjected to GMP, but that one should carefully consider in parallel with the ADI the levels of use, in order to ensure that the ADI will not be exceeded.

In connection with this point, the Community suggests it would be appropriate to include an explanation of GMP as follows : "No maximum level is specified. However food additives subject to GMP should be used according to good manufacturing practice at a level not higher than is necessary to achieve the intended purpose".

4. *Food Categorisation*

A food categorisation scheme is useful as a framework to indicate where additives may be used in general but such a scheme may prove too inflexible to allow adequate description of individual food products, or to allow new food products to be incorporated. Therefore the representative of the Community will say that any food categorization should not be too rigid.

5. *Consumption Surveys*

With regard to the estimation of intakes, it is important to have consumption surveys in order to verify that the ADIs are not exceeded. These surveys should be carried out by each country. The methodology used could be subject to coordination at the Codex Committee.

Agenda Item 8

Consideration of Specifications for the Identity and Purity of Food Additives (CX/FAC 92/5).

The Community's representative will raise the following points :

The Community has prepared identity and purity criteria for some additives.

The EC intends shortly to define the identity and purity criteria for all of the food additives for which the conditions of use will have been defined. A proposal for a Council Directive on sweeteners intended for use in foodstuffs and setting out their conditions of use is about to be adopted.

As part of its activities the Community intends to take into account of the purity criteria drawn up by the JECFA.

Agenda Item 9

Proposed amendments to the International Numbering System (INS)(Doc CX/FAC 92/6).

The INS established by the Codex is intended solely to provide a number for identification of food additives in ingredient/labelling of food.

It has been based on the existing EC numbers system and other numbers as contained in Commission Directive 83/463/EEC. (of 22 July 1983, JO L 255/1 15.9.83).

Active participation of the Community in this subject is necessary to prevent differences in numbers between Codex and EC which could cause confusion.

The representative of the Community will make a statement on the points mentioned hereafter.

The following comments are preliminary comments to the amendements proposed to the INS (July 1991).

a. Carotenoids (160 group) and xanthophylls (161 group) :

   It may be necessary to revise this section of the INS in the not too distant future.

b. Pectins 440 : in the EC, the intention is to have a sub-division for (a) Pectin 440, (b) Amidated Pectin 440.

c. Salts of Fatty Acids, 470 : in a draft Directive expected to be issued shortly, the EC is intending to designate the sodium, potassium and caldum salts as 470 (a) and the magnesium salts as 470 (b).

d. Thermally oxidised soya bean oil, 479 : in the EC, the intention is to have a sub-division for (a) oxidised oil, (b) the product interacted with mono- and diglycerides.

e. We suggest to sub-divide number 514 and 515 to distinguish the monobasic and dibasic salts as has been done for the salts of most of the other common organic and inorganic acids.

f. Within 553, Talc may be sufficiently different in terms of its origins and therefore its contaminants do merit a more pronounced differentiation from other magnesium silicates (It also has very much its own, commonly recognised identity). It might be better to reflect this by assigning it the number 553 (b) and for the other magnesium silicates by taking the numbers 553 (a) (i) and 553 (a) (ii).

g. The EC is intending to use the numbers 912 for Montan Acid Esters, 938 and 939 for Argon and Helium respectively, and 947 for Hydrogen, 948 for Oxygen. These numbers appear to be un-assigned in the INS at present.

h. It is not necessary to distinguish two different numbers, 1420 and 1421, to starch acetate solely on the basis of the reactant used in its manufacture. 1420 could be retained for "Starch Acetate" without qualifications as to the reactant used in its manufacture and 1421 and its description be deleted.

Agenda Item 13

Proposed Draft Codex General Principles for Contaminants (CX/FAC 92/10)

The Member States should bear in mind the fact that the community is developing a framework of Directive on contaminants and therefore it is desirable that Member States insure as far as possible that their position should not conflict with the work in hand in the Community.

It is desirable to develop General Principles for contaminants in food in Codex Alimentarius, on the basis of a "horizontal" approach for the regulatory control of contaminants in food. The paper presented is a very good basis for discussion.

The Member States should support the recommendation to apply a horizontal approach for the regulatory control of contaminants in foods, in particular, when setting future Codex Maximum Guideline Levels and when revising these levels in Codex standardized foods.

The criteria applied are the ones outlined in section 49 and Annex IV, used in a systematic manner.

The general approach proposed in Chapter IV of the paper and in particular the introduction of Action or Guideline levels as interim measures for use by the authorities when there is not sufficient information to establish Maximum levels should be the subject of further discussion inside the Codex.

The CCFAC should be encouraged to propose technological measures directed at controlling sources of contamination rather than imposing controls on final foods.
The measures should become recommendations from the CCFAC to Codex Alimentarius Commission.

The dietary recommendations should only be part of Codex work when applicable to certain parts of the population, leaving to national authorities the dietary recommendations specific for geographic areas.

Since the rational approach to control naturally occurring toxins is to a considerable extent similar to that of contaminants in general and since CCFAC is already studying these substances, it should be stated explicitly that naturally occurring toxins are part of the Codex Committee on Food Additives and Contaminants' work and examined if the Codex definition of contaminant should be modified to include these substances.

It might be advisable to establish a list of priorities as regards CCFAC's work on contaminants. To that effect a Working Party should be set up during the Codex meeting. The European Community and its Member States are prepared to participate in it.

Agenda item 14

Mycotoxins in Food and Feedstuffs (Doc Alinorm 91/12A - CX/FAC 92/11).

a) *Animal feedstuffs*

The Community spokesman will make a General Statement on the following lines :

Council Directive 74/63/EEC of 17 December 1973 lays down maximum limits for undesirable substances and products such as mycotoxins in animal feedstuffs. In the light of Directive 91/126/EEC of 13 February 1991 reducing the maximum permissible aflatoxin B1 contents in certain foodstuffs, there are currently no plans to make the relevant requirements more strigent.

Commission Directive 76/371/EEC of 1 March 1976 lays down the types of Community sampling used in the official inspection of animal feedstuffs. In view of the fact that aflatoxin B1 appeared in a highly heterogeneous manner in the batches of food and that provision should be made for adaptations for sampling from bulk carriers (very large batches), studies were to be carried out with a view to amending Directive 76/371/EEC.

Commission Directive 76/372/EEC of 1 March 1976 lays down the Community methods of analysis for the official inspection of animal feedstuffs. Changes to the above-mentioned methods of determination are in the process of being adopted, in view, in particular, of having available means of determining aflatoxin in foods containing citrus pulps and of improving the sensitivity of the method.

The Community is conducting a policy intended to check and improve food quality. As part of the research programmes the Commission was suggesting financial support for cooperative studies linking together several Community laboratories. Action has been undertaken with a view to preparing a research project involving the final touches to acceptability criteria for products contaminated by aflatoxin B1 and having been subjected to a detoxification treatment.

b. *Foods intended for human consumption :*

The Member States should not lose sight of the fact that the Community is currently examining the scope for legislation on standards relating to aflatoxin M1 in milk. It also intended to begin preparatory work on laying down maximum limits for mycotoxins present in other agricultural products such as nuts, dried figs, etc... Measures such as these could perhaps be supplemented by the drawing-up of framework regulations in line with the risks caused by the presence of mycotoxins in foodstuffs.

Agenda Item 15

Industrial and Environmental contaminants in food (Doc. CX/FAC 92/12).

It is necessary as regards the indicative limits for methylmercury in fish, that the Member States do not lose sight of the existence of Community regulations in this area and of the discussions begun within the Commission's working parties.

Indeed, the Commission recently adopted (on 2 July 1991) Directive 91/493/EC laying down health rules governing the production and marketing of fish products. Chapter V, items II.B and C of the Annex to that Directive provides that Member States must draw up a monitoring plan relating to the levels of contaminants in fish products (including mercury) that are present in an aquatic environment. That Directive also foresees a Community procedure laying down, before 31 December 1992, the level of contaminants to be respected.