codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 (b)

CX/FAC 06/38/9-Add. 1
(English only)

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-eighth Session

The Hague, the Netherlands, 24 – 28 April 2006

FOOD ADDITIVES PROVISIONS OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES

Comments

The following comments have been received from Canada, Sri Lanka, IADSA and CEFIC

CANADA

Canada actively participated in this electronic Working Group and generally supports the report.

The following additional comments pertain to aspartame, INS 951.

Aspartame, INS 951: Recommendation 3 - Request for information

Canada proposes to maintain the provisions of 2000 mg/kg in Category 04.1.2.6, Fruit-based spreads, excluding products of Food Category 04.1.2.5, and 10 000 mg/kg in Category 05.3, Chewing gum. These amounts were initially circulated for comments to members of the GSFA Quality Control Electronic Working Group and in the Circular Letter 34/2005-FAC. The safety assessments of aspartame conducted by Canada support these levels.

SRI LANKA

National CODEX Committee of Sri Lanka submitted its comments and arguments on the use food additive Sulpher Dioxide (SO2) in Food Category 12.2.1, as contained in document CX/FAC/06/38/9 part 1. The main objective of our submission is to establish MRL of SO2 in Cinnamon in order avoid SPS restriction in export markets. Following the EU's restriction applied for cinnamon on SO2, Sri Lanka also raised the issue of specific trade problem due to the non existence of international standard and guideline at the WTO SPS Committee where it was agreed to bring to the urgent attention of CODEX Committee. In this regard a copy of the letter sent by the Chairman of the WTO SPS Committee to the Chairperson of the Codex Alimentarius Commission is attached. In this background the key objective of this paper would be to summarize the main arguments and technical information contained in our proposal.

(2) Background of the Issue

Since November 2004, Sri Lanka has encountered problems with a number of consignments of " Ceylon Cinnamon " exported to the European Union on the grounds that the consignments contained **Sulphur Dioxide** (SO2). The EC authorities have sighted that this action was taken under a Technical regulation relating to the import of foodstuffs to the European Union (EU) contained in **European Parliament and Council Directive No. 95/2/EC** of the 20th of February 1995 & its' subsequent amendments. In this regard Sri Lanka has raised the issue under specific trade concerns of the SPS committee of the WTO in October 2005 emphasizing the adverse trade, and economic impact with a view to finding interim results and solutions.

Sulphur Dioxide (SO2) is a known, accepted & a widely used food additive & is described as ' *one of the most important & versatile additives with a good safety record* ' used in the food industry. (Chemistry in Britain1999).

Moreover, at the chemical evaluation of Food additives undertaken by JECFA at their 51st session in 1998, it has been determined that SO2 in **acceptable quantities*** as a food additive does not produce any adverse effects on human health. Codex General Standards for food additives (GSFA), Allinorm 01/124, Appendix IV, page 144 describes the applicability of SO2 & sulphites in food stuffs. The General Guidelines of CAC in identifying food additives and their respective technological functions recognizes that a single food additive such as SO2 can be used for a range of technological functions in food items. According to the list of Codex Advisory Specifications on Food Additives, SO2 has been adopted in 1999 as a permissible food additive. It is stated that SO2 may function as either a preservative or an antioxidant in food or as an anti – browning agent.

In Cinnamon, it functions as a preservative and an anti-browning agent in acceptable quantities. The same JECFA document of 1998 describes that an average daily intake **(ADI**) of **0.7 mg of SO2 / kg. b.w** (body weight) is permitted as safe.

(3) Trade and Economic importance of the Cinnamon Industry of Sri Lanka

Cinnamon represents the 3 rd largest export agriculture crop of Sri Lanka. It supports the lively hood of over 70,000 small holder cinnamon growers & provides employment to over 350,000 people. At present, Sri Lanka is the single largest exporter of true cinnamon (*Cinnamomum zeylancum*) in the world accounting for 75% of the world demand for cinnamon. The total quantity exported by Sri Lanka in the year 2004 is 11,300 MT. Exports to the EU constitute an approx 8% of the total exports & amounted to 900 mt for the year 2004.

Rejection of our product by the EU is of very serious concern to our country. While it deprives us of the much valued revenue it would also bring us 'disrepute' with the possibility of our products being rejected by the non EU countries as well. This is the reality that looms ahead. The European Spice Association is of view that it would not be possible to import cinnamon from Sri Lanka under the present regulations.

(4) Our request to the Codex Committee

As is known, there are no international standards that govern the use of SO2 in cinnamon as a food preservative or an anti-oxident or as an anti browning (bleaching) agent in foods & it would therefore be up to the individual countries to adopt their own standards. In doing so, under the WTO guidelines, such countries are expected to adopt their own measures based on **scientific evidence/guidelines** & established practices & are required to provide justification in the event higher than normal requirements are to be adopted.

Regrettably, the **guideline provided** by the WTO/FAO –JECFA on the use of SO2 (JECFA 51st session– 1998 indicated above) apparently had NOT been considered in the rejection of cinnamon by those countries. Had the JECFA ruling been considered, cinnamon would not be rejected for it residual SO2 content.

In the Codex classification under heading SULPHITES, SO2 & other sulphites (E 220 –E228) have been permitted to be used in food-stuffs with their Maximum Residual Limits (MRL) being indicated. CAC publication, Allinorm 01/124 – appendix IV page 144 identifies food stuffs in category 12.2 & described as **Herbs & Spices including seasoning & condiments** has been assigned a MRL of 500 ppm. for SO2. (subsequent change being proposed at the 37th session @ 200 ppm)

However **cinnamon** , although a **commonly used spice** has NOT been identified in the list of food stuffs & hence falls under the category NO residual sulphur permitted. This has caused the anomaly thus creating the problem for Sri Lanka.

Our request is to have cinnamon included in the list of food stuffs under appropriate sub heading of category 12.2 of the Codex classification referred to above. Although 500 ppm has been assigned (with revision under discussion), our request is for the Codex committee to **permit 200 ppm of residual sulphur as SO2** for cinnamon.

(5) Reasons for request & justification

The Cinnamon Industry in Sri Lanka has been a traditional industry spanning centuries. The variety of cinnamon grown is indigenous to our country & is known as Cinnamomum zeylanicum –commonly referred to as ‘sweet cinnamon’ or ‘true cinnamon’ (Cinnamomum verum, *verum = true*)

After harvesting, among the many steps involved in the processing of cinnamon, fumigation is one of the important & critical steps. In addition to the common aspects of avoidance of insect damage & destruction of microbes, it helps in the *fixation of the characteristic golden yellow colour of Ceylon Cinnamon*. Cassia bark – a substitute product which is also being traded as cinnamon could easily be differentiated by the unique golden yellow colour of Ceylon Cinnamon.

The cinnamon industry has traditional practices in cinnamon peeling & in fumigation & the use of SO2 has been known to the industry for centuries. SO2 has been used for 2 purposes, viz for its biocidal activity & for bleaching. **Even today** the CODEX ALLINORM described the use of SO2 for the **very same purpose** it was traditionally used in the Sri Lankan cinnamon industry for over 500 years.

The practice of burning Sulphur remotely, allowing the vapours to impinge usually over a period of 8-1 hours on the bundled quills & keeping them in a closed chamber has been quite effective form the producers point of view. This process bleaches the cinnamon to the desired level, eliminates or destroys insects present if any & prevents the growth of fungi & bacteria thereon. There are over 110 fumigation centers dispersed in the cinnamon growing areas.

SO2 fumigation is very effective & easy to use process & at plantation level where it is being handled by the plantation work force with a low level of education but with high competence. The process is being currently controlled by the experienced worker. Considering the conditions existent at the plantations, this fumigation is an ideal method that could be used very effectively to obtain the desired results.

However work is in progress to upgrade the fumigation process into a controllable scientific operation.

An illustrative example is provided in the Annex 1 to compare and show that consumption of Cinnamon with permissible level of SO2 pose no health risk to the consumers.

Annex 1

Levels of residual SO2 permitted

As seen, from the publications of the FAO & the Codex commission, various food stuffs, identified by type have been assigned very high levels of residual SO2. To quote a few examples:

Dried fruits	3000 ppm	(except Prunes @ 2000 ppm)
Dried Ginger	150 ppm	
Mustard	350 –500 ppm	

As an example, Ginger is traded in a very much larger quantity than cinnamon is. (210,000 mt in 2004 : WTO) & so would be dried fruits.

If we consider the EU countries:,

Total population	350 million
Adult population –say 40%	140 Million “
Imports of cinnamon	900 mt (900,000 kg) /annum
Consumption /adult	900 ,000/ 140,000,000 * 1000
	= 7.0 gr / annum (approx) of cinnamon

If cinnamon is permitted at 200 ppm of SO2, (200 mg /1000gr)

!.0 gr of cinnamon will contain = 0.20 mg of SO2

Therefore 7.0 gr of cinnamon will contain = 7.0 * 0.20

= 1.40 gr of SO2 (per annum’s consumption **)**

This would be the intake of SO2 / annum by an adult European as an average on the consumption of cinnamon.

If an adult is said to weigh 40 kg,

The permitted ADI of SO2 would be = 40 * 0.7 = 28 mg of SO2 /day

(average daily intake= 0.7mg)

As could be seen, the contribution form cinnamon / YEAR is ONLY 1.40 gr. of SO2

Theoretically, if a person eats 2 nos of processed Prunes /day (30 gr) at the permitted 2,000 ppm of SO2 , the SO2 intake would be **60 mg** of SO2 /day

Attachment

Letter to chair CAC;

As you are aware, the Committee on Sanitary and Phytosanitary Measures (the "SPS Committee") has been monitoring the use of international standards, guidelines and recommendations by WTO Members on the basis of a procedure it adopted in October 1997 and revised in June 2005 (G/SPS/11/Rev.1). The procedure in essence requires that a WTO Member bring to the attention of the SPS Committee concerns it may have regarding the non-use of existing international standards, guidelines or recommendations, or the lack of existence of such standards, in cases where this has a significant impact on their international trade. Other WTO Members are then invited to comment on these issues, and to indicate the extent to which they share this concern.

At the meeting of the SPS Committee on 24 October and 1-2 February 2006, the delegation of Sri Lanka brought to the Committee's attention particular problems that it is facing with the export of Ceylon cinnamon due to the non-existence of a Codex standard for sulphur dioxide (SO2) residues in cinnamon. More details are contained in the enclosed submission from Sri Lanka (G/SPS/W/187).

The usual procedure requires that I draw this matter to the attention of the Codex Alimentarius Commission following the adoption by the SPS Committee of its annual report regarding the procedure to monitor the process of international harmonization at its June meeting each year. However, in light of the importance of this matter to the exports of a developing country, and in the context of the upcoming meeting of the Codex Committee for Food Additives, the SPS Committee has agreed to the request by Sri Lanka that this matter be brought to your attention without delay. The SPS Committee would appreciate being kept informed of what consideration, if any, is given to the issue raised in this letter by the Codex.

IADSA

Polysorbates

Further to the Codex Circular letter CL 34/2005 – FAC, the International Alliance of Dietary/Food Supplement Associations (IADSA) provided information on the use of a number of additives in the category 13.6 Food Supplements. In addition, we would like to share with this Committee the following information in relation to Polysorbates that we trust it will be useful for the discussion.

Polysorbate 80 (INS 433) has two current technological applications in soft food supplement capsules:

a) As an edible surfactant to improve the delivery of odiferous / unpleasant tasting substances such as fish and fish-liver oils. The polysorbate 80 disperses and emulsifies the oil in the stomach and reduces post-ingestion odour / reflux.

b) As an agent for dispersing and emulsifying the non oil-soluble micronutrients (vitamins and minerals) in some formulations containing high mineral levels.

Usage Levels

To achieve the required technological effects the polysorbate 80 has to be used at about 2.5% of the capsule fill. The fill represents a proportion of the total capsule weight with the shell making up the rest. Soft capsules are designed to be swallowed and thus there is a size limitation. This is related to a weight of about 1850 mg/capsule.

The usage level of the polysorbate in the capsules is in the range 20 – 45 mg/capsule depending upon the formula. In the worse case of a larger capsule recommended to be taken three times a day the maximum daily intake of the polysorbate 80 is calculated as 135 mg/day. Most of the products deliver a much lower amount.

When the above usage is calculated in terms of mg/kg product the levels currently in products fall within the range 6000 – 25000 mg/kg. However, it should be appreciated that one kg of product could represent many hundreds of daily doses. For example, even at the highest capsule weight 1 kg represents 540 capsules, or over a year's supply for one person.

ADI

The 17th JECFA (1973) assigned a group ADI for polysorbates of 25 mg/kg/bw/d. For a 60 kg individual this equates to 1500 mg/day. In the worse case intake from soft-gelatin capsules would be under 150 mg/day.

CEFIC

INS 160 a Carotenes

β-Carotene for use as a food colour can be obtained from several natural sources but also synthetically.

The Draft General Standard presently proposes different provisions for vegetable and algal carotenes (INS 160aii) and for synthetic carotenes and carotenes originating from Blakeslea trispora (INS 160ai). The latter two are grouped together with β-apocarotenal and its esters (INS 160e and 160f) although their colouring use is not connected. The only connection is the provitamin A activity which was reasoned in the group ADI.

JECFA evaluations of carotenes of both sources are different as far as for the first group vegetable carotenes have an assessment "acceptable, provided the level of use does not exceed the level normally found in vegetables", while for algal carotenes "no ADI allocated" is listed. For the second group (160ai) a group ADI of 0 – 5 mg/kg bw was published. Specifications of these two groups are also different. While vegetable natural extracts require a level not lower than declared the assay for the second group must be not less than 96 %. Therefore it should be clarified that algal carotene with the same INS number should not be in the GFSA as substance without ADI should not find entrance into GSFA.

There are, however, no physiological or structural differences in β-carotene from these different sources. They have more or less the same use conditions and can be used as alternatives. There is, therefore, neither a physiological nor a technological basis justifying differences in use levels or use conditions. Accordingly, the EU as well as the USA have the same provisions for use of β-carotene as a food colour independent of its source.

It seems therefore justified and is proposed to list the same use conditions for all products based on β-carotene. In addition all use conditions should be referring to the same basis, in this case cartone pure

INS 172 Iron oxides

General comments

Iron oxides are rather neutral substances suitable for colouring purposes in foods other than liquid products as they are sparingly soluble to insoluble. The can provide shades from yellow over reddish to brown which are sometimes more difficult to achieve by other food colours. It should be noted that the EU authorises iron oxides for use in food in general with exception of a list of specific products under the quantum satis principle. The list of authorized products includes those of the products listed below. Uses in these products with shades from yellow to brown are considered technologically necessary.

Specific comments on the recommendation of the electronic working group

04.2.2.6 Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5

Iron oxide is proposed for product categories 4.2.2.3 and 4.2.2.4. by the electronic working group. The same technological requirements exist also for this category. It is therefore proposed to list iron oxide with the same use conditions, i. e. 75 mg/kg instead of GMP

05.1.3 Cocoa-based spreads, including fillings

These products normally have a brownish colour. Intensification of the colour may be necessary in products containing some cocoa but also other ingredients. It is therefore proposed to discontinue the GMP listing and to list 1000 mg/kg, a level sufficient to intensify the colour of these products.

05.3 Chewing gum

Certain flavours like cinnamon are associated with a brown colour of the product. Iron oxides are best suited to provide this colour in chewing gum. It is proposed to discontinue the GMP listing and replace it by 1000 mg/kg instead.

12.4 Mustards

Iron oxides are well suited to standardise the yellowish to brownish colour of mustard. It is therefore proposed to list iron oxides with a level of 1000 mg/kg

12.9.5 other protein products

The colour of such protein products may be pale and therefore impair their acceptance. It is therefore proposed to list iron oxides with 1000 mg/kg.

We wish to make comment regarding CCFAC, 38th Item 30. **Recommendation 1. – EDTA's INS 385,386** for use in Category 14.2.7. We suggest that this provision "to **discontinue** further work" be tabled for 12 months until further issues are resolved.

As supporting reason, there is growing concern regarding the effect of Ascorbic acid (INS. No. 300) on degradation of benzoate (INS No's. 210, 211, 212, 213) in beverage products. Heavy metals such as copper and iron are known to catalyze this reaction. EDTA's are known to mediate or prevent the benzoate degradation and may prove useful in affecting this problem[(1-5)].

1. **Benzene production from decarboxylation of benzoic acid in the presence of ascorbic acid and a transition-metal catalyst.** Gardner, Lalita K.; Lawrence, Glen D. Chem. Dep., Long Island Univ., Brooklyn, NY, USA. Journal of Agricultural and Food Chemistry (1993),

2. **Survey of benzene in foods by using headspace concentration techniques and capillary gas chromatography.** McNeal, Timothy P.; Nyman, Patricia J.; Diachenko, Gregory W.; Hollifield, Henry C. Div. Food Chem. Technol., U.S. Food Drug Adm., Washington, DC, USA. Journal of AOAC International

3. **Benzene formation in beverages.** Chang, Pichiou; Ku, Ken. Natl. Lab. Foods and Drugs, Dep. Health, Taiwan. Yaowu Shipin Fenxi (1993), 1(4), 385-93. CODEN: YSFEEP ISSN: 1021-9498. Journal written in Chinese.

4. **Survey of benzene in foods by using headspace concentration techniques and capillary gas chromatography**. McNeal T P; Nyman P J; Diachenko G W; Hollifield H C U.S. Food and Drug Administration, Division of Food and Chemical Technology, Washington, DC 20204 Journal of AOAC International (1993), 76(6), 1213-9.

5. **Letter Regarding Benzene Levels in Soft Drinks.** Robert E. Bracket, Ph.D. Director. CFSAN/Office of Food Additive Safety (US FDA). March 21, 2006. http://www.cfsan.fda.gov/~dms/benzltr.html