CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

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REVISION OF THE *GUIDELINES FOR THE SIMPLE EVALUATION OF FOOD ADDITIVE INTAKES* (CAC/GL 3-1989)(N08-2013)

Comments of European Union, India, Japan, Kenya and JECFA Secretariat

EUROPEAN UNION

The European Union (EU) would like to thank Brazil for chairing the electronic Working Group and developing the discussion paper.

The EU would like to provide the following comments:

General comments

The principle and scope should be clearly defined in the Guidelines. It should be borne in mind that the Guidelines are aimed at Codex Countries which might have limited food consumption information available and is intended to offer a stepwise guide from simplistic methods (e.g. budget) to TMDI and EDI and then signpost to EHC 240 where methods for more detailed and refined estimates are outlined. It is not intended to describe the usual calculations undertaken by JECFA and upon which entries to the GSFA should be considered.

(1) Exclusion of high consumers from the estimations

The EU recommends that high consumers are included in the revised Guidelines following the same approach as in the original Guidelines CAC/GL 3-1989 – i.e. by assuming that they are the high consumers of one product which contributes most to the exposure (a correction factor of 3 is used to extrapolate the consumption of high consumers from average ones).

(2) Assumptions as regards food consumption

The EU suggests that the Guidelines are adapted to reflect the proposal made by the WHO JECFA Secretariat "*to base the TMDI on broad food categories (e.g. categories 1 to 16 of the CCFA classification) rather than on foodstuff or food group as mentioned in the text"* (see paragraph 15 of CX/FA 13/45/6).

If an ADI is exceeded in this first step then as the second step the calculation using the data on eaters for the main contributors (as outlined on the page 14) could be used.

(3) Assumptions as regards food additive concentration

The EU notes that the mean concentration values are used for the main contributors (page 15). Such approach underestimates the exposure of the consumers who eat product(s) containing higher than the mean concentration of the food additive. The EU proposes that the highest reported/analytical values are used for the main contributors.

Specific comments

Paragraph 6: …Therefore, the present guidelines are intended to facilitate the work of governments, particularly of developing countries, on the assessment of dietary exposure to food additives **using deterministic approaches**.

Rationale: To emphasise that the guidelines are only dealing with deterministic approaches and do not consider more advanced exposure models to refine the assessment.

Paragraph 14: The TMDI is calculated by multiplying the average per capita daily food consumption for ~~each~~ **broad** food **category** by the maximum use level (ML) of the food additive established…

Paragraph 35: Estimates of dietary exposure may be sequentially calculated starting with the simplest TMDI and proceeding to more refined EDI if necessary. If available, data on consumption **of "eaters"** of specific foods should be used. When such data do not exist ~~suitable approximations can be adequate to support a safe use~~. ~~An estimate based upon a highly conservative approach, such as the TMDI, can give adequate assurance of safe use if the estimated exposure dietary is lower than the ADI.~~ **the mean per capita consumption data used in the TMDI should be based on broad food categories (i.e. categories 1 to 16 of the GSFA food category system).** However, if the estimated dietary exposure using this approach exceeds the ADI, a more refined estimate would be necessary. The TMDI can be refined by taking into account food consumption by appropriate population subgroups.

Rationale: ***Inclusion of "eaters"*** *- it should be clarified that if the data on eaters are available they should be used for the calculation since they represent the real consumption of foods in contrast to the mean consumption per capita. The mean consumption data can in certain cases highly underestimate the real consumption of eaters.*

Deletion of "suitable approximations can be adequate to support a safe use" *– the document should provide a clear guidance to its users how to proceed with the simple evaluation of dietary exposure to food additives. It is not clear what is meant by "suitable approximation".*

Inclusion of the text related to the use of broad food categories *– as it is obvious from the calculation on page 13 the use of the mean consumption per capita data for very specific food categories in which the additive is permitted could lead to a significant underestimation of the exposure estimates. Therefore such approach is not suitable to check whether an ADI could be exceeded. Reflecting the proposal made by the WHO JECFA Secretariat the EU recommends that the mean consumption per capita corresponding to the broad GSFA food categories is used as the first step to calculate the TMDI.*

Deletion of the sentence about the TMDI being a highly conservative approach assuring the safe use if the estimate is below the ADI *– the conservativeness of the method is not related only to the method itself but also to the assumptions made and the limitations (e.g. data sources). The EU is of the view that a method which excludes high consumers and intends to use the mean consumption per capita in very specific food categories as a first step cannot be regarded as a highly conservative.*

Paragraph 37, part A.3

A.3.2 When little information is available, the national population-based method (i.e. per capita estimate **corresponding to those broad GSFA categories 1 to 16 in which the additive is permitted**) should be used as a first step;

Rationale: see the comments above

A.3.3 **If the TMDI calculated using the broad GSFA categories and the maximum use levels is higher than the ADI a further refinement is needed. In this regard the data on "eaters" for specific food categories in which the additive is permitted are necessary.**

~~A.3.4 Check whether the average consumption of "eaters" is not much higher than the average consumption of the population. Consumption data for "eaters" should be used when "eaters" consume greater quantities of the food than the total population over long periods;~~

~~A.3.4 Obtain a better estimate of food consumption by replacing average values obtained from the national population-based method by average consumption for "eaters" (see example in the Annex).~~

Rationale: The proposed changes would basically eliminate the situation when only the mean per capita estimates for specific food categories are used for the calculation which as demonstrated on the page 13 could lead to a significant underestimation and incorrect conclusions as regards the safe use of an additive.

Page 13: the EU proposes to remove this page or to combine table 3 with table 4 on the page 14.

Rationale: The calculation of the TMDI based only on the mean consumption per capita of the specific food categories/products in which is the additive permitted (page 13) cannot be used on its own for the exposure estimates since it is not conservative enough (see the comments above). Instead, the EU recommends that on page 13 there is a calculation which would be based on the broad GSFA categories. The current table 3 can be combined with table 4 as a refinement of the TMDI to reflect the approach as described in the section A.3.3.

Page 15: the EU recommends that the actual maximum reported use levels are used in the most representative sources of the additive in the diet

Rationale: There is a discrepancy between the part B.2 (page 11) which refers to the use of actual maximum reported use levels and the example on page 15 which uses the mean reported use level.

The EU recommends that the maximum reported use levels are used to take into account the brand loyalty of the consumers.

Editorial comment

Paragraph 13: …; the use of actual levels of additive in foods obtained **from** the food industry and/or laboratory analysis to refine the concentration of the food additive in food;

INDIA

Paragraph 6: The last sentence should be amended as follows:

'Therefore, the present guidelines are intended to facilitate the work of governments~~, particularly of developing countries,~~ on the assessment of dietary exposure to food additives.'

Rationale: While it is important to take into account the concerns and capacity of developing countries while making decisions in Codex working, the standards developed by it need not be tagged to be of particular importance to a group of its members (except for the Regional standards).

Incorporation of the phrase 'particularly for developing countries' in these guidelines does not provide any additional benefit to developing countries and tends to create confusion as to the true status of the guidelines. On the other hand, the guidelines in the document would be equally useful to all Codex member countries. The guidelines will be complete even without the said phrase.

Paragraph 10: Delete this paragraph.

~~International assessments should provide dietary exposure estimates that are equal to or greater than the estimates carried out at the national level. It is assumed that the international estimate covers potential dietary exposure in countries for which no data were available.~~

Rationale: The guidelines in this document are intended to facilitate national exposure assessments by the governments. Reference to international assessments in this document is misplaced and confusing.

JAPAN

Japan would like to thank Brazil for chairing the electronic working group (eWG) on the revision of the Guidelines for the Simple Evaluation of Food Additive Intake. We are pleased to provide the following comments.

1) General comments

The Guidelines for the Simple Evaluation of Food Additive Intake (CAC/GL 3-1989) were established in 1989. The Codex Alimentarius Commission implemented risk analysis in its work related to food safety in 1993 and adopted *the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* in 2003. The working principles clearly state, "Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve." According to *the Definitions of Risk Analysis Terms Related to Food Safety*, "risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food."

The current guidelines established before 1993 use hazard-based approach but not risk-based approach. Therefore, the CCFA should develop risk-based guidelines in accordance with the working principles.

2) Specific comments

a) The proposal by the chair to ask JECFA to define low ADI.

Japan proposes removing the description about low ADI from the guidelines because it is not appropriate to prioritize food additives only based on ADI, which is based on hazard characterization.

Even if the same ADI has been assigned to two different food additives, it does not mean that these two food additives have the same toxicity because the ADI may be set basing on different toxicity of each additive. For example, if one food additive has an ADI based on reversible diarrhea and the other based on irreversible neurotoxicity, the latter should have priority over the former.

In addition, the level of risk of an additive is determined by comparing its dietary intake and toxicological endpoint such as ADI. Having lower ADI may not mean that the food additive is of higher risk, depending on its dietary intake.

b) The proposal by the chair to maintain the information about high percentiles of food consumption data from the document.

Japan is of the view that the description about dietary exposure estimated by high percentile of food consumption data should be removed from this guideline.

Paragraph 24 of *the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* states, "Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy."

If sub-population groups consume large quantities of particular foods, it is realistic and suitable to use mean consumption data for sub-population groups in estimating the dietary exposure to a food additive. Using high percentile of food consumption data for all populations would result in an unrealistic estimate of dietary exposure to a food additive, in particular, if the food additive is used widely in a variety of foods.

c) The proposal by the chair to maintain the information about "eaters"

Japan proposes revising A.3.3 in section 4.2 as follows (Addition is bold manner.):

> A.3.3 Check whether **(1)** the average consumption of "eaters" is not much higher than the average consumption of the population **and (2) the total food consumption per caput exceeds the realistic maximum consumption (physiological limits of consumption) per caput**. Consumption data for "eaters" should be used when "eaters" consume greater quantities of the food than the total population over long periods **and when the total food consumption per caput does not exceed the realistic maximum consumption per caput**;

Paragraph 24 *of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* states, "Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy."

If the consumption data for "eaters" is used in calculating dietary exposure to a food additive which is used widely in a variety of foods, the total food consumption would become unrealistically large. The chapter 6 of *Principles and Methods for the Risk Assessment of Chemicals in Food – Environmental Health Criteria (EHC) 240* states, "However, in order to effectively screen chemical substances and establish risk assessment priorities, the first steps of the procedure should not consider unsustainable diets, or the results will be too unrealistic to be useful. At a minimum, physiological limits of consumption should be taken into account." Therefore, it is necessary to check whether the total food consumption per caput does not exceed the realistic maximum consumption (physiological limits of consumption) per caput when considering the use of average food consumption of "eaters."

KENYA

In respect to the recommendation in paragraph 16 bullet 2, Kenya proposes that the committee request JECFA for both the definition of the term 'low ADI' as well as provide a list of the additives that have been assigned the low ADIs for ease of interpretation of the term as well as guiding on the additives in this group.

Comments on Annex 1:

General comments

Kenya strongly recommend that as an introduction the guide should emphasis that for any evaluation to be done on any food additive, practical data need to be collected as opposed to using assumption or theoretical measures.

Use of Theoretical Maximum Daily Intake (TMDI)

Kenya has reservation to the use of this model as it has many assumption as outlines paragraph 15 (pg 7) and that it clearly states that it does not take into consideration the special groups and hence its result may have safety issue to some part of the population. If allowed to be used, the recommendations should clearly indicate the limitations of the study and remain provisional until a more refined study is undertaken.

If the committee is agreeable to this proposal, then the example provided in page 13 too should be deleted from the text of the document.

JECFA SECRETARIAT

The JECFA Secretariat would like to thank Brazil for chairing the working group and provide the following comments and suggestions:

1. At its 45th meeting, the Committee recalled the scope of the work on the revision of the Guidelines and clearly stated what the current document was intended to do and not to do. The JECFA secretariat suggests to use the wording of the report of the 45th CCFA in the point 6 of the Introduction of the guidelines which would then read:

6. There are different approaches for estimating the probable daily dietary exposure to food additives. Some of these approaches are very expensive and time consuming and may pose difficulties to some countries in initiating such dietary exposure assessments for food additives. Therefore, the present guidelines are intended to facilitate the work of governments, particularly of developing countries, on the assessment of dietary exposure to food additives *by reflecting current procedures in place to carry out such work in a simple way. The present guidelines are not intended to provide support to CCFA on work on the GSFA as JECFA is the international expert scientific advisory body to provide such advice to the Committee based on the Principles and Methods for The Risk Assessment of Chemicals in Food - Environmental Health Criteria (EHC) 240*

2. The JECFA secretariat noted that the working group proposes criteria for prioritization of evaluation of dietary exposure to additives. The JECFA secretariat also noted the strong support of the working group to "additives with low ADI" as well as "additives authorized for use at a high level" as criteria for prioritization of food additives for the exposure assessment. The JECFA Secretariat would like to stress the fact that these 2 criteria are closely inter-connected by the formula:

$ML * \beta = ADI * 60 * 1000$ or $\beta = ADI * 60 * 1000 / ML$

β can be defined as the "amount of food containing the additive at the highest authorized level which should be consumed to reach the ADI for a 60 kg body weight adult" and seems to be a better criteria for prioritization of food additives for the exposure assessment. To support this view, the table in annex is compiling food additives and their maximum levels extracted from the Codex General Standard for Food Additives (GSFA) Online Database[1]. The ADIs of the same food additives are from the WHO JECFA evaluation summary database[2]. This exercise shows that for the top 10 additives in the table, 6 are assigned with low ADI (arbitrarily assumed as < 5 mg/kg bw) and 4 are authorized at high levels (arbitrarily assumed as above 10,000 mg/kg).

3. The JECFA secretariat also propose for consistency to include "*Additives that have been assigned a numerical ADI when they are used according to GMP*" as a criteria for prioritization of food additives for the exposure assessment.

4. The paragraph 4.1 Criteria for prioritization of evaluation of dietary exposure to food additives should then read: The following criteria may be used to prioritize those food additives for which a dietary exposure assessment is applicable:

(i) Additives *assigned a low ADI and* authorized for use at a high level in foods.

(ii) Additives *consumed in large quantities or by a significant proportion of the population or* consumed by potentially-at-risk subgroups (e.g., children, diabetics, pregnant women, elderly), as appropriate.

(iii) *Additives that have been assigned a numerical ADI when they are used according to GMP*

Table 1

[1] http://www.codexalimentarius.org/standards/gsfa/

[2] http://apps.who.int/food-additives-contaminants-jecfa-database/search.aspx

		Substances	ADI	Maxium Authorized Levels	Amount of food at ML to reach the ADI
			mg/kg bw	mg/kg food	grams of food for 60 kg bw
	78	beta-Carotenes, vegetable (160a(ii))	0.7	20000	2
	143	IRON OXIDES	0.5	7500	4
	200	Polyethylene glycol (1521)	10	70000	9
	69	Canthaxanthin (161g)	0.03	200	9
mtdi 70	197	PHOSPHATES	10	44000	14
	232	Propylene glycol esters of fatty acids (477)	25	100000	15
	95	Cyclodextrin, beta- (459)	5	20000	15
	34	ASCORBYL ESTERS	1.25	5000	15
	82	Castor oil (1503)	0.7	2100	20
	127	Grape skin extract (163(ii))	2.5	5000	30
	239	RIBOFLAVINS	0.5	1000	30
	109	Erythrosine (127)	0.1	200	30
	177	Microcrystalline wax (905c(i))	20	30000	40
	49	Butylated hydroxytoluene (BHT) (321)	0.3	400	45
	98	Diacetyltartaric and fatty acid esters of glycerol (472e)	50	50000	60
	205	POLYSORBATES	25	25000	60
	206	Polyvinyl alcohol (1203)	50	45000	67
	278	Steviol glycosides (960)	4	3500	69
	48	Butylated hydroxyanisole (BHA) (320)	0.5	400	75
	76	Carnauba wax (903)	7	5000	84
	233	Propyl gallate (310)	1.4	1000	84
	280	Sucroglycerides (474)	30	20000	90
	41	BENZOATES	5	3000	100
	128	Guaiac resin (314)	2.5	1500	100
	291	Tertiary butylhydroquinone (TBHQ) (319)	0.7	400	105
ptwi 7	14	Aluminium ammonium sulfate (523)	1	520	115
	179	Mineral oil, medium viscosity (905e)	10	5000	120
	240	SACCHARINS	5	2500	120
	186	Neotame (961)	2	1000	120
	24	Ammonium salts of phosphatidic acid (442)	30	10000	180
	1	Acesulfame potassium (950)	15	5000	180
	279	Sucralose (Trichlorogalactosucrose) (955)	15	5000	180
	294	THIODIPROPIONATES	3	1000	180
	276	Stearyl citrate (484)	50	15000	200
	11	Alitame (956)	1	300	200
	93	CYCLAMATES	11	3000	220
	70	Caramel III - ammonia caramel (150c)	200	50000	240
	73	Caramel IV - sulfite ammonia caramel (150d)	200	50000	240
	35	Aspartame (951)	40	10000	240
	238	Red 2G (128)	0.1	25	240
	267	SORBATES	25	5000	300
	132	Hexamethylene tetramine (239)	0.15	25	360
	293	Thermally oxidized soya bean oil interacted with mono- and diglycerides of fatty acids (479)	30	5000	360
	36	Aspartame-acesulfame salt (962)	15	2000	450
	185	Natamycin (Pimaricin) (235)	0.3	40	450
	301	Triethyl citrate (1505)	20	2500	480
	209	Ponceau 4R (Cochineal red A) (124)	4	500	480
	178	Mineral oil, high viscosity (905d)	20	2000	600
	75	Carmines (120)	5	500	600
	285	Sunset yellow FCF (110)	4	400	600
	140	Indigotine (Indigo carmine) (132)	5	450	667
	199	Polydimethylsiloxane (900a)	1.5	110	818
	236	QUILLAIA EXTRACTS	1	50	1200
	86	CHLOROPHYLLS AND CHLOROPHYLLINS, COPPER COMPLEXES	15	700	1286
	13	Allura red AC (129)	7	300	1400
	45	Brilliant blue FCF (133)	12.5	500	1500
	192	ORTHO-PHENYLPHENOLS	0.4	12	2000
	281	Sucrose acetate isobutyrate (444)	20	500	2400
	114	Fast green FCF (143)	25	600	2500
ptwi 14	271	Stannous chloride (512)	2	25	4800
pmtdi 0.8	115	Ferric ammonium citrate (381)	0.8	10	4800
	126	Glycerol ester of wood rosin (445(iii))	25	150	10000
	187	Nisin (234)	2	12	10000
	31	Annatto extracts, bixin-based (160b(i))	12	20	36000
	145	Isopropyl citrates (384)	14	GMP	Not applicable
	120	Fumaric acid (297)	3	GMP	Not applicable
	220	Potassium hydrogen sulfate (515(ii))	0.7	GMP	Not applicable
	155	Lycopene, Blakeslea trispora (160d(iii))	0.5	GMP	Not applicable
	156	Lycopene, synthetic (160d(i))	0.5	GMP	Not applicable