codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7(b) **CX/FA 10/42/13 Add.1**
February 2010

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-second Session

Beijing, China, 15-19 March 2010

COMMENTS ON DISCUSSION PAPER ON PRINCIPLES REGARDING THE NEED FOR JUSTIFICATION FOR PROPOSAL FOR CHANGES TO THE INS (CAC/GL 36-1989, REVISION 2008)

The following comments have been received from the following Codex members and observers:

Brazil, Cuba, India and Iran

BRAZIL

Appendix I

PROPOSED DRAFT PRINCIPLES REGARDING PROPOSALS FOR CHANGES TO THE INS

Brazil would like to make the following comments regarding to item 3 – **New or additional technological purposes**:

Bullet 1: according to information provided by the JECFA Secretariat in previous CCFA meetings, the functional classes contained in the food additive specification monographs are usually informed by the sponsors and not necessarily assessed by the Committee. Additionally, for a number of food additives the listed functional uses do not correspond to those included in the INS list.

Bullet 2: In general, national authorities that use Codex Standards as reference to approve food additives do not authorize functions that are not yet included in the JECFA specifications and/or GSFA. Also, many national regulations are older than these Codex/JECFA documents.

Bullet 4: The use of a food additive by industries should not be used as a criterion, but as additional information only.

Brazil considers that the use of one of these items individually can not demonstrate the new technological effect. Thus, we suggest that only bullet 3 be applied as a criterion to approve technological purposes: "evidence that the ~~additive~~ **compound** has been, or is capable of being, used effectively for the technological purpose proposed". The other proposed justifications could be used as additional information.

Regards to item 4 – **Modification of an existing INS name or INS number of an additive from the INS list**, Brazil agrees with the justifications proposed. However, we ask clarification and examples for the item: "the name in the INS list is unsuitable for labeling purposes".

Appendix II

DRAFT FORMAT FOR THE SUBMISSION OF INS CHANGES

Taking into account the comments above, Brazil suggests some changes to the "Justification for the requested INS change in Section 3: new or additional purpose":

Evidence presented on the requested INS change in Section 3: new or additional purpose (please annex documents and/or text to demonstrate the selected items)

□ **Experimental data**

□ **Interaction mode of the substance with the food**

□ **Literature references**

□ **Other: _____**

Additional information presented:

□ **JECFA specification monograph**

□ **National authority permission**

□ **Use by industry**

□ **Other: _____**

CUBA

Cuba agrees with the proposed FORMAT DRAFT FOR THE PRESENTATION OF CHANGES TO THE INS and merely points out that sheet 3 of this document should be checked where in point 4 "Modificación del nombre o número de un aditivo como figura en la lista del SIN" *[= modification of the name or number of an additive as shown in the INS]*, there is a typing error in the last line of this paragraph, where it says "hombres" it should say "nombres" instead.

INDIA

The proposed draft principles regarding proposals for changes to the INS are acceptable.

IRAN

Justification for the requested INS change in Section 3: deletion of additive X Health risk issues, such as a JECFA withdrawal of an acceptable daily intake (ADI) based on new toxicological data- Tartarzine-Saccharin.....,etc.

NO Evidence that the additive is not commercially manufactured or used . No Evidence that the additive cannot be considered to fall under the definition of a food additive

Other:

Text: Iranian CODEX deletes the items above based on conclusive evidence that these additives cause health hazards based on excessive consumption of products containing these referred additives by children, that is, passing the ADI, therefore, it demands very tight control by MOH authority. We will review these products every year in case of new clinical evidence which proves that these additives are not health hazards to certain group age and public health.