codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 9(b) **CX/FA 09/41/12 Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-first Session

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PROPOSALS FOR ADDITIONS AND CHANGES TO THE TEXT OF THE CIRCULAR LETTER ON PRIORITY LIST OF FOOD ADDITIVE PROPOSED FOR EVALUATION BY JECFA (REPLIES TO CL 2008/26-FA)

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

India, United States of America and CIAA

INDIA

The point 8 of the "form on which information on the additive to be evaluated by JECFA is provided" mentions that,

"Has the compound been approved for use in two or more countries?"

This requirement is not there in the Codex Procedural Manual – Risk Analysis Principle applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Food in para 20.

We believe that in a lot of countries JECFA evaluation is the basis for authorities to base their risk assessment as well as further approve or deliver an authorization for use of that additive. Hence making a minimum of two country approvals necessary before JECFA evaluation of the compound does not seem to be appropriate and achievable.

Therefore we do not support inclusion of point 8 as criteria of prioritisation and hence should be deleted as mandatory criteria.

However, we believe that this information on the evaluation status of the compound in other countries is important information and can be kept as an optional remark or general additional information at the end of the form.

UNITED STATES OF AMERICA

The USA suggests revising the current language for Item 8 of Annex 2 of CL 2008/26-FA. Annex 2 contains a list of 10 information items that should be provided to CCFA and JECFA on the additive proposed for evaluation. Item 8 currently reads as follows:

8. Has the compound been approved for use in 2 or more countries (please identify the countries)?

We believe that this question should be revised in order to focus on establishing that the additive is currently in international trade rather than whether the additive has been formally approved for use in more than one country. Requiring that an additive must be "approved" in two separate countries does not adequately cover all instances in which the food additive is used in foods traded internationally. It may be the case that a substance considered a food additive within the context of the Codex definition of a food additive does not require formal approval by a national regulatory authority in order for foods containing the substance to be lawfully sold. Moreover, requiring that two countries must have "approved" the use of a food additive also limits Codex's ability to quickly establish safe conditions of use for new additives and thus inhibits product innovation and may unintentionally be an artificial barrier to trade. As such, we believe that Item 8 should be revised as follows:

8. Is the compound currently added to foods in international trade? (Please specify)

CIAA (Confederation of the Food and Drink manufacturing industries of the EU)

CIAA, the Confederation of the Food and Drink manufacturing industries of the EU, appreciates the opportunity to respond to the "Request for information and comments on: (i) Priority List of Food Additives Proposed for Evaluation by JECFA; and (ii) Text of the Circular Letter on Priority List of Food Additives Proposed for Evaluation by JECFA" (CL 2008/26-FA) and would like to offer the following comments

The 40th CCFA Committee noted that the in-session Working Group on Priorities did not have enough time to consider the proposal by the Delegation of the USA to modify point 8 regarding "Form on which information on the additive to be evaluated by JECFA is provided" (requesting whether a compound has been approved for use in two or more countries). Therefore, the Committee agreed to request comments on the text of the Circular Letter, in particular on point 8 of the form, together with the request for comments, and additions to the priority list. Replies would be considered by the in-session Working Group to be established by the 41st Session of the CCFA (ALINORM 08/31/12, para. 172).

In Annex 2 "Form on which information on the additive to be evaluated by JECFA is provided", point 8 queries: **"***Has the compound been approved for use in 2 or more countries?"*

In several countries in which the submission of a substantiation dossier is mandatory for delivering an authorization, **JECFA evaluation is used as basis by the authorities**.

In our opinion the request of a minimum of two authorizations to submit a substance for JECFA evaluation should not be maintained. We propose that point 8 is withdrawn. Nevertheless, as we consider that this would provide valuable information, we propose to keep this point only as an optional remark or general information at the end of the form.