

ANNEX A

GUIDELINES FOR THE DEVELOPMENT OF MAXIMUM LEVELS FOR THE USE OF FOOD ADDITIVES WITH NUMERICAL ACCEPTABLE DAILY INTAKES

This annex is intended as a guidance to screen proposals for use of additives based on consideration of their maximum use level and the physiological upper limit to the amount of food and drink that can be consumed each day. The Annex is not intended for allocating provisions for the use of an additive and cannot be used for calculating accurate additive intakes.

I. FOOD ADDITIVES - BASIC PRINCIPLES FOR CALCULATION OF USE LEVELS**Guideline 1**

The levels and quantities of food additives used in the Budget Method calculations should be expressed on the same basis as the substances on which the ADI was allocated (e.g. an acid or its salts). For foods sold as concentrates or powders intended for reconstitution before consumption, the Budget calculation on the food additive use levels should be performed on the ready-to-eat product.

II. ESTIMATION OF THE SAFETY ASPECTS OF USE LEVELS - FOOD ADDITIVES WITH NO NUMERICAL ADI**Guideline 2*****Food Additives with an ADI of "Not Specified"***

When an additive has been allocated an ADI "not specified"¹² it could in principle, be allowed for use in foods in general with no limitation other than in accordance with Good Manufacturing Practices (GMP). It should, however, be born in mind that ADI not specified does not mean that unlimited intake is acceptable. The term is used by JECFA in case where "on the basis of the available data (chemical, biochemical, toxicological, and other) the total daily intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food does not, in the opinion of the Committee, represent a hazard to health"¹

If, therefore, a substance is used in larger amounts and/or in a wider range of foods than originally envisaged by JECFA it may be necessary to consult JECFA to ensure that the new uses fall within the evaluation. For example a substance may have been evaluated as a humectant without including a later use as a bulk sweetener, which could give considerable higher intake.

Guideline 3***Food Additives Evaluated as "Acceptable" for Certain Purposes***

In some cases, JECFA has been unable to allocate an ADI but nevertheless found a specific use of a substance acceptable. In such cases, the additive in question should only be authorized in accordance with the conditions specified. In case of any other reported uses CCFA should request JECFA to re-evaluate the additive in question in light of the new information on uses.

III. ESTIMATION OF THE SAFETY ASPECTS OF USE LEVELS - FOOD ADDITIVES WITH NUMERICAL ADI**Guideline 4*****Fractions of the ADI to be used for Solid Food and Beverages, Respectively***

If an additive is proposed for use in both solid food and in beverages the full ADI cannot be used for both for uses in solid food and uses in beverages. It is therefore necessary to allocate a fraction of the ADI to each of the applications. As a first approach, it may be appropriate to assume that one-half of the ADI is allocated to each solid and liquid foods. However, in special cases other fractions may be more appropriate as long as the sum of the fractions does not exceed the figure for the ADI (e.g. FS=1/4 and FB=3/4 ; FS=1/6 and FB=5/6), where **FS** is the fraction for use in solid food and **FB** is the fraction for use in beverages). If the additive is used only in solid food, then FS =1 and FB=0 and if the additive is used only in beverages, then FS=0 and FB=1.

¹² *Principles for the Safety Assessment of Food Additives and Contaminants in Food*. Geneva, World Health Organization, 1987 (Environmental Health Criteria, No. 70), p.83.

III(a) FOOD ADDITIVE USES IN SOLID FOOD (FS)**Guideline 5*****Use Levels Below FS x ADI x 40***

If the proposed use levels are below FS x ADI x 40, these food additive provisions could be suitable in food in general.

Guideline 6***Use Levels Below FS x ADI x 80***

If the proposed use levels are below FS x ADI x 80 they are acceptable provided the daily consumption of the foods containing the additive will usually not exceed half of the assumed maximum total solid food intake (i.e. 12.5 g/kg bw/day).

Guideline 7***Use Levels Below FS x ADI x 160***

If the proposed use levels are below FS x ADI x 160 they are acceptable provided the daily consumption of the foods containing the additive will usually not exceed one fourth of the assumed maximum total solid food intake (i.e. 6.25 g/kg bw/day).

Guideline 8***Use Levels Below FS x ADI x 320***

If the proposed use levels are below FS x ADI x 320 they could be accepted provided the daily consumption of the foods containing the additive will usually not exceed one eighth of the assumed maximum total food intake (i.e. 3.13 g/kg bw/day).

Guideline 9***Use Levels Above FS x ADI x 320***

If the proposed levels are higher than FS x ADI x 320 they should only be accepted for products where calculation of potential intake from all proposed uses will show that exceeding the ADI is unlikely, or if estimation of the intake of the additive based on more exact intake estimates methods show that the use levels are acceptable (e.g. food consumption surveys).

III(b) FOOD ADDITIVE USES IN BEVERAGES (FL)**Guideline 10*****Use Levels Below FL x ADI x 10***

If the proposed levels are below FL x ADI x 10, the additive could be accepted for use in all beverages in general.

Guideline 11***Use Levels Below FL x ADI x 20***

If the proposed use levels are below FL x ADI x 20 they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed half of the assumed maximum total intake of beverage (i.e. 50 ml/kg bw/day).

Guideline 12***Use Levels Below FS x ADI x 40***

If the proposed use levels are below FL x ADI x 40 they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed a fourth of the assumed maximum total intake of beverage (i.e. 25 ml/kg bw/day).

Guideline 13***Use Levels Below FL x ADI x 80***

If the proposed use levels are below FL x ADI x 80 they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed an eighth of the assumed maximum total intake of beverage (i.e. 12.5 ml/kg bw/day).

Guideline 14***Use Levels Above FL x ADI x 80***

Levels above FL x ADI x 80 should only be accepted for products where calculation of potential intake will show that exceeding the ADI is unlikely (e.g. strong alcoholic beverages).