The EU would like to thank the United States for the co-chairing of this work as well as all members of the EWG for their contributions to the discussion paper on the development of wording for an alternative to Note 161 relating to the use of sweeteners (CX/FA 19/51/10).

The European Union (EU) would like to submit the following comments.

**Recommendation 1**

The EU supports, as a general approach, the replacement of Note 161 by the proposed alternative Notes A and B in food categories contained in Lists T, U and Y in CX/FA 15/47/13.

The alternative notes capture the EU's approach on the use of sweeteners. In the EU, use of sweeteners is considered as technologically justified and having an advantage only if it is used for replacing sugars for the production of energy-reduced food, non-cariogenic food or food with no added sugars; or replacing sugars where this permits an increase in the shelf-life of the food; or producing food intended for particular nutritional uses.

As regards use of substances as flavour enhancers the EU establishes specific lower levels for certain uses in certain food categories. In cases where there is no specific lower level laid down, substances can be used as flavour enhancers at appropriate lower levels, but the applicable restrictions (e.g. only energy-reduced or with no added sugar) for those provisions primarily authorised for sweetening have to be respected.

**Recommendation 2**

The EU has the following additional comments on the adopted provisions:

**Alitame (INS 956)**

This sweetener is not currently authorised for use in the EU. Considering the low ADI established for this sweetener by JECFA of 0–1 mg/kg bw allocated by the Committee at its forty-sixth meeting (1999) and retained at subsequent meetings (2002) the levels and range of categories should be examined closely. In relation to the dietary intake of this additive, JECFA in their report of 2002 stated, inter alia, the following:

"No data on the dietary intake of alitame were available at the previous meetings of the Committee. At its present meeting, the Committee compared the maximum levels of alitame listed in the Codex draft with the theoretical maximum level calculated by the budget method. On the assumption that alitame is used in all foods, the theoretical maximum level of alitame, based on the current ADI, was calculated to be 40 mg/kg. The maximum levels in the GSFA are up to 300 mg/kg in a wide range of foods and beverages, with no limit

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1 [https://apps.who.int/iris/bitstream/handle/10665/42601/WHO_TRS_913.pdf;jsessionid=B949B006D4466AE8CD65D0E528E879D4?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/42601/WHO_TRS_913.pdf;jsessionid=B949B006D4466AE8CD65D0E528E879D4?sequence=1)
in 'other sugars and syrups' or in table-top sweeteners. Detailed assessments of the intake of alitame when used in foods were therefore required."

It should be pointed out that national assessments were provided showing exceedance of the ADI at the 95th percentile (148% or 140% respectively). JECFA noted that those estimates are based on data from only two countries and that further work is required to refine the intake estimates with recent data from other countries.

Taking into account the JECFA's assessment the EU is of the view that the provisions for alitame should be removed from the GSFA or a detailed exposure assessment should be carried out by JECFA that the Committee can determine appropriate MLs to ensure that the intake of alitame from all its uses does not exceed its ADI.

Saccharins (INS954(i)-(iv))

The EU would like to express its concern on the maximum use levels for saccharins in food categories 14.1.4.1, 14.1.4.2 and 14.1.4.3 (300 mg/kg). According to the GSFA Guidelines for the development of the MLs (i.e. Annex A to the GSFA) and by using the scenario 10 (the additive could be accepted for use in all beverages) the GSFA ML shall be below 25 mg/kg. Even according to Guideline 14 (i.e. 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. in strong alcoholic beverages) the calculated ML is 200 mg/kg.

The EU suggests 80 mg/kg as the appropriate and safe ML. To the EU's knowledge such ML is sufficient to address the technological need taking into account the common practice of using combinations of sweeteners. In addition, such ML would be aligned with the ML in category 01.1.4 'Flavoured fluid milk drinks'.

Acesulfame potassium (INS 950)

The EU would like to express its concern on the maximum use levels for acesulfame potassium in in food categories 14.1.4 and 14.1.5 (600 mg/kg). According to the GSFA Guidelines for the development of the MLs and by using the Guideline 10 the GSFA ML shall be below 75 mg/kg. The level calculated by Guidelines 13 and 14 equals the GSFA ML of 600 mg/kg. However, such ML is acceptable only for limited daily consumption only (not exceeding an eight of the assumed maximum total intake of beverage).

The EU suggests 350 mg/kg as the appropriate and safe ML. To the EU's knowledge such ML is sufficient to address the technological need. In addition, such ML would be aligned with the ML in category 01.1.4 'Flavoured fluid milk drinks'.

Category 07.1 'Bread and ordinary bakery wares and mixes'

The EU does not support the use of sweeteners in this food category. In the EU's view sweeteners are not technologically justified for use in bread and ordinary baker wares. In addition, the EU expresses potential exposure concerns from the use of sweeteners in such a staple food which might very significantly increase the overall exposure.

For the above reasons the EU suggests revoking the provisions for sweeteners in the category 07.1

Categories 12.2.2 'Seasonings and condiments' and 12.3 'Vinegars'

The EU does not support the use of sweeteners in category 12.2.2 and 12.3. In the EU's view the use of sweeteners in those food categories is not technologically justified and could mislead the consumer. For the above reasons the EU suggests revoking the provisions for sweeteners in the category 07.1.

Recommendation 3

The EU supports this Recommendation.

Recommendation 4

The EU supports this Recommendation.

Recommendation 5

The EU supports reconvening the EWG to continue working on the provisions in Lists V, W, X and Z.