



EUROPEAN  
COMMISSION

Brussels, **XXX**  
PLAN/2022/2332 ANNEX CIS  
(POOL/E2/2022/2332/2332-EN  
ANNEX CIS.docx)  
**[...]**(2023) **XXX** draft

ANNEX

## **ANNEXES**

**to the**

### **COMMISSION RECOMENDATION**

**on the methodology for the monitoring of food additive and food flavouring intake**

## **ANNEX**

### *Risk-based categorisation and prioritisation of food additives and food flavourings for monitoring*

#### **PART A: Food additive categorisation**

Food additives should be categorised into three groups:

- 1. Group 1: Food additives with an ‘acceptable daily intake not specified’ or for which the Authority or the Scientific Committee on Food has concluded in the most recent risk assessment that ‘there is no need for a numerical acceptable daily intake’**
  - 1a. food additives with no particular concern;
  - 1b. food additives which need to be kept under closer surveillance due to the presence of impurities or due to another reason.
- 2. Group 2: Food additives for which the Authority or the Scientific Committee on Food has set in the most recent risk assessment numerical acceptable daily intakes**
  - 2a. Food additives with no safety concern identified in the most recent risk assessment on the basis of maximum permitted levels or food additives for which the Authority calculated in the most recent risk assessment refined intake estimates not exceeding 50% of the acceptable daily intake for any of the age groups.
  - 2b. Food additives for which the Authority calculated in the most recent risk assessment refined intake estimates exceeding 50% of the acceptable daily intake for at least one age group.
  - 2c. Food additives not included in points 2a or 2b which need to be kept under closer surveillance due to the presence of impurities or due to another reason.
- 3. Group 3: Food additives for which the Authority concluded that there would be no safety concern despite missing data to establish a numerical acceptable daily intake**
  - 3a. Food additives for which the Authority indicated that there would be no safety concern at the reported uses and use levels despite missing data to establish a numerical acceptable daily intake and which do not need to be kept under closer surveillance.
  - 3b. Food additives for which the Authority indicated that there would be no safety concern at the reported uses and use levels despite missing data to establish a numerical acceptable daily intake but need to be kept under closer surveillance due to the presence of impurities or due to another reason.

#### **PART B: Food additive prioritisation**

Food additives should be classified into three levels of priority:

- 1. High priority**

Food additives from Group 2b for which there are indications that the dietary intake as assessed in the most recent risk assessment is outdated or underestimated.

## **2. Medium priority**

2.1 Food additives from Group 2b not covered under high priority.

2.2 Food additives from Group 2a for which there are indications that the dietary intake as assessed in the most recent risk assessment is outdated or underestimated.

2.3 Food additives from Group 3a for which there are indications that the dietary intake as assessed in the most recent risk assessment is outdated or underestimated.

2.4 Food additives from Group 2c

2.5 Food additives from Group 3b

2.6 Food additives from Group 1b

## **3. Low priority**

3.1 Food additives from Group 1a

3.2 Food additives from Group 2a not covered under medium priority

3.3 Food additives from Group 3a not covered under medium priority

## **PART C: Food flavouring categorisation**

Food flavourings should be categorised into five groups:

Group 1: Undesirable substances included in Annex III to Regulation (EC) No 1334/2008 of the European Parliament and of the Council<sup>1</sup>.

Group 2: Smoke flavourings as authorised by Commission Implementing Regulation (EU) No 1321/2013<sup>2</sup>.

Group 34: Food flavourings authorised for use with or without restrictions in accordance with Annex I to Regulation (EC) No 1334/2008 and for which the modified theoretical added maximum daily intake (mTAMDI) as calculated by the Authority in the most recent risk assessment exceeds the threshold of toxicological concern<sup>3</sup> value established by the Authority.

Group 45: Food flavourings and food ingredients with flavouring properties not covered by groups 1 to 4.

## **PART D: Food flavouring prioritisation**

---

<sup>1</sup> Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

<sup>2</sup> Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings (OJ L 333, 12.12.2013, p. 54).

<sup>3</sup> Threshold of toxicological concern values have been established for substances of similar chemical structure and likelihood of toxicity, based on extensive published toxicological data. There are three broad categories of low, moderate or high toxicity (EFSA Journal 2019;17(6):5708).

Food flavourings should be classified into three levels of priority

**1. High priority**

1.1 Food flavourings belonging to group 3 for which all the following conditions are met:

- (a) a reference point has been identified and intake assessment is available;
- (b) there are indications that the dietary intake as assessed in the most recent risk assessment is outdated or underestimated;
- (c) a doubling of the intake would pose a health concern.

1.2 Undesirable substances belonging to group 1.

1.3 Food flavourings which might also be present in flavouring preparations, and which have been removed from the union list of flavouring substances due to safety concerns.

**2. Medium priority**

2.1 Food flavourings belonging to group 3 for which mTAMDI as calculated in the most recent risk assessment exceeds the threshold of toxicological concern value and for which no reference point has been identified. Within this group, substances that exceed the threshold of toxicological concern value more should be taken first.

2.2 Substances belonging to group 2 (smoke flavourings).

**3. Low priority**

3.1 Food flavourings belonging to group 3 not covered under the high or medium priority.

3.2 Flavourings and food ingredients with flavouring properties belonging to group 4 not covered by the high priority group.