EUROPEAN
COMMISSION

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

COMMISSION RECOMMENDATION

of XXX

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

COMMISSION RECOMMENDATION

of XXX

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

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

(1) Regulation (EC) No 1333/2008 of the European Parliament and of the Council[1] lays down the provisions for monitoring food additive intake. In accordance with Article 27 of that Regulation, Member States are to maintain systems to monitor the consumption and use of food additives listed in Annex II, Part B to that Regulation (EC) No 1333/2008 following a risk-based approach and to report their findings with appropriate frequency to the Commission and the European Food Safety Authority ('the Authority'). To this end, the Commission was to adopt a common methodology for the gathering of information by the Member States on dietary intake of food additives in the Union.

(2) Regulation (EC) No 1334/2008 of the European Parliament and of the Council[2] lays down the provisions for monitoring food flavourings intake. In accordance with Article 20 of that Regulation, Member States are to establish systems to monitor, by using a risk-based approach, the consumption and use of flavourings set out in the Union list and the consumption of the substances listed in Annex III to that Regulation (EC) No 1334/2008, and to report their findings with appropriate frequency to the Commission and to the Authority. To this end, the Commission was to adopt a common methodology for the gathering of information by the Member States on dietary intake of food flavouring in the Union.

(3) While a common methodology is necessary to ensure that the intake of food additives and flavourings calculated by different Member States may be compared and that the collected data may be used to calculate the intake at Union level, the elaboration of that common methodology is hampered by the limited availability of methods of analysis, analytical standards and the lack of information on the use of food flavourings.

(4) However, on 23 June 2010[3] and 23 December 2022[4], the Authority provided guidance for estimating the dietary intake of food flavourings. For food additives, the Authority

---

1 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

2 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).

3 EFSA Journal 2010; 8(6):1623.

4 EFSA Journal 2022;20(12):7673.

provided on 18 July 2012 guidance on estimating dietary intake[5] and launched at the same time an exposure assessment tool for food additives namely the Food Additive Intake Model (FAIM). On 17 October 2017, the Authority published a statement on the approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation[6]. On the basis of that guidance and in order to gain experience, tackle some of the difficulties encountered and facilitate the adoption of a common methodology in the future, the Commission recommends Member States to apply the methodology provided in this Recommendation.

(5) Considering the high number of food additives and food flavourings that may be present in different foodstuffs on the market and consequently the high number of potential combinations of food additives and food flavourings with food categories, it is appropriate that Member States categorise and prioritise food additives and food flavourings based on the risk associated to them. In order to ensure an objective prioritisation, the risk should be assessed mainly on the basis of the outcome of the most recent risk assessment by the Authority or the Scientific Committee on Food, of other indications that a food additive or food flavouring needs to be kept under closer surveillance, such as the presence of impurities in case of food additives, or of indications that the dietary intake used for the safety assessment is outdated or underestimated. However, Member States should not categorise and prioritise food flavourings for which the Commission intends to request information from producers and users and those for which monitoring does not appear necessary based on the outcome of the last assessment made by the Authority. Furthermore, in order to ensure flexibility, Member States may adjust the priorities by taking other factors into account.

(6) In order to ensure the information is available among the Member States, the Commission and the Authority, Member States should reflect the outcome of the prioritisation carried out in a multi-annual monitoring plan and keep it updated.

(7) Since the collected data should allow for the calculation of the food additive and food flavouring intake, the collection of presence data only is not sufficient and Member States should collect at least one type of occurrence data. However, presence data may also be collected since they allow to identify whether a food additive or food flavouring is used or not used in a particular foodstuff.

(8) In order to ensure that the collected data is representative for the use of the food additive or food flavouring in foods on the market within the Member State and for estimating the intake of those food additives and food flavourings, Member States should decide on the foodstuffs where the presence or occurrence of food additives and food flavourings is to be monitored in accordance with criteria that take into account the relative contribution of foods or brands to the dietary intake. Furthermore, since certain substances, such as ascorbic acid, can occur in food due to natural presence, due to their addition as a nutrient source, or due to their addition as a food additive or food flavouring, Member States should also take into account foods that contribute to the dietary intake of a substance from sources other than its use as food additive or food flavouring, in order to allow for the calculation of the dietary intake from sources other than food additive or food flavouring use and for the calculation of the overall exposure to the concerned substance.

---

5 EFSA Journal 2012;10(7):2760.

6 EFSA Journal 2017;15(10):5042.

(9) To obtain a more complete view of the situation, Member States may complement monitoring data with data originating from official control tasks in accordance with Regulation (EU) No 2017/625 of the European Parliament and of the Council[7] that are representative for the use of food additives or food flavourings in food available on the market.

(10) In order to obtain reliable results, Member States should use methods of analysis referred to in Article 34 of Regulation (EU) No 2017/625, which contains a list of methods used for laboratory analyses.

(11) Given the diversity of food additives and flavourings, of the foods in which they are used and of their conditions of use, experience and knowledge gained by Member States may only be compared and assessed if they have been obtained on the same food additives and flavourings. Therefore, Member States should not only proceed to the prioritisation of food additives and flavourings and inform the other Member States, the Commission and the Authority, but, as a first stage, they should also agree to monitor at least a common, limited, list of foods additives and flavourings,

RECOMMENDS:

(1) For the purposes of this Recommendation the following definitions apply:

(a) 'monitoring of food additive and food flavouring intake' means the collection of data on the presence and occurrence of food additives and food flavourings in food in order to assess the national dietary intake of food additives and food flavourings and verify the occurrence data used and the dietary intake estimated at the time of the most recent exposure assessment by the Authority or the Scientific Committee on Food;

(b) 'presence data' means the presence or the absence of a specific food additive or food flavouring in a foodstuff;

(c) 'occurrence data' means the concentration (expressed as mg/l or mg/kg of food, as appropriate) of the food additive or food flavouring in a foodstuff, which includes actual use levels and analytical data;

(d) 'actual use levels' means the concentration of the food additive or food flavouring reported by business operators to be added to food;

(e) 'analytical data' means the concentration of the food additive or food flavouring measured in the food;

(f) 'the reference point' means the dose derived from experimental data that is used in risk assessment to establish a safe level (e.g an acceptable daily intake) or to explore safety

[7] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC ('Official Controls Regulation') (OJ L 95, 7.4.2017, p. 1).

concerns by calculating the margin of exposure in case it is not appropriate to establish a safe level or the available data do not allow to establish a safe level;

(g) 'the acceptable daily intake' is the estimated maximum amount of an agent, expressed on a body mass basis, to which individuals in a (sub)population may be exposed daily over their lifetimes without appreciable health risk[8].

(2) Member States should categorise food additives and food flavourings in accordance with, respectively, Parts A and C of the Annex. However, food additives that are under re-evaluation or for which the follow-up to the re-evaluation is on-going should not be subject to monitoring.

(3) Member States should allocate a priority to each food additive and food flavouring, in accordance with Parts B and D of the Annex.

Member States may take other legitimate factors into account, such as the dual use as food additive and food flavouring, the availability of analytical methods and standards, public concern, a particular high or low use of a specific food additive or food flavouring in their territory, frequent consumption by specific population groups, or the lack of information on the foods in which a flavour might have been used.

(4) Member States should by 30 September 2025:

(a) categorise and prioritise food additives;

(b) categorise and prioritise:

(i) food flavourings belonging to group 1, 2 and 5, as defined in Part C of the Annex;

(ii) the substances from group 4, as defined in Part C of the Annex, for which a reference point has been identified and an intake assessment is available.

From 2026, Member States should update the categorisation and prioritisation on a yearly basis, taking the outcome from the monitoring of the previous year and new risk assessments published by the Authority into account.

(5) Member States should prepare a multi-annual monitoring plan reflecting the outcome of the prioritisation. This multi-annual monitoring plan should cover at least three years and should list the food additives and food flavourings to be monitored each year. It should be updated on a yearly basis, taking the updated categorisation and prioritisation into account.

(6) Member States should collect at least one of the following types of data:

(a) actual use levels at national level, in the case of food additives;

(b) analytical data.

Member States may also collect presence data.

(7) Member States should decide on the foodstuffs where the occurrence of a food additive or food flavouring is to be monitored taking into account the following aspects:

[8] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760. [53 pp.] doi:10.2903/j.efsa.2012.2760.

(a) the food categories in which the presence of a food additive or food flavouring can be expected;

(b) the food categories assumed to be significant contributors to the food additive and food flavouring intake for the whole population or specific age groups;

(c) the main brands consumed;

(d) foods that can contribute to dietary intake from sources other than food additive or food flavouring use.

(8) Member States can complement monitoring data with data originating from official control tasks in accordance with Regulation (EU) No 2017/625, if the latter are representative for the use of food additives or food flavouring in food available on the market. When using data originating from official control tasks, Member States should only use data from the planned control programme, and should not use data from follow-up incidents.

(9) Member States should carry out the monitoring activities for food additives and food flavourings with appropriate methods of analysis that have been proven to generate reliable results. Methods used for laboratory analyses should comply with Article 34 of Regulation (EU) No 2017/625. As a minimum requirement for the monitoring of food additive and food flavouring intake, Member States should consider the use of a method validated with an inter- or intra-laboratory method validation study in accordance with internationally accepted scientific protocols.

(10) Where it is not possible to analyse the food flavouring in the final food Member States should analyse formulations, preparations or intermediate products. However, Member States should calculate the corresponding concentration of the food flavouring in the final food in order to allow for the calculation of the dietary intake of the food flavouring.

(11) Member States should provide the collected data to the Authority on a yearly basis, together with the information specified by the Authority and in the electronic format as set out by the Authority.

Member States should report to the Authority and the Commission on a yearly basis:

(a) the outcome of the prioritisation;

(b) the multi-annual monitoring plan;

(c) the applied methodology, in particular, where relevant, how the actual use levels and presence data were obtained and whether data originating from official control tasks were used to complement the monitoring data;

(d) whether non-authorised uses were identified.

(12) Member States should organise a pilot phase and to this end:

(a) propose to the other Member States and the Commission by April 2023 a list of five food additives and five food flavourings;

(b) agree on a list of five food additives and five food flavourings;

(c) collect data during the year 2024 for three of the food additives and two of the food flavourings included in the agreed list and report the data collected by 30 June 2025 to the Authority;

(d) collect data during the year 2025 for two of the food additives and three of the food flavourings included in the agreed list and report the data collected by June 2026 to the Authority.

Done at Brussels,

For the Commission
Stella Kyriakides
Member of the Commission