SANTE PLAN 2023 2726 Rev.6

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

amending Regulation (EC) No 333/2007 as regards the methods of sampling and analysis for the control of levels of mineral oil hydrocarbons in foodstuffs.

ANNEX

The Annex to Regulation (EC) No 333/2007 is amended as follows:

(1) Point B.1.3. is replaced by the following:

'B.1.3. **Precautions to be taken**

In the course of sampling, precautions shall be taken to avoid any changes which would affect the levels of contaminants, adversely affect the analytical determination or make the aggregate samples unrepresentative.

For the sampling for analyses of mineral oil hydrocarbons in food the following specific precautions shall be taken:

Materials used during sampling, sample storage and sample transmission shall be free of mineral oil residues and shall not release interfering substances. The sample shall be handled in order to prevent cross-contamination.'

(2) Point B.1.7. is replaced by the following:

'B.1.7. **Packaging and transmission of samples**.

Each sample shall be placed in a clean, inert container offering adequate protection from contamination, from loss of analytes by adsorption to the internal wall of the container and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the sample which might arise during transportation or storage.

In case of sampling for PAH analysis, plastic containers shall be avoided if possible as they could alter the PAH content of the sample. Inert, PAH-free glass containers, adequately protecting the sample from light, shall be used wherever possible. Where this is practically

impossible, at least direct contact of the sample with plastics shall be avoided, e.g. in case of solid samples by wrapping the sample in aluminium foil before placing it in the sampling container.

In case of sampling for the analysis of mineral oil hydrocarbons:

-After collecting samples, the sample container should be closed with a polytetrafluoroethylene (PTFE)-layered lid or a glass stopper. Otherwise, the sample container must be covered first with aluminium foil before sealing with a cap or stopper. No rubber rings should be used to close the container.

-Pre-packaged food or food contact materials should be wrapped in aluminium foil at the point of sampling and kept wrapped until analysis in order to prevent cross-contamination. Any pre-packaged food sample brought into the laboratory without aluminium foil wrapping should be properly documented. All contamination of the sample, e.g., by the use of tape or adhesives (paper/plastic labels) or contact with paper or paperboard, should be prevented. However, the sample must remain properly identifiable, e.g., by using a permanent marker.

- Sample containers and aluminium foil, if used, should be checked for mineral oil hydrocarbons contamination.

Furthermore the more detailed precautions for sampling for the analysis of mineral oil hydrocarbons as included in the JRC Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials (**) shall be followed or, in case other procedures are followed, equal performance of those procedures shall be ensured

(3) After point B.2.5 the following is added:

‘**B.2.6 Specific provisions for very large lots of cocoa beans**

For the sampling of very large lots of cocoa beans stored or transported in a way whereby sampling throughout the lot is not feasible, the provisions of section N of Annex I of Regulation (EU) 2023/2782 (*) on the sampling of mycotoxins may be applied, however for the rest the provisions of this Regulation remain applicable for the sampling of cocoa beans.

(*) Commission Implementing Regulation (EU) 2023/2782 of 14 December 2023 laying down the methods of sampling and analysis for the control of the levels of mycotoxins in food and repealing Regulation (EC) No 401/2006, OJ L 2782, 15.12.2023, p. 1. ELI: http://data.europa.eu/eli/reg_impl/2023/2782/oj.’

(4) After point C.2.2.2. the following is added:

‘C.2.2.3 Specific procedures for mineral oil hydrocarbons

The analyst shall ensure that samples do not become contaminated during sample preparation by following the precautions described in B.1. and C.2.1. Furthermore, wherever possible, the apparatus and equipment coming into contact with the sample shall not contain mineral oil or interfering substances.

Reagents and other equipment used for analysis and sampling shall be controlled to avoid possible introduction of mineral oil hydrocarbons.

A reagent blank analysis shall be performed by carrying out the entire analytical procedure in the same manner as the test sample. The levels in the reagent blanks shall be monitored in each sequence of samples.'

(5) Point C.3.2. is replaced by the following:

'C.3.2. General requirements

Methods of analysis used for food control purposes shall comply with the provisions of Annex III of Regulation (EU) 2017/625 (**).

Methods for analysis for total tin are appropriate for control on inorganic tin levels.

For the analysis of lead in wine, the methods and rules established by the OIV ([1]) apply in accordance with Article 80(5) of Regulation (EU) No 1308/2013 ([2]).

Methods for analysis for total arsenic are appropriate for screening purpose for control on inorganic arsenic levels. If the total arsenic concentration is below the maximum level for inorganic arsenic, no further testing is required and the sample is considered to be compliant with the maximum level for inorganic arsenic. If the total arsenic concentration is at or above the maximum level for inorganic arsenic, follow-up testing shall be conducted to determine if the inorganic arsenic concentration is above the maximum level for inorganic arsenic.

For mineral oil hydrocarbons the principles as described in the JRC Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials (***) shall be followed or, in case other procedures are followed, equal performance of those procedures shall be ensured.

(**) 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. ELI: http://data.europa.eu/eli/reg/2017/625/oj).

(***) https://op.europa.eu/en/publication-detail/-/publication/97cb92c2-d29e-11ed-a05c-01aa75ed71a1'

(6) After C.3.3.1 point (e) and before point (f) is the following is added:

'(f) Performance criteria for methods of analysis for total mineral oil saturated hydrocarbons and total mineral oil aromatic hydrocarbons:

Table 10

Parameter	Criterion
Applicability	Foods specified in Regulation (EU) 2023/915
Specificity	Analytical methods shall demonstrate the ability to reliably and consistently quantify MOSH and MOAH, excluding other co-extracted and possibly interfering compounds, that may be present. When needed, characterisation of interferences shall be done on the basis of comprehensive gas chromatography (GC×GC).
Recovery	70-120 % (The recovery can be lower than 70%, when applying a sample preparation with aluminium oxyde for the determination of mineral oil saturated hydrocarbons or when permorming a sample preparation with epoxidation for the analysis of mineral oil aromatic hydrocarbons.
Reproducibility (RSD_R)	≤ 20 % For certain products that contain endogenous interfering substances, the reproducibility can be higher than 20%.
LOQ	The fat/oil content refers to the declared fat/oil content or, in absence of a declared fat/oil content, to the fat/oil content as determined.
LOQ Food other than spices, dried herbs, food supplements, essential oil and oils produced from fishery products and	≤ 0.50 mg/kg

algae with a declared fat/ oil content of < 4 %	
LOQ Food other than spices, dried herbs, food supplements, essential oil and oils produced from fishery products and algae with a declared fat/ oil content of ≥ 4% and ≤ 50%, %	≤ 1.0 mg/kg or, in case the ML is ≤ 0.50 mg/kg, the LOQ shall be ≤ the ML.
LOQ Food other than spices, dried herbs, food supplements, essential oil and oils produced from fishery products and algae with a declared fat/ oil content of > 50 %, %	≤ 2.0 mg/kg
LOQ for spices, dried herbs, food supplements, essential oil and oils produced from fishery products and algae.	≤ 5.0 mg/kg

(6) Under C.3.3.1, for point '(f) Notes to the performance criteria:' the title '(f) Notes to the performance criteria:' is replaced by:

'(g) Notes to the performance criteria:'