



MINISTRY OF HEALTH OF UKRAINE

ORDER

of 28 February 2025 No. 338

**Registered at the Ministry of
of Justice of Ukraine
on 14 March 2025
under No. 425/43831**

**On Approval of Requirements for Food Flavorings With Smoke Aroma
(Smoke Flavorings)**

In accordance with part two of Article 6 and part one of Article 15 of the Law of Ukraine “On Basic Principles and Requirements for Food Safety and Quality”, subparagraph 14 of paragraph 4, paragraph 8 of the Regulation on the Ministry of Health of Ukraine, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 267 of 25 March 2015 (as amended by the Resolution of the Cabinet of Ministers of Ukraine No. 90 of 24 January 2020), the Association Agreement between Ukraine, of the one part, and the European Union, the European Atomic Energy Community and their Member States, of the other part, ratified by the Law of Ukraine No. 1678-VII of 16 September 2014, paragraph 240 of the Action Plan for the implementation of the Association Agreement between Ukraine, of the one part, and the European Union, the European Atomic Energy Community and their Member States, of the other part, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 1106 of 25 October 2017, in order to set out requirements for food flavorings with smoke aroma (smoke flavorings), **IT IS ORDERED:**

1. To approve Requirements for smoke flavorings, attached herewith.
2. The Department of Public Health shall ensure:
 - 1) submission of this Order for the state registration to the Ministry of Justice of Ukraine in accordance with the procedure established by law;
 - 2) the publication of this Order on the official website of the Ministry of Health of Ukraine after its state registration at the Ministry of Justice of Ukraine.
3. Control over the implementation of this Order shall be assigned to the Deputy Minister of Health of Ukraine - Chief State Sanitary Doctor of Ukraine.
4. This Order shall enter into force six months after its official publication.

The Minister

Viktor LYASHKO

APPROVED

**The Order of the Ministry of Health of
Ukraine No. 338 of 28 February 2025**

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Requirements for Food Flavorings With Smoke Aroma (Smoke Flavorings)

I. General provisions

1. These Requirements outline the general requirements for food flavorings with smoke aroma (hereinafter referred to as smoke flavorings), the conditions of their use and production.
2. These Requirements apply to:
 - 1) smoke flavorings used or intended for use in and/or on foods;
 - 2) source materials for the production of smoke flavorings;
 - 3) the conditions under which smoke flavorings are produced;
 - 4) foods in and/or on which smoke flavorings are present.
3. In these Requirements, the terms are used in the following meanings:
 - 1) primary smoke condensate - the purified water-based part of condensed smoke and fall within the definition of smoke flavorings;
 - 2) primary tar fraction - the purified fraction of the water-insoluble high-density tar phase of condensed smoke and fall within the definition of smoke flavorings;
 - 3) primary products - primary smoke condensates and primary tar fractions;
 - 4) derived smoke flavorings - smoke flavorings produced as a result of the further processing of primary products and which are used or intended to be used in or on foods in order to impart smoke flavor and aroma to those foods.

II. General conditions for the use of smoke flavorings

1. Smoked flavorings may be used in/on foods under the following conditions:
 - 1) if, according to existing scientific data, they do not pose a risk to human health;
 - 2) if their use does not mislead consumers.
2. It is prohibited to produce, use and put into circulation smoke flavorings, any food in and/or on which a smoke flavorings are present if the smoke flavoring is not a primary product or if is not derived therefrom, obtained from source materials for smoke flavoring permitted in accordance with the requirements of part one of Article 31¹ of the Law of Ukraine “On Basic Principles and Requirements for Food Safety and Quality”.

3. The wood used for the production of primary products shall not have been treated, whether intentionally or unintentionally, with chemicals substances during the six months immediately preceding felling or subsequent thereto, unless it can be confirmed that the substance used for the treatment does not give rise to potentially toxic substances during combustion.

The person who places on the market primary products shall be able to confirm by appropriate certificate or other document that the requirements specified in the first paragraph of this clause have been met.

4. Safety conditions for the production of primary products are laid down in Annex 1 to these Requirements. The water-insoluble oily phase, which is a by-product of the process, shall not be used for the production of smoke flavorings.

5. Primary products may be further processed by appropriate physical processes for the production of derived smoke flavorings.

6. Quality criteria for validated methods for sampling, identification and characterization of primary products are laid down in Annex 2 to these Requirements.

**Annex 1 to Requirements for food
flavorings with smoke aroma (smoke
flavorings)
(paragraph 4 of Section II)**

Safety conditions for the production of primary products

1. Smoke is generated from the wood referred to in paragraph 3 of Section II of Requirements for food flavorings with smoke aroma (smoke flavorings), approved by the Order of the Ministry of Health of Ukraine No 338 of 28 February 2025. During the production herbs, spices, twigs of juniper, needles and spruce cones may be added, provided that they are free of residues of intentional or unintentional chemical treatment.

The source material for the production of smoke flavorings (hereinafter referred to as smoke flavorings) is subjected to controlled burning, dry distillation or treatment with superheated steam in a controlled oxygen environment with a maximum temperature of 600 °C.

2. The smoke is condensed. During the smoke condensation process, drinking water and/or solvents may be added in order to achieve phase separation.

Physical processes may be used for isolation, fractionation and/or purification to obtain the following phases:

1) a primary smoke condensate mainly containing carboxylic acids, carbonylic and phenolic compounds, having a maximum content of:

benzo[a]pyrene 10 mg/kg

benz[a]anthracene 20 mg/kg;

2) a water-insoluble high-density tar phase which during the phase separation will precipitate and which can be used for the production of smoke flavorings but only after appropriate physical processing to obtain fractions which are low in polycyclic aromatic hydrocarbons, having a maximum content of:

benzo(a)pyrene 10 mg/kg;

benzo(a)anthracene 20 mg/kg;

3) water-insoluble oily phase. If no phase separation has occurred during or after the condensation, the smoke condensate obtained shall be regarded as a water-insoluble high-density tar phase, and must be processed by appropriate physical processing to obtain primary tar fractions which meets the requirements specified in subparagraph 2 of this paragraph.

**Annex 2 to Requirements for food
flavorings with smoke aroma (smoke
flavorings)
(paragraph 6 of Section II)**

**Quality criteria
for validated methods of sampling, identification and characterization
of primary products**

1. The basic requirement for sampling is to obtain a representative and homogeneous laboratory sample.

The analyst (laboratory specialist) shall ensure that the samples do not become contaminated during sample preparation. To minimize the risk of contamination, containers have to be rinsed with high purity acetone or hexane (p.A., HPLC grade or equivalent) before use. Whenever possible, apparatus that comes into contact with the sample shall be made of an inert materials, e.g. glass, polished stainless steel. The use of plastics, such as polypropylene, should be avoided, as the substance being analysed can adsorb onto these materials.

All of the sample material received by the laboratory shall be used for the preparation of test material. Only very finely homogenised samples give reproducible results.

The identification of a primary product is based on the result of a descriptive analysis that identifies the substances present in primary product.

Characterization of a primary product is assessed by identification of the major physical-chemical fractions and quantification and identification of the chemical constituents.

2. The validated method for identification and description of characteristics to be selected by the laboratory shall meet the quality criteria outlined in Tables 1 and 2 of this Annex.

Table 1

Quality criteria for methods for identification and quantification of chemical constituents in the solvent free mass and the volatile fraction of primary products

No	Parameter	Value/Comment
1	Solvent free mass (the mass of the material after abstraction of the solvent, which normally is water)	At least 50 % by mass shall be identified and quantified
2	Volatile fraction (the part of the solvent free mass, which is volatile and analysable by gas chromatography)	At least 80 % by mass shall be identified and quantified

Table 2

Minimum method quality criteria for analysing Polycyclic Aromatic Hydrocarbons (PAHs)

No	Analyte(s) (PAH)	RSD _i *, %	RSD _r * , %	RSD _R * , %	LOD***, µg/kg	LOQ** *, µg/kg	Analytical range***, µg/kg	Recovery *, %
1	benzo[a]pyrene	20	20	40	1,5	5,0	5,0-15	75-110
2	benzo[a]anthracene	20	20	40	3,0	10	10-30	75-110
3	cyclopenta[cd]pyrene** dibenzo[a,e]pyrene** dibenzo[a,i]pyrene** dibenzo[a,h]pyrene**	35	35	70	5,0	15	15-45	50-110
4	chrysene 5-methylchrysene benzo[b]fluoranthene benzo[j]fluoranthene benzo[k]fluoranthene indeno[123-cd]pyrene dibenzo[a,h]anthracene benzo[ghi]perylene dibenzo[a,l]pyrene	25	25	50	5,0	15	10-30	60-110

* Over the whole analytical range.

Notes 1:

** The RSD_i, RSD_r and RSD_R values are relatively high due to the low stability of the analytes in primary smoke condensate.

*** Corrected for recovery.

Notes 2:

LOQ – Limit of Quantification.

LOD – Limit of Detection.

S_i – The single-laboratory standard deviation, calculated based on results obtained under repeatability conditions as defined in DSTU GOST ISO 5725-1:2005 “Accuracy (trueness and precision) of measurement methods and results. Part 1. General principles and definitions”

(repeatability standard deviation estimated in a single laboratory approach according to the Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis applied in accordance with the legislation of the European Union).

S_r – The average value within the standard laboratory deviation, calculated based on results obtained under repeatability conditions as defined in DSTU GOST ISO 5725-1:2005 “Accuracy (trueness and precision) of measurement methods and results. Part 1. General principles and definitions” in a collaborative trial with a minimum of eight laboratories conducted according to the Protocol for the Design, Conduct and Interpretation of Method-Performance Studies applied in accordance with the legislation of the European Union.

S_R – The between laboratory standard deviation, calculated based on results obtained under reproducibility conditions as defined in DSTU GOST ISO 5725-1:2005 “Accuracy (trueness and precision) of measurement methods and results. Part 1. General principles and definitions” and in accordance with the Protocol for the Design, Conduct and Interpretation of Method-Performance Studies, applied in accordance with the legislation of the European Union.

RSD_i – Relative single-laboratory repeatability standard deviation (S_i , expressed in percent of the measured value).

RSD_r – Relative average repeatability standard deviation (S_r , expressed in percent of the measured value).

RSD_R – Relative reproducibility standard deviation (S_R , expressed in percent of the measured value).