Draft Guidance Novel Foods

Description, Composition, Production Process, Specifications

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STRUCTURE OF THE NOVEL FOOD GUIDANCE

- Background and Terms of Reference
- General Principles
- Information requirements

1. Description of the Novel Food
2. Production process
3. Compositional data
4. Specifications
5. History of use of the Novel Food and of its source
6. Proposed uses and use levels and anticipated intake
7. Absorption, distribution, metabolism, and excretion (ADME)
8. Nutritional information
9. Toxicological information
10. Allergenicity

- Concluding remarks

1. DESCRIPTION OF THE NOVEL FOOD

- **Introductory paragraph**
  - source
  - main aspects of production process
  - typical compositional features
  - purpose and intended use

- **Specific information**
  - depending on the category(ies) under which the Novel Food fall(s)

1. DESCRIPTION OF THE NOVEL FOOD

Categories

- Chemical substances
- Polymers
- Foods consisting of, isolated from or produced from
  - microorganisms, fungi or algae
  - material of mineral origin
  - plants or their parts
  - animals or their parts
  - cell or tissue cultures derived from animals, plants, fungi, algae
- Engineered nanomaterials

1. DESCRIPTION OF THE NOVEL FOOD

1.1 Chemical substances

- chemical name, when appropriate, according to IUPAC nomenclature rules
- CAS number (if this has been attributed) and other identification numbers
- synonyms, trade names, abbreviations
- molecular and structural formulae; stereochemistry
- molecular mass (Da)

1. DESCRIPTION OF THE NOVEL FOOD

1.5 Novel foods consisting of, isolated from or produced from plants or their parts

- scientific (Latin) name (botanical family, genus, species, subspecies, variety with author's name, chemotype, if applicable)
- synonyms (botanical name) that may be used interchangeably with the preferred scientific name
- common names (if a trivial or a common name is used extensively, it should be linked to the scientific name and part used)
- part used (e.g. root, leaf, seed, etc.)
- geographical origin (continent, country, region)

2. PRODUCTION PROCESS

- Detailed description of the employed process to produce the Novel food

  e.g. chemical synthesis
  enzyme-catalysis
  fermentation
  isolation from natural source

- focus on potential by-products, impurities and contaminants that could raise safety concerns

- novel aspects of the process (if applicable)

⇨ allow conclusions regarding the impact of the process on safety and nutritional value of the Novel Food

2. PRODUCTION PROCESS

- raw materials, starting substances
- handling of sources

  e.g. plants: cultivation practice (pesticides), time of harvest

  animals: breeding, farming, hunting conditions

  microorganisms: culture conditions
- Novel Foods from plants (particularly for use as ingredients in supplements)

  ⇨ EFSA guidance on safety assessment of botanicals and botanical preparations (EFSA, 2009)

2. PRODUCTION PROCESS

- operational limits and key parameters of the production process

  e.g. • Novel Foods obtained via chemical synthesis:

  - reaction conditions, reaction sequence, side reactions ,
  - purification steps (solvents)

  • conversion of raw material into a preparation:

  - extraction/processing steps
  - standardisation procedures

- measures implemented for production control and quality assurance (e.g., HACCP, GMP, ISO)

- production flow chart, including quality control checks

3. COMPOSITIONAL DATA

⇨ Qualitative and quantitative data on composition, physico-chemical, biochemical and microbiological properties

- identities and qualities of impurities, by-products or residues
- nutritionally relevant inherent constituents (e.g. micronutrients), toxic, addictive, psychotropic or other substances of possible concern to human health
- presence of potential allergens

- type and spectrum of target analytes depending on source and production process

e.g. - chemical synthesis ⇨ residual starting materials and by-products anticipated from side-reaction

- extraction ⇨ residues of solvent
- fermentation ⇨ mycotoxines

3. COMPOSITIONAL DATA

3.2 Single substances and simple mixtures thereof

single substances

- identity tests (e.g. UV-VIS, IR, NMR, GC-MS, LC-MS)
- physico-chemical properties (e.g. appearance, melting point, boiling point)
- solubility data in water and other common solvents
- particle size, shape and distribution
- minimum purity value

Simple mixtures

(components can be fully chemically characterised)

- information on the identities and the relative ratios of all components
- elaboration of a complete mass balance

3. COMPOSITIONAL DATA

3.3 Complex mixtures and whole foods

complex mixtures (e.g. extracts, protein hydrolysates)

whole foods (e.g. milk, meat, fruits, seeds)

⇨ not all constituents can be fully chemically characterised and/or identified

- qualitative and quantitative characterisation of the main constituents - at least via sum parameters
- whole foods: proximates analyses (i.e. ash, moisture, protein, fat and carbohydrate)
- for the classes of naturally or chemically derived components which characterise the nature of the Novel Food (e.g. peptides, phospholipids, carotenoids, phenolics, sterols): comprehensive qualitative and quantitative data
- set up of a mass balance
- indication of the amount of unidentified constituents, this should be as low as possible

3. COMPOSITIONAL DATA

- preferably data on at least five representative batches that have been independently produced
- use of validated methods,
  preferably nationally or internationally-recognised methods
  (e.g. AOAC, ACS, EP)
- description of methods
  - limits of detection
  - limits of quantification
  - references
- certificates of analyses and information on the accreditation of laboratories
- in-house methods: full description and validation of procedures

3. COMPOSITIONAL DATA

stability ⇨ identification of hazard which might arise during storage

- consideration of constituents/parameters
  - susceptible to changes during storage
  - direct effect on safety or indicator for safety-relevant alterations
- physico-chemical, biochemical and microbiological stability of the novel foods under normal conditions of storage
  - effects of packaging, storage temperature and environment
- use of the novel food as ingredient added to other foods

  ⇨ investigation of the stability in the processed foods

4. SPECIFICATIONS

- On the basis of analytical characterisation of the Novel Food
  - ⇨ proposal for specifications by the applicant, in the form of a table
- define key parameters which characterise and substantiate the identity of the Novel Food
- provide a rationale for the selected parameters
- set limit regarding minimal purity
- set acceptable limits for impurities and degradation products, in particular for those of toxicological and nutritional relevance
- in the absence if legal requirements, include maximum levels of contaminants
- provide the methods used for analysis of all parameters

Thank you for your attention !