THE EU SAFETY ASSESSMENT OF FOOD CHEMICAL MIXTURES

EU specialty food ingredients

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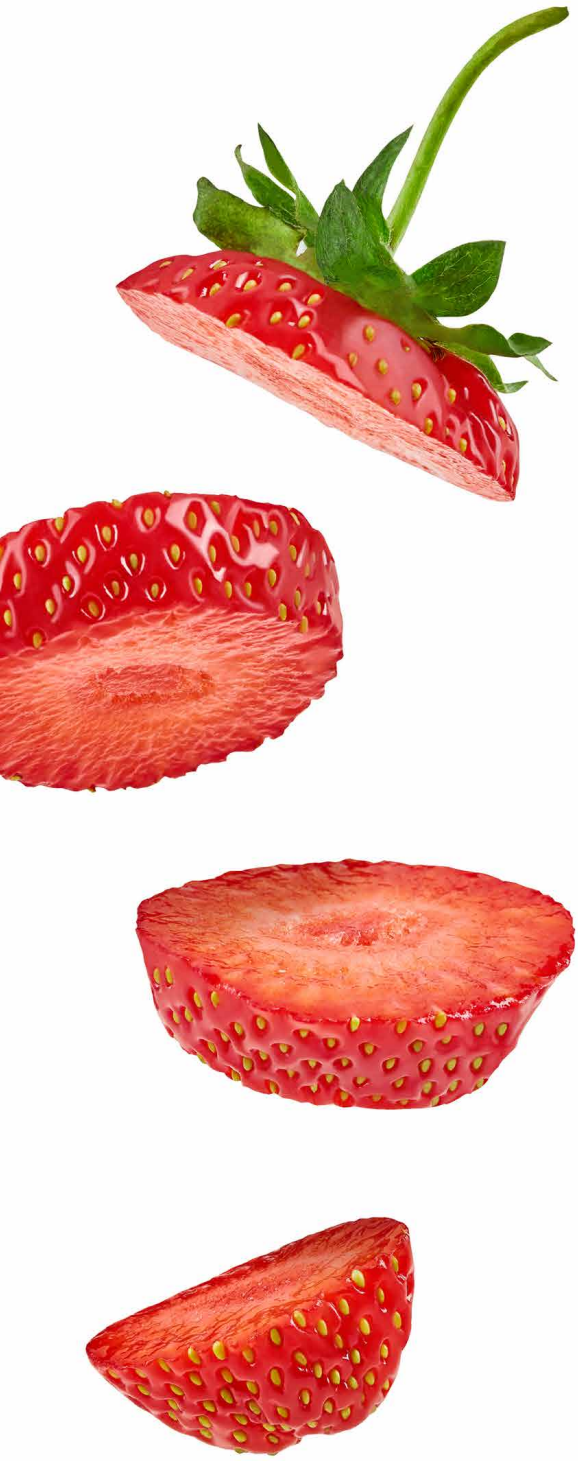
FOOD, WHATEVER ITS ORIGIN, WHATEVER IT IS PROCESSED OR NOT, IS THE RESULT OF A COMBINATION OF CHEMICAL SUBSTANCES.

Within the food matrix, these chemicals may interact: for example, a higher bioavailability of dietary iron can be achieved by increasing the content of food components enhancing iron absorption such as ascorbic acid or by decreasing the content of inhibitors such as phytates or tannins.



A STRAWBERRY IS A NATURAL COMPLEX COMBINATION OF CHEMICALS.[1]

Over 300 volatile components alone are present.[2] Some of these are indicated below, amongst other components:

Water; fructose; sucrose; cellulose E 460; ash; octadecadienoic acid; octadecatrienoic acid; octadecaenoic acid E 570 ; hexadecanoic acid; octadecanoic acid; hexadecaenoic acid; aspartic acid; glutamic acid E 620; leucine E 641; alanine; lysine; glycine; arginine; proline; serine; tyrosine; threonine; isoleucine; phenylalanine; valine; histidine; tryptophane; cysteine E 920; methionine; formic acid; malic acid E 296; carotenes E 160a; lutein E 161b; kryptoxanthin; chlorophylls and chlorophyllins E 140; rubixanthin; violoxanthin; canthaxanthin E 161g; zeaxanthin; ascorbic acid E 300; alpha-tocopherol E 307; folate; choline; betaine; phytosterols; 2,5-dimethyl-4-hydroxy-2H-furan-3-one; 2,5-dimethyl-4-methoxy-2H-furan)-3-one; gamma-decalactone; gamma-dodecalactone; 2-furfural; 5-hydroxy methyl-furfural; limonene; linalool; (E)-nerolidol; ethanol; hexanol; octanol; methyl butanoate; ethyl butanoate; methyl hexanoate; ethyl hexanoate; hexyl ethanoate; (E)-2-hexen-1-yl ethanoate; butyl ethanoate; methyl octanoate; ethyl octanoate; octyl-2-methyl butanoate; octyl hexanoate; decyl butanoate; decyl ethanoate; methanethiol; ethyl3-methylbutanoate; geraniol, benzoic acid E 210; farnesyl acetate; mesifurane; methyl anthranilate: gamma-decalactone; methional; dimethoxymethane; 1-butoxy-1-ethoxyethane; 2-(4-hydroxyphenyl)-ethylbeta-D-glucopyranoside.

1. https://jameskennedymonash.wordpress.com/category/infographics/all-natural-banana-and-other-fruits/
2. L.M. Nijssen; Volatile compounds in food: qualitative and quantitative data, TNO Nutrition and Food research Institute, 1996-1998

As underlined by the European Food Safety Authority (EFSA),

"UNDERSTANDING HOW COMBINED CHEMICALS BEHAVE IS COMPLEX AND THE NUMBER OF COMBINATIONS IS POTENTIALLY INFINITE";[3]

yet the combination of food ingredients used to produce foodstuffs shall not raise safety issues.

Many food ingredients are subject to an assessment of their safety by EFSA before they are permitted for use in foods and beverages. The assessment shall be carried on single substances, in accordance with the EU legislative requirements.[4] Nevertheless, this does not imply that combined exposures are never addressed by EFSA: for example, EFSA has assessed combined exposure to multiple novel food ingredients such as fermented black bean extract[5] or an extract derived from the roots or rootstock of *Glycyrrhiza glabra.*[6]

In March 2019,[3] EFSA has developed a harmonised framework to use when evaluating the potential "combined effects" of chemical mixtures in food and feed. The approach gives EFSA's scientists the tools to follow a mixtures approach when needed, which complements the current EU regulatory requirements for assessing single substances.

3. https://www.efsa.europa.eu/en/press/news/190325
4. e.g. Regulation (EU) 2015/2283 on Novel Foods; Regulation (EC) 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings
5. https://www.efsa.europa.eu/fr/efsajournal/pub/2136
6. https://www.efsa.europa.eu/fr/efsajournal/pub/2287

EU SPECIALTY FOOD INGREDIENTS:

Welcomes the adoption in 2019 of the EFSA Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals ("MIXTOX Guidance"). It equips the risk assessor with robust scientific principles to assess when needed the safety of the exposure to combination of regulated substances, including food ingredients.

Welcomes EFSA's continuous collaboration with the scientific community (EFSA International Workshop on Risk Assessment of Combined Exposure to Multiple Chemicals – 2021) and the adoption of related scientific outputs like EFSA Guidance Document on Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals (2021).

Notes for example that EFSA, in the context of the need for further harmonisation between OECD and EFSA guidance documents, is planning to develop roadmaps and to move towards open-source platforms and data consolidation, food additives being also considered now amongst other substances.[7]

Supports the update of such harmonised approaches to the risk assessment of food ingredients in light of new scientific evidence.

7. EFSA International Workshop on RA of Combined Exposure to Multiple Chemicals – Event report, published 22 July 2022

THE IMPORTANCE OF THE CHARACTERISATION OF A MIXTURE, AS UNDERLINED IN EFSA MIXTOX GUIDANCE.

"The extent of characterisation of a mixture is an important factor in determining the approach to risk assessment. Examples of chemically fully defined mixtures are a mixture produced by adding together separate chemical substances, a chemically well-characterised mixture produced by a controlled process, or a group of separate chemical substances to which combined exposure can occur, such as [...] food additives. The Scientific Committee notes that the term 'chemically fully defined' does not mean that all chemical components have to be known. As with individual chemical substances, which in practice are never 100% pure, the acceptable impurities in a chemical mixture are usually defined in the specifications. It is not possible to define a generic 'cut-off' value, i.e. the minimum percentage of unidentified chemical substances that can be present in a mixture for it to be considered to be fully chemically defined, and below which it is considered poorly defined, since this will be dependent on the nature of the mixture and of possible impurities. If a mixture is judged to be fully chemically defined, the preferred approach is generally component-based, i.e. the risk is assessed based on exposure and effect data of its individual components. In contrast, if a mixture is poorly defined, then it may only be feasible to apply a whole mixture approach in which the mixture is treated as a single entity, similar to single chemicals. Examples of poorly defined mixtures include certain botanicals and novel foods."

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