"SYNTHETIC" FOOD INGREDIENTS: DEBUNKING THE MYTHS WITH FACTS

EU specialty food ingredients

specialtyfoodingredients.eu

The production of food ingredients, irrespective of their manufacturing procedure or their source of raw materials, are assessed using the proper methodologies in place to ensure they are safe, bearing minimal environmental impact, and that their health claims are justified. Their labelling should therefore rather reflect these elements, irrespective of whether they are considered natural or synthetic.

The lines between natural and synthetic will increasingly blur. Industry is constantly innovating in the food space to meet consumer's evolving demand: delivering nutritional, technological and health benefits, specialty food ingredients play a key role in the creation of safe, nutritious, tasty, convenient and sustainable food and drink products.

This paper debunks some myths on synthetic food ingredients with facts.

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BACKGROUND

A number of stereotypes can be observed when it comes to "synthetic" versus "natural" ingredients, notably regarding their respective safety and environmental impact.

A typical example is the following statement: *"requiring same labelling standards for different food components will confuse synthetic and natural ingredients preventing consumers to make conscious, healthier, and sustainable choices"* ("SAFE" brochure)[1], which implies that in contrast to "natural" ingredients, "synthetic" ingredients cannot relate to "healthier and sustainable choices".

A similar biased statement can be found in para 95 of the EP AGRI/ ENVI report on the Farm to Fork strategy adopted on 20 October 2021[2]: *"notes that healthy products, including food, may contain natural or synthetic ingredients which have different impacts on the environment and the health of consumers".*

This paper aims at inviting to critical reading of such sweeping judgments, based on FACTS.

1. Source: Safe Food Advocacy brochure: "Ensuring proper food information to consumers from misleading use of natural" on food products" – November 2020
2. TA MEF (europa.eu)

WHAT IS A "SYNTHETIC" FOOD INGREDIENT?

First and foremost, **there is no legal definition of a "synthetic" food ingredient in the EU food legislation**; this notion is generally opposed to the notion of "natural" ingredient that is not legally defined either, except in some vertical legislation like the Flavouring legislation[3]. The term is often used with a negative connotation, in association with the poor perception of "chemicals" in general[4].

For the purpose of this paper, like in the SAFE brochure[1], "synthetic" food ingredient is understood as obtained entirely by a chemical synthesis[5]. It does not include any enzymatic- or fermentation-, or microbiological- or other naturally occurring biological manufacturing processes.

3. Regulation (EC) 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods; Regulation (EU) 1169/2001 on the provision of food information to consumers
4. 84% of Europeans are worried about the impact of chemicals present in everyday products on their health, and 90% are worried about the impact of chemicals on the environment: Eurostat, Eurobarometer 2020
5. Chemical synthesis is used to produce food ingredients that are also found in nature or in the human diet but are chemically synthetised for various reasons, including sustainability, or which are artificial (not occurring in nature)

"Synthetic" food ingredients:

SAFETY AND HEALTH

SAFETY

According to the General Food Law[6], "food" (or "foodstuff") means *any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*, and it includes any substance, intentionally incorporated into the food during its manufacture, preparation or treatment.

Hence food ingredients used in the formulation of foodstuffs fall within the legal definition of 'food' and as such shall not be placed on the market if unsafe, whatever their origin or production mode.

Food, including food ingredients, shall be deemed to be unsafe if it is considered to be:

(a) injurious to health;

(b) unfit for human consumption[7].

Whilst it is the responsibility of the business operator to ensure that the food put on the market is safe, i.e., not injurious to health and fit for human consumption, several food ingredients are also subject to pre-market authorisations involving a safety risk assessment by the European Food Safety Authority (EFSA). These ingredients include:

- food additives[8]
- novel food ingredients[9].

6. Regulation (EC) 178/2002
7. Article 14 of Regulation 178/2002
8. Regulation (EC) 1333/2008
9. Regulation (EU) 2015/2283

This safety assessment applies to all food additives and novel food ingredients, irrespective whether they are the result of a chemical synthesis ("synthetic") or of an extraction process from a natural starting material or of any other method of production.
Data required for the safety assessment must be provided in accordance with EFSA scientific guidance for submission for food additives evaluations [10] and with EFSA scientific guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (Revision 1) [11].

For example, in all cases of an application of a substance as a food additive, a detailed description of the manufacturing process should be provided covering the method of manufacture (e.g., raw materials, the process by which the raw materials are converted to the finished product), production controls and quality assurance. The approach is further adapted to identify accurately relevant impurities, reaction intermediates, precursors and reagents that could present a hazard (see Table 1) and which will be controlled by means of an appropriate legally binding specification.

Table 1 – Food additive applications – Information required by EFSA on manufacturing process

For substances synthesised chemically	For substances derived from botanical, animal, microbiological sources
i) factors such as reaction sequence, side reactions, purification and preparation of the product to be commercialised, which may assist in determining likely impurities and their influence on the toxicological evaluation; ii) information on substances entering the manufacturing process, e.g., identity of the extraction solvent, reagents, special precautions (light and temperature), chemical or physical decontamination methods should be provided	i) information on the method(s) of manufacture should include the process by which the raw material is converted into a preparation, such as extraction or other procedure(s); ii) information on substances entering the manufacturing process, e.g., identity of the extraction solvent, reagents, special precautions (light and temperature); iii) standardisation criteria (e.g., see European Pharmacopoeia, 2011); for botanicals further guidance can be found in EFSA Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements

10. Guidance for submission for food additive evaluations - - 2012 - EFSA Journal - Wiley Online Library
11. Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/22831 (Revision 1)2 - - 2021 - EFSA Journal - Wiley Online Library

A similar approach applies to novel food ingredients: EFSA requires that the process(es) employed to produce the novel food (e.g., chemical synthesis, enzyme-catalysis, fermentation or isolation from a natural source, etc.) should be described. The description of the production process should be detailed enough to provide the information that will form the basis for the evaluation of the bioavailability, nutritional value and safety, which should be addressed in the respective sections.

With regard to safety, the description should include information on potential by-products, impurities or contaminants (see Table 2).

Table 2 - Novel food ingredient applications – Information required by EFSA on manufacturing process

For novel foods obtained via chemical synthesis	For novel foods consisting of, isolated from or produced from plant, animal or microbiological sources
The reaction sequence, side reactions and purification steps should be described. Information on reaction conditions (e.g., reagents, temperature, duration of the reaction, and catalyst), chemical or physical purification methods (e.g., solvent extraction and crystallisation) should be reported.	The applicant should describe in detail the process by which the raw material is converted into an ingredient or a preparation intended for a food product. Examples may include heat treatment, extraction, distillation, squeezing, fractionation, purification, concentration, fermentation, or other procedure(s). Information on substances used in the manufacturing process, e.g., identity of the extraction solvents, ratio of extraction solvent to the material, reagents, residues remaining in the final product and any special precautions (light and temperature) should be provided. For novel foods consisting of, isolated from or produced from plants-specific considerations and complementary information are provided in the EFSA guidance on safety assessment of botanicals and botanical preparations.

Furthermore, the chemical substances used as sources of vitamins [12] and minerals, which may be added to foods should be safe and also be bio-available i.e., available to be used by the body, irrespective of their source and production process. A positive list of these substances is established and the addition of vitamins and minerals to food is regulated [13].

Finally, it should be kept in mind that naturalness is not a marker for harmless: mycotoxins or botulinum toxin for example are naturally bio-synthetized components.

12. Certain substances such as ascorbic acid or riboflavin are added to food as vitamins (respectively C and B2) or as food additives (respectively E 330 and E 101). Their safety is assessed irrespective of their source and production process.
13. Regulation (EU) 1925/2006 on addition of vitamins, minerals and certain other substances to foods

HEALTH CLAIMS

All food ingredients, independent from source, mode of manufacture and legal status, are eligible to health claims, which may be granted after a scientific assessment of the highest possible standard by EFSA [14]. The Authority considers whether the beneficial effect of a food/constituent on a function or a risk factor for disease is substantiated by generally accepted scientific evidence, by taking into account the totality of the available scientific data and, where applicable, by weighing the evidence, irrespective of the origin or production process of the food or of the food ingredient.

FACT

All food ingredients, including those that have been synthesized chemically:

- must be safe, i.e., not injurious to health and fit for human consumption,
- may possess particular health benefits that are recognised through relevant health claims.

For example:

- Carbamide, a food ingredient synthetised from ammonia and carbon dioxide, is explicitly referred to in the authorised health claim *"Sugar-free chewing gum with carbamide neutralises plaque acids more effectively than sugar-free chewing gums without carbamide"* [15].
- Melatonin, or N-acetyl-5-methoxytryptamine, is synthetised from the amino acid tryptophan, and is granted the two following claims: *"Melatonin contributes to the alleviation of subjective feelings of jet lag"* and *"Melatonin contributes to the reduction of time taken to fall asleep"* [15] .
- Vitamin C, or ascorbic acid, is obtained by chemical synthesis and is granted several claims in relation to its contribution to:
  - physical exercise,
  - normal collagen formation for the normal function of blood vessels, bones, cartilage, gums, skin and teeth, normal energy-yielding metabolism
  - normal functioning of the nervous system
  - normal psychological function
  - normal function of the immune system
  - protection of cells from oxidative stress
  - reduction of tiredness and fatigue
  - regeneration of the reduced from of vitamin E
  - increase of iron absorption [15].

14. Regulation (EC) 1924/2006 on nutrition and health claims
15. Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

"Synthetic" food ingredients:

ENVIRONMENT

Like all food ingredients, the environmental impact of "synthetic" food ingredients shall be assessed on a case-by-case basis, according to established methodologies such as the Product Environmental Footprint (PEF), which is a multi-criteria measure of the environmental performance of e.g., a food ingredient throughout its life cycle.

Bias that "synthetic" food ingredients are less sustainably produced than other food ingredients, in particular "natural" ingredients, is purely subjective: whilst the environmental impact of food ingredients may differ, this is not necessarily in relation to the use of chemical synthesis vs. a process by which a raw material is converted into an ingredient. Many factors shall be taken into consideration, e.g., sustainable sourcing in relation to biodiversity and the risk of natural resources' depletion, water and energy consumption and other relevant factors.

Moreover, a statement such as "products made of natural ingredients are fully biodegradable unlike their synthetic counterparts" is highly questionable: it does not take into account that biodegradation, i.e., the break down by biological agents such as bacteria and/or fungi, is not applicable to minerals used as food ingredients like the food additive E 551 (silicon dioxide).

Furthermore, synthetic amorphous silicon dioxide, which is industrially produced from raw material sand through either precipitation methods or flame processes, is not distinguishable from naturally occurring amorphous silica e.g., in plants and integrates again into the natural cycle of silica: at the end, it sediments as sand and forms rocks.

In its Communication entitled "A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system" [16], the European Commission states that it *"will examine ways to harmonise voluntary green claims and to create a sustainable labelling framework that covers, in synergy with other relevant initiatives, the nutritional, climate, environmental and social aspects of food products"*. It is hoped that the approach will dismiss snap judgments about "synthetic" food ingredients and the environmental aspects to the benefit of science-based results.

FACT

Like the production of any other food ingredients, the production of "synthetic" food ingredients has an environmental impact. However, chemical synthesis does not necessarily lead to an environmental impact higher than other production processes. This shall be measured according to established methodologies.

16. EUR-Lex - 52020DC0381 - EN - EUR-Lex (europa.eu)

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Edited by EU Specialty Food Ingredients, August 2022

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