foodwatch advocacy briefing – EU (re)authorisation system of food additives

April 2025

What are food additives?

According to the EU regulation on food additives (Regulation 1333/2008), "food additives are substances that are not normally consumed as food itself but are added to food intentionally for a technological purpose described in this Regulation, such as the preservation of food."[1]

This addition can happen at different stages of production (manufacturing, packaging, storage…) and serve different purposes, for instance: to ensure food safety (preservatives, antioxidants), to provide a specific texture (thickeners, gelling agents), to modify the appearance or taste of the food (colourings, flavour enhancers, sweeteners), or to guarantee recipe stability (emulsifiers, anti-caking agents, stabilisers).

In parallel to the increased industrialisation of the food chain, the use of food additives has been growing in the last decades. According to the European Food Safety Agency (EFSA)[2], there are currently over 300 food additives authorised on EU market[3].

Under which conditions can a food additive be authorised?

Article 6 of Regulation 1333/2008 lays out the conditions that an additive must meet in order to be authorised. The substance must:

- Does not pose a safety concern to the health of consumers, according to the scientific evidence available;
- satisfy a reasonable technological need that cannot be met by other methods;
- not mislead the consumer;
- be of benefit in terms of consumption, whether this involves preserving the nutritional quality of the food or improving its organoleptic properties (its taste, colour or smell, for example).

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[1] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, EUR-Lex - 02008R1333-20231029 - EN - EUR-Lex

[2] Food additives | EFSA

[3] For more information, see Food Additives: Safety, Regulations, and Loopholes | Foodwatch EN

These conditions fall under the general objective of "ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair trade practices in food trade, taking into account, where appropriate, the protection for the environment", detailed in Article 1 of the same regulation.

Based on safety data provided by food companies, EFSA carries out a scientific evaluation of the substance. It then provides the European Commission and Member States with a **scientific opinion**, on the basis of which they take a decision on the authorisation of the substance and related conditions (acceptable daily intake etc).

Regulation 257/2010 sets out a re-evaluation programme for the additives approved before 2009. This programme, which was supposed to be completed by 2020, is still ongoing in 2025, with 30% of the substances still to be reevaluated. At the time of writing, some of the reevaluations that have been completed already date back more than a decade ago (for instance, the sweetener aspartame was reevaluated in 2013). There are no set dates for reevaluation for additives approved after 2009.

What are the problems with the authorisation system and what are foodwatch demands to address them?

While in theory the regulatory pieces currently in place set out clear criteria for the approval process of food additives and their reviews, there are numerous loopholes in their implementation that put the delivery of the EU's protection obligation at risk and need addressing.

1) **Evaluation process**

- **Assessment process of food additives is too dependent on industry data.** For many of the additives, the publicly available data (regulatory studies or publications in scientific journals) is very limited, as EFSA itself admits. The agency therefore regularly issues *calls for data* – mostly directed at industry players - which constitute the main basis for its assessments.

- **Risk assessments are often incomplete.** As the *calls for data* are often unsuccessful, EFSA is left unable to identify relevant health hazards in a comprehensive way and to accurately estimate the consequences of exposure, particularly for young children.

Moreover, not all toxicities are equally covered in the evaluations. Standard regulatory tests requested by authorities only cover possible toxicities: long-term cumulative effects are underestimated, as is the cocktail effect resulting from exposure to multiple additives. Endocrine disrupting effects or effects on the microbiota are often not taken into account appropriately.

Epidemiological studies, which are important to investigate associations between exposure to multiple additives and pathologies in combination with toxicological studies, are not fully, or not at all, integrated into the risk assessment process.

- **Assessment process lacks transparency.**

  The Transparency regulation, which came into force in 2021, requires all studies submitted by industry to be made public. However, the data submitted in assessments that took place before, or were still ongoing at that date, is not covered.

  Moreover, the EFSA opinions do not give precise details on how the studies reviewed in the course of the assessment were weighed against one another.

2) **Review of existing authorisations**

– **Food additives are not re-evaluated on a regular basis:** continuous monitoring and periodic re-evaluation of additives are necessary to incorporate new scientific findings and review authorisations.

– **The 2010 reevaluation programme is the only official document setting deadlines for the review of authorisations granted before 2009**. While it was supposed to be completed by 2020, 30% of the substances have not yet been reassessed at the time of writing, and those that have been are sometimes already more than a decade old (e.g. Aspartame).

– **Substances put on the market from 2009 onwards are not tied to time-limited authorisations –** unlike substances for other uses, such as pesticides, which have an authorisation for a specific period of time that needs to be renewed. It takes the European Commission to specifically mandate EFSA to re-evaluate an additive for a review to take place. There are no review mechanisms that would allow incorporating the latest scientific evidence on a regular basis. This means that a large number of the additives on the market today have never been reevaluated after their initial authorisation. In the case of E171 titanium dioxide, it took an

accumulation of studies and even a ban on the colouring agent by France for the Commission to finally mandate a new assessment by EFSA.

3) **Untransparent labelling provisions for the consumer**

The rules for the labelling of additives sold to the final consumer fall under two different legal regulations.

- The additives regulation (1333/2008) article 23, describes provisions for the additives being sold alone or mixed together, for example a sweetener, and there the label must show the name **and E-number.**

- However, when the additive is sold in a food product, its labelling falls under the Food Information to Consumers regulation (1169/2011) Annex VI Part C. Here the legislation states that the label must have the name of the category of additive, e.g. sweetener or emulsifier, followed by their specific name, **or, if appropriate**, E number.

  This is confusing – and potentially misleading for the consumer – for several reasons:

  - Food businesses prefer 'clean labels', therefore if putting the E number is an option, they will often choose not to. Consumers do not know that 'rosemary extract', 'yeast extract' and caramel are in fact all chemical additives.
  - This can also mean that labelling will vary depending on the product, brand, retailer or country where the consumer is shopping. Food businesses know which countries are more sensitive to food additives in food and can adapt their labelling accordingly
  - Food businesses sometimes use different names for the same substance: E 150d is sometimes labelled caramel, sometimes ammonium sulphite caramel. This causes further confusion to consumers.
  - Chemicals used as processing aids or transfer additives which may still leave traces in the foods, do not need to be labelled on the final product: they circumvent the labelling obligation[4].

  The lack of clarity around labelling rules leaves too many open loopholes for companies to exploit, in a context of limited enforcement capacities at national

[4] For more information, see Food Additive Safety and Consumer Transparency Issues | Foodwatch EN

level (and therefore limited risks to be caught red-handed in case of non-compliance).

foodwatch demands

✓ **Strengthen the implementation of the legislation**

EFSA and the European Commission need to follow the letter of the law and only greenlight substances that fully comply with the conditions set out in Regulation 1333/2008: safe, necessary, not mis-leading.

EFSA needs more resources to handle (re-)evaluation dossiers in a more comprehensive and timely way, starting by completing the 2010 review programme as soon as possible.

The Commission and EFSA should consider whether certain bottlenecks and loopholes can be addressed by way of additional guidance documents. This includes improved guidance to address certain toxicities that are not well taken into account in standard test guidelines but nonetheless relevant for human health protection (e.g. endocrine disruption, immunotoxicity, effects on the microbiome) and to account for the cocktail effects arising from people's real-life exposure to multiple additives in one single food product.

The Commission should take measures to allow for automatic time-bound reviews of authorised additives, be it through the establishment of new reevaluation programmes or by introducing deadlines when issuing new authorisations.

The Commission should also consider provisions to allow EFSA to pick up on relevant scientific alerts and findings without having to wait for a mandate from the Commission in order to update its assessments.

✓ **Use the precautionary principle in case of uncertainties**

The Precautionary Principle laid down in Article 7 of General Food Law (178/2002) states clearly that when there is a possibility of harmful effects but 'scientific uncertainty persists', risk management measures can be taken.

When EFSA is struggling to finalise (re-)evaluations due to a lack of safety data from industry, then the authorisations need to be suspended out of precaution until the risk assessor has all the information necessary to proceed. Industry should not be

able to take advantage of their own failure to comply with data requirements at the expense of human health protection.

The existence of scientific uncertainties with regards to certain effects – either due to contradictory data, or the lack of standardised data for certain endpoints – should be transparently documented in EFSA opinions and lead to precautionary recommendations regarding the use of the substance.

- ✓ **Update the list of authorised food additives according to reality of use**

  Not all of the over 300 food additives authorised on the EU market are still currently in use by industry players. The Commission and Member States should update the list to reflect the reality of the current industry use.

  No new substance should be added to the list, if its assessment was not complete or left with uncertainties as regards effects for human health. See criteria above.

- ✓ **Make labelling more transparent**

  foodwatch demands that **both** the name **and** the E number are mandatory on the list of ingredients so that all consumers have access to the full information.

  Manufacturers should not be able to evade transparency obligations by using different names for the same substances or by using processing aids or transfer additives to hide the presence of a substance in an ingredients' list.