

The Consumer Voice in Europe

CLOSING THE TRUST GAP BETWEEN CONSUMERS AND THE EU FOOD REGULATORY SYSTEM

BEUC's view on the Commission's proposal on the transparency
and sustainability of the EU risk assessment in the food chain



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Why it matters to consumers

Public controversies around GMOs, pesticides or some food contaminants coupled to a series of food crises have shaken consumer confidence in the way the EU regulates food safety. Consumers shall be able to trust that EU policy decisions about food are transparently made and put food safety and the protection of their interests first.

Summary

BEUC welcomes the European Commission's move to make EFSA's scientific assessments more transparent. Nevertheless, we recommend strengthening the proposal with the following clarifications/changes:

- It must better ensure that public health prevails over commercial considerations when examining industry confidentiality requests. No important piece of safety-related information should be hidden away from the public;
- It must allow independent scientists to quote or re-use the data disclosed by EFSA without having to ask for industry's permission;
- It must foresee meaningful sanctions for industry applicants failing to notify EFSA of studies commissioned to support a regulatory dossier;
- If pre-submission meetings between EFSA staff and industry applicants are introduced, the proposal must guarantee that they are held in full transparency and that they do not lead to any shift in the allocation of EFSA internal resources, at the expense of other activities of public interest;
- The changes proposed to the governance of EFSA must not jeopardise the clear separation between risk assessment and risk management.

We also support the Commission's intention to make risk communication more effective. It will help streamline the interaction with stakeholders throughout the risk analysis process. We recommend that the future 'General Plan for Risk Communication' should:

- Consider that stakeholders have different resources and capacity to contribute to the policy-making process. It should strive to compensate for this imbalance;
- Apply to communication at times of crisis, by laying down rules on how consumers and the public need to be informed by competent authorities in the event of a food (safety or fraud) crisis;
- Ensure that EU risk-managers better explain to the public the political choices (including possible trade-offs) behind any policy decision about food.

Yet, to rebuild consumer trust in the EU food regulatory system in the long run, we urge EU decision-makers to take good note of the other key findings of the General Food Law fitness check and follow-up on them within the best delays. This includes making healthy and sustainable food choices a higher priority, filling the regulatory gaps for increased consumer protection and choice, and ensuring an effective and harmonised enforcement of EU food law.

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1. Introduction

The General Food Law (Regulation (EC) 178/2002 – hereafter ‘GFL’) has made the EU one of the safest places in the world to be a food consumer. The law was adopted in the early 2000s in the aftermaths of major food safety scandals such as the ‘mad cow’¹ and dioxins² crises.

Yet there is a growing consumer concern over the way the EU ensures food safety. High-profile public controversies have emerged in the recent years around the safety of certain products and substances used in the agri-food chain (e.g. aspartame, Bisphenol A, glyphosate). Conflicts of interests (real or perceived) among those in charge of food safety evaluations, a growing public distrust of industry-sponsored research and diverging scientific opinions between food safety agencies at EU and national or international level have all fuelled consumer distrust.

Consumer negative perceptions are due, among several reasons, to the fact that the European Food Safety Authority (EFSA) essentially relies on scientific studies funded by the industry to evaluate the safety of products such as pesticides or GMOs. This is in line with the EU’s principle that taxpayers’ money should not be used to help companies put products on the market. Nevertheless, this situation has prompted calls for increasing the transparency of risk assessment in the EU food chain.

Consumers are also eager to better understand how EU policy decisions about their food are made. The way policy-makers weigh conflicting considerations when they adopt food-related measures remains too opaque.

In January 2018, the European Commission published the findings of the REFIT evaluation of the GFL³. The report concludes that the GFL remains broadly fit for purpose. Nevertheless, it also identifies some shortcomings, such as the lack of transparency of EFSA risk assessments and national authorities’ inconsistent interpretation and enforcement of existing EU food regulations. It also points at persisting regulatory gaps, and insufficient EU action to tackle nutrition issues and misleading food labelling practices.

On 11 April 2018, the European Commission put forward a proposal for a regulation revising the GFL to increase the transparency and sustainability of the EU risk assessment in the food chain⁴. BEUC welcomes the Commission’s move to make EFSA’s scientific assessments more transparent and improve risk communication around food safety issues. We believe it is a first positive step towards restoring consumer confidence in their food and the way the EU regulates it.

The present paper includes our recommendations for strengthening the proposal even further. In addition, to rebuild consumer trust in the long run, we wish to encourage EU decision-makers to take good note of the other key findings of the GFL REFIT evaluation and follow-up on them within the best delays.

¹ The Bovine Spongiform Encephalopathy (‘BSE’) crisis that struck in the late 1990s made over 200 Europeans ill. It originated in UK cattle being fed meat and bone meals of ruminant infected by an infectious agent called ‘prion’.

² The Belgian dioxin crisis was caused by the use in animal feed of fat contaminated with dioxins. Meat products from poultry, pigs and cattle as well as eggs were contaminated with elevated levels of dioxin, posing a risk to human health.

³ https://ec.europa.eu/food/sites/food/files/gfl_fitc_comm_staff_work_doc_2018_part1_en.pdf

⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1523604766591&uri=COM:2018:179:FIN>

2. More transparent food safety assessments

2.1. Public access to industry study data

We welcome the new obligation for EFSA to automatically publish the non-confidential versions of product authorisation dossiers (new Art. 39b). We also support, as proposed by the European Commission, that the onus be placed on industry applicants to prove that publication of certain information will “*significantly harm*” their interests. Criteria shall be set in the proposal to unequivocally define what ‘significant harm’ means in relation to commercial interests.

In determining which information and/or data can receive confidential treatment following industry request (new Art. 39), **public health interests should always prevail over commercial considerations**. The horizontal list of information items for which confidential treatment may be granted shall be restricted to the minimum. For greater legal clarity, we recommend spelling out in more details in the proposal which information items can be eligible for confidential treatment. **No important piece of safety-related information shall be hidden away from the public**. This should be the rule in all cases, and not just in emergency situations (new Art. 39(4)).

To enhance scientific scrutiny, EFSA assessments should be fully reproducible by other scientists. They should have the possibility to readily re-use non-confidential industry study data, including for new scientific publications. It means the format in which the data is made public should be easily processed by a computer (i.e. ‘machine-readable’). This point

Disclosure of industry studies

- No important piece of safety-related information shall be hidden away from the public;
- Independent scientists should be free to quote or re-use the data disclosed by EFSA without having to ask for industry’s permission.

must be made clearer in the proposal, which currently only provides that the data “*shall be available to download, print and search through in an electronic format*” (proposed amendment to Art. 38(1)).

Finally, the Commission’s proposal implies that independent scientists would have to seek industry’s permission to be able to re-use the data published by EFSA

and reference it in their publications. We are concerned this hurdle could discourage many of them to do so. **If independent scientific scrutiny of EFSA outputs is to be enhanced, then scientists should not need industry approval to quote or re-use data disclosed by EFSA.**

2.2. No study kept in the drawer

BEUC welcomes the establishment of an ‘Union Register of Studies’ coupled with an obligation for companies and Union laboratories to notify EFSA of any study commissioned with a view to supporting a future authorisation dossier (new Art. 32b).

Evidence⁵ shows that industry-sponsored research often favours the interests of the sponsor, either by design or because of publication bias. It occurs when entire research studies are not published, or only selected results from the studies are published. The EU register of planned studies will prevent that any industry research giving unfavourable results is left in a drawer – if not stopped at the lab stage.

⁵ Lesser, L.I., C.B. Ebbeling, M. Gozner, D. Wypij, and D.S. Ludwig. 2007. ‘Relationship between funding source and conclusion among nutrition-related scientific articles’. Public Library of Science Medicine 4:41-46.

The Union Register of Studies, however, will only be useful if companies effectively abide by the notification obligation. To drive compliance, meaningful sanctions should be foreseen for industry applicants failing to notify studies commissioned to support a regulatory dossier. As such, instead of EFSA developing internal rules on this matter (as currently proposed), we rather recommend that **the European Commission should set in the law, by means of a delegated act, the consequences to be faced by companies breaching the notification obligation.**

2.3. Open science

When assessing industry application dossiers for new product authorisations, EFSA is already required to consider not only the safety studies submitted by companies, but also the broader available evidence – which may or may not confirm industry data.

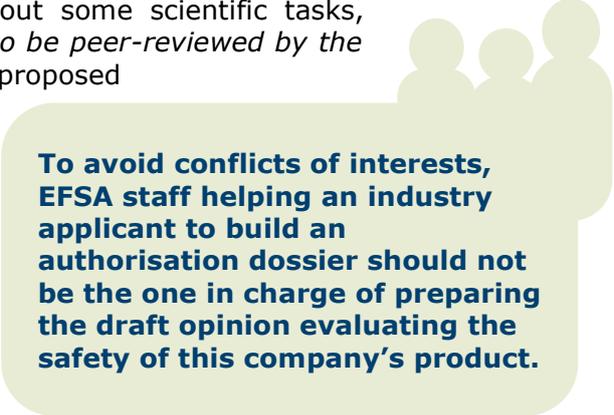
Yet to ensure that EFSA does not miss out on any relevant study, we support, in theory, the Commission's intention to organise public consultations on studies supporting an authorisation dossier (new Art. 32c). The practical ways for stakeholders and the public to submit additional data and/or studies for EFSA's consideration should be user-friendly enough so as not to discourage contributions. BEUC equally supports that EFSA consults stakeholders and the public on planned studies for product authorisation renewals.

In practice, however, we wonder whether all categories of stakeholders will have the necessary resources to make use of these new opportunities for providing input. We recommend **evaluating the new system of public consultations on authorisation dossiers after a few years' time**, to assess whether its use by various stakeholder categories is sufficiently balanced.

2.4. Caution needed on pre-submission meetings with industry applicants

It is a longstanding BEUC position that face-to-face meetings between EFSA and individual industry applicants should be prohibited. Such meetings can increase pressure on scientific experts and be excessively burdensome for EFSA staff. We argue that it is very difficult to gather knowledge from stakeholders in practice without being influenced by their evaluations. EFSA should focus instead on improving the Application Desk services and organising technical meetings with groups of applicants to make sure food manufacturers are informed about the kind of scientific evidence EFSA requires to perform proper scientific assessments.

The Commission's proposal foresees that 'general advice' meetings could be allowed between EFSA staff and food companies to help them better understand the required content of authorisation dossiers (new Art. 32a). While panel experts would not be involved, the provisions are still cause for concern when read in conjunction with the suggestion that EFSA's staff might carry out some scientific tasks, including *"preparing the scientific opinions to be peer-reviewed by the Panels before they adopt them"* (see proposed amendment to Art. 28, new paragraph 5f p. 25). It should be ensured that the **EFSA staff providing 'general advice' to industry applicants on how to build their dossiers is not subsequently in charge of pre-writing the opinions evaluating the companies' products.**



To avoid conflicts of interests, EFSA staff helping an industry applicant to build an authorisation dossier should not be the one in charge of preparing the draft opinion evaluating the safety of this company's product.

If such 'general advice' meetings are eventually introduced, **EFSA shall make public the list of companies it met with and the advice it provided**, as foreseen in the amendment to Art. 38 (new paragraph 1(i), p. 27). Moreover, **we recommend that a review clause be introduced to examine the impact of such measure after one year**. Attention should be paid to the additional workload triggered by this new EFSA 'service' to industry applicants, and whether it has led to any shift in the allocation of EFSA internal resources, at the expense of other activities of public interest.

2.5. Who should foot the bill for verification studies?

The proposal foresees that, in exceptional circumstances (e.g. high-profile public controversies such as the one around glyphosate), the Commission may request EFSA to commission extra studies to verify the reliability of industry data (new Art. 32e). BEUC believes it should be possible for Member States to signal to the Commission the need for such verification studies. We also recommend that the proposal should define what these "exceptional circumstances" shall be.

The costs for carrying out these studies will be borne by the EU budget. We would rather suggest that companies whose products are subjected to extra testing should pay for these verification studies, unless the latter confirm the findings of the studies they themselves submitted to EFSA.

3. Improved risk communication

The General Food Law defines risk communication as the "*interactive exchange of information and opinions throughout the risk analysis⁶ process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions*".

Recent controversies around glyphosate, Bisphenol-A, endocrine disruptors or even acrylamide have served to illustrate deficiencies in EU risk communication, and we welcome the European Commission's move to tackle them.

3.1. Treating all 'interested parties' on an equal footing

We support the Commission's intention to make risk communication more effective by developing a 'General Plan for Risk Communication' (new Art. 8c). It will help streamline the interaction with stakeholders throughout the risk analysis process, hopefully ensuring it is sufficiently inclusive and balanced.



The 'General Plan for Risk Communication' shall consider that stakeholders have different resources and capacity to contribute to the policy-making process. It should strive to compensate for this imbalance.

⁶ Risk analysis comprises risk assessment, risk management and risk communication.

Risk assessors and risk managers should keep in mind the discrepancy in resources across different stakeholder categories and, to the greatest possible extent, the future risk communication framework shall compensate for this imbalance. It is essential that risk assessors and risk managers are not perceived as being more open (rightly or wrongly) to the input of some stakeholders compared to others.

The proposed amendments on risk communication (new Art. 8a, 8b, 8c) repeatedly refer to 'interested parties', which should be involved and should receive information throughout the risk analysis process. It is however not clear who these 'interested parties' are, i.e. whether they would systematically comprise all food chain stakeholders or, if not, who would decide on which parties are 'interested' in a specific issue or stage in the risk analysis process.

This is especially relevant in the case of regulated products (e.g. food additives, novel foods): would it be considered that only the industry applicant is an 'interested party' in the evaluation and approval process? **We strongly recommend that 'consumers' and 'consumer organisations' be explicitly mentioned as key 'interested parties'**. As an example, BEUC has on several occasions – but without success – called on the European Commission to find ways to better involve consumer organisations in discussions pertaining to new and extended food additive uses.

Moreover, the tailoring of risk communication to the needs of various target audience groups **shall never result in an unequal level of involvement, nor should it lead to some groups receiving truncated or distorted information.**

As intended by the Commission, it will be important for the new risk communication framework to apply both at EU and national levels. Experience from BEUC member organisations shows that Member States have varied and inconsistent approaches to engaging with stakeholders, with some being much more inclusive and transparent than others. For instance, some Member States (e.g. the Netherlands) have an excellent track-record in sharing agendas and detailed minutes of Standing Committee and European Commission working group meetings with all stakeholders. We would welcome it if other Member States would have similar transparency standards.

Finally, **BEUC calls for the 'General Plan for Risk Communication' to also apply to communication at times of crisis**⁷. It should therefore lay down rules on how consumers and the public need to be informed in the event of a food crisis. The GFL fitness check pointed at inconsistent national approaches to crisis communication and product withdrawals in the event of a widespread food safety- or fraud-related incident. This shortcoming must be addressed (see also point 5.2 of this paper).

3.2. Better explaining risk management decisions

If they are to trust the EU food regulatory system, consumers need to be able to understand the reasons leading to some policy options being chosen over others to address the risk(s) identified during risk assessment. This is the case for example for decisions to resort to the precautionary principle or not; to go for full ban vs. setting of legal limit, etc. As such we welcome the new Art. 8a (c) which calls for risk communication to "*provide a sound basis for understanding risk management decisions*".

⁷ The GFL REFIT report distinguishes between 'risk communication' (i.e. the interactive exchange of information and opinions throughout the risk analysis process among all concerned actors) and 'communication at times of crisis' (i.e. communication when food crises erupt).

Indeed, disagreements over a product/substance authorisation can arise from considerations that go beyond science/risk assessment and belong to the “other legitimate factors” to be considered in risk management. Such factors can be for instance the technological need and the risk to mislead consumers when it comes to food additives, or the nutritional relevance when it comes to authorising a new health claim⁸.

From the consumer perspective, it is important that EU policy-makers consider these ‘other legitimate factors’. Not only science and safety deserve full consideration by decision-makers when weighing policy options, but also socio-economic, ethical, environmental, etc. aspects as well as consumer preferences and attitudes towards certain technologies.



EU risk-managers must better explain to the public the political choices (including possible trade-offs) behind any policy decision about food.

We have occasionally deplored the relative weight given to various conflicting considerations in decision-making. The future ‘General Plan for Risk Communication’ must ensure that **EU risk managers better explain the political choices**

(including possible trade-offs) behind any measure for it to be better understood by consumers.

Ultimately, for risk management decisions to be fully transparent, **Member States’ votes in so-called Comitology procedures should become public**⁹.

We are aware of the separate Commission’s proposal to increase transparency and accountability in the procedures for implementation of EU legislation¹⁰ (i.e. Comitology) – still under examination by the Council and European Parliament. Yet we believe it is necessary to increase voting transparency not just at Appeal Committee level, but already at Standing Committee level.

This will help ensure greater accountability in the decision-making process. Until such more fundamental change takes place, the improvements to risk communication put forward by the European Commission are a first step in the right direction.

4. An effective EFSA

4.1. Greater Member States’ involvement must not jeopardise EFSA’s independence

To address EFSA’s difficulties in attracting the best possible scientific expertise, the Commission wants Member States to put forward lists of potential experts to sit on EFSA panels (amendment to GFL Art. 28). It also proposes that Member States shall be represented on the EFSA Management Board (amendment to GFL Art. 25). This would align the composition of EFSA’s Management Board with that of other EU decentralised agencies (such as the EU Chemicals Agency and the EU Medicines Agency)¹¹.

⁸ Claims on the health effects of glucose, although found to be substantiated by EFSA, were [refused by the European Commission and Member States](#) as they would have conveyed a conflicting and confusing message to consumers, by encouraging consumption of sugars.

⁹ Risk management decisions on whether to authorise new food additives, novel foods, GMOs, etc. or not are made according to the Comitology procedure.

¹⁰ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017PC0085&from=EN>

¹¹ [Joint statement](#) of the European Parliament, the Council of the EU and the European Commission on decentralised agencies

A greater involvement of Member States can be positive provided it leads to strengthened scientific cooperation between EFSA and national food safety agencies or/and to Member States control authorities sending EFSA more data (e.g. on contaminants, food additive uses).

However, it must not jeopardise the clear separation between risk assessment and risk management, which has been set up as one of the key measures to restore consumer trust in food safety after a series of major crisis (BSE, dioxins) back in the early 2000s.



Those who assess risks should not be the ones managing such risks. A greater involvement of Member States with EFSA must uphold this clear separation.

The Commission's proposal provides that experts appointed to EFSA panels upon Member States' suggestion shall not receive any instruction at the national level. While it is certainly essential, this will be difficult to verify in practice. As a complement to the lists of candidates to be nominated by Member States, **EFSA should consider maintaining a parallel, open call for experts to whom a certain number of seats on EFSA panels would be reserved.**

As for Member States' representatives on the Management Board, their background and experience should be such as not to risk making the Advisory Forum (which comprises representatives of Member States' national food safety authorities) redundant.

4.2. EFSA review clause

Finally, BEUC is concerned with the revised review clause (Art. 61), which in our view gives the European Commission too much influence on EFSA. It foresees that EFSA's performance should be evaluated by the Commission, instead of an independent external auditor as is the case today. The evaluation would follow some Commission guidelines, whereas today it is based on terms of references issued by the Management Board.

Of concern are also the new provisions whereby "*where the Commission considers that the continuation of the Authority is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose that the relevant provisions of this Regulation be amended accordingly or repealed*" (revised Art. 61(3)).

In the interest of EFSA's independence, we would recommend deleting those altogether and reverting to the current review clause under the GFL which foresees that changes to EFSA and/or its working practices may only be proposed by the Management Board.

5. What about other key findings from the GFL REFIT?

The proposal to increase the transparency of EU food risk assessment is certainly welcome, but it will take more than this 'quick fix' – however positive – to fully restore consumer trust in EU policy decisions about food. Thus, we urge the European Commission and Member States to also follow-up on other key findings of the GFL REFIT.

5.1. Make healthy and sustainable food choices a higher EU priority

As the GFL REFIT found, nutrition-related issues have not progressed as much as food safety. An EU legal limit on trans fats in food is yet to be established, nutrient profiles are long overdue (and now subject to a specific REFIT evaluation) and reformulation initiatives to cut levels of salt, saturated fat and added sugars in food are progressing at a very slow pace. Consumers still have a challenging time figuring out the nutritional value of food and drinks in the absence of simplified nutrition labelling, and children remain widely exposed to the marketing and advertising of food high in fat, sugars and salt.

In general, the protection of consumers' interests about food beyond safety is lagging (e.g. in relation to food origin information) and more needs to be done to combat fraud and misleading practices (e.g. dishonest food labels). The REFIT report also notes the GFL is not fully adequate to address food sustainability and waste.

The General Food Law REFIT highlighted

- insufficient progress on nutrition-related issues;
- inconsistent approaches to managing food safety crises by Member States;
- persisting regulatory gaps in certain areas of EU food law;
- differences in the way Member States interpret, implement and enforce EU food law requirements.

Healthy food, honest labels and sustainable food choices are critical issues for EU consumers. The protection of consumers' health (incl. nutrition) and interests in relation to food is already a key principle of the GFL and should therefore be implemented more effectively and consistently throughout EU secondary legislation. For issues less adequately addressed by the

GFL, such as sustainability, the Commission should make full use of other relevant EU policies to tackle them (e.g. the Common Agricultural Policy).

5.2. Improved communication at time of crisis

The 2017 Fipronil in eggs scandal shed light on diverging national approaches to product withdrawals and their communication to the public, with a direct impact on consumer trust. Certain Member States published - proactively or following pressure by consumer groups - the lists of withdrawn egg-based processed foodstuffs found to contain Fipronil levels above the legal limit (i.e. non-compliant but not necessarily risky for health). Others only published information on recalled products (i.e. posing an immediate risk to health). It resulted in confusing situations for consumers, whereby products appearing on a given country's list were still available on supermarket shelves in another country.

In a Single Market, there is a need for a more consistent and transparent approach to product withdrawals in the event of a widespread food safety- or fraud-related incident. The Ministerial Conference on Fipronil held in September 2017 agreed on a set of measures to be implemented to improve food crisis management at EU level in the future¹². We urge the Commission and Member States to follow-up on them, particularly as regards the need to improve official communication to the public on food incidents.

¹² https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_fipronil-incident_conclusions_201709.pdf

5.3. Fill the regulatory gaps for increased consumer protection and choice

Some areas of EU food law remain incompletely harmonised. One example is the food supplements market, with a patchy regulatory framework resulting in varying rules for product classification, substance authorisation and information requirements.

In the absence of EU rules, Member States have no choice but to develop their own national measures to protect their consumers. The industry often denounces such measures as being 'trade barriers' in the Single Market, whereas they are in fact important consumer protection rules. We therefore encourage the Commission to consider harmonising those areas that remain incompletely regulated at EU level, in the interest of consumers and businesses alike. To start with, the Commission could work on setting long overdue maximum levels for vitamins and minerals in food supplements.

5.4. Ensure an effective and harmonised enforcement of EU food law

The GFL REFIT highlighted diverging interpretations of EU legislation by Member States, variable national approaches to the implementation of official controls (with some Member States relying more than others on industry's own checks), as well as differences in the severity of national measures and penalties. For instance, a recent access-to-document request¹³ exposed the hugely inconsistent fines that various Member States apply to companies who breach the Novel Foods Regulation.

This does not come as a surprise, as reports by DG SANTE's audit and inspection services (former Food and Veterinary Office) have regularly pointed at these national differences¹⁴. **In a Single Market, it is vital that all Member States correctly and effectively perform their enforcement duty.** Recent incidents of contaminated baby formula in France, and meat produced in unhygienic conditions in the UK and Belgium show us the need for tighter food controls. Governments must allocate sufficient resources for official controls instead of relying ever more on industry's own checks. The Commission has a key role to play in assisting Member States to correctly interpret and enforce EU law.

END.

¹³ https://www.asktheeu.org/en/request/penalties_notification_regulatio

¹⁴ See for instance overview reports on [Controls on Food Supplements](#) or on [Official Controls of Food Additives and Smoke Flavourings in Meat Products](#).



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