SAFE'S FEEDBACK TO THE EUROPEAN COMMISSION CONSULTATION ON "TRANSPARENCY AND SUSTAINABILITY OF THE EU RISK ASSESSMENT MODEL IN THE FOOD CHAIN"

In January 2018, SAFE provided its feedback on the European Commission Consultation titled "Transparency and Sustainability of the EU risk assessment model in the food chain", aimed at solving the concerns arising when assessing the safety and the security of food and feed products in the European Union. Following the consultation, SAFE participated in the ad hoc *meeting of the Advisory Group on the food chain and animal and plant health on Transparency and sustainability of the EU food and feed safety risk assessment model, which took place on the 5th of February 2018 and was chaired by the DG SANTE Director for Food Chain: stakeholder and international relations.*

BACKGROUND: EFSA AND THE EUROPEAN COMMISSION CONSULTATION

The European Food Safety Authority (EFSA) was established in 2002 as the EU public and independent risk assessment body in the EU food system. Its role is to evaluate food and feed products that require a safety assessment before they can be used on the EU market. EFSA is also tasked with collecting data on food consumption patterns, biological risk, contaminants in food and feed, as well as residues. It is important to underline that **EFSA does not perform the scientific studies itself**, as its role is to assess the available scientific studies (and data-gathering methodologies) relating to a specific issue about food and feed safety. Therefore, **EFSA is tasked to perform an independent scientific peer review of the assessment report produced by designated rapporteur Member State, in cooperation with all Member States**.

Over the last few years, EFSA has been in the spotlight on many occasions, mostly in relation to its lack of independence, transparency and (therefore) credibility. With the European Citizens' Initiative "*Ban glyphosate and protect people and the environment from toxic pesticides*" (ECI 'ban glyphosate'), the petitioners requested to "*modify the EU pesticide approval procedure to tackle the transparency and independence of the scientific studies used to support authorisation dossiers*". Indeed, **the current procedures are not allowing the European consumers to benefit from the best level of safety of the food they consume**. Responding to the ECI 'ban glyphosate', the Commission acknowledged that "*transparency in scientific assessments and decision-making is vital to ensuring trust in the regulatory system. It also attaches continued importance to the quality and independence of the scientific studies that are the basis of the EU risk assessment carried out by EFSA*". Therefore, **the Commission agreed to come forward with a legislative proposal by May 2018** covering these issues as well as other aspects (such as the governance of EFSA), drawing on the results of the Fitness check of the General Food Law Regulation and after a public consultation. **The stated aim of the Commission is to adjust the current processes while responding to new challenges by increasing the transparency, the accountability and the sustainability of the related risk assessment process.**

LACK OF INDEPENDENCE

One of the main characteristics of EFSA is to be the independent agency that will assess the scientific studies relating to food and feed safety. As expected, the capacity to gather independent experts not linked to the industry has been a crucial issue for EFSA, as well as a strong source of criticism from many NGOs. In its roadmap, the Commission pointed out that distrust over the EU's food regulatory system was due to "*EFSA's evaluations of authorisation dossiers being essentially based on studies, data and information generated (and paid for) by the applicant for authorisation*". Under the current procedures, the applicant for an authorisation must "*provide the scientific evidence supporting it*",

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which means such applicant will have to spend its own funds in costly studies. In the absence of independent studies on which to build a comparative analysis, the controlled becomes the controller. While the funding ratio behind this principle is overwhelmingly accepted, the current EFSA's administrative structure has three main consequences on its independence.

The first consequence directly relates to the **impartiality of scientific studies and data collections** (which, under the present rules, are always coming from industrial applicants) on which the peer review is performed. As various members of SAFE have noted on multiple occasions, there cannot be a fair, independent assessment if there is no access to data collections, independent collection of data, and third-party reviews of data gathered and independent studies. Due to the lack of independent studies available to the scientific community, scientific scrutiny of the studies that underpin the EU policy-making cannot be peer-reviewed and evaluated; thus, no benchmarking or comparative analysis is possible, which results in a serious lack of scientific basis for EFSA's authorisation of substances and European policies. The second consequence regards the **general administrative organisation and governance of EFSA**, and in particular of its Management Board. EFSA's current rules are making it more difficult to attract new, independent experts, not linked to the applicant (industry) authorisations' requests. Thus, SAFE believes that the current organisation is a serious limitation to EFSA's work, and prevents the Agency from reaching its objective of granting EU consumers that the food and drinks they purchase in the EU are healthy and safe. The third consequence is strongly linked to the previous one, as even **the recruitment process at EFSA has shown a lack of independence**. In June 2017, after a very long drafting process by EFSA's Management Board, EFSA adopted and published its new independence policy, replacing the previous rules (which existed since 2011) that had been criticised by many, including the European Parliament. This internal policy change was done just in time for the selection of the EFSA's 2018-2021 panel. Although the new policy is a moderate improvement, it did not solve the policy's main and various conflicts of interests remain, especially on financial grounds.

LACK OF TRANSPARENCY

As acknowledged by the same European Commission, "*Citizens perceive the risk assessment process (and the decision-making based on it) as opaque*". The main reason for this is the plethora of transparency and confidentiality rules that are applicable to the risk assessment and decision-making process, that are often not fully understood by the EU citizens, contributing to the opacity of the risk assessment process. Indeed, the capacity of EFSA to ensure transparency in its procedures conflicts with its rules on confidentiality: while EFSA should be open on the scientific studies (and sources) and on data collections (including the data-gathering methodologies), it must avoid harming intellectual property rights and commercial and manufacturing secrets coming from the applicants. This means that, at the request of the applicant, some documents may not be available to the public. However, as the applicant is in general the industry and has little interest in rendering any document available to the public, an increasing number of documents has not been made open for public review, up to the point that there are more confidential documents than publicly available documents in EFSA's dossiers. While it is understandable that commercial stakeholders wish little disclosure of their industrial secrets in order to protect their business, the fact that they also have the full burden of the proof for food and feed safety means that they are enabled to request that the risk assessment documents will not be public. These provisions are highly problematic for the scientific scrutiny of studies that underpin the EU policy-making as, by definition, a confidential unpublished study cannot be peer-reviewed and evaluated by the scientific community. In fact, **EFSA used confidentiality of the source as the main reason to prevent access to many documents, including important sources of research and data that later justified its authorisation decisions.** As constantly reminded by scientists, disclosing all sources and be based on publicly available evidence is "*a requirement for*

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publication in virtually all scientific journals where financial support, conflicts of interest and affiliations of authors are fully disclosed". As these documents are unlikely to be released, the decision made by EFSA are less and less transparent, strengthening the image of opaque procedures.

This lack of transparency was recently pointed out in many dossiers, but mostly in reference to the risk assessment of glyphosate. In that circumstance, **EFSA refused to share the raw data of three important scientific studies used for the evaluation, justifying its stance by saying that the disclosure of this evidence would undermine corporate secrets and intellectual property rights.** After multiple requests, including from Members of the European Parliament (MEPs), as well as by the institution itself, to enable public access to documents, **in December 2016 EFSA released multiple redacted documents; the extent of the "hidden" parts of the documents rendered said documents mostly useless** not only to competitors, but also to scientists and to the public. EFSA rejected that the documents were not useful, arguing that, when combined with the detailed background documents already published on EFSA's website, the information provided would have been sufficient to enable a third-party scientist to scrutinise EFSA's evaluation of glyphosate. Nonetheless, in the case of glyphosate as well as on other dossiers, **many scientists and experts expressed their concerns on such a system, highlighting that transparency and the ability to question or debate the findings of others are a crucial aspect of the scientific method, which is based on a careful and constant evaluation of raw data of other studies.**

LACK OF CREDIBILITY

The negative perception on the lack of its independence and transparency has clearly affected EFSA's credibility. As said before, it is not credible, for EFSA, to perform a transparent peer review of the applicants' requests for authorisation if there is no public access to documents, if the experts chosen to perform this peer review are not impartial, and if there is a lack of independent scientific studies to perform such peer reviews. EFSA's credibility was called into question on all these issues during the risk assessment for the glyphosate (re)-authorisation, as it was noted in the ECI 'ban glyphosate'.

EFSA's credibility was also undermined in relation to other international assessment institutions such as the International Agency for Research on Cancer (IARC), whose *ad hoc* Working Group on the glyphosate (IARC WG) came up with a different conclusion compared to EFSA's. The latter's assessment on glyphosate has been considered as poorly-motivated when confronted to the IARC WG, as it failed to base itself on publicly available studies, thus rendering impossible to perform peer review, as we already mentioned. It has been debated, in the scientific community, that EFSA incorrectly dismissed evidence as "chance occurrences". It has also made evident that the methods used by EFSA to review studies in the glyphosate assessment regarding historical controls and trend analysis are inconsistent with the EFSA's self-appointed guidelines (made by the OECD and by the European Chemicals Agency Guidance).

Last year, at SAFE's 2017 Annual Conference titled "EU Food Safety Regulation: Putting Consumers First – An overview of current issues and how to increase consumers' protection", participants (which included experts from EFSA) agreed that there are EFSA's opinions that remain subject to controversy. This was the case with glyphosate's license renewal, as Member States such as Italy, France and Belgium did not trust EFSA's risk assessment and voted against the renovation of glyphosate's license. This behaviour has a particular weight regarding the credibility of a European agency such as EFSA, which plays a key role in the assessment of food safety for consumers.

CONCERNS FOR EFSA'S FINANCIAL AND SCIENTIFIC SUSTAINABILITY

Both EFSA and the EU risk assessment model in the food chain have been called into question with regards to their sustainability. An important issue on EFSA's sustainability is related to its funding, as **the Agency is under-funded and under-staffed**. While part of the financing of scientific studies for the assessment of applicants' requests seemed to have been solved by putting the burden of the proof on applicants (normally private stakeholders, i.e. industry), nothing was foreseen to foster independent studies that could be used in order to peer-review the so-called "industry-generated studies and data". On the contrary, **EFSA should be able to finance independent research**, in order to benchmark and perform comparative analyses on the data made available by the applicants. However, to provide funds for the independence of research, **EFSA needs to achieve its own economic independence and this could be achieved through an "industry tax"**, a fixed tax rate to be paid by agri-food industries in order to provide funds that EFSA will allocate to independent researchers that are not related to the agri-food industry sector.

As far as EFSA's scientific sustainability is concerned, the issue at stake is its capacity to continue to work as an independent science-based agency. As the Commission warned in its Initiative's Roadmap, the "*high level of scientific expertise*" that should be provided by EFSA is related to "*its capacity to pool expertise from Member States*". It is therefore important that EFSA's rules create the possibility to attract new, independent experts – not linked to the applicant authorisations' requests – so that EFSA can pursue its mission to provide EU consumers with healthy and safe food.

CONCLUSIONS

The current risk assessment of EFSA clearly lacks independence, transparency and credibility. As food safety in Europe depends on the capacity of the Agency to carry out a proper assessment on the potential harmful effects of the tested substances, **performing an unreliable risk assessment based on non-publicly available documents and non-independent experts can weaken the outcome of the assessment and of the political decisions based on it, hampering the health and safety of EU citizens**. SAFE believes that it is fundamental for EFSA to regain a serious credibility in the EU. In fact, if its work is not deemed trustworthy by the EU consumers and by independent scientists, EFSA cannot efficiently support strong European policies. The glyphosate affair demonstrated the lack of trust from founding Member States such as Italy, France and Belgium towards EFSA's risk assessment on the pesticide. This is a very risky and dangerous position for the future of EFSA, which is why there is an urgent need to improve the Agency's risk assessment model. **During its 2017 Annual Conference** titled "*EU Food Safety Regulation: Putting Consumers First – An overview of current issues and how to increase consumers' protection*", **SAFE proposed various solutions to the EU risk assessment model's transparency and sustainability in the food chain**. Confronted to the question "*How can EFSA bring consumers and stakeholders together?*", the participants proposed the following **recommendations for EFSA, later presented at EFSA's Conference in May 2017**:

- Strengthen the information to consumers and raise awareness about food components, which should be done by enhancing direct communication via short commercials on social media and on television;
- Provide independent, industry-free information to consumers;
- Organise forums and discussion that will effectively involve all stakeholders in the risk assessment process, and that should not be just consultative events;
- Strengthen the data transparency by publishing all research documents from EFSA;
- Provide for the independence of research, thanks to economic independence of EFSA – to be done through an "industry tax".