European Ombudsman

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European Ombudsman

Mr Jean-Claude Juncker

President of the European Commission

Strasbourg, 19/03/2018

Strategic initiative SI/1/2018/KR

Subject: Public consultation on the transparency and sustainability of the EU risk assessment model in the food chain (DG Sante, directorate D, unit D1) - Contribution from the European Ombudsman

Dear Mr President,

I am very pleased to be able to contribute to this important public consultation which, I understand, will inform the European Commission's proposals for new legislation to (among other things) improve the EU's regulatory decision-making system in the area of food safety.

My Office has in recent years carried out inquiries and activities related to the EU risk assessment model in the food chain. This letter (and the completed questionnaire attached) sets out my views and reflects my work in this area to date.

On 18 October 2017, I hosted a stakeholder discussion on how the EU's agencies can implement the highest ethical and transparency standards to protect themselves from reputational damage. This discussion revealed a broad consensus that greater transparency of the information that agencies process, combined with exchange and engagement with stakeholders, is crucial for establishing and maintaining trust.

This is why I suggest three guiding principles for improving the EU's risk assessment model in the food chain, namely **that it is independent, transparent, and ensures meaningful engagement with stakeholders and the wider public**. I have structured this letter along those three key principles, and have included some remarks on **effective risk communication**.

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1. Independence

The independence of EFSA is enshrined in EU law. Beyond this legal obligation, it is crucial that, in the eyes of the public, EFSA is seen as being fully independent in how it operates.

There are limits and constraints applying to EFSA's risk assessment work. EFSA's scientific opinions and advice is based on assessments of sometimes conflicting, or at least not uniform, evidence. These assessments are based on agreed procedures and on agreed criteria regarding what evidence must be taken into account. It is crucial that the procedures followed, and the decisions on what evidence is 'admissible' or relevant, are taken in good faith by experts acting independently, professionally and in the public interest.[1]

In its procedures, for example when preparing a recommendation for the EU-level authorisation of a substance, EFSA is legally bound to base its assessment, in part, on studies submitted by the applicant (the company seeking authorisation). **Safeguards need to be in place to ensure that the applicant's input is factually correct and consists of a representative sample of all relevant data**. As a risk assessor, EFSA also needs to be seen, from the public perspective, to be critically scrutinising the application. **Should it appear that relevant facts have been overlooked or not reported by the applicant, EFSA should correct this without undue delay and on the record**.

In my decision on a recent inquiry, I found that making public as much information as possible about applications avoids misunderstandings and builds public trust in EFSA's procedures. This is why I suggested that, **where EFSA requests and receives additional data from an applicant, it should make this additional data publicly-available** in order to avoid any public perception that the file is incomplete.[2]

Aside from the procedural aspects of EFSA's risk assessment work, the experts involved have an important role in ensuring EFSA's independence. It is thus key that **experts and staff members involved in EFSA's work are open and frank about any interests they have that are relevant to their work**.

EFSA, along with other EU agencies, has at times been criticised for being too close to industry. In an attempt to raise awareness among staff working in the EU institutions and agencies of the influential role that industry plays in shaping policy decisions, I have issued practical recommendations (10 Dos and 10 Don'ts) to guide EU civil servants in how they engage with interest representatives.[3]

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[1] It is of course necessary for EFSA to constantly monitor the real life impact of regulatory decisions, including any emerging new evidence, in order to determine if the regulatory assessments were correct or if they still apply.

[2] See the European Ombudsman's decision in case 176/2015/JF on the alleged failure of the European Food Safety Authority to reply adequately to questions about an authorisation application for genetically modified maize, point 24 and Conclusion: https://www.ombudsman.europa.eu/cases/decision.faces/en/87372/html.bookmark.

[3] 'Practical recommendations for public officials' interaction with interest representatives', see: https://www.ombudsman.europa.eu/cases/correspondence.faces/en/79435/html.bookmark.

2. Transparency

An essential element of the scientific method is that research findings are published, and that authors of studies are identified. This allows fellow researchers to scrutinise the results by replicating experiments, and the public to check whether there are any conflicts of interests. There is a legitimate public expectation that this should apply to public authorities that conduct scientific assessments. If the data on which an EU risk assessment is based (or part thereof) is not made publicly-available, it is difficult or impossible for third parties to verify the conclusions. This risks undermining trust in the EU risk assessment model in the food chain.

In the cases I deal with, I at times come across instances where information is not disclosed because it is deemed confidential business information. There might be valid reasons why certain information cannot be released. However, I believe that, to the extent possible, non-confidential summaries should be drawn up of such confidential information. **Given the regulatory responsibilities of EU agencies, the point of departure for discussion has to be that the public has a right to know on what basis decisions are made**.

Risk assessments of food and feed products, as well as of active substances for plant protection products that are currently on the market, are generally of interest to the public. The public should be able to ascertain on what basis the conclusions in EFSA risk assessments are reached. This would have a positive impact on public trust in EFSA's ability to carry out its tasks in full independence.

In recent years, the EU risk assessment model for medicines has made important progress in terms of providing transparency on the evidence that is considered in assessing whether medicines are sufficiently safe. On 1 January 2015, the European Medicines Agency (EMA) started to proactively publish clinical data submitted to it. In considering applications for 'marketing authorisations' of medicines, EMA looks at clinical data that is submitted with the application. The applicants use this data to seek to demonstrate the safety and efficacy of a medicinal product. This is comparable to the process by which EFSA uses 'guideline studies' (provided by industry applicants) when it carries out its scientific assessments. In both cases, data provided by the industry applicants is used to assess the safety of the products or substances for which an authorisation is being sought. I believe that EMA's proactive publication policy for clinical data[4] can be an exemplar for improvements in the EU risk assessment model in the food chain.

An important difference, however, between the risk assessment model for medicines and the risk assessment model in the food chain is that the medicines are not yet on the market (at least for the indications under assessment), whereas the food and feed products and certain active substances in plant protection products (like glyphosate) are on the market *pending* their

[4] See: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf.

assessment. Greater p**ublic scrutiny of EFSA's risk assessment duties at an early stage in the process is thus warranted, arguably before EFSA has adopted its opinion.**

EU institutions, bodies and agencies should give citizens and interested parties the tools to inform themselves. In my view, it is not enough to release a mass of information on a website and consider that, from that point, the public will be able to make use of it. **Ideally, the information should be made public in a structured way, in a single location, and be regularly updated.** It would therefore be useful to create an open registry of studies, which are published in a machine readable format, with a view to facilitating public access.

It is neither necessary nor desirable to differentiate between those who might potentially seek to access such information, by creating different levels of access for different stakeholder groups. Doing so could be burdensome for officials who would have to assess each request for access individually. This could create a barrier between the public and information whose disclosure is likely to be in the public interest. It might also be at odds with EU rules on public access to documents. In my view, **it would be better to create a system that makes all relevant information publicly-available, and which does not restrict certain information to certain groups of stakeholders**.

3. Ensuring meaningful engagement

EFSA is committed to involving the public and its stakeholders in the process of risk assessment. In my view, that engagement should be **inclusive**. It should strive to strike a balance between stakeholders with limited resources and well-resourced, larger entities. I note that the European Chemicals Agency (ECHA), on occasion, offers to reimburse travel and accommodation costs for organisations that otherwise would lack the financial means to participate in relevant meetings during its process for assessing substances.

Equal access to information implies ensuring that the wider public, beyond EFSA's accredited stakeholders, can follow EFSA's activities. This is in line with EFSA's objectives on openness and cooperation. Since 2014, through its 'Open Plenaries', EFSA has given the public and stakeholders the chance to take part in meetings. In 2018, EFSA's Panel on Plant Health will be the first to open its plenary meetings to observers.[5] I encourage EFSA to explore whether the **web-streaming of** meetings of its scientific panels and committees can become its default practice.

EFSA should **publish agendas and minutes of meetings it organises**, without undue delay, so the public has the possibility to follow these meetings. It is important that such agendas and minutes contain meaningful information and are complete. Operating transparently, and giving the public easy access to the mandates for opinions, scientific opinions and reports, is also very important for ensuring public trust in the process.

[5] See: https://www.efsa.europa.eu/en/press/news/171206.

The issue of when industry studies are made available is an important question, as this will undoubtedly determine to what extent the public will be able to engage in and contribute to EFSA's work.

It is likely there will be higher than average levels of public interest where companies are seeking authorisations (or renewals of authorisations) for active substances in herbicides or pesticides or for genetically-modified organisms (GMOs). In such cases, access to the studies at an early stage could help to build trust in the risk assessment procedure. To this end, **publishing the non-confidential parts of the industry studies before EFSA's opinion has been adopted** and once the confidentiality claims, if any, have been assessed, is likely to have the most positive impact on the transparency of the risk assessment system. This way, any pertinent observations that other interested scientific or third parties make on the basis of the released data could be taken into account in the deliberations that precede EFSA's opinion, allowing more meaningful public engagement.

Depending on the extent to which the studies are made public, it could also have a positive impact on enabling other scientific and third parties to scrutinise the data. This is a delicate point, however, which I feel should be explained in some detail.

The public consultation asks what impact would the publication of industry studies (including raw/aggregated data) used in the EU risk assessment, with the exception of business secrets or other confidential information, have on 'allowing scrutiny by other scientific and third parties'.

In response to a request for public access to documents[6], EFSA released the raw data behind the industry guideline studies that it had used in its assessment of glyphosate. At the time, EFSA argued that, together with its conclusion and other background documents related to its assessment of glyphosate, the raw data would "provide enough information to allow full independent scrutiny of the EU scientific assessment".[7] A third party who attempted to scrutinise that assessment, and subsequently made his views public in an open letter[8], has claimed that for a proper 'reassessment', additional sections of the safety records linked to the industry studies would need to be released. This, according to the third party, would include the "materials and methods, analysis and [the] discussion sections". Without this data, he said, it would be impossible to scrutinise "the quality of the studies", or "the rigor of the methods used to analyze the data".

It is not possible for me to take a position on precisely what information other scientific or third parties would need in order to be able to do a full reassessment of the industry studies used by EFSA in its assessments. However, I do point out that, in line with principles of public access to documents held by EU institutions, agencies and bodies, **the narrowest interpretation of what information is deemed commercially confidential appears necessary in order**

[6] See: https://www.asktheeu.org/en/request/is_glyphosate_safe_we_have_the_r
[7] See: https://www.efsa.europa.eu/en/press/news/161209.
[8] See: https://www.nrdc.org/sites/default/files/open-letter-from-dr-christopher-portier.pdf, p. 5.

to preserve the scientific utility of the published data, that is, to allow for a meaningful scientific reassessment. There are also very strong reasons why there would, in any case, be an overriding public interest in access to such information since the public interest in the robustness of scientific studies, which provide the basis for regulatory assessments, will usually trump commercial interests in having scientific findings protected.

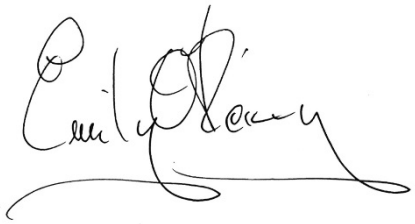
Risk communication

The public information tools that EFSA uses to raise awareness about the risks associated with certain substances or products should be available in all 24 official EU languages, so that this information is available to as wide a public as possible. It is also important that the rights of people with disabilities are respected, and that risk communication takes account of their needs.

Regulatory agencies have a difficult task in carrying out their scientific assessments and in explaining the conclusions of their assessments to applicants and the wider public. EFSA's assessment procedures are complex, and the body of data forming the basis for risk assessments can be extensive. The public generally does not have the knowledge or the expertise to critically assess either the research on which regulatory decisions are based or the procedures followed by the regulatory authorities. This makes it even more **essential that EFSA has accessible and easy-to-understand information** to explain its assessments and conclusions. Doing so can help to minimise the chances that this information is misunderstood or misinterpreted in the public debate. Members of the public expect and are entitled to not just information on risk, but a reliable explanation of what this means for them.

I would be grateful if you would take this contribution into account when considering the proposal for new measures to enhance transparency and sustainability in the EU regulatory system. Should you require any further information or clarifications concerning this contribution, please contact Fergal Ó Regan, head of unit (Tel: +32 228 43548).

Yours sincerely,



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Enclosure: European Ombudsman response to the questionnaire.