Joint Submission to EFSA's public consultation on its policy document

« Transformation to an Open EFSA »

by Bee Life, Corporate Europe Observatory, Earth Open Source, Fondation Sciences Citoyennes, GM Watch, Pesticides Action Network Europe

1) Are you satisfied that EFSA has identified the societal and normative expectations it has to comply with or would you suggest additional ones that the paper does not capture?

We would first of all like to thank EFSA for taking this long-expected initiative to evolve towards a more transparent Authority. This is a demand we have been making for many years and we are glad that the Authority has listened to our concerns and published this first public draft of a concrete plan to reach that goal.

A first observation is that there is a general tension in the document "Transformation to an open EFSA", issued by the Authority for this consultation, between the need to improve the Authority's openness and transparency and the necessity to safeguard its independence. This raises several questions.

We welcome EFSA's objective to become more transparent, especially with regard to the data it uses when carrying out risk assessments. In particular, we believe the mid-term objective that EFSA assigned to itself, namely to make its work "reproducible by interested parties" (§7 p.13), is fundamental to align EFSA's work with general scientific methodologies. However such transparency must entail a meaningful public access to all the data held by EFSA, not only to the data EFSA says to have used for its risk assessments. This will enable an informed public debate about EFSA's scientific opinions, helping the authority to regain the credibility it lost due to many scandals where the Authority's independence was shown to be compromised. There is obviously a lot of work still needed to reach that stage but we are happy to contribute to it, to the best of our capacity.

Regarding the term "openness", similarly, there is an ambiguity that would need clarification. Openness as a value is to be encouraged. However, we would criticise an openness that leads the Authority to increase its vulnerability to the influence of applicants and, generally, all interests aiming to capture the Authority's work for their private benefit. Experience with opening panel meetings to observers, for instance, shows that most "openings" to "stakeholders" are usually dominated by commercial players due to their substantial financial resources: a general and indiscriminate opening of the Authority's work to external contributions is therefore very likely to lead to an increased capture of the Authority's work.

Independence is one of the core founding principles of EFSA. We lament the fact that the document fails to mention it when listing the "high standards" EFSA must adhere to (§2 p.6). While the "open government" model is an important reference for governments, EFSA's duty as an expert public institution is also to be independent and issue the best possible scientific opinions to protect public health and food safety. While one of the obvious reasons for the Authority to launch this initiative is to regain public trust, the Authority's real and perceived lack of independence from commercial interests was and remains a crucial reason why EFSA's credibility has been undermined. This is actually the reproach that could be made to the document's vision statement, "Society engages in

EFSA's scientific work and gains trust in the EU food safety system" (p.8): to a large extent, and as this consultation illustrates, many members of the civil society already engage with EFSA's scientific work and this is why trust in the Authority's work was undermined! Giving more transparency on a compromised independence would just add to the problem: **EFSA's transparency and independence policies must be strengthened together. In other words, we consider that transparency and openness principles should be used to enable properly informed analysis of EFSA's work by society, but should not become ways for vested interests to influence the Authority's work or, worse, arguments to excuse the existence of this influence.**

A second observation relates to the methodology foreseen by EFSA for the assessment of the policy options it will consider: the "cost-benefit" analysis planned ("phase 3", p.12) is not clearly defined – nor is the identity of the person/institution who would perform the said analysis. While the implementation costs and benefits of policy options could perhaps be financially measured from EFSA's financial and accounting point of view, there are pending questions about the accountancy perimeter considered: will these costs and benefits only be assessed from EFSA's institutional point of view or will broader costs on industrial competitiveness and public health be considered too? Qualitative aspects must also be addressed, as the importance of certain policy options is not proportional to their financial implications for EFSA. However, the document is mute on the indicators foreseen, which undermines the transparency of the whole consultation exercise itself. Publishing the detailed cost/benefit analysis once it is performed would be very important for all to better understand the constraints EFSA is facing as well as where it stands regarding the various policy options considered.

A third and last observation is that EFSA's calendar aiming at finalising the development of its initiative in 2016 is really long and probably too long. Developing this draft policy document already took more than a year! We think EFSA must consider the emergency to regain citizens' trust and shorten its calendar.

2) **How can EFSA increase its openness to meaningful contributions from individuals and organisations beyond its Panels and Committee? Should a two-way interaction between EFSA's Panels and interested parties be facilitated? What limits should be set to such interaction?**

EFSA must open itself to contributions from anyone in the EU and not just "interested parties and qualified individuals" as such a definition of who is legitimate to interact with EFSA is too restrictive. Procedures must however be designed to allow meaningful contributions from outside EFSA that at the same time prevent attempts to capture EFSA's work by vested interests, starting with applicants themselves in the case of regulated products or producers in the case of commercial products more generally, as is well pointed in the document ("*greater involvement and participation could also hide potential risks, such as disproportionate influence of a limited number of acyors or loss of control by the Authority over the content of a document*" §6 p.7). This echoes what was said above about the need to jointly develop EFSA's transparency and independence policies.

In the current context where applicants perform the safety tests on their products and report the results, and in the light of EFSA's institutional and financial limitations, a good transparency policy will be one of the few real defence mechanisms available to EFSA against potential regulatory capture in the field of regulated products. This means, in principle, a complete, unrestricted and **proactive** online publication of full applicants' files when these reach EFSA in order to enable the reproducibility of the risk assessment performed (as opposed to the current reactive regime which is time and resource-consuming for the Authority).

A way to both strengthen the transparency of the risk assessment process and its independence will also be to ensure the highest level of transparency about the interests of the decision-makers involved in the risk assessment process (EFSA experts and staff). This is an aspect that we think is insufficiently emphasised in the document. On this issue, EFSA must implement a proactive publication of declarations of interests of EFSA's experts (including Working Groups members) and employees, kept online for five years after their employment at EFSA has expired. These should be regularly checked for accuracy and completeness by the Authority by using all public sources of information available.

In terms of the actual policy options considered, we now go through all of them with comments. The first figure refers to the step in EFSA's decision-making workflow, while the second figure is the policy option considered.

- 1.1 "Public consultation if a self task or issue of high public interest":
In general, we would not recommend this option because the mandate is the starting point of the whole work of EFSA, which means its wording is absolutely strategic. Most mandates received by EFSA come from the European Commission and comments should therefore be directed towards the European Commission on that point, not EFSA. We consider that EFSA's duty and responsibility is to deliver the best possible risk assessments: that should of course include closely monitor the evolution of scientific knowledge and societal debates to identify areas for self tasking, including remaining open to external suggestions, but we would not recommend systematically opening mandates formulation to public comments. If a public consultation was still seen as needed by EFSA on this point, it should be transparent in terms of the contributions received and in terms of the reasons why comments were taken on board or not.

- 1.2 "Pre-submission meetings (in case of regulated products)"
This option has been proposed repeatedly over the past years by EFSA's management and criticised each time by both non-commercial stakeholders and EFSA's Management Board, all the more when such proposals were accompanied by the idea to introduce fees for applicants for additional advice. We repeat our criticism here and oppose the idea to introduce such meetings. EFSA has already created an Application Desk to answer applicants' questions. Panel members must be protected from the pressures from applicants and the introduction of fees, on top of placing an additional burden on SMEs compared to large economic players, would introduce a commercial relationship between the Authority and applicants. This is unacceptable. EFSA is a public administration performing a public service, and this must remain so. Recent statements by the Authority to develop a "customer-oriented approach for regulated products" (October 2) are scandalous: the risk assessments performed by EFSA are not a commercial service provided to industry clients but a public responsibility to protect public health! We will remain vigilant in the future that EFSA drops this kind of unacceptable wording.

- 1.3 "Meetings with stakeholders and NGOs" (in case of general RAs)
We do not recommend this option for the same reasons detailed at 1.1.

- 2 "The mandate is published and explained in the context of previous work (if applicable)"
Yes.

- 3 Critical success factor
The "Critical success factor" of step 3, "Reassurance that the selection process reflects expertise needed to address mandate and that selection process is objective and unbiased" misses a key component: <u>independence</u>! The critical success factor should be "Reassurance that the selection process reflects expertise <u>and independence</u> needed to address mandate and that selection process is

objective and unbiased".

- 3.1 "Publish biographies and Annual Declarations of Interests"

Yes, ADOIs of most WG members are already published but it is important that this practice becomes systematic. Publication of biographies on top of it would be a good means to help whoever interested determine their completeness, but public scrutiny cannot replace EFSA's proactive checks in all publicly available sources for this.

- 3.2 "Documentation on the criteria of selection of WG available in the final output"

Yes.

- 3.3 "Open calls for hearing experts if appropriate"

Yes, this would be the best means for EFSA to reach out to missing expertise while preserving its independence when independent experts with the required expertise would not be found. It must be absolutely clear though that the role of hearing experts is strictly limited to answering the questions of the WG members. The hearing experts' list must be made public and declarations of interests must be provided as with EFSA's staff and experts.

- 4 Critical Success Factors

The first "Critical success factor" of step 4, "Methodology/data/information meets EFSA's and international standards" is extremely important and is defined too restrictively. It should be completed as follows: "Methodology/data/information meets EFSA's and international standards when it concerns applicants' analysis". Furthermore, this risk assessment must not be limited to the application received: scientific literature at large must be taken into consideration. This scientific literature is to be considered not under regulatory standards but as fundamental science - Methodology/data/information guarantees that all relevant and publicly available scientific data is used, without giving certain studies superior status just because they would abide to certain regulatory toxicology standards such as OECD or GLP. Anecdotal evidence undermining the reliability of certain studies used in the past by EFSA must also be taken into account to update EFSA's relevant opinions.

The second "Critical success factor" of step 4, "Documentation on the methodology/data/information used" is very important too; this documentation must be exhaustive. The unacceptable practice of selective citing and presenting only those data that fit the own pre-conceived safety assumption is unacceptable. EFSA must consider all kind of studies, no matter if the conclusion does not fit safety assurances, and those studies are to be listed in the opinion. Such studies are not to be considered individually.

We consider that the third "Critical success factor" of step 4, "Ensuring reproducibility of the Risk Assessment", is absolutely paramount in this whole initiative and must be given top priority, with everything this entails in terms of data transparency.

- 4.1 "Public consultation, e.g. statistical data models for analysis, if applicable"

We consider that public consultations are not an appropriate tool for EFSA to seek external contributions for such technical and strategic information.

- 4.2 "Consultation reports, including inclusion/exclusion criteria"

Yes, this is indeed very important to justify the bodies of evidence considered and excluded in the risk assessment work, a recurring criticism. See above comment for the second Critical success factor of step 4.

- 4.3 "Open and/or targeted call for data/information"

Yes, if needed. It must be very clear though that no information coming from entities with a direct

or indirect commercial interest in the work being done should be accepted.

- 4.4 "Pre-publication of the methodological approach chosen or reference to a given guidance document upon which the assessment will be based"

Yes.

- 5.1 "Consultation on possible missing data/info to be considered by EFSA"

Two cases must be considered. If such consultations mean that EFSA asks the applicant about missing data / information in the application files, then yes, such consultations must occur as it is already the case. If such consultations are about missing data / information in the general scientific literature, then such consultations should also take place but here EFSA must exclude scientific studies sponsored and/or authored by individuals or entities with a commercial interest in regulatory approval of the product or substance. EFSA must also detail data gaps in its final opinion when this is the case.

- 5.2 "Proactive release of information used in a readable format"

Pro-active release of the information used is obviously good but readable format is not enough (what would be the point of releasing information in an unreadable format anyway?), the point is to release this information in an editable format enabling its reuse. In general, we agree that all data submitted for regulatory approval – including raw data – should be pro-actively published before it is used, in order to enable peer review (as opposed to the current reactive regime for the disclosure of such data).

- 5.3 "Proactive release of information not used in a readable format"

Same comment as above: yes to proactive disclosure, and the point is about releasing editable formats for data reuse, not only readable.

- 5.4 "Minutes representing collegial discussions and eventual diverging opinions (Article 30)"

Yes. At the moment, WG meeting minutes hardly contain anything beyond agenda points; panel plenary meetings minutes are better but are sometimes incomplete. Procedures guaranteeing that minority opinions are duly recorded and published must be developed and implemented.

- 5.5 "Public meetings on Expert Knowledge elicitation" (EKE)

We do consider that EFSA is responsible for conducting a trustworthy risk assessment. This responsibility was given by the European Commission. Public consultation on self-task or vague "issue of high public interest" are therefore not in line with this approach.

- 5.6 "Public consultation on draft opinions"

Yes, this has been used a lot by EFSA since it was created to engage with the public upon its draft opinions and the practice should go on. The way EFSA has dealt with the input received in those consultations, though, has been widely criticised for its arbitrary and opaque character and clearer procedures should be defined to solve this problem. Particularly, these consultations should be transparent in terms of the contributions received and in terms of the reasons why comments were taken on board or not.

- 5.7 "Technical hearings in dedicated consultative meetings"

Yes – the minutes of these meetings should also be published and be comprehensive.

- 5.8 "Consultative meetings with Member States"

Yes, if need be – the minutes of these meetings should also be published, and, crucially, detail the position of each Member State. All Member States should be invited to contribute, thus avoiding the bias that can occur when only Member States with a strong interest in a certain outcome contribute.

- 6.1 “Open plenary meetings”
This has already been tried by EFSA for some time and the lessons from that experience show that the resource discrepancy between commercial stakeholders and the others causes an overwhelming and problematic domination of the first among the observers. Besides, even though there was a formal interdiction of exchanges between observers and panel members, this rule has been breached and will be breached again, as it is simply natural for human beings in a same room to exchange at one point or another! We do ask to stop opening panel meetings to observers: scientists' freedom of expression must be protected. Specific insurance schemes covering these experts' decisions against possible legal threats targeting their work within EFSA could be considered.

- 6.2 “Main decisions available shortly after the plenary meetings”
Yes, of course.

- 6.3 “Publication of a flash summary/abstract immediately after the plenary meeting”
Yes.

- 7.1 “Pre-notification”
Yes – this already happens.

- 7.2 “Publication in EFSA journal
a. Publication of the output-decision
Yes, this already happens.
b. Publication of data/info used and discarded
Yes, on top of the proactive disclosure of all received information from applicants. This would be crucial to enable the reproduction of the risk assessment. Data gaps should also be mentioned whenever they exist.
c. Publication of methodology used (i.e. analysis models)
Yes, and this would be crucial to enable the reproduction of the risk assessment.

- 7.3 “Broad array of communication channels depending upon target audience”
Yes

- 7.4 “Follow-up meetings”
This policy option is not clearly defined. Meeting between who and whom? Just as we oppose pre-submission meetings, we would oppose follow-up meetings between applicants and panel members, and in general contacts between commercial companies falling under EFSA's remit and EFSA's scientific panels and working group members.

- 7.5 “Consultation reports, including inclusion/exclusion criteria”
Yes, this is indeed very important to justify the bodies of evidence considered and excluded in the risk assessment work, a recurring criticism. See comments under about the second “Critical success factor” of step 4.

- 8 “The updated 'file' is publicly available”
The only policy option considered for the very important step 8 (“Monitoring/evaluation of new scientific evidence”), should be detailed further; relevant studies published in the scientific literature for instance could be added whenever they appear, which would provide a great public service of ongoing monitoring scientific evidence for whoever is interested in getting an overview of the available scientific evidence on topics followed upon by EFSA. This function could easily benefit from spontaneous contributions from the public as well as scientists who monitor these issues on an ongoing basis.

- 9 New (self) mandate accompanied by contextual risk communications
See comments for policy options 1.1 regarding self-mandates.

3) **How can EFSA ensure that commercially sensitive information and data are protected while providing access to key information, data and documents necessary to make its assessments reproducible? Should EFSA embrace the principle of reusability? Who should be in charge of striking the balance between the need to allow reproducibility and respecting the rights of data owners? Can guiding principles and standards be established?**

Transparency is legally required. International (Aarhus Convention) and European legislation (Regulations 1049/2001, 178/2002, 1367/2006 and 503/2013) make it mandatory for the administration to grant citizens complete access to documents and information it retains, with clearly delineated and limited exceptions. Such exceptions are to be interpreted in a restrictive manner, taking into account the public interest served by disclosure. Particularly, the exemptions relating to (inter alia) commercial and industrial information (including intellectual property) but also information relating to inspections and audits may under no circumstances be applied to information that relates to emissions into the environment.

Article 4(1) of EU Regulation 1367/2006 provides that "Community institutions and bodies shall make all reasonable efforts to maintain environmental information held by them in forms or formats that are readily reproducible and accessible by computer, telecommunications or by other means". Article 5 of the same Regulation provides that "the information that is compiled by them, or on their behalf, is up-to-date, accurate and comparable". The institutions and bodies shall also upon request "inform the applicant of the place where the information on the measurement procedures, including methods of analysis, sampling and pre-treatment of samples, used in compiling the information can be found, if it is available."

Individual confidentiality considerations to protect the privacy of officials must be balanced against the public's right to know these persons' interests in their performance of public duties. This balance is the decision of the European Commission based on the existing legislation.

The data contained must be accessible to everyone without justification or identification, and re-publishable. The available data (including raw data) should be published in a usable, editable format (e.g. spreadsheet) in order for the re-analysis work to be possible.

Whichever option is considered, it cannot degrade EFSA's existing disclosure regime. Options proposed so far by industry such as a reading chamber are simply not acceptable from this perspective.

4) **How can EFSA foster even further an environment of creative debate amongst its experts while striking the appropriate balance between availability and quality of information?**

We do consider that transparency does not cover the field of "an environment of creative debate amongst its experts". Transparency towards European citizens means that EFSA's task is to ensure that EFSA's opinions are transparent, not necessarily its internal debates as indeed it is important that free speech rights of its experts is safeguarded (as the document points well, §1-2 p.11). Ensuring transparency through the pro-active and complete publication of applicants' files would help the Authority by enabling external analysis of these, but EFSA's proposal to open its meeting or to have pre-submission meetings is not about transparency towards the citizens, as those are not involved in this step and are probably only rarely able to. .

5) Would you identify any other strategic drivers, contextual elements or policy options for the Authority to consider when implementing its vision of becoming an Open EFSA?

As transparency involves the publication of the applicants' full dossiers, it also involves the content of those dossiers. Applications should not only include the raw data but also the detailed protocols and research material used (whether biological or technical, such as the name of the software used by the applicant and all information needed for the exhaustive comprehension of the operation, use of the software and the obtained results: design of experiments and the materials used are indeed critical for making sense of the raw data), the names of the laboratories that led the experiments and funding sources for this experiment. Similarly to the new Clinical Trials Regulation, applications should include all the data related to risk assessment which industry has in order to avoid the applicants selecting only favourable data to be submitted.

We suggest adding a policy option to step 4: developing standards for reporting in the dossiers all available relevant biosafety evidence. This should be demanded and enforced and punished if not followed - e.g. dossier returned for revision or rejected.

Again, the core issue is trust and transparency alone does not enable that. People with links to commercial entities falling under EFSA's remit must be prevented from joining EFSA's panels and working groups, which is not currently the case. Making conflicts of interests more visible will not help the Authority regain public trust, far from it.