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Public Consultation on the transparency and sustainability of the EU risk assessment model in the food chain

Fields marked with * are mandatory.

1 General information about the respondent

*1.1 You are replying

- As an individual in your personal capacity
- On behalf of an organisation

*1.2 If you are replying on behalf of an organisation, please provide the name of your organisation

Bayer AG

*1.3 Please indicate whether your organisation is listed in the Transparency Register

In the interest of transparency, organisations and associations have been invited to provide the public with relevant information about themselves by registering in the Transparency Register and subscribing to its Code of Conduct. If the organisation or association is not registered, the submission will be published separately from the registered organisations/associations.

- Yes
- No

*1.4 Please indicate the country where your organisation is based or if you reply in your personal capacity, your country of residence

Germany

*1.5 Please provide your first name and family name (or that of a contact person)

Martyn GRIFFITHS

*1.6 Please indicate your e-mail address (or that of a contact person)

martyn.griffiths@bayer.com

*1.7 Your contribution

Note that, whatever option chosen, your answers may be subject to a request for public access to documents under Regulation (EC) N°1049/2001

- ○ can be published with your personal information (I consent to the publication of all information in my contribution in whole or in part including my name or my organisation's name, and I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication)
- ◉ can be published in a form which does not provide the following data categories: first name, family name, name of the organisation, country where an organisation is based, country of residence, e-mail addresses, registration in the Transparency Register of the European Commission and the European Parliament (I consent to the publication of all the other information in my contribution in whole or in part (which may include quotes or opinions I express). I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent the publication.

*1.8 How would you evaluate your knowledge of the EU assessment system for food safety and the related regulatory framework?

- ◉ Very good
- ○ Good
- ○ Sufficient
- ○ Little
- ○ None

2 Transparency and Independence of studies

EFSA, the independent scientific body entrusted with EU risk assessment, relies on both published and unpublished data to carry out scientific assessments and provide scientific advice to EU risk managers. It is bound by strict confidentiality rules and, in particular for the regulated food and feed products and processes, industry studies form part of the evidence considered for its risk assessments as laid down in EU food legislation. According to the recently published Fitness Check on the General Food Law Regulation, these elements lead civil society to perceive a certain lack of transparency and independence. The following questions explore ways to improve - within the existing legal framework including, where relevant, the Aarhus Convention - transparency and independence of studies in terms of risk assessment without jeopardising confidentiality of business secrets or other confidential information.

2.1 How important is public access to the following sources of information to ensure trust in the EU food safety risk assessment?

	Not at all important	Not very important	Important	Very important	No opinion /Don't know
* Annual Declarations of Interest of members of EFSA's Management Board and EFSA's Management Team	○	○	○	◉	○
* Annual Declarations of Interest of scientific experts in EFSA's Scientific Committee/Scientific Panels/Working Groups	○	○	○	◉	○
* Annual Declarations of interest of members of EFSA's Advisory Forum	○	○	○	◉	○
* EFSA's scientific opinions and reports	○	○	○	◉	○
* EFSA's agendas and minutes of meetings	○	○	○	◉	○
* EFSA's mandates for opinions	○	○	○	◉	○
* Public meetings of EFSA's Management Board	○	○	○	◉	○
* Meetings of EFSA's Scientific Committee and Panels open to the public	○	○	○	◉	○

* Public access to industry studies used in risk assessment with the exception of the business secrets and other confidential information contained therein	○	○	○	◉	○

2.2 What impact would the publication of industry studies (including raw/aggregated data) used in EU risk assessment, with the exception of business secrets or other confidential information (in particular information about undertakings, their business relations or their cost components) have on the following objectives?

	Very negative	Negative	No impact	Positive	Very positive	No opinion /Don't know
* Enhancing transparency in the EU risk assessment system	○	○	○	○	◉	○
* Strengthening consumer trust in the EU risk assessment system	○	○	○	◉	○	○
* Increasing competitiveness of the industry	○	○	◉	○	○	○
* Allowing scrutiny by other scientific and third parties	○	○	○	○	◉	○
* Promoting innovation	○	◉	○	○	○	○
* Enhancing the exchange of information on risks amongst interested parties and stakeholders (e.g. EFSA, national agencies, Member States, EU Institutions, consumers, food and feed businesses, NGOs, academics, etc.)	○	○	○	○	◉	○

2.3 What impact would the different possible timings for the publication of industry studies have on the transparency of the EU risk assessment system?

	Very negative	Negative	No impact	Positive	Very positive	No opinion /Don't know
* **Immediate publication** of the parts of the industry studies identified by the industry as non-confidential at the beginning of the EU risk assessment process, **before a decision has been taken on the validity of the confidentiality claims**, if any, and **before EFSA's opinion**	○	○	◉	○	○	○
* **Publication** of the non-confidential parts of the industry studies **once the confidentiality claims**, if any, **have been assessed** and **before EFSA's opinion has been adopted**	○	○	○	◉	○	○
* **Publication** of the non-confidential parts of the industry studies **upon delivery of EFSA's opinion**	○	○	○	◉	○	○
* **Publication** of the non-confidential parts of the industry studies **upon adoption of any EU risk management decision (e.g. authorisation of a substance)**	○	○	○	◉	○	○

* Never	○	◉	○	○	○	○

2.4 What impact would the different possible timings for the publication of industry studies have on industry competitiveness?

	Very negative	Negative	No impact	Positive	Very positive	No opinion /Don't know
* **Immediate publication** of the parts of the industry studies identified by the industry as non-confidential at the beginning of the EU risk assessment process, **before a decision has been taken on the validity of the confidentiality claims**, if any, and **before EFSA's opinion**	○	◉	○	○	○	○
* **Publication** of the non-confidential parts of the industry studies **once the confidentiality claims**, if any, **have been assessed** and **before EFSA's opinion has been adopted**	○	○	◉	○	○	○
* **Publication** of the non-confidential parts of the industry studies **upon delivery of EFSA's opinion**	○	○	◉	○	○	○
* **Publication** of the non-confidential parts of the industry studies **upon adoption of any EU risk management decision (e.g. authorisation of a substance)**	○	○	◉	○	○	○

* Never	○	○	◉	○	○	○

2.5 If industry studies used in EU risk assessment were to be published with the exception of confidential data, how useful would the following tools/procedures be?

	Not at all useful	Not very useful	Useful	Very useful	No opinion /Don't know
* An open registry of studies	○	○	○	◉	○
* Studies in publishable and machine readable formats	○	◉	○	○	○
* Different levels of accessibility to the studies depending on the interested stakeholder	○	○	◉	○	○

2.6 Is there any additional information/observation you wish to provide within the scope of this section ?

1000 character(s) maximum

Bayer fully supports greater public access to studies underlying the EU risk assessment, as emphasised in our Bayer transparency initiative launched Dec 2017. A Balance needs to be made between greater transparency and the need to avoid unfair commercial use of studies worldwide. Disclosure should be implemented via specific mechanism to prevent unfair commercial use, and that misuse is enforceable. Confidential data, personal data and raw data (OECD definition) should be clearly defined and excluded from disclosure. Bayer also supports the establishment of a register of studies in order to improve public trust in the Regulatory process. For active substances, a difference is required in timing of disclosure of data for new substances (not yet on EU market) compared to renewals of substances. Any disclosure of data must be presented in an understandable manner, with clear explanations on the background why studies are generated and submitted for Regulatory purposes.

3 Evidence from industry studies

Among the different sources of evidence, the EU safety risk assessment system for regulated food and feed products and processes relies on evidence set out in studies commissioned by industry. These studies (and the laboratories carrying them out) follow international quality standards. The following questions aim to gather your views on how important the existing elements are contributing to the quality of this system and how new additional measures could further strengthen it.

3.1 How important are the following existing elements to ensure that the scientific studies provided by industry are sufficiently robust to serve EFSA's risk assessments?

	Not at all important	Not very important	Important	Very important	No opinion /Don't know
* EFSA documents indicating the design and quality of studies needed	○	○	◉	○	○
* The studies commissioned by industry are based on internationally recognised principles (for example, those established by OECD)	○	○	○	◉	○
* EFSA can request Member States to audit a laboratory on a specific study	○	○	◉	○	○
* The Member States audit the laboratories carrying out the industry studies	○	○	◉	○	○

3.2 Without prejudice to the responsibility of applicant's for authorisations to prove that their products are safe, how much would the following additional measures regarding industry studies contribute to further strengthening EFSA's risk assessments?

	Not at all	Not very much	To some extent	To a large extent	No opinion /Don't know
* Further guidance to industry on the specific studies needed	○	○	◉	○	○
* Pre-submission advice to individual applicants on the nature and design of studies needed	○	○	○	◉	○
* Complementing industry studies for verification purposes in particular cases	◉	○	○	○	○
* Re-enforcement of the audit system programme on the laboratories carrying out industry studies	○	○	◉	○	○
* Allocation of more resources by national authorities to finance studies on food safety	○	◉	○	○	○
* Allocation of more resources by the EU to finance studies on food safety	◉	○	○	○	○

*3.3 A single safety study done as part of a dossier submitted by industry to EFSA for scientific assessment of a substance has a cost of up to 1 million EURO. In your opinion, and if EFSA should be exceptionally able to complement industry studies for verification purposes, which should be the source of its financing?

- ◉ The EU budget
- ○ A common fund to which all industry applicants requesting EFSA's assessment would systematically contribute
- ○ The individual applicant concerned
- ○ A combination of public and industry funding
- ○ I do not have an opinion
- ○ I do not know

3.4 Is there any additional information/observation you wish to provide within the scope of this section ?

1000 character(s) maximum

Responsibility for Commissioning and financing studies should remain fully with companies who submit dossiers for Regulatory purposes. Instead we believe greater emphasis should be placed on the recommendations put forward to strengthen the governance for conducting studies, through a register of studies, and a Data call-in system where studies to be conducted will be subject to a public consultation before initiation of these studies. There should be more involvement of EFSA in the process of agreeing the nature and design of studies through pre-submission meetings between EFSA, and applicants (and with RMS in case of PPP submissions). Bayer believes a scientific dialogue with EFSA is very important, especially pre-submission meetings, like in the processes established already by EMA and ECHA. We fully respect the independence of EFSA, EMA and ECHA.

4 Risk Communication in the agri-food chain

According to the recently published Fitness Check on the General Food Law Regulation, risk communication has not always been effective. It has sometimes had a negative impact on consumers' trust in the EU decision-making process in relation to the food chain. The following questions explore ways to improve risk communication to strengthen consumers' trust.

*4.1 To what extent the existing risk communication contributes to buidling trust in the EU decision-making procress in the food chain?

- ○ Not at all
- ◉ Not very much
- ○ To some extent
- ○ To a large extent
- ○ No opinion/Don't know

4.2 How effective could the following be in strengthening the consistency of risk communication in the EU?

	Not at all effective	Not very effective	Effective	Very effective	No opinion/ Don't know
* Include in legislation general principles of risk communication applicable both to risk assessors and risk managers	○	○	○	◉	○
* Develop risk communication plans involving EU and national stakeholders	○	○	○	◉	○
* Strengthen cooperation between risk assessors and risk managers	○	○	○	◉	○
* Increase involvement of stakeholders in risk communication activities	○	◉	○	○	○

4.3 Is there any additional information/observation you wish to provide within the scope of this section ?

1000 character(s) maximum

We believe that there should be increased risk communication on issues relevant to the agri-food chain, especially by EFSA but also importantly by DG SANTE. Improved communication needs a full cooperation across risk assessors/risk managers at both national and EU level. Communication of why studies are required (Data requirements, GLP/GEP procédures) are necessary to inform the public on the Regulatory process. Video's should be established by EFSA to complement the already very informative video's that EFSA make available on their website, which help to explain complex scientific processes.

5 Sustainability of the risk assessment system and involvement of Member States

High scientific quality, independence, transparency and efficiency are key elements to the EU risk assessment system. To this end, involvement of Member States is indispensable to strengthen the EU risk assessment capacity. The following questions aim to explore your views on the suitability of the tools already existing, how to further involve the Member States in the procedures and how to keep/improve the sustainability of the EU risk assessment system.

5.1 To what extent have the existing tools for scientific cooperation contributed to engaging Member States in the EU risk assessment system?

	Not at all	Not very much	To some extent	To a large extent	No opinion /Don't know
* All national agencies/bodies responsible for risk assessment exchange information and collaborate with EFSA	○	○	◉	○	○
* National scientific bodies can receive funds from the EU budget when undertaking specific scientific work contributing to EFSA tasks	○	○	◉	○	○
* Member States can request EFSA to provide scientific advice	○	○	◉	○	○
* Independent scientific experts from Member States are members of EFSA's Scientific Committee and Panels	○	○	◉	○	○

5.2 To what extent do you agree or disagree with the following statements regarding the general involvement of the Member States in EFSA's work?

	Strongly disagree	Tend to disagree	Tend to agree	Strongly agree	No opinion /Don't know

* In the current system, there is sufficient involvement of Member States in EFSA's work	○	◉	○	○	○
* When the scientific contribution of national bodies to EFSA's tasks generates costs for these national bodies, these costs should be adequately compensated	○	○	◉	○	○
* An increased involvement of Member States is important to ensure that EFSA has a large pool of excellent and independent experts from a range of Member States for its Panels /Scientific Committee	○	○	○	◉	○
* The Member States should be represented in EFSA Management Board	○	○	○	◉	○

5.3 To what extent are the following elements useful for the EU risk assessment system?

	Not at all useful	Not very useful	Useful	Very useful	No opinion /Don't know
* Excellent and independent experts can be chosen from a large pool of candidates	○	○	○	◉	○
* EFSA being independent from risk managers (Commission/Member States)	○	○	○	◉	○
* EFSA being independent from industry	○	○	◉	○	○
* High level of cooperation between EFSA and the national public authorities	○	○	○	◉	○
* Avoidance of duplication of risk assessment between EU and national levels	○	○	◉	○	○
* Avoidance of scientific divergences between EU and national levels	○	○	◉	○	○
* EFSA 's level of resources	○	○	◉	○	○

5.4 Is there any additional information /observation you wish to provide within the scope of this section ?

1000 character(s) maximum

A proper training of risk assessors needs to be in place to ensure high quality Risk Assessment. Also, Bayer believes than an appeals procedure should be established to review the work of EFSA in special circumstances. Many EU Agencies already have an appeals procedure including EMA and ECHA. We believe there should be increased involvement of MS within EFSA's work both at Management board level and within the risk assessment process to ensure robust, quality outputs which provide Risk Managers with the right options for decision making. This will ensure EFSA opinions are supported by MS. We believe that EFSA should consider more reviews done by international and EU Agencies, where substance/issues have been recently evaluated. Bayer agrees that EFSA needs to be independent from all stakeholders, but Bayer would really appreciate a scientific dialogue with EFSA and MS to ensure a robustness of scientific evaluations.

6 Glossary

6.1 Backgroud Documents

Background Documents

GLOSAR - RO (/eusurvey/files/9b3ec1ee-ab84-49a6-9f2f-0bdae919248d)

GLOSAR - SL (/eusurvey/files/4eb2f75c-5229-4928-bd02-eefb8963f607)

GLOSARIO - ES (/eusurvey/files/6df76b23-fe50-4dbf-ad72-b7ad17730d74)

GLOSARIUSZ - PL (/eusurvey/files/6aeddb6b-19d0-4554-b8c0-ca72ac2a9e31)

GLOSSAIRE - FR (/eusurvey/files/e1780abf-63d6-4876-a63b-1ea230541c94)

GLOSSAR - DE (/eusurvey/files/deec5b9d-edda-49d9-b8ca-4ad1730442bf)

GLOSSARIO - IT (/eusurvey/files/d397a368-f70a-4d01-84c8-17fa50e3c4e1)

GLOSSARJU - MT (/eusurvey/files/40a31194-2f54-4a46-a08c-8bf892c5992e)

GLOSSARY - EN (/eusurvey/files/b7a96757-0d53-4a83-ba52-03df4c927d9c)

GLOSSZRIUM - HU (/eusurvey/files/e9740a19-af58-46e9-8778-66578896e8a8)

GLOSSRIO - PT (/eusurvey/files/76b2bd17-f916-44f8-a4c3-78916bc27192)

GLOSR - SK (/eusurvey/files/2feed3ca-1e6b-4efb-9bb2-b28e4254f954)

GLOSŘ - CS (/eusurvey/files/f95af37a-5b9c-4cd8-9a33-68d217c1d909)

GLOSĀRIJS - LV (/eusurvey/files/46c55100-722a-473e-85b2-5b1e0d1dce06)

ORDLISTA - SV (/eusurvey/files/3941bd1d-d8d9-4376-a1e3-5bb433bc6748)

ORDLISTE - DA (/eusurvey/files/a3289266-fc2b-4cd3-a6ad-d31e7755a50f)

POJMOVNIK - HR (/eusurvey/files/9f92b2bd-1ec2-4a27-a04e-5c910364e855)

SANASTO - FI (/eusurvey/files/221bffc6-6ffe-48a1-a202-a6fa6dc1324e)

SNASTIK - ET (/eusurvey/files/9ec5f080-6367-4ed7-ae3e-529d9c4cc29c)

TERMINŲ ŽODYNĖLIS - LT (/eusurvey/files/c3112a23-3f74-4f90-a3e2-b2b67fc98337)

WOORDENLIJST - NL (/eusurvey/files/0edfe00a-489e-4f49-90f3-f535e77e34dc)

- EL (/eusurvey/files/e6aca093-c86f-4746-a94f-c959aacc2389)

РЕЧНИК НА ТЕРМИНИТЕ - BG (/eusurvey/files/8e43b6b1-6d29-4aba-8ed3-075599738d2e)

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