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Synopsis report

Accompanying the document

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EC) No 2015/2283 [on novel foods]

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Synopsis report

1. INTRODUCTION

This report covers feedback from citizens and national authorities, groups and organisations ('stakeholders') as regards the initiative for a Commission proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain ('Commission proposal'). The Commission proposal would amend Regulation (EC) No 178/2002 which sets out the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and defines procedures in matters of food safety. For consistency, the Commission proposal would also amend other sectoral food legislation. The Commission proposal builds on the findings of the Fitness Check of the General Food Law[1] and follows the Commission Communication on the European Citizens' Initiative to "Ban glyphosate and protect people and the environment from toxic pesticides"[2].

Citizens and stakeholders had the opportunity to provide feedback on a **Commission roadmap**[3] from 20 December 2017 to 17 January 2018. 20 stakeholders (15 trade and business associations, four Non-Governmental Organisations (NGOs) and one Member State (MS) authority) and one citizen submitted feedback.

This was followed by an **open public consultation** (OPC)[4], targeting citizens and stakeholders, open from 23 January 2018 to 20 March 2018. The OPC received replies from 471 participants: 318 citizens and 153 stakeholders. 18 of the stakeholders had also provided feedback on the roadmap.

The stakeholders that took part represented a variety of sectors: trade and business associations (39.22 %), companies and groups (14.38 %), NGOs (13.07 %), professional associations (8.5 %), national/regional authorities (8.5 %), governmental agencies (5.23 %), research institutes (3.92 %), public bodies (1.96 %), professional consultancies (1.96 %), think-tanks (1.31 %), law firms (0.65 %), EU Institutions (0.65 %), and other (0.65 %). As regards the citizens who took part, 318 replies came from 26 MS, 10 came from a European Free Trade Association country and five from other non-EU countries.

Citizens evaluated their level of knowledge of the EU assessment system for food safety and its regulatory framework as very good (22.64 %), good (33.65 %), sufficient (26.42 %), little (14.78 %) or none (2.52 %). Organisations evaluated their level of knowledge as very good (37.25 %), good (47.06 %), sufficient (14.38 %), little (0.65 %) or none (0.65 %).

Targeted consultations with specific stakeholder groups also took place. EU-level stakeholder organisations representing farmers, cooperatives, the food industry, retailers, consumers, professionals and civil society were consulted in a working group meeting of the **Advisory**

[1] https://ec.europa.eu/food/safety/general_food_law/fitness_check_en
[2] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_eci_final.pdf
[3] http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-6265773
[4] https://ec.europa.eu/info/consultations/public-consultation-transparency-and-sustainability-eu-risk-assessment-food-chain_en

Group on the Food Chain and Animal and Plant Health[5]. Consultations also took place via the **EFSA Advisory Forum**[6] (national food safety authorities) and the **Commission Expert Group on General Food Law**[7] and with the **Scientific Committee of EFSA**[8].

A letter of the European Ombudsman to the President of the European Commission on ensuring the EU risk assessment model in the food chain is independent, transparent, and allows for meaningful stakeholder engagement, was also considered.

Feedback received during the consultations was not taken into account if it went beyond the scope of the Commission proposal.

2. TRANSPARENCY OF INDUSTRY STUDIES

Citizens and stakeholders acknowledged the importance of **public access to the industry studies** used by EFSA in its risk assessments, with the exception of the business secrets and other confidential information, as a significant element of ensuring trust in the EU's food safety risk assessment. The OPC showed such access as important or very important in 86.8 % of citizen replies and 88.2 % of stakeholder replies. The information that EFSA makes public on its activities and contributions was also judged as very important.

Citizens and stakeholders found that **publishing industry studies**, including raw/aggregated data but excluding business secrets or other confidential information, has a positive or very positive impact on:

- enhancing the transparency of the EU risk assessment system: 87.4 % of replies from citizens, 91.5 % from stakeholders,
- strengthening consumer trust in the EU risk assessment system: 84.9 % of replies from citizens, 73.9 % from stakeholders,
- allowing scrutiny by other scientific and third parties: 81.8 % of replies from citizens, 80.4 % from stakeholders,
- enhancing the exchange of information on risk among interested parties: 81.5 % of replies from citizens, 76.5 % from stakeholders.

As consumers may in general lack the scientific knowledge to use these studies, consumer organisations suggested that trust would depend on other factors, e.g. third-party scrutiny of the studies.

As regards the **impact of publishing industry studies,** 42.1 % of citizen replies and 21.6 % of stakeholder replies state that it is important or very important **for competitiveness**; 56.3 % of citizen replies and 31.4 % of stakeholder replies state that it is positive or very positive **for innovation**. Furthermore, about 35 % of replies from stakeholders, in this case mainly industry organisations, state that publishing industry studies will be negative or very negative

[5] https://ec.europa.eu/food/expert-groups/ag-ap/adv-grp_fchaph/wg_2018_en
[6] https://www.efsa.europa.eu/en/events/event/180206
[7] https://ec.europa.eu/food/safety/general_food_law/expert_group_en
[8] https://www.efsa.europa.eu/sites/default/files/event/180214-m.pdf

for both competitiveness and promoting innovation. Industry organisations commented that there is a risk of the published data being misuse.

There were different views on the **timing of publishing non-confidential parts** of industry studies throughout the risk assessment process and the **impact on transparency.** Among citizens, 58.8 % considered that immediate publication without confidentiality checks would have a positive or very positive impact, 6.9 % consider it would have no impact and 28.9 % considered that the impact would be negative or very negative. Replies on the other scenarios related to the timing of publication do not showed strong polarisation of opinions, with the exception of the option to not publish industry studies at all: 77.1 % of citizens state that this would have a negative or very negative impact, with only 4.1 % considering that it would have a positive or very positive impact. For stakeholders, 71.9 % believe that the non-publication of industry studies would have a negative or very negative impact and only 1.3 % considered that it would have a positive impact.

In general, industry stakeholders state that the timing of publication could have a negative or very negative **impact on competitiveness**, in particular if publication happens early in the assessment process. Industry stakeholders also highlighted the need to avoid unfair use of commercial data. Some comments from MS authorities reflect on the need to specify what should be considered confidential in legislation. NGOs commented on the need to review the validity of the confidentiality claims made in relation to industry studies.

Both citizen and stakeholder replies to the OPC showed that an open registry of studies, the use of machine readable formats and having different levels of access to studies would be useful or very useful tools. Regarding the establishment of a register of industry studies, mainly MS authorities highlighted the challenges as regards applicability outside the EU. Some MS authorities and industry stakeholders considered that it may have a detrimental impact on EU innovation.

3. EVIDENCE FROM INDUSTRY STUDIES

Most citizens and stakeholders found important or very important the **elements currently in place** to ensure that the studies provided by industry are sufficiently robust to serve EFSA's risk assessment needs.

In general, citizens found that all the **additional measures regarding industry studies** proposed in the OPC contribute to some or a large extent to strengthening EFSA's risk assessments; over 75 % of replies regarding the single measures acknowledged this. Although, in general, stakeholders showed similar views, some saw certain measures as having different levels of importance. In particular, industry stakeholders considered valuable to some or to a large extent the possibility for providing pre-submission advice to individual applicants, while consumer organisations and some other NGOs considered that it would not contribute very much. The latter also highlighted the need to ensure the independence of EFSA's scientific processes. Some MS saw the potentially for a small value of pre-submission advice in relation to its cost vs benefit analysis.

83.7 % of replies from citizens and by 63.4 % from stakeholders stated that **complementing industry studies with verification studies** would strengthen EFSA's risk assessment to some or to a large extent. As regards the financing of these verification studies, a small percentage of both citizens and stakeholders considered that the costs should be covered by the individual applicant concerned. The other financing options proposed, i.e. the EU budget, common funding provided by all industry applicants or a combination of public and industry funding, were considered relevant by 32.1 %, 27 % and 25.2 % of citizens, respectively. For respondents from the stakeholder group, these percentages were 47.7 %, 21.6 % and 9.2 %, respectively.

As regards the potential to **re-enforce the audit system used for laboratories** carrying out industry studies, the majority of both citizens (78.3 % of respondents) and stakeholders (72.6 % of respondents) considered that this would contribute to some or to a large extent to strengthening EFSA's risk assessments. Some MS expressed reservations on the potential added value of this measure.

Both citizens and stakeholders considered that **allocating more public resources to financing food safety studies** is important for strengthening EFSA's risk assessment: around 80 % of citizen replies state that EU or national funding could contribute to some or to a large extent; the figure for stakeholders is slightly lower. Some NGOs and EFSA's Scientific Committee supported the added value of more public resources dedicated to food safety studies.

Discussions with stakeholders highlighted the potential for establishing procedures for open consultations on data related to the studies submitted by industry as part of authorisation dossiers. Although this was in general welcomed, some MS authorities and industry stakeholders mentioned the potential negative impact on the length of EFSA's risk assessment processes. The latter also highlighted the potential negative impact on competitiveness and innovation, in particular on new substances due to risks relating to potential unfair use of disclosed data and concerns over intellectual property rights.

4. RISK COMMUNICATION

Overall, all consulted parties acknowledged the value of the actions aiming to improve risk communication.

In the OPC, over a third of citizens consider that **existing risk communication** does not contribute very much or at all to building trust in the EU's decision-making process in the food chain. All the **new measures proposed** as potentially strengthening the consistency of risk communication were considered by most respondents from both groups to be effective or very effective (between 61.4 % and 92.2 % of replies). There is an exception to this in the stakeholder group of respondents: some NGOs (23.5 % of replies from stakeholders) do not consider that including general principles of risk communication in legislation would be very effective.

Some citizens highlighted the need to avoid complexity and/or confusion in risk communication, and recommended making it clearer and simpler. Consumer organisations commented on the need to clearly explain the political choices made and improve the MS involvement in risk communication. MS acknowledged the need for more coordination among all actors.

5. SUSTAINABILITY OF THE RISK ASSESSMENT SYSTEM AND INVOLVEMENT OF MS

It was found that the **tools currently available** to support scientific cooperation between EFSA and MS to a significant extent already engage MS in the EU risk assessment system: over 70 % of respondents (both citizen and stakeholder groups) found that all the tools described contribute to some or a large extent.

Over 40 % of citizen replies disagreed or strongly disagreed with the statement suggesting that **MS are sufficiently involved in EFSA's work**. There was a similar response from the stakeholder group. In addition, both citizens (75.2 %) and stakeholders (79.7 %) agree or strongly agree that the costs of national bodies' scientific contribution to EFSA's tasks should be adequately compensated. Most respondents (over 75 % in both the citizen and stakeholder groups) agreed or strongly agreed that an increased involvement of MS is important to ensure that EFSA has a large pool of experts from MS. MS authorities highlighted the importance of incentives when promoting cooperation. Some MS, industry stakeholders, NGOs including consumer associations, and EFSA's Scientific Committee stressed that cooperation with MS needs to respect the independence of the experts in their contribution to EFSA and the separation between risk assessment and risk management.

As regards **MS being represented in EFSA's Management Board**, 57.5 % of citizens and 53.6 % of stakeholders agreed or strongly agreed. However, 27.7 % of citizen replies and 26.1 % of stakeholder replies disagree or strongly disagree with this statement. Some citizens and stakeholders (including MS authorities) highlighted the need to clearly separate risk assessment and risk management and suggested having representation from other stakeholder groups as well. MS authorities also considered the importance of defining clear roles for the Management Board to avoid duplication with EFSA's Advisory Forum.

Elements including EFSA being able to choose excellent and independent experts from a large pool of candidates, as well as its independence from risk managers (Commission and MS) and from industry, were found by over 80 % of respondents in both the citizen and stakeholder groups to be useful or very useful. The possibility of choosing excellent and independent experts from a large pool of candidates scored higher, with 96.2 % of citizen replies and 98.7 % of stakeholder replies considering it useful or very useful. Avoiding scientific divergences between the EU and national levels was considered to be useful or very useful by 72.3 % of respondents from the citizen group; this equals 79.1 % for the stakeholder group. Over 75 % of respondents from both groups considered it useful or very useful to avoid duplication of risk assessments between EU and national levels, and to ensure an appropriate level of resources for EFSA.

Some MS authorities highlighted the need to ensure a proper balance between EFSA's independence policies and its links with scientific excellence, and the need to consider incentives to stimulate the contribution of MS experts to EFSA's work, including financial and non-financial elements.

6. CONCLUSIONS

Overall, in their replies citizens and stakeholders expressed the importance of the elements addressed by the Commission initiative to improve the EU risk assessment in the food chain. They also highlighted the need to ensure that the Commission proposal strengthens these elements while safeguarding the principles on which the EU food safety system is based.

The contributions to the different consultations showed a **need to consider the following** when preparing the Commission proposal:

- The earlier the access to industry studies in the risk assessment process, the greater its impact on transparency.
- Safeguarding confidentiality and intellectual property rights is fundamental in order to avoid hampering innovation and competitiveness.
- Details on what information from industry studies can be claimed as confidential need to be clear, and the related claims must be thoroughly assessed.
- Need for proportionate verification processes on the quality of industry studies as regards compliance with relevant standards.
- Potential value of EFSA's pre-submission advice to industry applicants while fully respecting the independence of scientific processes.
- Capacity for more public resources to finance studies on food safety.
- Need to tackle potential negative impacts of consultations on studies submitted on the length of the assessment processes. Need to ensure the protection of confidential data and personal data.
- Risk communication on food safety can be further strengthened by improving coordination and involving relevant stakeholders.
- Further involvement of MS authorities in EFSA's activities must continue to ensure the separation between risk assessment and risk management.
- Scientific independence and excellence of experts are cornerstones of the EU risk assessment system.
- Adequate incentives are needed in order to ensure that EFSA obtains the expertise it needs from MS.