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Proposal for a

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 (EU) No 2015/2283 [on novel foods]

(Text with EEA relevance)

{SWD(2018) 97 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

Regulation (EC) No 178/2002 on general food law (the "GFL" Regulation) provides for a comprehensive harmonised legal framework. It establishes certain general principles to underpin all future Union and national food law, the most important of which is the risk analysis principle. The risk analysis principle consists of three separate but interconnected components: risk assessment, risk management and risk communication. Risk assessment is defined as the scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation. Risk management is defined as the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options. Risk communication is defined as the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions amongst risk assessors, risk managers, consumers, feed and food businesses, the academic community, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk assessment at Union level is carried out by an autonomous agency established by the GFL Regulation, the European Food Safety Authority (EFSA), separately from the risk management function of the Union Institutions, and mainly that of the Commission. Its primary mission is to provide scientific advice at the request of the Commission, Member States and the European Parliament and on its own motion. Its mandate is broad and covers all issues impacting directly or indirectly on food and feed safety (including the evaluation of dossiers put forward for the approval of substances[1]), animal health and animal welfare, plant health, human nutrition, and GMO issues.

As confirmed in the recently published Fitness Check of the GFL Regulation (GFL Fitness Check)[2], the rigorous implementation of the risk analysis principle throughout the Union law has overall raised the level of protection from potential food safety risks in a number of ways. Indeed, the science-based approach to food legislation, underpinned by the establishment and operation of EFSA at centralised level, has overall improved the scientific basis of measures taken in the area of food law and has further contributed to harmonised views between Member States on key safety issues as well as to the Union product safety recognition worldwide.

The impetus for the GFL Regulation came from a succession of food related crises, notably the Bovine Spongiform Encephalopathy (BSE) crisis, foot and mouth disease and dioxin in the late 90s-early 2000s. These put public health at great risk and the resulting market support measures and trade disruption cost a huge amount. They also seriously undermined public confidence in the Union food safety regulatory framework. The political response was to adopt a White Paper on Food Safety in

[1] Food law authorisations cover different subject matters: substances, products, health claims and processes but for the ease of reading, the reference to substances in the text covers all.

[2] Commission Staff Working Document, "The REFIT evaluation of the General Food Law (Regulation (EC) No 178/2002)", SWD (2018)38 final, dated 15.1.2018.

January 2000. This paved the way for a complete overhaul of the regulatory framework, with the focus on the GFL Regulation in 2002. The separation of risk management and risk assessment, with the newly created EFSA responsible for risk assessment, was the single biggest innovation in the GFL Regulation.

In its Communication replying to the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides"[3], the Commission also announced the preparation of a legislative proposal "covering transparency in scientific assessments, quality and independence of the scientific studies that are the basis of the Union risk assessment carried out by EFSA and the governance of EFSA". In parallel, the Commission's Scientific Advice Mechanism has been asked to prepare an opinion on the authorisation process of plant protection products.

These developments took place against the backdrop of public controversy over the approach towards the assessment and management of sensitive substances such as genetically modified organisms, and plant protection products, especially those containing glyphosate or potentially negative health impacts arising from endocrine disruptors.

The main objectives of this initiative are to update the GFL Regulation so as to:

- tighten and clarify the rules on transparency, especially with regard to the scientific studies used as the basis for risk assessment the EFSA carries out;
- increase the guarantees of reliability, objectivity and independence of studies the EFSA uses in its risk assessment, in particular in the context of authorisation applications;
- improve the governance of and strengthen the scientific cooperation of Member States with and their involvement in the EFSA;
- strengthen the ability of EFSA to maintain a high level of scientific expertise in the different areas of its work, especially its capacity to attract excellent scientists to be members of its Scientific Panels; bearing the related financial and budgetary aspects in mind too, and,
- develop a comprehensive and effective risk communication strategy, involving the Commission, Member States and the EFSA throughout the risk analysis process, combined with open dialogue amongst all interested parties.

Problems that the initiative aims to tackle

The GFL Fitness Check and recent public debates have shown that certain aspects of the current legislative framework need to be addressed. In particular:

- Citizens demand that the risk assessment process in the area of food law (and the decision-making based on it) be more transparent. Transparency and confidentiality rules currently vary depending on the sub-area of regulation concerned.
- Many stakeholders and citizens complain that the EFSA's evaluations of authorisation applications are essentially based on studies, data and information generated (and paid for) by the applicant for authorisation. Current procedures are based on the principle that it is for the applicant to prove that the subject

[3] C(2017) 8414 final.

matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This principle is based on the premise that public health is better protected when the burden is on the applicant to prove that a particular food or feed is safe prior to its placing on the market, instead of the public authorities having to prove that it is unsafe. Moreover, public money should not be used to commission costly studies (several thousand to several million Euros) that will eventually help the industry to place a product on the market. This principle remains valid, but the concerns on the transparency and independence of industry-generated studies and data should be addressed.

- Risk communication was also found not to be effective enough. Evidence has pointed to occasional divergences and, in very few occasions, conflicting communications amongst Union and national risk assessors and risk managers, which may have an adverse impact on public perception as regards the assessment and management of risk related to the agri-food chain. Divergences between Union and national risk assessors, however, do not necessarily question the work of the different scientific bodies. These can be explained by a variety of factors including for instance: the legal framework to which the question refers, the type of question put to scientific bodies by the relevant risk managers and how these are framed, whether the assessment relates to a hazard or a risk, the methodologies followed, or the data, which are utilised. The reasons underlying differences in the assessments and conclusions of scientific bodies should be better communicated to the public in order to facilitate their understanding. Furthermore, scientific divergences related to food and feed safety are particularly high on the public agenda, whether these are real or perceived, especially where other societal choices are at stake, such as the protection of the environment or consumers' right to choose the type of foods which they eat. EFSA is currently empowered to communicate on its own initiative in the fields within its mission, without prejudice to the Commission's competence to communicate its risk management decisions. However, given the limits of its competence, EFSA's risk communication activities cannot address questions on issues other than science, notably the risk management decisions informed by its scientific advice. It is therefore necessary to ensure a more comprehensive and continuous risk communication process throughout the risk analysis process, involving Union and national risk assessors and risk managers combined with open dialogue amongst all interested parties.
- The EFSA's effectiveness depends on its capacity to attract and pool expertise from Member States. The following factors have an impact on this:
  - Difficulties in attracting new experts due to insufficient recognition of scientists' career, inadequate financial compensation in particular for their employers and excessive demand on their time.
  - Dependence on a small number of Member States that provide more than two thirds of the EFSA's Scientific Panels' experts and difficulties in receiving sufficient support from many Member States for its scientific work (e.g. by providing studies, or data).

In addition, unlike in the case of other Union Agencies, EFSA governance has not yet been brought in line with the Common Approach on Union decentralised agencies, including with regard to the composition of its Management Board.

- **Consistency with existing policy provisions in the policy area**

As far as transparency and confidentiality aspects are concerned, it is necessary to amend not only the General Food Law Regulation but also the following eight additional sectoral legislative acts covering the food chain, *i.e.* Directive 2001/18/EC of the European Parliament and of the Council[4], Regulation (EC) No 1829/2003 of the European Parliament and of the Council[5], Regulation (EC) No 1831/2003 of the European Parliament and of the Council[6], Regulation (EC) No 2065/2003 of the European Parliament and of the Council[7], Regulation (EC) No 1935/2004 of the European Parliament and of the Council[8], Regulation (EC) No 1331/2008 of the European Parliament and of the Council[9], Regulation (EC) No 1107/2009 of the European Parliament and of the Council[10] and Regulation (EU) 2015/2283 of the European Parliament and of the Council[11].

Regulation (EC) No 178/2002, Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003 and Regulation (EC) No 2065/2003 are currently included in the Commission's horizontal alignment legislative proposal adopted in 2016[12]. As explained in the Explanatory Memorandum of the latter proposal, the Commission did not include in its horizontal alignment legislative proposal, amongst others, Regulation (EC) No 1935/2004, Regulation (EC) No 1331/2008 and Regulation (EC) No 1107/2009, as it is reflecting on whether there is a more appropriate way to structure these acts as concerns individual authorisations/setting of values/listing of specific substances based on the specific criteria set out in those acts, bearing in mind the improved approach adopted by the co-legislators in the context of Regulation (EU) 2015/2283 and the ongoing REFIT

4 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

5 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

6 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

7 Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1).

8 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

9 Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).

10 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

11 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

12 Proposal for a Regulation of the European Parliament and of the Council adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union, COM(2016)799 final, dated 14.12.2016.

reviews of Regulation (EC) No 1935/2004 and Regulation (EC) No 1107/2009. These reasons are still valid. The present proposal provides one empowerment for a delegated act in the context of Regulation (EC) No 178/2002, which is in the process of being aligned.

- **Consistency with other Union policies**

Targeted changes are proposed to align the composition of the Management Board of EFSA and the procedure for the external evaluation of EFSA to the Common Approach set out in the annex to the 2012 inter-institutional joint statement on Union decentralised agencies.

Since some specific changes of EFSA's functioning (pre-submission advice, composition of the Panels) are proposed, care has been taken to take into account procedures followed by other scientific agencies with special attention to European Chemicals Agency (ECHA) and European Medicines Agency (EMA).

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The proposal is based on Articles 43, 114, and 168(4)(b) of the Treaty on the Functioning of the European Union.

- **Subsidiarity (for non-exclusive competence)**

The GFL Fitness Check has clearly shown that a high level of protection of public health and consumers' interests across the Union in the area of food is best achieved through Union action. In particular, the systematic implementation of the risk analysis principle at Union level has raised the overall level of protection of human health across the Union and minimised differences in approach between Member States to key food safety risks. This in turn ensures that there is a common understanding of and approach to food safety that promotes both the effective implementation and enforcement of legislation and facilitates the operation of the internal market in a key sector of the European economy. Member States appreciate that the challenges in relation to food safety, in an environment with very high levels of trade and a complex food supply chain, require a strong Union regulatory system. Business and civil society stakeholders are of the same mind. There are still strong memories of the damage caused by successive food safety crises prior to the GFL Regulation which undermined the credibility of the Union to ensure that food is safe. Moreover, as indicated in the GFL Fitness Check, food and feed safety measures have the greatest effect when taken at Union level.

- **Proportionality**

Given the problems identified above, the purpose of this Regulation is to introduce changes to the existing legal framework which are limited to what is strictly necessary to achieve the objectives set up for the initiative in order to improve citizen and stakeholder confidence in the transparency and sustainability of the Union approach towards food safety, notably in relation to risk assessment.

In particular, the increased level of transparency and accountability of the studies EFSA uses to assess risks could not be achieved without opening up those studies and the data they use to public scrutiny. In addition, the current rules on confidentiality vary according to the sub-area concerned, thus not ensuring a consistent way to manage transparency. It is proportionate to harmonise these rules

while preserving, where needed, the specific balance of interests in sectoral legislations. Appropriate provisions are included to protect the rights of commercial applicants.

The assessment of the impacts outlines how the proposal achieves the best balance in meeting the objectives laid out by the initiative, ensuring benefits for citizens, stakeholders and Member States, while not significantly impacting on industry and innovation. The consultation carried out demonstrates an overall support of stakeholders to the initiative.

The regulatory regime on food safety needs to be strong to ensure its credibility and effectiveness. Problems in relation to safety have a huge impact on consumers' confidence and consequently on market stability, trade flows and the climate for innovation.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The GFL Fitness Check, completed on 15 January 2018, concluded that the systematic implementation of the risk analysis principle in Union food law has increased overall protection of public health. Setting up the EFSA has given Union measures a sounder scientific basis. It has made major progress on increasing its scientific capacity of expertise, boosting the quality of its scientific outputs, expanding its collection of scientific data and developing and harmonising risk assessment methodologies. It has also strengthened the cooperation with national and international scientific bodies as well as the exchange of information between Member States, the Commission and EFSA itself. This has resulted in a mutual understanding of risks, minimised duplications of work and limited the number of scientific divergences between the EFSA and other risk assessment bodies. The EFSA also regularly fine-tunes and strengthens its strict policies on independence, transparency and openness.

Nevertheless, the following challenges have been identified: national differences in the implementation of the GFL Regulation at Member State level have been observed, creating in some instances uneven playing field for businesses; a perceived lack of transparency of the risk analysis process; risk communication is, overall, considered not to be effective enough, thus creating a negative impact on consumers' confidence and on the acceptability of risk management decisions; certain limitations in EFSA's capacity to ensure in the long-term sufficient expertise and to fully engage all Member States in scientific cooperation; lengthy authorisation procedures in some sectors.

This proposal is addressing those challenges directly linked to the GFL Regulation and EFSA.

- **Stakeholder consultations**

Member States were consulted in a meeting of the Expert Group on the General Food Law on 5 March 2018. The national food safety authorities of the Member States

(meeting of the EFSA Advisory Forum on 6 February 2018[13]) and the Scientific Committee of EFSA (15 February 2018) were also consulted.

European stakeholder organisations representing farmers, cooperatives, the food industry, retailers, consumers, professionals and civil society were consulted at an ad hoc meeting of the Advisory Group on the Food Chain, Animal and Plant Health on 5 February 2018[14].

A public consultation on the initiative in all Union official languages was launched on 23 January 2018 and ran until 20 March 2018; 471 replies were received (318 from individuals and 153 from organisations).

The contributions received from citizens and stakeholders confirmed the importance of the aspects of the Union food safety risk assessment model this proposal addresses and the need to ensure that the proposal strengthens all those aspects, while safeguarding the principles on which the Union food safety system is based.

In drafting the proposal, contributions have been taken into account for measures in four specific areas: the publication of studies supporting industry applications of regulated products while protecting confidential and personal data; guarantees in the Union to verify the reliability, and independence of the evidence taken from industry studies; making risk communication more efficient; and strengthening EFSA's sustainability and governance while ensuring the independence and excellence of the expertise made available to the Authority by the Union Member States.

The results of all consultation activities are summarised in the synopsis report[15].

- **Collection and use of expertise**

Extensive consultation and data collection (including external studies, extensive surveys, case studies and workshops as well as in-depth interviews with relevant stakeholders) has taken place on the issues this proposal addresses in the context of the GFL Fitness Check[16].

- **Impact assessment**

As explained in the Roadmap[17], no impact assessment was carried out for this initiative, as the measures that are to be introduced by the proposal will mainly concern the transparency and the way the Commission as risk manager and the EFSA as risk assessor will gather and manage the evidence needed to perform their tasks on the basis of unchanged criteria. Such measures are therefore not expected to have significant socio-economic and environmental impacts that are clearly identifiable ex ante.

A number of impacts were however considered during the preparation process as follows:

Transparency: The proposal aims at strengthening the transparency of the risk assessment process. This should give EFSA greater legitimacy in the eyes of consumers and the general public, increasing their confidence in its work. Since duly

13 https://www.efsa.europa.eu/sites/default/files/event/180206/180206-m.pdf
14 https://ec.europa.eu/food/expert-groups/ag-ap/adv-grp_fchaph/wg_2018_en
15 Commission Staff Working Document, Synopsis Report, SWD(2018)97, [dated 11.04.2018].
16 https://ec.europa.eu/food/safety/general_food_law/fitness_check_en
17 https://ec.europa.eu/info/law/better-regulation/initiative/151777/attachment/090166e5b7579aa2_en

justified confidential information is protected, incentives for innovation should remain unchanged. The proposal will not impinge on any intellectual property right which may exist over documents or their content, nor on any regulatory protection set out in Union sectoral legislation covering the agri-food chain rewarding investments (the so-called "data exclusivity rules"). Compliance costs for businesses will not increase because existing rules already require applications including studies to be submitted to the relevant regulatory authority, e.g. the Commission, EFSA and the Member States, followed by confidentiality claims. The main identified costs fall on EFSA, since it will have the main responsibility of taking a decision, within tight deadlines to avoid making the authorisation procedures longer, on all confidentiality claims made by applicants in the context of authorisation procedures, in cases in which an opinion of EFSA is to be provided.

Governance and greater Member State involvement in the Management Board: The proposal will align EFSA's governance with the model used for other Union agencies in line with the inter-institutional Common Approach on Union decentralised agencies, thus increasing the global consistency of the Union agencies' Management Board model. This should have a positive impact since experience from other Union agencies demonstrates that this model ensures efficient supervision of the functioning of agencies and coordinated views between the Union and national level. As for other agencies, EFSA independence is appropriately safeguarded by the criteria for nomination that privilege members with a profile of risk assessor and the strong provisions on independence and on transparency since the rules providing that the members of the Management Board have to act independently in the public interest and make an annual public declaration of interests remain unchanged. In addition, the role of the Management Board is focussed on administration and finances.

Governance and greater Member State involvement in nominating Scientific Panel experts: the benefit of greater Member State involvement in this aspect of EFSA's work is expected to be to ensure it has access to a sufficiently large pool of independent and excellent experts meeting its needs in the different disciplines areas it deals with. This in turn is expected to have a positive impact on the sustainability of the Union risk assessment system. The risk that some Member States might not have enough experts to be able to provide the EFSA with valuable candidates is alleviated by the possibility for EFSA to select and appoint additional experts of its own accord and the possibility for Member States to appoint experts who have the nationality of other Member States. This risk is also addressed by the better financial compensation of Member States contributing to EFSA's work by sending experts or providing preparatory work. Provisions in relation to the nomination, selection and appointment of experts include strict criteria on independence, thus providing appropriate safeguards. The involvement of the EFSA Executive Director in the selection process is an additional guarantee that the independence criteria will be met. In particular, the Executive Director, whose function is to defend EFSA's independent point of view and interests, selects the experts proposed for appointment to the Management Board from the large pool of experts nominated by Member States. The selection process by the Executive Director involves checking that the experts it proposes are in line with EFSA's policy and rules on independence and it is expected that the Executive Director, given its specific role, will be vigilant on this key issue for EFSA.

With regard to the reliability and robustness of studies submitted by industry in the context of authorisation procedures, the following impacts were in particular considered:

The measures establishing a register of commissioned studies and the measure providing for a consultation on submitted studies will bring benefits by ensuring that EFSA has access to as much evidence as possible on a substance submitted for its assessment. The register of commissioned studies will have a positive impact on the objectivity of the evidence submitted by industry since it will provide additional guarantee that applicants submit **all studies** they have performed on a substance - whatever their results. In particular EFSA will be able to cross-check the information on the studies performed (the laboratories being an external source of information). The consultation on submitted studies will identify other available relevant scientific data or studies on a substance subject to authorisation thus strengthening EFSA's evidence base and diminishing its reliance on only industry studies. The impact on the timing of authorisation is minimal since the notification of commissioned studies takes place at the pre-submission stage and the risk assessment will run in parallel of the consultation on submitted studies

The notification of commissioned studies creates a minimal burden. The consultation on submitted studies does not create additional burdens since the obligation to submit studies to EFSA, Commission and Member States already exists. There is only a very limited risk that notification by laboratories, meaning only Union laboratories, could have negative impacts on their competitiveness vis-à-vis non-Union laboratories, or that the overall effectiveness of the measure may be undermined by applicants deciding to carry out studies in laboratories outside the Union to circumvent the notification obligation. This is because companies going to laboratories outside the Union would take the risk to be perceived as evading the rules.

The specific obligations in the case of renewals of authorisations: The obligation to notify EFSA of planned studies and to systematically carry out consultation on these planned studies with the EFSA issuing systematic advice on the content of the intended application are expected to have a positive balance of effects. Since they concern the authorisation of a substance already on the market for several years and given that they address planned studies, the experience from the similar procedures under ECHA shows that there is public knowledge and in some cases new data that can be usefully shared concerning the substance at issue. Such obligations avoid the unnecessary repetition of studies on vertebrates and enlarge the evidence base of EFSA, without jeopardising the competitiveness of the relevant applicant. Indeed, the notification of planned studies represents a relatively small burden for the applicant. It is also proportionate given that the applicant can get useful advice on the content of its intended application following the consultation on the planned studies and this at an early stage of the process. The impact on the duration of the authorisation procedures is minimal since this procedure is at the pre-submission stage and it may have a positive impact in reducing the length of authorisation procedures, as concerns may be raised and addressed early on in the process. The impact in terms of costs and resources needed is mostly on EFSA.

The pre-submission procedure ensures an additional involvement of EFSA, to ensure that the applicant is aware of and can adhere to the applicable requirements relating to the content of authorisation applications. It addresses industry demands (in particular SMEs) for further support in the preparation of the authorisation application. This should also lead to more adequate and complete evidence being

submitted and thus improve the efficiency of the risk assessment process in EFSA. It will help applicants in particular small and medium sized enterprises in understanding how to prepare authorisation applications. EFSA's independence will not be affected to any extent since the scope of the advice that EFSA provides is limited to what the relevant provisions are and what the required content of the application at stake is. Furthermore, the EFSA staff will provide the advice without the involvement of the Scientific Panels. EFSA provides the advice in a transparent way since it makes it public.

There should be no negative impact for innovation from the measures on the reliability and robustness of studies. As indicated, the measures create small additional burdens for applicants since they are limited to the notifications of commissioned studies in all cases and of planned studies in the case of renewals, given that the submission of studies in authorisation application is already foreseen in existing legislation. The potential impact of revealing the business strategy of a company by the notification of commissioned studies on a new substance has been neutralised since this information is made public only when the studies included in the corresponding authorisation application are made public so at a time where such a publication cannot have the effect to reveal a business strategy. In addition, the confidentiality regime established by the proposal provides that any information revealing the business strategy of the applicant is confidential. The impact for innovation (divulging business strategy) is not significant for the notification of planned studies in case of renewals since the substance is already known and the date of renewal is set up in legislation The pre-submission procedure will help the SME's access to innovation and is at the request of the applicant except for renewals which represent a specific case and a limited number of applications. It will not divert positive investments for innovation to defensive investments, since the measures are limited to providing transparent information on studies that in any case the applicant has to carry out in accordance with already existing legislation. Enhanced transparency is expected to contribute to strengthening a climate of consumers' confidence that is beneficial for stimulating innovation and for the Union product safety recognition worldwide. The impact on the timing of authorisation is minimal as detailed for each measure.

Globally, all these measures will also contribute to an increased involvement of stakeholders in the risk assessment system and thus to a more effective risk communication.

With regard to additional controls on the conduct of studies, the two measures proposed (audit/controls by Union inspectors and possibility to commission ad hoc studies in exceptional circumstances with the aim to verify evidence used by EFSA in its risk assessment), will provide additional assurances on the quality and objectivity of the studies used by EFSA for its risk assessment while not impacting on innovation since limited to specific or exceptional cases.

Auditing by the European Commission: This will strengthen the guarantees on the quality of the studies EFSA takes into consideration in its risk assessments, in particular with regard to the reproducibility of results. The risk of duplicating with activities Member States carry out under OECD agreements is addressed since the Commission auditing programme will be complementary to and coordinated with OECD Good Laboratory Practices (GLP) auditing programmes, which currently audit each Member State monitoring authority every 10 years. The lack of legal basis to audit the monitoring authorities of non-European Union countries is dealt with by

coordinating activities with the Member States and OECD GLP programmes and by seeking to conclude bilateral international agreements. There are no negative impacts in the duration of authorisation procedures since this is a parallel activity. The Commission will bear the limited costs.

The possibility to ask the **EFSA to exceptionally commission studies:** This is an additional tool where scientific evidence upon which EFSA relies needs to be verified. It ensures that action can be taken at Union level where there are exceptional circumstances of serious controversies or conflicting results. The risk of this tool being disproportionally used to unnecessarily commission studies is limited: it is to be triggered by the Commission since it will be financed by the Union budget and only in exceptional circumstances. There is no risk of public authorities becoming responsible for providing evidence on the safety of substance for EFSA's assessment, since the principle that it is the responsibility of the industry (applicants) to provide such evidence during the risk assessment process remains. There is no risk of duplication with the actual capacity of EFSA to commission scientific studies necessary for the performance of its mission (Article 32 of the GFL Regulation) as this is to be considered as a risk management tool.

Alternatives considered:

The option having Member States requesting EFSA to commission studies in exceptional circumstances as well as the option having EFSA commissioning such studies on its own motion were not chosen in the end for reasons of proportionality (public financing) but also because the EFSA and Member States can already signal to the Commission specific reasons to make use of this specific tool.

- **Regulatory fitness and simplification**

As announced in the Communication replying to the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", this proposal is a targeted revision of the GFL Regulation (and other measures adopted in that framework) in order to improve transparency in risk assessment, reliability, objectivity and independence of studies used by EFSA in its risk assessment, risk communication, and governance of EFSA. As this is a revision of an existing piece of legislation falling under the Commission's Regulatory Fitness and Performance Programme REFIT, the Commission has looked at opportunities to simplify and reduce burdens. Given the targeted nature of this revision, focussing on transparency, the main simplification aspect concerns the introduction of a pre-submission advice which should provide support to applicants, in particular SMEs, to better understand the specifications on content of applications.

Other simplification aspects include the harmonisation of the confidentiality rules across different sectors providing a similar baseline to all industry applicants in terms of predictability.

On transparency, the measures envisaged (i.e. proactive disclosure of non-confidential data, register of commissioned studies, voluntary pre-submission procedure, pre-notification of, and advice on planned studies in case of renewals, consultation of third parties on submitted studies) provide a robust framework which is proportional to the objective of enhancing citizens' confidence in the transparency of the system. The Commission does not see scope to simplify or reduce these steps as this could have a negative impact not only on the perception of the transparency of

the system but also on ensuring that the evidence presented for EFSA's assessments is complete.

- **Fundamental rights**

To determine what level of disclosure strikes the appropriate balance, the public interest in ensuring greater transparency in the risk assessment process is weighted up against the commercial interests at stake. This means taking into account the general objectives of the GFL Regulation, namely a high level of protection of human health and consumers' interests and the effective functioning of the internal market. To this end, the proposal sets out a cross-sectoral list of information items whose disclosure might be considered to significantly harm the commercial interests at stake and should therefore not be disclosed to the public. The proposal also stipulates that personal data be protected taking into account the applicable Union legislative framework on the processing of such data.

4. BUDGETARY IMPLICATIONS

The main objective of the proposal is to make studies used in risk assessment more transparent and address the demands of society for a more transparent and independent risk assessment process and more effective risk communication. By strengthening the EFSA's governance and making risk assessment more sustainable, it will ensure that EFSA will continue to play a fundamental role in the Union food safety system and to contribute to the health and wellbeing of Union citizens and to an innovative and competitive Union agri-food industry.

To address these issues, the Commission has come up with a wide ranging and ambitious proposal requiring a significant increase in the resources available to the EFSA to enable it to discharge its existing and proposed new responsibilities.

Member States that provide the EFSA with expertise also need to receive more compensation.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The GFL Fitness Check has also highlighted the need to establish a more comprehensive monitoring system of the implementation of Union food law, so as to provide policy makers and the public with more solid data and evidence base to regularly assess the relevant impacts. It underlined that this lack should be addressed in future policy development, for instance by making better coordinated use of existing reporting requirements. Although in principle a revision of Regulation (EC) No 178/2002 could be used as an opportunity to set up a more comprehensive monitoring system of the implementation of Union food law, the targeted scope of this proposal is too limited to accommodate the establishment of such a system.

Transitions measures are provided. The proposal at hand provides for a periodic overall evaluation of the agency, to be commissioned by the Commission, as per the Common Approach on Decentralised Agencies.

- **Detailed explanation of the specific provisions of the proposal**

1) **The proposal ensures that scientists and citizens have access to key safety related information being assessed by EFSA at an early stage of the risk assessment**. In particular, the new provisions provide that all supporting data and information relating to applications for authorisation are to be made public by EFSA upon receipt (as applications will be submitted either directly to EFSA or forwarded to EFSA by Member States or by the Commission), including supplementary information, except for duly justified confidentiality information. In that respect, the proposal sets outs which type of information is to be considered confidential. The transparency provisions are without prejudice to any existing Intellectual Property Rights and data exclusivity provisions set out in Union sectoral food legislation. The process to be followed for the processing of confidentiality claims is also set up.

2) **It will help to improve citizens' confidence in the credibility of scientific studies and consequently confidence in the Union risk assessment system**. The proposal will provide for a series of measures to ensure that EFSA has access to the broadest relevant scientific evidence possible related to a request for authorisation and to increase the guarantees of reliability, objectivity and independence of studies used by EFSA in its risk assessment. First, it will establish a Union register of commissioned studies on substances subject to a food law authorisation system, to be managed by EFSA. The second measure sets out a pre-submission procedure, by which EFSA can provide advice to an applicant (without entering into the design of the study) and this advice will be made public. In the case of renewals, the pre-submission procedure foresees that studies planned by a potential applicant will have to be notified to EFSA and, after public consultation on these planned studies, the Authority will systematically provide advice to the applicants. The third measure provides that at the stage of submission of authorisation application, when all studies are made public according to the new provisions on transparency, a consultation of third parties will be launched with the aim to identify whether other relevant scientific data or studies are available. The fourth measure provides for controls and audits by Commission inspectors in relation to studies. Finally, the proposal introduces the possibility for the Commission to request EFSA to commission studies in exceptional circumstances (e.g. controversies) for the purpose of verification.

3) **Better Involving Members States in EFSA's governance structure and Scientific Panels and thus support the sustainability in the long-term of EFSA risk assessment without touching on its independence**. It aligns the composition of EFSA's Management Board with the Common Approach on decentralized agencies by including representatives of all Member States. It will also address the findings of the GFL Fitness Check that identified challenges to EFSA's capacity to maintain its high level of scientific expertise by providing for an increased involvement of Member States in the nomination process of Panels' members. The proposal respects the needs of EFSA for independence, excellence and multi-disciplinary expertise. In particular, the existing strict criteria on independence are maintained and specific provisions require Member States to set up specific measures ensuring that the experts have concrete means to act independently as required by the proposal. The proposal also provides for a better organisation of the Panels' work.

4) **Strengthen risk communication between the Commission/EFSA /Members States and public /stakeholders**. It is proposed to lay down in legislation the objectives and general principles governing risk communication, taking into account the respective roles of risk assessors and managers pursuant to Article 40 of Regulation (EC) No 178/2002 and, based on these objectives and general principles,

to draw up a general plan on risk communication ("general plan"). The general plan should identify the key factors that need to be taken into account when considering the type and level of communication activities needed, ascertain the tools and channels for the relevant risk communication initiatives taking into account the relevant target audience groups; and, establish appropriate mechanisms to ensure coherent risk communication.

It is proposed to empower the Commission to draw up this general plan for the purposes of Regulation (EC) No 178/2002 by means of delegated acts.

In parallel to the legislative measures, the Commission will also continue to provide support to food safety via its Research and Innovation policies and contribute to strengthening coordination, cooperation and cohesion of food safety research and innovation activities in the Union and its Member States in particular when building the forthcoming ninth European Research and Innovation Framework Programme.

2018/0088 (COD)

Proposal for a

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 (EU) No 2015/2283 [on novel foods]

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43, 114, and 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[18],

Having regard to the opinion of the Committee of the Regions[19],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Regulation (EC) No 178/2002 of the European Parliament and of the Council[20] lays down the general principles and requirements of food law, so as to form a common basis for measures governing food law both at Union and Member State level. It provides, amongst others, that food law must be based on risk analysis, except where this is not appropriate to the circumstances or the nature of the measure.

(2) Regulation (EC) No 178/2002 defines "risk analysis" as a process consisting of three interconnected components: risk assessment, risk management and risk communication. For the purposes of risk assessment at Union level, it establishes the European Food Safety Authority ("the Authority"), as the responsible Union risk assessment body in matters relating to food and feed safety. Risk communication is an essential part of the risk analysis process.

[18] OJ C , , p. .

[19] OJ C , , p. .

[20] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, (OJ L 31, 1.2.2002, p. 1).

(3) The evaluation of Regulation (EC) No 178/2002[21], ("Fitness Check of the General Food Law"), found that risk communication is overall, not considered to be effective enough, which has an impact on consumers' confidence on the outcome of the risk analysis process.

(4) It is therefore necessary to ensure a comprehensive and continuous risk communication process throughout risk analysis, involving Union and national risk assessors and risk managers. That process should be combined with an open dialogue between all interested parties to ensure the coherence and consistency within the risk analysis process.

(5) Particular emphasis should be placed on explaining in a coherent, appropriate and timely manner not only risk assessment findings themselves but also how these are utilized to help inform risk management decisions along with other legitimate factors, where relevant.

(6) To this effect, it is necessary to establish general objectives and principles of risk communication, taking into account the respective roles of risk assessors and managers.

(7) Based on these general objectives and principles, a general plan on risk communication should be established in close cooperation with the Authority and the Member States, and following relevant public consultations.

(8) The general plan should identify the key factors to be taken into account when risk communications' activities are considered, such as the different levels of risk, the nature of the risk and its potential public health impact, who and what are directly or indirectly affected by the risk, the levels of risk exposure, the ability to control risk and other factors that influence risk perception including the level of urgency as well as the applicable legislative framework and relevant market context. The general plan should also identify the tools and channels to be used and should establish appropriate mechanisms to ensure coherent risk communication.

(9) Transparency of the risk assessment process contributes to the Authority acquiring greater legitimacy in the eyes of the consumers and general public in pursuing its mission, increases their confidence in its work and ensures that the Authority is more accountable to the Union citizens in a democratic system. It is therefore essential to maintain the confidence of the general public and other interested parties in the risk analysis process underpinning Union food law and in particular in the risk assessment, including the organisation and independence of the Authority and transparency.

(10) It is appropriate to align the composition of the Management Board of the Authority to the Common Approach on decentralised agencies, in accordance with the Joint Statement of the European Parliament, the Council of the European Union and the European Commission on decentralised agencies of 2012[22].

(11) Experience shows that the role of the Management Board of the Authority is focussed on administrative and financial aspects and does not impact on the independence of the scientific work performed by the Authority. It is thus appropriate to include representatives of all Member States in the Management Board of the Authority, while providing that those representatives should have experience in particular on risk assessment.

(12) The Management Board should be selected in such a way as to secure the highest standards of competence and a broad range of relevant experience available amongst the representatives of the Member States, the European Parliament and the Commission.

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21 Commission Staff Working Document, "The REFIT evaluation of the General Food Law (Regulation (EC) No 178/2002)", SWD(2018)38 final, dated 15.1.2018.

22 https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

(13) The Fitness Check of the General Food Law identified certain shortcomings in the long-term capability of the Authority to maintain its high-level expertise. In particular, there has been a decrease in the number of candidates applying to be members of the Scientific Panels. The system has thus to be strengthened and Member States should take a more active role to ensure that a sufficient pool of experts is available to meet the needs of the Union risk assessment system in terms of high level of scientific expertise, independence and multidisciplinary expertise.

(14) To preserve the independence of the risk assessment from risk management and from other interests at Union level, it is appropriate that the nomination of the members of the Scientific Panels by the Member States, their selection by the Executive Director of the Authority and their appointment by the Management Board of the Authority are based on strict criteria ensuring the excellence and independence of the experts while ensuring the required multidisciplinary expertise for each Panel. It is also essential to this end that the Executive Director whose function is to defend EFSA's interests and in particular the independence of its expertise has a role in the selection and appointment of those scientific experts. Further measures should also be put in place to ensure that scientific experts have the means to act independently.

(15) It is essential to ensure the efficient operation of the Authority and to improve the sustainability of its expertise. It is therefore necessary to strengthen the support provided by the Authority and the Member States to the work of the Authority's Scientific Panels. In particular, the Authority should organise the preparatory work supporting the Panels' tasks, including by requesting the Authority's staff or national scientific organisations networking with the Authority to draft preparatory scientific opinions to be peer-reviewed and adopted by the Panels.

(16) Authorisations procedures are based on the principle that it is for the applicant to prove that the subject matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This principle is based on the premise that public health is better protected when the burden of proof is on the applicant since it has to prove that a particular subject matter is safe prior to its placing on the market, instead of the public authorities having to prove that a subject matter is unsafe in order to be able to ban it from the market. Moreover, public money should not be used to commission costly studies that will in the end help the industry to place a product on the market. According to this principle and in accordance with applicable regulatory requirements, in support of applications for an authorisation under Union sectoral food law applicants are required to submit relevant studies, including tests, to demonstrate the safety and in some cases the efficacy of a subject matter.

(17) Provisions exist on the content of applications for authorisations. It is essential that the application for authorisation submitted to the Authority for its risk assessment meets the applicable specifications to ensure the best quality scientific assessment by the Authority. Applicants and in particular small- and medium-sized enterprises do not always have a clear understanding of these specifications. It should be thus appropriate that the Authority provides advice to a potential applicant, upon request, on the applicable rules and the required content of an application for authorisation, before an application is formally submitted, while not entering into the design of the studies to be submitted that remain the applicant's responsibility. To ensure the transparency of this process, the advice of the Authority should be made public.

(18) The Authority should have knowledge of the subject matter of all studies performed by an applicant with a view to a future application for an authorisation under Union food law. To this end, it is necessary and appropriate that business operators commissioning the studies and laboratories carrying them out notify those studies to the Authority when commissioned. Information about the notified studies should be made public only once a corresponding

application for authorisation has been made public in accordance with the applicable rules on transparency.

(19) In the case of applications to request the renewal of an authorisation, the authorised substance or product has already been on the market for several years. Therefore experience and knowledge exist on this substance or product. It is therefore appropriate that the studies planned for supporting requests for renewals should be notified by the applicant to the Authority and that following a consultation of third parties on these planned studies, the Authority systematically provides advice to the applicants on the content of the intended renewal application, taking into account the received comments.

(20) There are certain public concerns about the Authority's assessment in the area of authorisation being primarily based on industry studies. The Authority already makes searches in scientific literature to be able to consider other data and studies existing on the subject matter submitted to its assessment. In order to provide an additional level of guarantee ensuring that the Authority can have access to all relevant scientific data and studies available on a subject matter of an authorisation procedure, it is appropriate to provide for a consultation of third parties in order to identify whether other relevant scientific data or studies are available. To increase the effectiveness of the consultation, the consultation should take place when the studies submitted by industry included in an application for authorisation are made public, under the transparency rules of this Regulation.

(21) Studies, including tests, submitted by business operators in support of applications for authorisations under Union sectoral food law usually comply with internationally recognised principles, which provide a uniform basis for their quality in particular in terms of reproducibility of results. However, issues of compliance with the applicable standards may arise in some cases and this is why national systems are in place to verify such compliance. It is appropriate to provide an additional level of guarantees to reassure the general public on the quality of studies and to lay down an enhanced auditing system whereby Member State controls on the implementation of those principles by the laboratories carrying out such studies and tests would be verified by the Commission.

(22) Food safety is a sensitive matter of prime interest for all Union citizens. While maintaining the principle that the burden is on the industry to prove compliance with Union requirements, it is important to establish an additional verification tool to address specific cases of high societal importance where there is a controversy on safety issues, namely the commissioning of additional studies with the objective of verifying evidence used in the context of risk assessment. Considering that it would be financed by the Union budget and that the use of this exceptional verification tool should remain proportionate, the Commission should be responsible for triggering the commissioning of such verification studies. Account should be taken of the fact that in some specific cases the studies commissioned may need to have a wider scope than the evidence at stake (for example new scientific developments becoming available).

(23) The Fitness Check of the General Food Law demonstrated that although the Authority has made considerable progress in terms of transparency, the risk assessment process, especially in the context of authorisation procedures covering the agri-food chain, is not always perceived as fully transparent. This is also partly due to the different transparency and confidentiality rules that are laid down not only in Regulation (EC) No 178/2002 but also in other Union legislative acts covering the agri-food chain. Their interplay can impact on the acceptability of the risk assessment by the general public.

(24) The European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides" further confirmed concerns regarding transparency with respect to studies commissioned by the industry and submitted in authorisation application[23].

(25) It is therefore necessary to strengthen the transparency of the risk assessment process in a proactive manner. Public access to all scientific data and information supporting requests for authorisations under Union food law as well as other requests for scientific output should be ensured, as early as possible in the risk assessment process. However, this process should be without prejudice to existing intellectual property rights or to any provisions of Union food law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations.

(26) Where the opinion of the Authority is requested in relation to authorisation procedures under Union food law and having regard to its obligation to ensure public access to all supporting information with respect to the provision of its scientific outputs, the Authority should have responsibility for assessing confidentiality requests.

(27) To determine what level of disclosure strikes the appropriate balance, the relevant rights of the public to transparency in the risk assessment process, should be weighted up against the rights of commercial applicants, taking into account the objectives of Regulation (EC) No 178/2002.

(28) Accordingly and with respect to the procedures governing requests for authorisation procedures provided in Union food law, experience gained so far has shown that certain information items are generally considered sensitive and should remain confidential across the different sectoral authorisation procedures. It is appropriate to lay down in Regulation (EC) No 178/2002 a horizontal list of information items whose disclosure may be considered to significantly harm the commercial interests concerned and should not therefore be disclosed to the public, ("general horizontal list of confidential items"). Only in very limited and exceptional circumstances relating to foreseeable health effects and urgent needs to protect human health, animal health or the environment, such information should be disclosed.

(29) For the purposes of clarity and to increase legal certainty, it is necessary to set out the specific procedural requirements to be followed in respect of a request for information submitted for the purposes of authorisation procedures under Union food law to be treated in a confidential manner.

(30) It is also necessary to set out specific requirements with respect to the protection of personal data for the purposes of the transparency of the risk assessment process taking into account Regulation (EC) No 45/2001 of the European Parliament and of the Council[24] and Regulation (EU) 2016/679 of the European Parliament and of the Council[25]. Accordingly, no personal data should be made publicly available under this Regulation, unless it is necessary and proportionate for the purposes of ensuring the transparency, independence and the reliability of the risk assessment process, while preventing conflicts of interests.

(31) For the purposes of increased transparency and in order to ensure that requests for scientific outputs received by the Authority are processed in an effective manner, standard data

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23 Communication from the Commission on the ECI "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final.

24 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

25 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

formats and software packages should be developed. In order to ensure uniform conditions for the implementation of Regulation (EC) No 178/2002 with regard to the adoption of standard data formats and software packages, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[26].

(32) Having regard to the fact that the Authority would be required to store scientific data, including confidential and personal data, it is necessary to ensure that such storage is carried out in accordance with a high level of security.

(33) Furthermore, in order to assess the effectiveness and efficiency of the different provisions applying to the Authority, it is also appropriate to provide for a Commission evaluation of the Authority, in accordance with the Common Approach on Decentralised Agencies. The evaluation should, in particular, review the procedures for selecting the members of Scientific Committee and Panels, for their degree of transparency, cost-effectiveness, and suitability to ensure independence and competence, and to prevent conflicts of interests.

(34) In order to ensure consistency with the proposed adaptations in Regulation (EC) No 178/2002, provisions relating to public access and the protection of confidential information in Directive 2001/18/EC of the European Parliament and of the Council[27], Regulation (EC) No 1829/2003 of the European Parliament and of the Council[28], in Regulation (EC) No 1831/2003 of the European Parliament and of the Council[29], in Regulation (EC) No 2065/2003 of the European Parliament and of the Council[30], in Regulation (EC) No 1935/2004 of the European Parliament and of the Council[31], in Regulation (EC) No 1331/2008 of the European Parliament and of the Council[32], in Regulation (EC) No 1107/2009 of the European Parliament and of the Council[33] and in Regulation (EU) 2015/2283 of the European Parliament and of the Council[34] should be amended.

(35) For the purposes of ensuring transparency of the risk assessment process, it is also necessary to extend the scope of Regulation (EC) No 178/2002, currently limited to food law, to also cover applications for authorisations in the context of Regulation (EC) No 1831/2003 as

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26 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, (OJ L 55, 28.2.2011, p. 13).

27 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

28 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

29 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

30 Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1).

31 Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

32 Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).

33 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

34 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

regards feed additives, Regulation (EC) No 1935/2004 as regards food contact materials and Regulation (EC) No 1107/2009 as regards plant protection products.

(36) To ensure that sectoral specificities with respect to confidential information are taken into account, it is necessary to weigh up the relevant rights of the public to transparency in the risk assessment process, including those flowing from the Aarhus Convention[35], against the rights of commercial applicants, taking into account the specific objectives of sectoral Union legislation as well as experienced gained. Accordingly, it is necessary to amend Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 1935/2004 and Regulation (EC) No 1107/2009 to provide for additional confidential items to those set out in Regulation (EC) No 178/2002.

(37) In order to further strengthen the link between risk assessors and risk managers at Union and national levels as well as the coherence and consistency of risk communication, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission to adopt a general plan on risk communication on matters covering the agri-food chain. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(38) In order to enable the Authority and the business operators to adapt to the new requirements while ensuring that the Authority continues its smooth operation, it is necessary to provide for transitional measures for the application of this Regulation.

(39) The appointment of the Scientific Committee and Scientific Panels' members being dependent of the entry in function of the new Management Board, it is necessary to provide for specific transitional provisions allowing a prolongation of the current term of office of the members of the Scientific Committee and Scientific Panels members.

(40) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 of the European Parliament and of the Council[36] and delivered an opinion on […],

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 178/2002

Regulation (EC) No 178/2002 is amended as follows:

(1) in Chapter II the following SECTION 1a is inserted:

"SECTION 1a

RISK COMMUNICATION

[35] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p.13).

[36] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

Article 8a

Objectives of risk communication

Risk communication shall pursue the following objectives, while taking into account the respective roles of risk assessors and risk managers:

(a) promote awareness and understanding of the specific issues under consideration during the entire risk analysis process;

(b) promote consistency and transparency in formulating risk management recommendations;

(c) provide a sound basis for understanding risk management decisions;

(d) foster public understanding of the risk analysis process so as to enhance confidence in its outcome;

(e) promote appropriate involvement of all interested parties; and,

(f) ensure appropriate exchange of information with interested parties in relation to risks associated with the agri-food chain.

Article 8b

General principles of risk communication

Taking into account the respective roles of risk assessors and risk managers, risk communication shall:

(a) ensure that accurate, appropriate and timely information is interactively exchanged, based on the principles of transparency, openness, and responsiveness;

(b) provide transparent information at each stage of the risk analysis process from the framing of requests for scientific advice to the provision of risk assessment and the adoption of risk management decisions;

(c) take into account risk perceptions;

(d) facilitate understanding and dialogue amongst all interested parties; and,

(e) be accessible, including to those not directly involved in the process, while taking into account confidentiality and protection of personal data.

Article 8c

General plan for risk communication

1. The Commission, in close cooperation with the Authority, the Member States and following appropriate public consultations shall be empowered to adopt delegated acts in accordance with Article 57a establishing a general plan for risk communication on matters relating to the agri-food chain, taking into account the relevant objectives and general principles set out in Articles 8a and 8b.

2. The general plan for risk communication shall promote an integrated risk communication framework to be followed both by the risk assessors and the risk managers in a coherent and systematic manner both at Union and national level. It shall:

   (a) identify the key factors that need to be taken into account when considering the type and level of risk communications' activities needed;

   (b) identify the appropriate main tools and channels to be used for risk communication purposes, taking into account the needs of relevant target audience groups; and,

(c) establish appropriate mechanisms in order to strengthen coherence of risk communication amongst risk assessors and risk managers and ensure an open dialogue amongst all interested parties.

3. The Commission shall adopt the general plan for risk communication within [*two years from the date of application of this Regulation*] and shall keep it updated, taking into account technical and scientific progress and experience gained.";

(2) Article 25 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. Each Member State shall nominate a member and an alternate member to the Management Board. The members and alternate members thus nominated shall be appointed by the Council and have voting rights. ",

(b) the following paragraphs 1a and 1b are inserted:

"1a. In addition to members and alternate members referred to in paragraph 1, the Management Board shall include:

(a) two members and the alternate members appointed by the Commission and representing the Commission, with the right to vote.

(b) one member appointed by the European Parliament, with the right to vote.

(c) four members with the right to vote representing civil society and food chain interests namely, one from consumers organisations, one from environmental non-governmental organisations, one from farmers organisations and one from industry organisations. Those members shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible and within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint those members.

1b. The members of the Management Board and where relevant, the alternate members shall be appointed taking into account high competence in the area of food safety risk assessment as well as competences in the food chain safety legislation and policy, and relevant managerial, administrative and budgetary/financial skills.",

(c) paragraph 2 is replaced by the following:

"2. The term of office of members and alternate members shall be four years. However, the term of office of the members referred to in paragraph 1a(a) and (b) shall not be limited in duration. The term of office of the members referred to in paragraph 1a(c) may be renewable only once.",

(d) the second subparagraph of paragraph 5 is replaced by the following:

"Unless otherwise provided, the Management Board shall act by a majority of its members. Alternate members shall represent the member in his absence and vote on his behalf.";

(3) Article 28 is amended as follows:

(a) Paragraph 5 is replaced by the following:

"5. The members of the Scientific Committee who are not members of Scientific Panels and the additional members referred to in paragraph 5b shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a five year term of office, which may be renewable, following publication in the *Official Journal of the European Union*, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest.",

(b) The following paragraphs 5a to 5g are inserted:

"5a. The members of the Scientific Panels shall be appointed by the Management Board for a renewable five year term of office in accordance with the following procedure:

(a) The Executive Director, after consulting the Management Board, shall send to the Member States the request for the specific multidisciplinary expertise needed in each Scientific Panel and shall indicate the number of experts to be nominated by the Member States. The Executive Director shall notify the Member States of the Authority's independence policy and implementing rules applicable to Scientific Panels' members. Member States shall launch a call for interest as a basis for their nominations. The Executive Director shall inform the Management Board of the requests sent to the Member States.

(b) Member States shall nominate experts with a view to collectively reach the number indicated by the Executive Director. Each Member State shall nominate at least 12 scientific experts. Member States may nominate nationals of other Member States.

(c) On the basis of the nominations made by Member States, the Executive Director shall draw for each Scientific Panel a list of experts larger than the number of members to be appointed. The Executive Director may not draw up such a list where he/she can justify that the nominations received do not allow him, given the criteria for selection set up in point d) of this paragraph, to draw up a larger list. The Executive Director shall submit the list to the Management Board for appointment.

(d) The nominations by the Member States, the selection by the Executive Director and the appointments by the Management Board shall be made on the basis of the following criteria:

(i) A high level of scientific expertise;

(ii) Independence and absence of conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementing rules on the independence of the Scientific Panels' members;

(iii) Meeting the needs for the specific multi-disciplinary expertise of the Panel to which they will be appointed and the applicable language regime.

(e) The Management Board shall ensure that the broadest possible geographical distribution is achieved in the final appointments.

5b. When the Authority identifies that specific expertise is missing in a Panel or several Panels, the Executive Director shall propose additional members of the Panel(s) for appointment to the Management Board in accordance with the procedure laid down in paragraph 5.

5c. The Management Board shall adopt, on the basis of a proposal of the Executive Director, rules on the detailed organisation and timing of the procedures set up in paragraphs 5a and 5b of the present Article.

5d. The Member States shall put in place measures ensuring that the members of the Scientific Panels act independently and remain free from conflict of interests as provided for in Article 37(2) and the Authority's internal measures. Member States shall ensure that the members of the Scientific Panels have the means to dedicate the necessary time and effort to contribute to the work of the Authority. Member States shall ensure that the members of the Scientific Panels do not receive any instruction at any national level and that their independent scientific contribution to the risk assessment system at Union level is recognised as a priority task for the protection of the safety of the food chain.

5e. Member States shall ensure that the public bodies employing those scientific experts and those having responsibility for the setting of priorities of the scientific bodies employing those experts implement the measures provided for in paragraph 5d.

5f. The Authority shall support the tasks of the Panels by organising their work, in particular the preparatory work to be undertaken by the Authority's staff or by designated national scientific organisations referred to in the Article 36 including by organising the possibility for preparing scientific opinions to be peer-reviewed by the Panels before they adopt them.

5g. Each Panel shall include a maximum of 21 members.",

(c) paragraph 9(b) is replaced by the following:

"The number of members in each Scientific Panel within the maximum provided for in paragraph 5g.";

(4) the following Articles 32a, 32b, 32c, 32d and 32e are inserted:

"Article 32a

General advice

At the request of a potential applicant for a food law authorisation, the staff of the Authority shall advise on the relevant provisions and the required content of the application for authorisation. The advice provided by the staff of the Authority shall be without prejudice and non-committal as to the subsequent assessment of applications for authorisation by the Scientific Panels.

Article 32b

Union Register of Studies

1. A Union register of studies commissioned by business operators to obtain an authorisation under Union food law is hereby established. Business operators shall notify, without delay, to the Authority the subject matter of any study commissioned to support a future application for an authorisation under Union food law. The register shall be managed by the Authority.

2. The notification obligation under paragraph 1, also applies to Union laboratories carrying out those studies.

3. The notified information shall be made public only in case a corresponding application for authorisation has been received and after the Authority has decided on the disclosure of the accompanying studies in accordance with Article 38 and Articles 39 to 39f.

4. The Authority shall lay down in its internal rules the practical arrangements for implementing the notification obligations laid down in paragraphs 1 and 2, including consequences of non-compliance with the notification obligation. Those arrangements shall however be in accordance with the present Regulation and other Union sectoral food law.

Article 32c

Consultation of third parties

1. Where Union food law provides that an authorisation may be renewed, the potential applicant for the renewal shall notify the Authority of the studies it intends to perform for that purpose. Following this notification, the Authority shall launch a consultation of stakeholders and the public on the intended studies for renewal and shall provide advice on the content of the intended renewal application taking into account the received comments. The advice provided by the Authority shall be without prejudice and non-committal as to the subsequent assessment of the applications for renewal of authorisation by the Scientific Panels.

2. The Authority shall consult stakeholders and the public regarding the studies supporting applications for authorisation once they are made public by the Authority in accordance with Article 38 and Articles 39 to 39f in order to identify whether other relevant scientific data or studies are available on the subject matter concerned by the application for authorisation. This provision does not apply to the submission of any supplementary information by the applicants during the risk assessment process.

3. The Authority shall lay down in its internal rules the practical arrangement for implementing the procedures referred to in Articles 32a and this Article.

Article 32d

Controls

The Commission experts shall perform controls, including audits, to obtain assurance that testing facilities comply with relevant standards for carrying out tests and studies submitted to the Authority as part of an application for an authorisation under Union food law. These controls shall be organised in cooperation with the competent authorities of the Member States.

Article 32e

Verification studies

Without prejudice to the obligation of applicants for authorisations under food law to demonstrate the safety of a subject matter submitted to a system of authorisation, the Commission, in exceptional circumstances, may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.";

(5) Article 38 is amended as follows:

(a) Paragraph 1 is replaced by the following:

"1. The Authority shall carry out its activities with a high level of transparency. It shall in particular make public without delay:

(a) agendas and minutes of the Scientific Committee and the Scientific Panels and their Working Groups;

(b) all its scientific outputs, including the opinions of the Scientific Committee and the Scientific Panels after adoption, minority opinions and results of consultations performed during the risk assessment process always being included;

(c) scientific data, studies and other information supporting applications for authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion, taking into account protection of confidential information and protection of personal data in accordance with Articles 39 to 39f.

(d) the information on which its scientific outputs, including scientific opinions are based, taking into account protection of confidential data and protection of personal data in accordance with Articles 39 to 39f;

(e) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee, Scientific Panels and of their Working Groups, as well as the declarations of interest made in relation to items on the agendas of meetings;

(f) its scientific studies in accordance with Articles 32 and 32e;

(g) the annual report of its activities;

(h) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

(i) advice provided by the Authority to potential applicants at pre-submission phase pursuant to Article 32a and 32c.

Those items referred to in the first subparagraph shall be made public on a dedicated section of the Authority's website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print and search through in an electronic format.",

(b) the following paragraph 1a is inserted:

"1a. The disclosure of the information mentioned in paragraph (1)(c) to the public shall be without prejudice:

(a) to any intellectual property right which may exist over documents or their content; and,

(b) any provisions set out in Union food law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations ('data exclusivity rules').

The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be used, reproduced, or otherwise exploited and its use by third parties shall not engage the responsibility of the European Union."

(c) paragraph 3 is replaced by the following:

"3. The Authority shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred to in paragraphs 1, 1a and 2 of this Article, taking into account Articles 39 to 39g and Article 41.";

(6) Article 39 is replaced by the following:

"Article 39

Confidentiality

1. By way of derogation from Article 38, the Authority shall not make public information for which confidential treatment has been requested under the conditions laid down in this Article.

2. The Authority may only accept to provide confidential treatment in relation to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:

   (1) the method and other technical and industrial specifications relating to that method, used to manufacture or produce the subject matter of the request for a scientific output, including a scientific opinion;

   (2) commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;

   (3) commercial information revealing sourcing, market shares or business strategy of the applicant; and,

   (4) quantitative composition of the subject matter of the request for a scientific output, including a scientific opinion.

3. The list of information referred to in paragraph 2 shall be without prejudice to any specific Union food law.

4. Notwithstanding paragraphs 2 and 3, the following information shall nevertheless be made public:

   (a) Where urgent action is essential to protect public health, animal health or the environment, such as in emergency situations, the Authority may disclose the information referred to paragraphs 2 and 3; and,

   (b) information which forms part of conclusions of scientific outputs, including scientific opinions, delivered by the Authority and which relate to foreseeable health effects.";

(7) the following Articles 39a to 39g are inserted:

"Article 39a

Request for confidentiality

1. When submitting an application for an authorisation, supporting scientific data and other supplementary information in accordance with Union food law, the applicant may request certain parts of the information submitted to be kept confidential in accordance with paragraphs 2 and 3 of Article 39. This request shall be accompanied by verifiable justification demonstrating how making public the information concerned significantly harms the interests concerned in accordance with paragraphs 2 and 3 of Article 39.

2. Where an applicant submits a request for confidentiality, it shall provide a non-confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall be without the information the applicant deems

confidential in accordance with paragraphs 2 and 3 of Article 39. The confidential version shall contain all information submitted, including information the applicant deems confidential. Information requested to be treated as confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate the grounds on the basis of which confidentiality is requested for the different pieces of information.

Article 39b

Decision on confidentiality

1. The Authority shall:

   (a) make public, without delay, the non-confidential version, as submitted by the applicant;

   (b) proceed, without delay, to a concrete and individual examination of the confidentiality request in accordance with this Article;

   (c) inform the applicant in writing of its intention to disclose information and the reasons for it, before the Authority formally takes a decision on the confidentiality request. If the applicant disagrees with the assessment of the Authority it may state its views or withdraw its application within two weeks from the date on which it was notified of the Authority's position.

   (d) adopt a reasoned decision on the confidentiality request taking into account the observations of the applicant within ten weeks from the date of receipt of the confidentiality request with respect to applications for authorisation and without undue delay in the case of supplementary data and information and notify the applicant and inform the Commission and the Member States, as appropriate, of its decision; and,

   (e) make public any additional data and information for which the confidentiality request has not been accepted as justified not earlier than two weeks after the notification of its decision to the applicant has taken place, pursuant to point (d).

   Decisions taken by the Authority pursuant to this Article may be subject to an action before the Court of Justice of the European Union, under the conditions laid down in Articles 263 and 278 of the Treaty respectively.

Article 39c

Review of confidentiality

Before the Authority issues its scientific outputs, including scientific opinions, it shall review whether information that has been previously accepted as confidential may nevertheless be made public in accordance with paragraph 4(b) of Article 39. Should that be the case, the Authority shall follow the procedure laid down in Article 39b, which shall apply *mutatis mutandis*.

Article 39d

Obligations with regard to confidentiality

1. The Authority shall make available, upon request, to the Commission and the Member States all information in its possession relating to an application for an authorisation or to a request by the European Parliament, the Commission or the Member States for a scientific output, including a scientific opinion, unless otherwise indicated in specific Union food law.

2. The Commission and the Member States shall take the necessary measures so that information received by them under Union food law for which confidential treatment has been requested is not made public until a decision on the confidentiality request has been taken by the Authority and has become definitive. The Commission and the Member States shall also take the necessary measures so that information for which confidential treatment has been accepted by the Authority is not made public.

3. If an applicant in the context of an authorisation procedure withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information as accepted by the Authority in accordance with Articles 39to 39f. The application shall be considered withdrawn as of the moment the written request is received by the competent body that had received the original application. Where the withdrawal of the application takes place before the Authority has decided on the relevant confidentiality request, the Authority, the Commission and the Member States shall not make public the information for which confidentiality has been requested.

4. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of confidentiality pursuant to Article 339 of the Treaty.

5. The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules laid down in Articles 39, 39a, 39b, 39e and this Article, including arrangements concerning the submission and treatment of confidentiality requests with respect to information to be made public under Article 38, and taking into account Articles 39f and 39g.";

Article 39e

Protection of personal data

1. With respect to requests for scientific outputs, including scientific opinions under Union food law, the Authority shall always make public:

   (a) the name and address of the applicant;

   (b) the names of authors of published, or publicly available, studies supporting such requests; and

   (c) the names of all participants in meetings of the Scientific Committee and the Scientific Panels and their Working Groups.

2. Notwithstanding paragraph 1, disclosure of names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information shall be deemed to significantly harm the privacy and the integrity of those natural persons and shall not be made publicly available, unless there is an overriding public interest.

3. Regulation (EU) 2016/679 of the European Parliament and of the Council[37] and Regulation (EC) No 45/2001 of the European Parliament and of the Council[38] shall

[37] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation), (OJ L 119, 4.5.2016, p. 1).

[38] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

apply to the processing of personal data carried out pursuant to this Regulation. Any personal data made public pursuant to Article 38 and this article shall only be used to ensure the transparency of risk assessment process under this Regulation and not be further processed in a manner that is incompatible with these purposes, in the meaning of Article 5(1)(b) of Regulation (EU) 2016/679 and Article 4(1)(b) of Regulation (EC) No 45/2001, as the case may be.

Article 39f

Standard data formats

1. For the purposes of Article 38(1)(c) and in order to ensure the efficient processing of requests to the Authority for a scientific output, standard data formats and software packages shall be adopted to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union food law. These draft standard data formats and software packages shall not be based on proprietary standards and shall ensure interoperability with existing data submission approaches to the extent possible.

2. For the adoption of standard data formats and software packages the following procedure shall be followed:

   (a) The Authority shall draw up draft standard data formats and software packages for the purposes of the different authorisation procedures in Union food law and relevant requests for a scientific output by the European Parliament, the Commission and the Member States.

   (b) Taking into account the applicable requirements in the different authorisation procedures and other legislative frameworks and following any necessary adaptations, the Commission shall adopt standard data formats and software by means of implementing acts. Those implementing acts shall be adopted in accordance with Article 58(2).

   (c) The Authority shall make the standard data formats and software packages, as adopted, available on its website.

   (d) Where standard data formats and software packages have been adopted pursuant to this article, applications as well as requests for a scientific output, including a scientific opinion by the European Parliament, the Commission and the Member States under Union food law, shall only be submitted in accordance with the standard data formats and software packages laid down in those acts.

Article 39g

Information systems

The information systems operated by the Authority to store its data, including confidential and personal data shall be designed to a high level of security appropriate to the security risks at stake, taking into account Articles 39 to 39f of this Regulation. Access shall be based at the minimum on a system requiring two factor authentication or providing an equivalent level of security. The system shall ensure that any access to it is fully auditable.";

(8) in Article 40, the second subparagraph of paragraph 3 is replaced by the following:

"The Authority shall publish all scientific outputs including the scientific opinions issued by it and supporting scientific data and other information in accordance with Article 38 and Articles 39 a to 39f.";

(9) in Article 41, the following sentence is added at the end of paragraph 1:

"Where environmental information is concerned, Articles 6 and Article 7 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council[39] shall also apply.";

(10) the following Article 57a is inserted after the title of Section 1 in Chapter V:

"*Article 57a*

Exercise of the delegation

1. The power to adopt delegated acts is conferred upon the Commission subject to the conditions laid down in this Article.

2. The powers to adopt delegated acts referred to in Article 8(c) shall be conferred upon the Commission for an indeterminate period of time from [date of entry into force of this Regulation].

3. The delegation of power referred to in Article 8(c) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement on Better Law-Making of 13 April 2016[40].

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 8(c) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.";

(11) Article 61 is replaced by the following:

"*Article 61*

Review clause

1. The Commission shall ensure the regular review of the application of this Regulation.

2. Not later than five years after the date referred to in Article [entry into force of the Regulation amending the GFL], and every five years thereafter, the Commission shall assess the Authority's performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines. The evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification.

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[39] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13).

[40] OJ L 123, 12.5.2016, p. 1.

3. Where the Commission considers that the continuation of the Authority is no longer justified with regard to its assigned objectives, mandate and tasks, it may propose that the relevant provisions of this Regulation be amended accordingly or repealed.

4. The Commission shall report to the European Parliament, the Council and the Management Board on the evaluation findings. The findings of the evaluation shall be made public."

Article 2

Amendments to Directive (EC) 2001/18/EC on the deliberate release into the environment of genetically modified organisms

Directive (EC) No 2001/18/EC is amended as follows:

(1) In Article 6, the following paragraph 2a is inserted:

"2a. The notification referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist, pursuant to Article 39f of Regulation (EC) No 178/2002.";

(2) In Article 13, the following paragraph 2a is inserted:

"2a. The notification referred to in paragraph 1 shall be submitted in accordance with standard data formats, where they exist, pursuant to Article 39f of Regulation (EC) No 178/2002.";

(3) Article 25 is replaced by the following:

"*Article 25*

Confidentiality

1. In accordance with the conditions and the procedures laid down in Article 39 to 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*, and this article,

   (a) the notifier/applicant may request certain information submitted under this Directive to be kept confidential, accompanied by verifiable justification; and,

   (b) the competent authority shall assess the confidentiality request submitted by the notifier/applicant.

2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, which shall apply *mutatis mutandis*, confidential treatment may be accepted with respect to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:

(a) DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and,

(b) breeding patterns and strategies.";

(4) In Article 28, the following paragraph 4 is added:

"4. Where the relevant Scientific Committee is consulted under paragraph 1, it shall make public the notification/application, relevant supporting information and any supplementary information supplied by the notifier/applicant, as well as its scientific opinions, in accordance with Article 38 and Articles 39 to 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis,* and Article 25 of this Directive.".

Article 3

Amendments to Regulation (EC) No 1829/2003 on genetically modified food and feed

Regulation (EC) No 1829/2003 is amended as follows:

(1) Article 5 is amended as follows:

(a) in paragraph 3 the introductory sentence is replaced by the following:

"The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall be accompanied by the following:";

(b) in paragraph 3 point (l) is replaced by the following:

"(l) an identification of the parts of the application and any other supplementary information that the applicant requests to be kept confidential, accompanied by verifiable justification, pursuant to Articles 30 of this Regulation and Article 39 of Regulation (EC) No 178/2002; ";

(c) in paragraph 3 the following point (m) is added :

"(m) a summary of the dossier in a standardised form.";

(2) in Article 6, paragraph 7 is replaced by the following:

"7. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Articles 39 of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.";

(3) in Article 10, paragraph 1 is replaced by the following:

"1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 3(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 39 of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.";

(4) in Article 11(2), the introductory sentence is replaced by the following:

"2. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002 and accompanied by the following:";

(5) Article 17 is amended as follows:

(a) in paragraph 3 the introductory sentence is replaced by the following:

"The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and accompanied by the following:",

(b) in paragraph 3 point (l) is replaced by the following:

"(l) an identification of the parts of the application and any other supplementary information that the applicant requests to be kept confidential, accompanied by verifiable justification, pursuant to Articles 30 of this Regulation and Articles 39 to 39f of Regulation (EC) No 178/2002; ",

(c) in paragraph 3 the following point (m) is added:

"(m) a summary of the dossier in a standardised form.";

(6) in Article 18, paragraph 7 is replaced by the following:

"7. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Articles 39 to 39f of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.";

(7) in Article 22, paragraph 1 is replaced by the following:

"1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 15(1) still meets the conditions set by this Regulation. It shall forthwith transmit this opinion to the Commission, the authorisation-holder and the Member States. The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 39 to 39f of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication.";

(8) in Article 23, the introductory sentence of paragraph 2 is replaced by the following:

"2. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002 and accompanied by the following:";

(9) in Article 29, paragraphs 1 and 2 are replaced by the following:

"1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions and opinions from the competent authorities referred to in Article 4 of Directive 2001/18/EC, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002 and taking into account Article 30 of this Regulation.

2. The Authority shall apply Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents when handling applications for access to documents held by the Authority.";

(10) Article 30 is replaced by the following:

"Article 30

Confidentiality

1. In accordance with the conditions and the procedures laid down in Article 39 to 39f of Regulation (EC) No 178/2002 and this article,

   (a) the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification; and,

   (b) the Authority shall assess the confidentiality request submitted by the applicant.

2. In addition to Article 39(2) and pursuant to Article 39(3) of Regulation (EC) No 178/2002, the Authority may also accept to provide confidential treatment to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:

   (a) DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and,

   (b) breeding patterns and strategies.

3. The use of the detection methods and the reproduction of the reference materials, provided under Article 5(3) and 17(3) for the purpose of applying this Regulation to the GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights or otherwise."

Article 4

Amendments to Regulation (EC) 1831/2003 on feed additives

Regulation (EC) No 1831/2003 is amended as follows:

(1) Article 7 is amended as follows:

   (a) paragraph 1 is replaced by the following:

   "1. An application for an authorisation as provided for in Article 4 shall be sent to the Commission, in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*. The Commission shall without delay inform the Member States and forward the application to the European Food Safety Authority (hereinafter referred to as the Authority).";

   (b) in paragraph 2 point (c) is replaced by the following:

   "(c) ensure public access to the application and any information supplied by the applicant, in accordance with Article 18.";

(2) Article 18 is replaced by the following:

"Article 18

Transparency and confidentiality

1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.

2. In accordance with the conditions and the procedures laid down in Articles 39 to 39f of Regulation (EC) No 178/2002 and this Article, the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification; and, the Authority shall assess the confidentiality request submitted by the applicant.

3. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also accept to provide confidential treatment to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:

(a) the study plan for studies demonstrating the efficacy of a feed additive in terms of the aims of its intended use as defined in Article 6(1) and Annex I to this Regulation; and,

(b) specifications of the impurities of the active substance and the relevant methods of analysis developed internally by the applicant, except for impurities that may have adverse effects on animal health, human health, or the environment.".

Article 5

Amendments to Regulation (EC) No 2065/2003 on smoke flavourings

Regulation (EC) No 2065/2003 is amended as follows:

(1) Article 7 is amended as follows:

(a) in paragraph 2, point (c) is replaced by the following:

"(c) The Authority shall:

(i) inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them; and,

(ii) ensure public access to the application, relevant supporting information and any supplementary information supplied by the applicant, in accordance with Articles 14 and 15.";

(b) paragraph 4 is replaced by the following:

"The Authority shall publish detailed guidance, following the agreement with the Commission, concerning the preparation and the submission of the application, referred to in paragraph (1), taking into account standard data formats, where they exist in accordance with Article 39f of Regulation (EC) No 178/2002.";

(2) in Article 14, paragraph 1 is replaced by the following:

"1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant as well as its scientific opinions, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002.";

(3) Article 15 is replaced by the following:

"Article 15

Confidentiality

In accordance with the conditions and the procedures laid down in Articles 39 to 39f of Regulation (EC) No 178/2002,

(a) the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification; and,

(b) the Authority shall assess the confidentiality request submitted by the applicant.".

Article 6

Amendments to Regulation (EC) No 1935/2004 on Food Contact Materials

Regulation (EC) No 1935/2004 is amended as follows:

(1) Article 9 is amended as follows:

(a) in paragraph 1 point (c) is replaced by the following:

"(c) the Authority shall without delay:

(i) inform the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them; and,

(ii) ensure public access to the application, relevant supporting information and any supplementary information supplied by the applicant, in accordance with Articles 19 and 20.";

(b) paragraph 2 is replaced by the following:

"2. The Authority shall issue and publish detailed guidelines, following agreement with the Commission, concerning the preparation and the submission of the application, taking into account standard data formats, where they exist in accordance with Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.";

(2) in Article 19, paragraph 1 is replaced by the following:

"1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis* and Article 20 of this Regulation.";

(3) Article 20 is replaced by the following:

"Article 20

Confidentiality

1. In accordance with the conditions and the procedures laid down in Articles 39 to 39f of Regulation (EC) No 178/2002 and this article:

(a) the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification; and,

(b) the Authority shall assess the confidentiality request submitted by the applicant.

2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) of that Regulation, the Authority may also accept to provide confidential treatment to the following information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:

(a) any information provided in detailed descriptions of starting substances and preparations used to manufacture the substance subject to the authorisation, the composition of preparations, materials or articles in which the applicant intends to use this substance, the manufacturing methods of these preparations, materials or articles, impurities, and migration testing results;

(b) the trademark under which the substance, shall be marketed as well as the tradename of the preparations, material or articles in which it shall be used, where applicable; and,

(c) any other information deemed confidential within the specific procedural rules referred to in Article 5(1)(n) of this Regulation.".

Article 7

Amendments to Regulation (EC) No 1331/2008 on the common authorisation procedure for food additives, food enzymes and food flavourings

Regulation (EC) No 1331/2008 is amended as follows:

(1) in Article 6, the following paragraph 5 is added:

"5. The Authority shall ensure public access to the additional information supplied by the applicant in accordance with Articles 11 and 12.";

(2) Article 11 is replaced by the following:

"Where the Commission requests its opinion in accordance with Article 3(2) of this Regulation, the Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Article 38, Articles 39to 39f and Article 40 of Regulation (EC) No 178/2002. It shall also make public any request for its opinion as well as any extension of period pursuant to Article 6(1) of this Regulation.";

(3) Article 12 is replaced by the following:

"Article 12

Confidentiality

1. The applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification, upon submission of the application.

2. Where an opinion by the Authority is required in accordance with Article 3(2) of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39f of Regulation (EC) No 178/2002.

3. Where an opinion by the Authority is not required in accordance with Article 3(2) of this Regulation, the Commission shall assess the confidentiality request submitted by the applicant. Articles 39 to 39f of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.";

Article 8

Amendments to Regulation (EC) No 1107/2009 on plant protection products

Regulation (EC) No 1107/2009 is amended as follows:

(1) Article 7 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to a Member State, (the rapporteur Member State), together with a summary and a complete dossier as provided for in Article 8(1) and (2) of this Regulation or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the

approval criteria provided for in Article 4 of this Regulation. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.",

(b) paragraph 3 is replaced by the following:

"3. When submitting the application, the applicant may pursuant to Article 63 request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

Member States shall assess the confidentiality requests. Upon a request for access to information and after consultation with the Authority, the rapporteur Member States shall decide what information is to be kept confidential, in accordance with Article 63.";

(2) Article 10 is replaced by the following:

"Article 10

Public access to the dossiers

The Authority shall without delay make the dossiers referred to in Article 8 of this Regulation including any supplementary information supplied by the applicant, available to the public, excluding any information in respect of which confidential treatment has been requested and accepted by the Authority pursuant to Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis* and pursuant to Article 63 of this Regulation.";

(3) In Article 15, paragraph 1 is replaced by the following:

"1. The application provided for in Article 14 of this Regulation shall be submitted by a producer of the active substance to a Member State, with a copy to the other Member States, the Commission and the Authority, no later than three years before the expiry of the approval. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.";

(4) Article 16 is replaced by the following:

"Article 16

Access to the information for renewal

The Authority shall assess, without delay, any request for confidentiality and make available to the public the information provided by the applicant under Article 15 as well as any other supplementary information submitted by the applicant, except for information in respect of which confidential treatment has been requested and accepted by the Authority pursuant to Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis* and pursuant to Article 63 of this Regulation.";

(5) in Article 63, paragraphs 1 and 2 are replaced by the following:

"1. In accordance with the conditions and the procedures laid down in Article 39 of Regulation (EC) No 178/2002 and this article, the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification.

2. In addition to Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3), confidential treatment may be accepted with respect to the following

information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned:

(a) the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for these impurities;

(b) results of production batches of the active substance including impurities; and,

(c) information on the complete composition of a plant protection product.";

Article 9

Amendments to Regulation (EU) No 2015/2283 on novel foods

Regulation (EU) No 2015/2283 is amended as follows:

(1) Article 10 is amended as follows:

(a) paragraph 1 is replaced by the following:

"1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 of this Regulation shall start either on the Commission's initiative or following an application to the Commission by an applicant, in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002. The Commission shall make the application available to the Member States without delay.";

(b) paragraph 3 is replaced by the following:

"3. Where the Commission requests an opinion from, the European Food Safety Authority ('the Authority'), the Authority shall ensure public access to the application in accordance with Article 23 and shall give its opinion as to whether the update is liable to have an effect on human health.";

(2) in Article 15, at the end of paragraph 1 the following sentence is added:

"The Authority shall ensure public access to the notification pursuant to Article 23.";

(3) Article 16 is amended as follows:

(a) the following sentence is added at the end of the first paragraph:

"The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002.",

(b) the following sentence is added at the end of the second paragraph:

"The Authority shall ensure public access to the application, relevant supporting information and any supplementary information supplied by the applicant in accordance with Article 23.";

(4) Article 23 is replaced by the following:

"Article 23

Transparency and confidentiality

1. Where the Commission requests its opinion in accordance with Articles 10(3) and 16 of this Regulation, the Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the

applicant, as well as its scientific opinions, in accordance with Article 38, Articles 39 to 39f and Article 40 of Regulation (EC) No 178/2002 and with this Article.

2. The applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by verifiable justification, upon submission of the application.

3. Where the Commission requests its opinion in accordance with Articles 10(3) and 16 of this Regulation, the Authority shall assess the confidentiality request submitted by the applicant, in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002.

4. Where the Commission does not request the Authority's opinion pursuant to Articles 10 and 16, the Commission shall assess the confidentiality request submitted by the applicant. Article 39 and 39a of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.".

Article 10
Transitional measures

The provisions of this Regulation shall not apply to applications for authorisations under Union food law as well as requests for scientific outputs submitted to the Authority prior to [*general date of entry of application:18 months after its entry into force*].

Article 11
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*18 months after its entry into force*], except for the following provisions:

(a) Article 1(2) shall apply from 1st July 2022.

(b) Article 1(3) shall apply as from the date of appointment of the members of the Scientific Panels, which shall be announced in a notice in the 'C' series of the *Official Journal of the European Union*. The current term of office of the Scientific Committee and Panel members shall be prolonged until that date.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

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3.2.5. Third-party contributions

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LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a 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 (EU) No 2015/2283 [on novel foods.

1.2. Policy area(s) concerned

Policy area: [Food Safety]

Activity: [General Food Law]

1.3. Nature of the proposal/initiative

☐ The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[41]

☐ The proposal/initiative relates to **the extension of an existing action**

XThe proposal/initiative relates to **an action redirected towards a new action**

1.4. Objective(s)

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

The Commission acknowledged in its Communication in reply to the European Citizen's Initiative (ECI) "Ban glyphosate and protect people and environment from toxic pesticides" that "transparency in scientific assessments and decision-making is vital to ensuring consumers' confidence in the regulatory system. It also attaches continuous importance to the quality and independence of scientific studies that are the basis of the EU risk assessment carried out by EFSA". The Commission therefore committed to come forward with a legislative proposal by May 2018 covering these and other aspects such as the governance of EFSA drawing up on the results of the Fitness Check of the GFL Regulation and after a public consultation.

The Commission open public consultation is published on:
https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en

1.4.2. Specific objective(s)

Specific objective No

[41] As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

[1) improve and clarify the rules on transparency, especially with regard to the scientific studies supporting the risk assessment;

2) increase the guarantees of reliability, objectivity and independence of studies used by EFSA in its risk assessment, in particular in the framework of authorisation applications;

3) improve the governance, strengthen the involvement of Member States and address the limitations affecting the long term scientific capacity of EFSA taking also account of the related financial and budgetary aspects,

4) develop a more effective and transparent risk communication with the public in collaboration with Member States]

Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

1) **The proposal ensures that scientists and citizens have access to key safety related information being assessed by EFSA at an early stage of the risk assessment**. In particular, the new provisions provide that all supporting data and information relating to applications for authorisation are to be made public by EFSA upon receipt (as applications will be submitted either directly to EFSA or forwarded to EFSA by Member States or by the Commission), including supplementary information, except for duly justified confidentiality information. In that respect, the proposal sets outs which type of information is to be considered confidential. The transparency provisions are without prejudice to any existing Intellectual Property Rights and data exclusivity provisions set out in Union sectoral food legislation. The process to be followed for the processing of confidentiality claims is also set up.

2) **It will help to improve citizens' confidence in the credibility of scientific studies and consequently confidence in the Union risk assessment system**. The proposal will provide for a series of measures to ensure that EFSA has access to the broadest relevant scientific evidence possible related to a request for authorisation and to increase the guarantees of reliability, objectivity and independence of studies used by EFSA in its risk assessment. First, it will establish a Union register of commissioned studies on substances subject to a food law authorisation system, to be managed by EFSA. The second measure sets out a pre-submission procedure, by which EFSA can provide advice to an applicant (without entering into the design of the study) and this advice will be made public. In the case of renewals, the pre-submission procedure foresees that studies planned by a potential applicant will have to be notified to EFSA and, after consultation of third parties on these planned studies, the Authority will systematically provide advice to the applicants. The third measure provides that at the stage of submission of authorisation application, when all studies are made public according to the new provisions on transparency, a consultation of third parties will be launched with the aim to identify whether other relevant scientific data or studies are available. The fourth measure provides for controls and audits by Commission inspectors in relation to studies. Finally, the proposal introduces the possibility for the Commission to request EFSA to commission studies in exceptional circumstances (e.g. controversies) for the purpose of verification.

3) **Better Involving Members States in EFSA's governance structure and Scientific Panels and thus support the sustainability in the long-term of EFSA risk assessment without touching on its independence**. It aligns the composition of EFSA's Management Board with the Common Approach on Union decentralised agencies by including representatives of all Member States. It will also address the findings of the GFL Fitness

Check that identified challenges to EFSA's capacity to maintain its high level of scientific expertise by providing for an increased involvement of Member States in the nomination process of Panels' members. The proposal respects the needs of EFSA for independence, excellence and multi-disciplinary expertise. In particular, the existing strict criteria on independence are maintained and specific provisions require Member States to set up specific measures ensuring that the experts have concrete means to act independently as required by the proposal. The proposal also provides for a better organisation of the Panels' work.

4) **Strengthen risk communication between the Commission/EFSA /Members States and public /stakeholders**. It is proposed to lay down in legislation the objectives and general principles governing risk communication, taking into account the respective roles of risk assessors and managers pursuant to Article 40 of Regulation (EC) No 178/2002 and, based on these objectives and general principles, to draw up a general plan on risk communication ("general plan"). The general plan should identify the key factors that need to be taken into account when considering the type and level of communication activities needed, ascertain the tools and channels for the relevant risk communication initiatives taking into account the relevant target audience groups; and, establish appropriate mechanisms to ensure coherent risk communication.

1.4.3. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

N° of documents (or parts of) subject to claims of confidentiality;

N° of requests for access to documents addressed to EFSA and the Commission.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The challenges to be addressed related to transparency, sustainability of the EU risk assessment system (which for authorisations of products/substances is an EU centralised system, with the exception of pesticides dual system) and the demand for risk communication to be more effective.

Citizens / civil society perceive the risk assessment process as opaque and demand more transparency, due to several different transparency and confidentiality rules applicable to risk assessment and decision-making process, making the system complex and non-uniform.

Recent debates raised concerns on transparency and independence of industry-generated studies and data. EFSA's evaluations of authorisation applications are essentially based on industry studies (burden of proof of safety of products on the applicant) also perceived as non-transparent by civil society.

1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention which is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at European level (ex-ante)

To address the emerging challenges in the area of food law in light of the experience gained to date (Fitness Check of the GFL Regulation published on 15 January 2018) and the Commission's reply to the ECI. Any actions in these areas need to take place at Union level and primarily within the existing Union legislative framework established by the GFL Regulation and in seven other relevant sectoral legislative acts.

Expected generated Union added value (ex-post)

The proposal is expected to contribute to the Union risk assessment system acquiring greater legitimacy in the eyes of the Union consumers and general public, increasing their confidence in its outcome and ensure that it is more accountable to the Union citizens. At the same time, the proposal is expected to ensure the long-term sustainability of EFSA's capacity of scientific expertise.

1.5.3. Lessons learned from similar experiences in the past

This urgent proposal draws up from the findings of the Fitness Check of the GFL Regulation and is based on the commitments made by the Commission's reply to the ECI Communication.

1.5.4. Compatibility and possible synergy with other appropriate instruments

To improve transparency of studies and address the societal concerns for a more transparent and independent risk assessment process and a more effective risk communication.

To align EFSA Management Board with the Inter-Institutional agreement to include Member States in the Management Board, similarly to other Union agencies and provide for an increased involvement of Member States in the appointment of scientific experts as it is the case in other similar scientific Union agencies.

To guarantee maintenance of a high level of scientific expertise in EFSA and its risk assessment capacity to ensure the sustainability of the Union risk assessment system that is the basis of all measures taken on food safety.

Laboratory related audit can be performed by existing service SANTE.F "Health and Food audits and analysis".

1.6. Duration and financial impact

☐ Proposal/initiative of **limited duration**

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

X Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from 2020 to 2022

– followed by full-scale operation.

1.7. Management mode(s) planned[42]

☐ **Direct management** by the Commission through

– ☐ executive agencies

☐ **Shared management** with the Member States

X **Indirect management** by entrusting budget implementation tasks to:

☐ international organisations and their agencies (to be specified);

☐the EIB and the European Investment Fund;

X bodies referred to in Articles 208 and 209;

☐ public law bodies;

☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

Comments

Impact on the European Food Safety Authority (EFSA)

[42] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: https://myintracomm.ec.europa.eu/budgweb/EN/man/budgmanag/Pages/budgmanag.aspx.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

EFSA Single Programming Document (SPD), EFSA Management Board meeting (responsible for Authority's governance), EFSA Annual report activities.

2.2. Management and control system

2.2.1. Risk(s) identified

As risks due to an important exposure to potential conflicts of interest in EU decentralised agencies and Scientific Committees are assessed as significant (see DG SANTE's 2017 MP), DG SANTE's planned actions focus on improving the handling of conflict of interest situations.

2.2.2. EFSA has in place and strictly monitors its rules on "independence" and "conflict of interest"; Control method(s) envisaged

DG SANTE actively monitors the compliance of agencies' independence policies with the Commission's guidelines on independence through a DG SANTE's task force including all SANTE's agencies and through bilateral contacts. In addition to monitoring compliance, DG SANTE identifies and disseminates good practices in collaboration with the agencies.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

In addition to the application of all regulatory control mechanisms, the responsible services will devise an anti-fraud strategy in line with the Commission's anti-fraud strategy (CAFS) adopted on 24 June 2011 in order to ensure inter alia that its internal anti-fraud related controls are fully aligned with the CAFS and that its fraud risk management approach is geared to identify fraud risk areas and adequate responses. Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases related to the financing implementing activities of this Regulation will be set up.

In particular a series of measures will be put in place such as:

- decisions, agreements and contracts resulting from the financing implementing activities of the Regulation will expressly entitle the Commission/EFSA, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections;

- during the evaluation phase of a call for proposals/tender, the proposers and tenderers are checked against the published exclusion criteria based on declarations and the Early Detection and Exclusion System (EDES);

- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

Moreover, a strict application of the rules on conflict of interests provided in the proposal will be ensured.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading……...……]	Diff./Non-diff.[43]	from EFTA countries [44]	from candidate countries [45]	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
3	17.03 11 European Food Safety Authority	Diff.	YES	NO	NO	NO

The estimated impact on expenditure and staffing for the years 2021 and beyond in this legislative financial statement is added for illustrative purpose and does not pre-judge the next multiannual financial framework.

Please note that inflation adjustments to the figures mentioned in the tables below, need to be considered as from the year 2023 onwards.

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading……]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
[…]	[XX.YY.YY.YY] […]	[…]	YES/ NO	YES /NO	YES NO	YES/NO

[43] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

[44] EFTA: European Free Trade Association.

[45] Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated impact on EFSA expenditure

3.2.1. Summary of estimated impact on expenditure

Heading of multiannual financial framework	**3**	Security and Citizenship

EUR million (to three decimal places)

[Body]: <EFSA.>			Year **2020**	Year **2021**	Year **2022**	Year **2023**	**2024 esq.** (see point 1.6)			**TOTAL**
Title 1: Staff expenditure	Commitments	(1)	5.490	9.608	13.726	13.726	13.726			**56.276**
	Payments	(2)	5.490	9.608	13.726	13.726	13.726			**56.276**
Title 2: Infrastructure and operating expenditure	Commitments	(1a)								
	Payments	(2a)								
Title 3: Operational expenditure	Commitments	(3a)	**19.512**	**34.145**	**48.779**	**48.779**	**48.779**			**199.994**
	Payments	(3b)	**19.512**	**34.145**	**48.779**	**48.779**	**48.779**			**199.994**
TOTAL appropriations for [body] <EFSA.>	Commitments	=1+1a +3a	25.002	43.753	62.505	62.505	62.505			**256.270**
	Payments	=2+2a +3b	25.002	43.753	62.505	62.505	62.505			**256.270**

Heading of multiannual financial framework	**5**	'Administrative expenditure'

EUR million (to three decimal places)

		Year **2020**	Year **2021**	Year **2022**	Year **2023**	**2024 esq.** (see point 1.6)			**TOTAL**
DG: <…….>									
• Human Resources									
• Other administrative expenditure									
TOTAL DG <…….>	Appropriations								

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)								

EUR million (to three decimal places)

		Year **2020**	Year **2021**	Year **2022**	Year **2023**	**2024 esq.** (see point 1.6)			**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	25.002	43.753	62.505	62.505	62.505			**256.270**
	Payments	25.002	43.753	62.505	62.505	62.505			**256.270**

3.2.2. Estimated impact on [body]'s appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– X The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **2020**		Year **2021**		Year **2022**		Year **2023**		**2024 esq.** (see point 1.6)						**TOTAL**	
	OUTPUTS																	
	Type[46]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[47] improve and clarify the rules on transparency, especially with regard to the scientific studies supporting the risk assessment																		
Register of commissioned studies	Development & run			0.160		0.280		0.400		0.400		0.400						1.640

[46] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

[47] As described in point 1.4.2. 'Specific objective(s)…'

IT support for data disclosure	Licences/maintenance/storage/security			0.960		1.680		2.400		2.400		2.400						9.840
Subtotal for specific objective No 1				1.120		1.960		2.800		2.800		2.800						11.480
SPECIFIC OBJECTIVE No 2 . increase the guarantees of reliability, objectivity and independence of studies used by EFSA in its risk assessment for authorisation purposes																		
Additional ad hoc studies		16 ad hoc studies		6.000		10.500		15.000		15.000		15.000						61.500
Subtotal for specific objective No 2				6.000		10.500		15.000		15.000		15.000						61.500
SPECIFIC OBJECTIVE No 3 improve the governance, strengthen the involvement of Member States and address the limitations affecting the long term scientific capacity of EFSA																		

MB with MSs & observers	27 MSs + 4/6 observers	Tot. day cost= 1152		0.048		0.084		0.120		0.120		0.120						0.492
21 Panel members	10 panels x6meetings/y	Tot. day cost= 1.152		0.221		0.387		0.553		0.553		0.553						2.267
New indemnity regime panels experts	2520 panel members days year	Tot. day cost= 2549		1.408		2.464		3.520		3.520		3.520						14.432
New indemnity regime working groups	Tot. No experts w.days	Tot. day cost= 2549		2.571		4.492		6.426		6.426		6.426						26.347
Capacity building	10 panels/ 21 members	7 days/training /y		0.224		0.392		0.560		0.560		0.560						2.296
Preparatory work sharing with MSs		grants/ procurements		5.120		8.960		12.800		12.800		12.800						52.480
Subtotal for specific objective No 3				9.592		16.785		23.979		23.979		23.979						98.314
SPECIFIC OBJECTIVE No 4 develop a more effective and transparent risk communication with the public in collaboration with Member States																		

Stakeholders engagement in RA process	50 events/ year	10 panels 5event panel/ y		0.600		1.050		1.500		1.500		1.500						6.150
Strengthened analysis of social science survey analysis				0.500		0.875		1.250		1.250		1.250						5.125
Strengthen advocacy: targeted messages, narrative, translations, etc	Increas e targete d comm unicati on key topics Sc.liter acy actions			1.700		2.975		4.250		4.250		4.250						17.425
Subtotal for specific objective No 4				2.800		4.900		7.000		7.000		7.000						28.700
TOTAL COST				19.512		34.145		48.779		48.779		48.779						199.994

3.2.3. Estimated impact on [body]'s human resources

3.2.3.1. Summary

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– X The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year **2020**	Year **2021**	Year **2022**	Year **2023**	**2024 esq.** (see point 1.6)	**TOTAL**

Officials (AD Grades)								
Officials (AST grades)								
Contract staff	0.629	1.101	1.572	1.572	1.572			**6.446**
Temporary staff	4.861	8.507	12.154	12.154	12.154			**49.830**
Seconded National Experts								

TOTAL	**5.490**	**9.608**	**13.726**	**13.726**	**13.726**			**56.276**

Estimated impact on the staff (additional FTE) – establishment plan

Function group and grade	Year **2020**	Year **2021**	Year **2022**	Year **2023**	**2024 esq.** (see point 1.6)
AD16					
AD15					
AD14					
AD13					
AD12					
AD11					
AD10					
AD9					

AD8 AD7 AD6 AD5					
AD Total					
AST11 AST10 AST9 AST8 AST7 AST6 AST5 AST4 AST3 AST2 AST1					
AST Total					
AST/SC 6 AST/SC 5 AST/SC 4 AST/SC 3 AST/SC 2 AST/SC 1					

AST/SCTotal					
GRAND TOTAL	34	60	85	85	85

Estimated impact on the staff (additional) – external personnel

Contract agents	Year **2020**	Year **2021**	Year **2022**	Year **2023**	**2024 esq.** (see point 1.6)
Function group IV Function group III Function group II Function group I					
Total	8.5	14.9	21.2	21.2	21.2

Seconded National Experts	Year **2020**	Year **2021**	Year **2022**	Year **2023**	**2024 esq.** (see point 1.6)
Total					

Please indicate the planned recruitment date and adapt the amount accordingly (if recruitment occurs in July, only 50 % of the average cost is taken into account) and provide further explanations in an annex.

1) improve and clarify the rules on transparency

Actions and total No FTEs	Details	Details		2020 Million		2021 Million		2022 Million
Confidentiality checks 25.2 FTEs	12.600 studies 450 dossiers	80%confid.studies 0.4day scrutiny Average No studies /dossier= 35		1.302		2.279		3.256
Appeals 8.4 FTEs	450/ dossier 10% =45 appeals	10% confid. claims /dossier		0.432		0.757		1.081

2) increase reliability, objectivity and independence of studies

Actions and total No FTEs	Details	Details		2020 Million		2021 Million		2022 Million
Register of commissioned studies 2 FTEs				0.103		0.181		0.258
Pre-submission meetings without PC 6.2 FTEs	176 dossiers & meetings	7 days/dossier		0.318		0.557		0.796
Pre-submission meetings for all renewals with PC 4.3 FTEs	74applications	7 man-days+ 4 PC		0.220		0.385		0.550
PC on all dossiers 8.5 FTEs	376dossiers for PC	0.5 effort/day+4 outcome		0.437		0.765		1.093
Laboratory related audit 2FTEs				0.103		0.181		0.258
Additional ad hoc studies 4FTEs				0.207		0.362		0.517
Toxicological studies (H2020-FP9) 2FTEs				0.103		0.181		0.258

3) improve the governance, strengthen the involvement of Member States and address the limitations affecting the long term scientific capacity of EFSA

Actions and total No FTEs	Detai ls	Details		2020 Millio		2021 Millio		2022 Millio
MB with MSs & observers 0.2 FTEs				0.010		0.018		0.025
Capacity building 2.4 FTEs				0.124		0.217		0.310
Preparatory work sharing with MSs 6.9 FTEs				0.356		0.624		0.891
Insourcing routine work 15 FTEs				0.775		1.357		1.938

4) develop a more effective and transparent risk communication with the public in collaboration with Member States

Actions and total No FTEs	Details	Details		2020 Million		2021 Million		2022 Million
Stakeholders engagement in RA process 12.5 FTES				0.646		1.131		1.615
Strengthened analysis of social science survey analysis 2 FTEs				0.103		0.181		0.258
Strengthen advocacy: targeted messages, narrative, translations etc 4.8 FTEs				0.248		0.434		0.620

3.2.3.2. Estimated requirements of human resources for the parent DG

– ☐ The proposal/initiative does not require the use of human resources.

– ☐ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

		Year **2020**	Year **2021**	Year **2022**	Year **2023**	**2024 esq.** (see point 1.6)		
• **Establishment plan posts (officials and temporary staff)**								
XX 01 01 01 (Headquarters and Commission's Representation Offices)								
XX 01 01 02 (Delegations)								
XX 01 05 01 (Indirect research)								
10 01 05 01 (Direct research)								
• **External staff (in Full Time Equivalent unit: FTE)**[48]								
XX 01 02 01 (AC, END, INT from the 'global envelope')								
XX 01 02 02 (AC, AL, END, INT and JED in the Delegations)								
XX 01 04 ***yy***[49]	- at Headquarters[50]							
	- in Delegations							
XX 01 05 02 (AC, END, INT – Indirect research)								
10 01 05 02 (AC, END, INT – Direct research)								

48 AC = Contract Staff; AL = Local Staff; END = Seconded National Expert; INT = agency staff; JED = Junior Experts in Delegations.

49 Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

50 Mainly for the Structural Funds, the European Agricultural Fund for Rural Development (EAFRD) and the European Fisheries Fund (EFF).

Other budget lines (specify)							
TOTAL							

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	
External staff	

Description of the calculation of cost for FTE units should be included in the Annex V, section 3.

3.2.4. Compatibility with the current multiannual financial framework

– X The proposal is compatible with the current multiannual financial framework and may entail the use of special instruments as defined in Council Regulation (EU, Euratom) No 1311/2013.

– ☐ The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts. […]

– ☐ The proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[51].

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts. […]

[51] See Articles 11 and 17 of Council Regulation (EU, Euratom) No 1311/2013 laying down the multiannual financial framework for the years 2014-2020.

3.2.5. Third-party contributions

– **X** The proposal/initiative does not provide for co-financing by third parties.

– The proposal/initiative provides for the co-financing estimated below:

EUR million (to three decimal places)

	Year **2020**	Year **2021**	Year **2022**	Year **2023**	**2024 esq.** (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

3.3. Estimated impact on EFSA revenue

– **X** The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

– ☐ on own resources

– ☐ on miscellaneous revenue

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[52]				
		Year **2020**	Year **2021**	Year **2022**	Year **2023**	**2024 esq.** (see point 1.6)

[52] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25 % for collection costs.

Article …….								

For miscellaneous ‘assigned’ revenue, specify the budget expenditure line(s) affected.

[…]

Specify the method for calculating the impact on revenue.

[…]