BRIEFING

EU Legislation in Progress

European Parliament

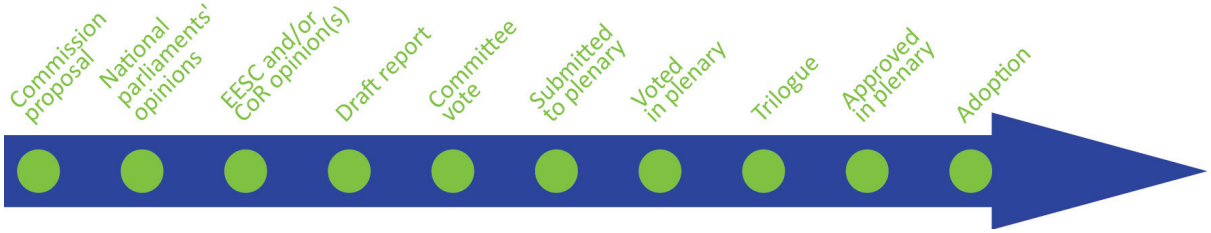
Reconsidering the General Food Law

OVERVIEW

On 11 April 2018, the European Commission published a proposal to review the General Food Law Regulation and amend eight legislative acts dealing with specific food chain sectors. The proposal follows up on the European Citizens' Initiative on glyphosate; and especially on concerns regarding the transparency of the scientific studies used in the evaluation of pesticides. The proposal also responds to a fitness check of the General Food Law, completed in January 2018. The proposal's objective is to increase the transparency and sustainability of the EU scientific assessment model, and other aspects such as governance of the European Food Safety Authority (EFSA). In the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) adopted its report on 27 November 2018. A vote in plenary to finalise Parliament's position took place on 11 December and the Council adopted its position on 12 December 2018. A provisional agreement was reached in trilogue on 11 February 2019 and endorsed in the ENVI committee on 20 February. The European Parliament adopted the text at first reading on 17 April; the Council adopted it on 13 June. The final act, signed on 20 June, was published in the Official Journal on 6 September 2019 and is applicable, for the most part, from 27 March 2021.

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]

Committee responsible:	Environment, Public Health and Food Safety (ENVI)	COM(2018) 179 11.4.2018
Rapporteur:	Pilar Ayuso (EPP, Spain)	2018/0088(COD)
Shadow rapporteurs:	Pavel Poc (S&D, Czech Republic) Arne Gericke (ECR, Germany) Fredrick Federley (ALDE, Sweden) Anja Hazekamp (GUE/NGL, the Netherlands) Martin Häusling (Greens/EFA, Germany) Piernicola Pedicini (EFDD, Italy)	Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
Procedure completed.	Regulation (EU) 2019/1381 OJ L 231, 6.9.2019, pp. 1–28	



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Author: Tarja Laaninen
Members' Research Service

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Introduction

The proposal can be seen against the backdrop of public controversy over the risk assessment of certain sensitive issues, such as genetically modified organisms (GMOs) and plant protection products. The initiative follows from the findings of a Fitness Check of the General Food Law and responds to the European Citizens' Initiative (ECI) 'Ban glyphosate', submitted to the Commission in October 2017. The proposal aims at improving public access to industry studies used by the European Food Safety Authority (EFSA) in its risk assessments. It also seeks to safeguard EFSA's ability to recruit scientific experts, reinforce cooperation between EFSA and national scientific bodies and to increase Member States' involvement in EFSA's operations.

In an interlinked development, following the controversy over the renewal of glyphosate, the European Parliament decided in February 2018 to set up a special committee to assess the Union's authorisation procedure for pesticides (PEST). The PEST committee examined the roles of all the bodies involved in the authorisation process: the relevant national authorities, the European Commission as well as EFSA. The PEST committee's report was debated in plenary in January 2019, and its recommendations endorsed.

Existing situation

The General Food Law Regulation (Regulation (EC) No 178/2002, 'the GFL Regulation') is the founding act of current EU food and feed legislation. It lays down general principles, requirements and procedures related to decision-making in food and feed safety, covering all stages of the food chain from production and processing to transport and distribution. It also established the European Food Safety Authority (EFSA), an independent agency tasked with providing decision-makers with scientific advice concerning food safety issues.

An important general principle established in the GFL Regulation is that food law must be based on **risk analysis**. Risk analysis is defined in the GFL Regulation as a process consisting of three interconnected components: risk assessment, risk management and risk communication. **Risk assessment** must be undertaken in an independent, objective and transparent manner, based on the best available scientific evidence. The role of risk assessor at Union level is essentially given to EFSA, whose task it is to undertake scientific and technical evaluations. **Risk management** is defined as the process of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and selecting appropriate prevention and control options. Risk managers must take into account the results of risk assessment and, in particular, the opinions of EFSA. **Risk communication** is defined as the interactive exchange of information and opinions throughout the risk analysis process.

The **precautionary principle** is also one of the basic principles underlying food and feed law. According to Article 7 of the Regulation, 'in specific circumstances, where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment'. Precautionary measures adopted must be 'proportionate and no more restrictive of trade than is required' to protect public health.

According to the **principle of transparency** (defined in Articles 9 and 10), there has to be open public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food and feed law. Where there are 'reasonable grounds to suspect that a food or a feed may present a risk' for human or animal health, public authorities must inform the general public of the nature of the risk.

The General Food Law Regulation is the founding regulation of EFSA, which began its work on 1 January 2002. EFSA is an independent European agency, funded under the EU budget, which operates separately from the European Commission, European Parliament and EU Member States.

EFSA's mission is to provide **scientific advice** and scientific and technical support for EU legislation and policies in all fields that have a direct or indirect impact on food and feed safety. Scientific opinions drafted by EFSA serve as a scientific basis for the elaboration and adoption of EU measures (Article 22 of the Regulation). EFSA plays the role of risk assessor in the EU food regulatory system, while the Commission, European Parliament and Member States are risk managers.

EFSA's core tasks are to provide EU risk managers with independent, up-to-date scientific advice on questions related to food and feed safety, animal health and welfare, plant health, nutrition, and environmental issues related to these. It evaluates food and feed products that **require a safety assessment** before they can be used on the EU market. EFSA is also tasked with **collecting data** in the fields within its mission, and **communicating** on risks to EU institutions and Member States, stakeholders and the public, as well as identifying **emerging risks**.

Most of EFSA's work is undertaken in response to requests for scientific advice from the European Commission, the European Parliament or the Member States. It also carries out work on its own initiative, in particular relating to emerging issues and new hazards. EFSA coordinates working groups of scientists and external experts and networks of EU Member State organisations that have expertise in specific scientific fields (for example emerging risks or pesticide residue monitoring). In accordance with Article 36 of the Regulation, a list is drawn up of Member State designated competent organisations, which may assist EFSA with its work. These 'Article 36 organisations' can carry out various tasks on EFSA's behalf; in particular preparatory work for scientific opinions, scientific assistance, collection of data and identification of emerging risks.

EFSA usually sets up a working group of experts to carry out a risk assessment. The working group – typically comprising members of a scientific panel[1] plus additional scientists from specialist fields – assesses the scientific information available, which may include data supplied by Member States, research institutes or companies. If there is a need for further data it may draw on EFSA's data collection networks or launch an open call for data on the EFSA website.

EFSA is governed by a management board, composed of 15 members, appointed by the Council after consulting the European Parliament, from a list drawn up by the Commission. Four of the members must have a background in organisations representing consumers and other interests in the food chain. There is also one representative of the European Commission.

In assessing **pesticide active substances**, EFSA performs an independent scientific **peer review** of the assessment report produced by the designated rapporteur Member State. These peer reviews are conducted in cooperation with all Member States.

Article 39 of the Regulation concerns the **confidentiality** of EFSA's work. According to the article, 'the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health'.

Parliament's starting position

In its resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate, Parliament called on the Commission to renew the approval for seven years only, and not to permit use by non-professionals as well as in and around public areas. It also called on the Commission and EFSA to disclose all the scientific evidence used in the risk assessment.

As part of EFSA's budget discharge procedure, in its decision of 28 April 2016, the Parliament reminded EFSA that the first objective of its independence policy should be its reputation, and therefore to make sure that the Authority is free from real or perceived conflicts of interest, in particular with the economic sectors it is de facto regulating. It called for EFSA to apply a two-year cooling-off period and said that it did not accept EFSA's justification for its refusal to implement the

discharge authority's repeated demands for such a two-year cooling-off period to be established on all material interests related to the companies it regulates.

In its decision of 27 April 2017, the Parliament stressed that experts with financial interests linked to companies whose substances are evaluated by EFSA should not be allowed to sit on EFSA's scientific panels or working groups, and that no such expert should be appointed by EFSA until two years after his/her interests have ceased. The Parliament regretted that EFSA had not included research funding in the list of interests to be covered by the two-year cooling-off period.

In its resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate, Parliament called on the Commission and Member States not to permit household use of the substance, use in and around public areas, as well as agricultural use where non-chemical alternatives exist, after 15 December 2017, with all agricultural use to be phased out by 15 December 2022. It also called for risk assessments to be based only on published, peer-reviewed and independent studies.

In February 2018, the European Parliament set up a special committee on the European Union's authorisation procedure for pesticides (PEST). The special committee, composed of 30 members from across all of Parliament's political groups, assessed the authorisation procedure for pesticides in the EU; potential failures in how substances are scientifically evaluated; the role of the European Commission in renewing the approval of glyphosate; possible conflicts of interest in the approval procedure; and the role of EU agencies, including whether they are adequately staffed and funded to fulfil their obligations. The final report of the special committee was discussed in plenary, and a resolution on its work voted on 16 January 2019.

In its decision of 18 April 2018, the Parliament observed that the management board of EFSA adopted a new policy on independence on 21 June 2017, and noted that the policy includes a new definition of what constitutes a conflict of interest and a comprehensive set of 'cooling-off' rules. The Parliament was concerned, however, that the scope of EFSA's new independence policy, which only takes interests on 'matters falling under the mandate of the relevant EFSA scientific group' into account and not 'all material interests related to the companies whose products are assessed by the Authority and to any organisations funded by them', as Parliament demanded, remains too narrow and thus perpetuates EFSA's previous independence policy's biggest limitation. The Parliament was also concerned that EFSA ignored Parliament's repeated calls to include research funding in the list of interests to be covered by the two-year cooling-off period, research funding being the main source of financial conflicts of interest among EFSA's external experts.

In its own-initiative report adopted on 13 September 2018, on the implementation of the Plant Protection Products Regulation, Parliament urged the Commission to propose improvements to further enhance the transparency of the regulatory process, including on access to the data in safety studies submitted by producers as part of their applications for market authorisation. The Parliament recognised the need to review the procedure in order to improve evaluations, increase the independence of the authorities tasked with carrying out studies, avoid conflicts of interest and make the procedure more transparent.

In May 2017, four Members of the European Parliament took EFSA to the European Court of Justice for refusing to disclose the information they had requested (Hautala and Others v EFSA (case T-329/17, action brought on 24 May 2017)). On 7 March 2019, the General Court gave its judgment, annulling the EFSA decision refusing access.

Preparation of the proposal

In view of the revision of the General Food Law Regulation, a Fitness Check was launched in 2014 to assess whether the legislative framework for the entire food and feed sector is 'fit for purpose' to meet the demands of today. The fitness check was supported by two external studies.[2] With respect to EFSA, the Commission produced an internal intermediary report, which updated the external

evaluation of EFSA (published in 2012),[3] in order to cover the period up to 2013-2014. Stakeholder consultations were performed to collect the views of relevant actors in the food chain.

In its reply to the European Citizens' Initiative (ECI) 'Ban glyphosate and protect people and the environment from toxic pesticides' in December 2017, the Commission committed to come forward with a legislative proposal covering the transparency and independence of the scientific studies that are the basis of the EU risk assessment of regulated products and substances carried out by EFSA, as well as other aspects, such as the governance of EFSA.

The GFL Fitness Check evaluation was completed in January 2018. It concluded that the GFL Regulation is still relevant today, that the systematic implementation of the risk analysis principle in EU food law has raised the level of protection of public health overall, that the creation of EFSA has improved the scientific basis of EU measures, and that the Regulation met the objectives of ensuring a high level of food safety and harmonisation of the internal market. Nevertheless, certain shortcomings were identified, such as differences in the implementation and enforcement of certain requirements of GFL at national level (for example differences in relation to information to the public on food safety incidents; variable approaches to the implementation of official controls), in some instances creating an uneven playing field for businesses. Also, a perceived lack of transparency in risk analysis was found to be an issue: EFSA is bound by strict confidentiality rules and by the legal requirement to primarily base its assessment on industry studies, which leads civil society to perceive a lack of transparency and independence, with a negative impact on the acceptability of EFSA's scientific work. Risk communication was also considered insufficiently effective, with a negative impact on consumers' trust in consequence. It was also noted that EFSA had difficulties in attracting new panel members, and that scientific expertise often originates from only a few Member States.[4]

A synopsis report covers the feedback, from citizens, national authorities and various stakeholders, given on a Commission roadmap preparing the upcoming proposal in the consultation period (from 20 December 2017 to 17 January 2018), as well as during a public consultation open from 23 January 2018 to 20 March 2018. EU-level stakeholder organisations representing farmers, cooperatives, the food industry, retailers, consumers, professionals and civil society were consulted in a working group meeting of the Advisory Group on the Food Chain and Animal and Plant Health. National food safety authorities were consulted via the EFSA Advisory Forum. Several stakeholders and citizens complained that EFSA's evaluations are essentially based on studies and data generated by the applicant for authorisation. Industry stakeholders stated that the timing of the publication of studies could have a negative or very negative impact on competitiveness, in particular if publication happens early in the assessment process.

The Commission's Scientific Advice Mechanism (SAM) was asked to prepare a scientific opinion on EU authorisation process for plant protection products, which was published in June 2018. In its opinion, SAM recommends, inter alia, mandatory pre-registration of pre-market studies, to improve openness and public confidence in the process and to ensure that no relevant studies are omitted from the risk assessment. The SAM also makes some recommendations as to how to help resolve divergent assessments between the EU and international bodies, in the rare cases when they occur.

The changes the proposal would bring

In April 2018, the Commission proposed a targeted revision of the General Food Law Regulation. The proposal aims at improving public access to industry studies used by the European Food Safety Authority (EFSA) in its risk assessments. In the interests of coherence, eight legal acts relating to the sector are to be harmonised as regards transparency and confidentiality.

The aim of the proposal is to improve citizens' confidence in the credibility of scientific studies and consequently confidence in the Union risk assessment system. The proposal also seeks to safeguard EFSA's ability to recruit scientific experts, reinforce cooperation between EFSA and national scientific bodies, and to increase Member States' involvement in EFSA's operations. Risk communication is

also to be improved, to ensure coherence and to better explain scientific opinions. For this, a general plan on risk communication is to be drawn up. In its press release on the occasion of the proposal's publication, the Commission states that it aims for the proposal to be adopted within the current legislative period, by mid-2019, for subsequent swift implementation.

Transparency

The Commission proposes that all studies submitted to EFSA for risk assessments are made public proactively and automatically at an early stage of the risk assessment via EFSA's website. The applicant for authorisation should submit both a non-confidential and a confidential version of the submitted studies and other information. EFSA would then make the non-confidential version of the submitted studies and information public without delay. In parallel, within a short period from the date of receipt, EFSA would assess the confidentiality claim.[5] Once the assessment is completed, any additional data and information for which confidentiality requests have been considered as unjustified would also be made public.

Currently, the transparency and confidentiality rules vary depending on the sub-area concerned. With its proposal, the Commission aims to harmonise these rules and sets out which type of information could be considered confidential (proposed Article 39 on confidentiality). Confidential information could nevertheless be made public where urgent action is essential to protect public health, animal health or the environment.

A common European register of commissioned studies would be created, so that EFSA can double-check that the applicant does not withhold any unfavourable studies. Stakeholders and the general public would be consulted on submitted studies. In the case of renewals of previously authorised substances, stakeholders and the general public would be consulted on planned studies. The Commission inspectors would conduct audits to verify the quality of the studies carried out by laboratories.

A pre-submission procedure would be set up, by which EFSA could provide advice to an applicant. For transparency, this advice would be made public.

The current authorisation procedures are based on the principle that public money should not be used to commission costly (several thousand to several million euros) studies that help industry to place a product on the market; therefore, it is for the applicant to prove that their product is safe. In the future, according to the Commission proposal, the Commission could ask EFSA to commission additional studies in exceptional circumstances, such as in the case of highly controversial substances or conflicting results. These studies would be financed from the EU budget.

For the specific pieces of legislation (concerning GMOs, additives and flavourings, novel foods, food contact materials and plant protection products), the proposal adds provisions concerning transparency and confidentiality, referring to the new articles proposed as an addition to the GFL regulation.

Improving EFSA governance and Member States' involvement

As for other EU scientific agencies such as the European Medicines Agency (EMA) and European Chemicals Agency (ECHA), EFSA is dependent on its capacity to combine expertise from the Member States. National scientific organisations contribute to EFSA's work by allowing their experts to work as experts on EFSA's scientific panels, and by providing EFSA with scientific data and studies. At present, however, a small number of Member States provides more than two thirds of the experts on EFSA's ten scientific panels, and there are increasing difficulties in attracting enough new candidates to work in them.

The Commission proposal addresses these problems by aiming at reinforcing EFSA's own scientific capacity and by strengthening scientific cooperation with national scientific organisations. According to the proposal, the Member States should ensure that a sufficient pool of experts is

available, and would be asked to propose experts, from among which the members of the scientific panels would be selected. Each Member State would nominate at least 12 scientific experts.[6] Each panel would include a maximum of 21 members.

In contrast with other EU agencies, Member States are not currently represented on the EFSA Management Board. According to the proposal, all Member States would also be represented on the EFSA Management Board, in line with the common approach used in other decentralised agencies. In addition, the Management Board would include two members representing the Commission, one member appointed by the European Parliament, as well as one member each from consumer organisations, environmental NGOs, farmers' organisations, and industry organisations.

Risk communication

The proposal also intends to strengthen risk communication to citizens. The aim is to enhance consumer confidence by better explaining EFSA's scientific opinions, as well as the basis for risk management decisions. The proposal sets out a framework of objectives and general principles for risk communication. The Commission, in its capacity as risk manager, would then draw up a general plan on risk communication. The general plan would identify key factors that need to be taken into account when considering the type and level of communication activities. It will determine the tools and channels for the relevant risk communication depending on the specificities of the various target groups, and establish mechanisms to ensure coherent risk communication. The main objective is to improve coordination between EU and national risk assessors.

Budget

As for budgetary implications, the Commission says its 'wide ranging and ambitious' proposal requires a significant increase in the resources available to EFSA to enable it to accomplish its new responsibilities. EFSA's budget is currently about €80 million a year. The Commission is proposing an increase of €25 million for the 2020 EFSA budget, €43.7 million for 2021, and an extra €62.5 million a year from 2022 onwards. In addition, according to the Commission, Member States that provide EFSA with expertise also need to receive more compensation.

The allocation of new resources, however, depends on the results of the negotiations between the Union institutions and Member States on the new Multiannual Financial Framework for 2021-2027.

Advisory committees

The European Economic and Social Committee (EESC) adopted its opinion on 19 September 2018 (rapporteur: Antonello Pezzini, Employers – Group I, Italy). The EESC strongly advocates the need to strengthen EFSA to make sure risk managers have the best possible scientific advice. The EESC reminds that EFSA has proved to be competent throughout its existence, and says there is no doubt that it plays a very important role in preventing health risks in Europe. The EESC wholeheartedly backs the proposal for greater Member State and civil society involvement in EFSA's management structure and scientific panels.

The European Committee of the Regions (CoR) adopted its opinion on 10 October 2018 (rapporteur general: Miloslav Repaský, EA, Slovakia). The CoR welcomes the Commission's initiative and believes it to be a move in the right direction, but notes that doubts persist about whether the proposed changes will enable an independent scientific scrutiny of studies and data used in the risk assessments of regulated products and substances. The CoR takes the view that the EU rules on public access to information should be applied in a coherent way by all EU scientific advisory bodies and their proactive disclosure policy should be coherent in order to guarantee predictability.

National parliaments

The subsidiarity deadline for the national parliaments was 27 June 2018. None of the parliaments submitted reasoned opinions. The senate of the Parliament of the Czech Republic observes, however, that although it supports the proposal, it believes it is necessary to establish a clearly defined timeframe for the consultations with stakeholders and the public, to prevent potentially endless disputes over the relevant scientific data or studies available. It also considers it to be important to ensure strict compliance with the confidentiality rules in case of publication of data, because the authorisation application may often contain sensitive data (e.g. business strategy, technical specifications or quantitative composition of the product) the publication of which could seriously harm the applicant.

Stakeholders' views[7]

In a statement, the group of non-governmental organisations (NGOs) who organised the European Citizens' Initiative 'Ban glyphosate', welcome the Commission proposal to oblige EFSA to proactively publish all industry studies as soon as it receives them. They claim, however, that newly introduced confidentiality rules would allow industry to withhold important information contained in these documents, making it impossible for scientists to scrutinise industry's safety claims and determine potential impacts on people's health and the environment. They also claim that the new confidentiality regime could prevent EFSA from disclosing information to individuals upon request. They also warn that EFSA should be protected from legal challenges by industry. ECI organisers also welcomed the result of the EP plenary vote on its position on the proposal in December 2018.

The European Consumer Organisation (BEUC) welcomes the Commission proposal and recommends some changes to strengthen it further, such as including meaningful sanctions for industry applicants that fail to notify EFSA of studies commissioned, and making sure that the planned 'general plan for risk communication' ensures that EU-risk-managers improve their explanations of the political choices behind any policy decision about food to the public.

The European Crop Protection Association (ECPA), representing the agrochemical sector, supports the overall objectives of the proposal, but says that the provisions related to when non-confidential information will be made public (Article 38), how it should be disclosed (Article 38), and the definition and protection of confidential information (Article 39), should be improved, to strike the correct balance between ensuring greater transparency and protecting legitimate confidential business information. According to ECPA, disclosing scientific information before EFSA reaches the conclusions of its risk assessment could cause delays in the assessment, or even lead to undue political pressure, thereby threatening EFSA's independence. In its letter dated 13 November 2018, ECPA recalls that an important aspect is also to prevent those producing counterfeit or illegal pesticides – according to ECPA currently 15 % of the market – from having free access to confidential business information. It also regrets the lack of an appeals process in the Commission proposal.

The European Livestock and Meat Trading Union (UECBV) welcomes the proposal and its objectives for further transparency. Nevertheless, it highlights that research and innovation has to be protected, and that a reasonable time should be allowed for food business operators – particularly SMEs – to react in case there is a disagreement with EFSA on the confidentiality of information. The organisation notes that the two week window given in the proposal seems short.

The European Federation of Associations of Health Product Manufacturers (EHPM) in its statement deplores that the entire REFIT of General Food Law has been hijacked due to the controversy around glyphosate, and says that it would prefer that a much more thorough proposal be brought forward in the next Commission, instead of what is currently on table.

Legislative process

In the European Parliament, the Committee on Environment, Public Health and Food Safety (ENVI) is responsible for the file. Renate Sommer (EPP, Germany) was appointed rapporteur on 3 May 2018.

The European Food Safety Authority welcomed the Commission proposal as an opportunity to boost EFSA's openness. In a hearing in the ENVI committee in the European Parliament on 18 October 2018, the Executive Director of EFSA, Bernhard Url, urged the European Parliament to work on the proposal as quickly as possible. He deplored that the legal situation does not allow EFSA to be as open as it would like, saying that the Commission proposal would give EFSA the legal basis and resources to improve transparency. Url also pointed out that the European Medicines Agency (EMA) currently has twice as much staff and four times the budget compared to EFSA. According to Url, in this respect, EFSA would be well resourced with a budget of around €200 million a year.

The draft report was published on 18 July 2018 and considered in the ENVI committee meeting of 29-30 August 2018. The 539 amendments tabled (63 proposed by the rapporteur and 476 by other Members) were considered during the ENVI committee meeting of 1 October 2018.

The Committee on Fisheries (PECH) and the Committee on Legal Affairs (JURI) gave their opinions in October 2018. The Committee on Agriculture and Rural Development (AGRI), which was to give an opinion, rejected a draft opinion in its meeting of 22 October 2018.

The ENVI committee adopted its report on 27 November 2018, by 43 votes in favour to 16 against, with one abstention. ENVI voted for publishing the studies at the beginning of the assessment process, as proposed by the Commission. The changes to the Commission proposal voted include: nomination of experts based on a call for expressions of interest; audits of the testing facilities also to include third countries; not limiting citizens' rights of access to EU documents or the Aarhus Convention right of access to information; publishing minutes and voting results of standing and appeal committees; that confidential information should be published where an over-riding public interest in disclosure exists or urgent action is needed to protect public health, animal health or the environment; and the possibility for an applicant to ask for re-examination of a confidentiality claim in case of disagreement with EFSA.

A plenary vote on the committee report, to confirm Parliament's position, was held on 11 December 2018. The Parliament adopted further amendments to the Commission proposal. In order to ensure transparent risk management, the Commission and Member States should be required to make public the draft risk-management measures envisaged, and the agenda and detailed minutes of meetings of Member State working groups at which risk-management measures are discussed. Evaluators would integrate the assessment of 'cocktail effects' into their work. The EFSA Management Board should include (i) two full and alternate members appointed by the Commission, (ii) two representatives appointed by the European Parliament, and (iii) six full members representing the interests of civil society and the food chain sector, including one representative of public non-governmental organisations specialised in health, farmers' organisations and agrochemical organisations. The Parliament voted for an amendment according to which EFSA's Scientific Panels would be composed of independent scientists who are actively conducting research, and publishing their research findings in peer-reviewed scientific journals. The Parliament supported the view that all supporting data and information relating to applications for authorisation should be made public by EFSA upon receipt, except for duly justified confidential information. The matter was referred back to the committee responsible for interinstitutional negotiations. The rapporteur, Renate Sommer, resigned from her role and Pilar Ayuso (EPP, Spain) took over as the new rapporteur.

As for the Council, the Commissioner for Health and Food Safety, Vytenis Andriukaitis, presented the proposal at the Agriculture and Fisheries Council meeting on 16 April 2018. Ministers generally welcomed the proposal and the Commission invited the Council to make progress so that the

proposal could be adopted in a timely fashion. An ad hoc working party on the General Food Law was set up in the Council, with several meetings held from June until November 2018.

The Council adopted its general approach on 12 December 2018. The Council position remains close to the spirit of the Commission's proposal. According to the Council, all supporting data and information linked to an application for authorisation should be made public by EFSA after the assessment of the validity of the application, unless the applicant requested confidential treatment for this information. EFSA would consider the validity of the confidentiality request and communicate the results to the applicant. If the applicant disagrees with EFSA's position, it could file a confirmatory request. In order to safeguard the interests of businesses, in the period during which the confirmatory request is assessed, the information could not be made public. In order for EFSA to be able to attract more scientists to participate in its scientific panels, Member States would take a more active role in promoting the calls for expressions of interest coming from EFSA and in encouraging national experts to apply. As is the case today, it would be the responsibility of EFSA to draw up lists of experts to be appointed by the management board.

A first trilogue meeting was held on 14 January 2019 in Strasbourg and a second on 24 January in Brussels. The third meeting, held on 11 February in Strasbourg, led to a provisional agreement.

According to the provisional agreement, data linked to an application for authorisation will be made public '**without delay once an application has been considered valid or admissible**'. It should be ensured, however, that public disclosure is not considered as permission for further uses or exploitation. EFSA shall make public the non-confidential version of the application as submitted by the applicant, and 'proceed, without delay, to examination of the confidentiality request'. Before taking a decision, EFSA will inform the applicant of its intention to disclose information. If the applicant disagrees with the assessment, it may withdraw its application or make a **confirmatory application**. The information shall not be made public while the confirmatory application is being examined.

Article 39 on confidentiality further lists the information that EFSA can grant confidential treatment to, and only where the **applicant demonstrates that the disclosure of such information would potentially harm its interest to a significant degree**. Examples of information that could be kept confidential include the manufacturing process and quantitative composition of the subject matter – except for information which is relevant to the safety assessment. Confidential information can be disclosed by EFSA, where 'urgent action is essential to protect public health, animal health or the environment, such as in emergency situations'.

A **database of studies commissioned** to support an application will be established. The notification obligation shall also apply to laboratories and other testing facilities located in third countries. The Commission will carry out fact-finding missions to laboratories and other testing facilities, to assess whether they apply the relevant standards for carrying out tests and studies submitted to EFSA as part of an application. To address specific cases where there are **serious controversies or conflicting results**, the Commission can ask EFSA to commission additional verifying studies.

Member States will not propose candidates for the Scientific Panels of EFSA; instead, the members of the panels will be selected on the basis of applications received to calls for expressions of interest. The Parliament's demand that experts appointed in the Scientific Panels should be scientists who are also actively conducting research, and publishing their research findings in peer-reviewed scientific journals, is mentioned in recital 14 of the new regulation.

The EFSA Management Board will include one member and an alternate member representing each Member State, two members appointed by the Commission, two representatives appointed by the European Parliament, and four (instead of the six requested by Parliament) members representing the interests of civil society and the food chain sector. Moreover, the Commission shall adopt, by

means of implementing acts, a **general plan for risk communication** to ensure a coherent risk communication strategy throughout the risk analysis process.

The Committee of Permanent Representatives (Coreper) endorsed the agreement on behalf of the Council on 15 February, and the ENVI committee approved it on 20 February 2019. The European Parliament adopted the text at first reading on 17 April; the Council adopted it on 13 June 2019. The final act, signed on 20 June 2019, was published in the Official Journal on 6 September 2019 and will be applicable as of 27 March 2021 (with the exception of provisions on the membership of the EFSA Management Board and Scientific Committee, which apply from July 2022).

EP SUPPORTING ANALYSIS

Bourguignon D., Authorisation of pesticides in the EU – With a focus on glyphosate, EPRS, European Parliament, February 2018.

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Laaninen T., The EU's General Food Law Regulation - An introduction to the founding principles and the fitness check, EPRS, European Parliament, January 2017.

Nganga J., Bisonni M. and Christodoulou M., Guidelines for submission and evaluation of applications for the approval of active substances in pesticides, Study, Directorate-General for Internal Policies, European Parliament, September 2018.

OTHER SOURCES

Transparency and sustainability of the EU risk assessment in the food chain, European Parliament, Legislative Observatory (OEIL).

ENDNOTES

1 The panels are composed of scientific experts with a three-year mandate. At present, ten panels are operating. The Commission may adapt the number and names of the scientific panels in the light of technical and scientific developments, at EFSA's request.

2 External study on the general part of General Food Law Regulation (Articles 1-21) and external study on the RASFF (the Rapid Alert System for Food and Feed) and the management of emergencies/crises (Articles 50 to 57). These studies were completed in December 2015.

3 Under Article 61 of the GFL Regulation, EFSA is subject to a regular external evaluation every six years. The 2012 evaluation covered the period from January 2006 to December 2010. The third independent external evaluation of EFSA, covering the years 2011-2016, was published in June 2018. The next evaluation was launched in 2017.

4 According to the Commission's roadmap, more than two thirds of EFSA's scientific panel experts (69 %) originate from only six Member States, and the difficulties EFSA encountered in receiving sufficient support from many Member States for its scientific work (e.g. via studies, provision of data), clearly point to future challenges in ensuring sufficient expertise in the long-term and in fully engaging all Member States in scientific cooperation.

5 In cases where an EFSA opinion is not required, it would be for the Commission to assess the confidentiality request.

6 According to the proposal (amended Article 28), Member States may also nominate nationals of other Member States.

7 This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'EP supporting analysis'.

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