# Procedure file

## Basic information

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| COD - Ordinary legislative procedure (ex-codecision procedure)<br>Regulation | 2018/0088(COD) |
| Transparency and sustainability of the EU risk assessment in the food chain<br><br>Amending Directive 2001/18/EC 1998/0072(COD)<br>Amending Regulation (EC) No 178/2002 2000/0286(COD)<br>Amending Regulation (EC) No 1829/2003 2001/0173(COD)<br>Amending Regulation (EC) No 1831/2003 2002/0073(COD)<br>Amending Regulation (EC) No 2065/2003 2002/0163(COD)<br>Amending Regulation (EC) No 1935/2004 2003/0272(COD)<br>Amending Regulation (EC) No 1107/2009 2006/0136(COD)<br>Amending Regulation (EC) No 1331/2008 2006/0143(COD)<br>Amending Regulation (EU) No 2015/2283 2013/0435(COD)<br><br>Subject<br>3.10.03 Marketing and trade of agricultural products and livestock<br>3.10.10 Foodstuffs, foodstuffs legislation<br>3.40.13 Food industry<br>4.60 Consumers' protection in general<br>4.60.04.04 Food safety<br>8.40.08 Agencies and bodies of the EU | Procedure completed |

## Key players

### European Parliament

| Committee responsible | Rapporteur | Appointed |
|---|---|---|
| ENVI Environment, Public Health and Food Safety | | 03/05/2018 |
| | PPE AYUSO Pilar | |
| | Shadow rapporteur | |
| | S&D POC Pavel | |
| | ECR GERICKE Arne | |
| | ALDE FEDERLEY Fredrick | |
| | GUE/NGL HAZEKAMP Anja | |
| | Verts/ALE HÄUSLING Martin | |
| | EFDD PEDICINI Piernicola | |

| Committee for opinion | Rapporteur for opinion | Appointed |
|---|---|---|
| BUDG Budgets | The committee decided not to give an opinion. | |
| ITRE Industry, Research and Energy | The committee decided not to give an opinion. | |
| IMCO Internal Market and Consumer Protection | The committee decided not to give an opinion. | |
| AGRI Agriculture and Rural Development | | 29/05/2018 |
| | S&D KADENBACH Karin | |
| PECH Fisheries | | 31/05/2018 |
| | S&D SERRÃO SANTOS Ricardo | |
| JURI Legal Affairs | | 23/04/2018 |
| | PPE SVOBODA Pavel | |

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|---|---|---|---|
| | Committee for opinion on the legal basis | Rapporteur for opinion | Appointed |
| | JURI Legal Affairs | | 05/12/2018 |
| | | PPE VOSS Axel | |
| Council of the European Union | Council configuration | Meeting | Date |
| | Employment, Social Policy, Health and Consumer Affairs | 3698 | 13/06/2019 |
| | Agriculture and Fisheries | 3664 | 17/12/2018 |
| European Commission | Commission DG | Commissioner | |
| | Health and Food Safety | ANDRIUKAITIS Vytenis Povilas | |
| European Economic and Social Committee | | | |
| European Committee of the Regions | | | |

## Key events

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|---|---|---|---|
| 11/04/2018 | Legislative proposal published | COM(2018)0179 | Summary |
| 28/05/2018 | Committee referral announced in Parliament, 1st reading/single reading | | |
| 27/11/2018 | Vote in committee, 1st reading/single reading | | |
| 29/11/2018 | Committee report tabled for plenary, 1st reading/single reading | A8-0417/2018 | Summary |
| 10/12/2018 | Debate in Parliament | | |
| 11/12/2018 | Results of vote in Parliament | | |
| 11/12/2018 | Decision by Parliament, 1st reading/single reading | T8-0489/2018 | Summary |
| 11/12/2018 | Matter referred back to the committee responsible | | |
| 20/02/2019 | Approval in committee of the text agreed at 1st reading interinstitutional negotiations | PE636.018 GEDA/A/(2019)001497 | |
| 16/04/2019 | Debate in Parliament | | |
| 17/04/2019 | Decision by Parliament, 1st reading/single reading | T8-0400/2019 | Summary |
| 13/06/2019 | Act adopted by Council after Parliament's 1st reading | | |
| 20/06/2019 | Final act signed | | |
| 20/06/2019 | End of procedure in Parliament | | |
| 06/09/2019 | Final act published in Official Journal | | |

## Technical information

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|---|---|
| Procedure reference | 2018/0088(COD) |
| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |
| Procedure subtype | Legislation |
| Legislative instrument | Regulation |

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|---|---|
| | Amending Directive 2001/18/EC 1998/0072(COD)<br>Amending Regulation (EC) No 178/2002 2000/0286(COD)<br>Amending Regulation (EC) No 1829/2003 2001/0173(COD)<br>Amending Regulation (EC) No 1831/2003 2002/0073(COD)<br>Amending Regulation (EC) No 2065/2003 2002/0163(COD)<br>Amending Regulation (EC) No 1935/2004 2003/0272(COD)<br>Amending Regulation (EC) No 1107/2009 2006/0136(COD)<br>Amending Regulation (EC) No 1331/2008 2006/0143(COD)<br>Amending Regulation (EU) No 2015/2283 2013/0435(COD) |
| Legal basis | Rules of Procedure EP 59-p4; Treaty on the Functioning of the EU TFEU 114; Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 043-p2 |
| Mandatory consultation of other institutions | European Economic and Social Committee<br>European Committee of the Regions |
| Stage reached in procedure | Procedure completed |
| Committee dossier | ENVI/8/12782 |

## Documentation gateway

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|---|---|---|---|---|---|
| Legislative proposal | | COM(2018)0179 | 11/04/2018 | EC | Summary |
| Document attached to the procedure | | SWD(2018)0097 | 12/04/2018 | EC | |
| Committee draft report | | PE623.765 | 18/07/2018 | EP | |
| Economic and Social Committee: opinion, report | | CES2522/2018 | 19/09/2018 | ESC | |
| Amendments tabled in committee | | PE627.781 | 21/09/2018 | EP | |
| Amendments tabled in committee | | PE627.946 | 21/09/2018 | EP | |
| Committee of the Regions: opinion | | CDR2837/2018 | 10/10/2018 | CofR | |
| Committee opinion | PECH | PE625.411 | 11/10/2018 | EP | |
| Committee opinion | JURI | PE625.400 | 15/10/2018 | EP | |
| Committee opinion | AGRI | PE625.353 | 30/10/2018 | EP | |
| Amendments tabled in committee | | PE628.598 | 27/11/2018 | EP | |
| Committee report tabled for plenary, 1st reading/single reading | | A8-0417/2018 | 29/11/2018 | EP | Summary |
| Specific opinion | JURI | PE631.927 | 06/12/2018 | EP | |
| Text adopted by Parliament, partial vote at 1st reading/single reading | | T8-0489/2018 | 11/12/2018 | EP | Summary |
| Coreper letter confirming interinstitutional agreement | | GEDA/A/(2019)001497 | 15/02/2019 | CSL | |
| Text adopted by Parliament, 1st reading/single reading | | T8-0400/2019 | 17/04/2019 | EP | Summary |
| Draft final act | | 00041/2019/LEX | 20/06/2019 | CSL | |
| Commission response to text adopted in plenary | | SP(2019)440 | 08/08/2019 | EC | |

## Additional information

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| Research document | Briefing |

## Final act

Regulation 2019/1381
OJ L 231 06.09.2019, p. 0001 Summary

# 2018/0088(COD) - 11/04/2018 Legislative proposal

PURPOSE: to improve the transparency of scientific studies in the field of food safety.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Regulation (EC) No 178/2002 on general food law (the GFL Regulation) established the principle of risk analysis as a general principle in EU food law. Risk assessment at EU level is carried out by the European Food Safety Authority (EFSA), independently of the risk management function, which is entrusted to the EU institutions, and more particularly to the Commission.

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

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 EFSAs evaluations of authorisation applications are essentially based on studies, data and information generated (and paid for) by the applicant for authorisation. Risk communication was also found not to be effective enough.

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.

CONTENT: the proposal seeks to amend not only the GFL Regulation but also eight additional sectoral legislative acts relating to the food chain. The main objectives of the proposed amendments are:

- ensure greater transparency by ensuring that scientists and citizens have access to key safety related information being assessed by EFSA at an early stage in the risk assessment. All supporting data and information relating to applications for authorisation are to be made public by EFSA upon receipt, including additional information, with the exception of information for which confidentiality is duly justified;
- improve citizens confidence in the credibility of scientific studies by:

    i. establishing a Union register of commissioned studies on substances subject to a food law authorisation system, to be managed by EFSA; 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;

    ii. providing a pre-submission procedure, by which EFSA may provide advice to an applicant, such advice being made public;

    iii. providing 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;

    iv. providing for controls and audits by Commission inspectors in relation to studies;

    v. introducing the possibility for the Commission to request EFSA to commission studies in exceptional circumstances (e.g. controversies) for the purpose of verification.

- better involving Members States in EFSAs governance structure and scientific panels without touching on its independence: the proposal aligns the composition of EFSAs Management Board with the Common Approach on decentralised agencies by including representatives of all Member States. It will also increase the involvement of Member States in the nomination process of Panels members. 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.
- strengthen risk communication: the proposal ensures a 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.

BUDGETARY IMPLICATIONS: the Commission considers that by strengthening the EFSAs governance and making risk assessment more sustainable, EFSA will continue to play a fundamental role in the Union food safety system and to contribute to the health and well-being 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.

The impact on EFSA's expenditure is estimated at EUR 256.270 million for the period 2020-2024 (staff costs: EUR 56.276 million; operational expenditure: EUR 199.994 million).

## 2018/0088(COD) - 29/11/2018 Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Renate SOMMER (EPP, DE) on the 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 and amending and amending eight sectoral legislative acts in terms of transparency and confidentiality.

As a reminder, the proposal for the revision of Regulation (EC) No 178/2002 on general food law (the GFL Regulation") aims to (i) strengthen the transparency rules applicable to the European Food Safety Authority (EFSA), (ii) increase the reliability, objectivity and independence of the studies on which EFSA relies for risk assessment and (iii) improve EFSA's governance and (iv) strengthen risk communication.

The committee recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the Commission's proposal as follows.

Risk communication: Members believe that risk management, risk assessment and communication actions shall be based in particular on the thorough application of the precautionary principle. To regain public confidence, they called for a transparent, independent, continuous and inclusive process of risk communication throughout the risk analysis, involving Union and national risk assessors and risk managers.

Members have indicated that risk communication shall:

- foster public understanding of the risk analysis process, in particular by providing clear and consistent information on the respective tasks, powers and responsibilities of risk assessors and risk assessors;
- promote the balanced involvement of all interested parties, including economic operators in the food chain as well as consumers and civil society organisations;
- inform consumers about risk prevention strategies;
- combat the dissemination of false information and sources thereof.

In order to ensure transparent risk management, the Commission and the Member States shall be required to make public the draft risk management measures envisaged and the agenda and detailed minutes of the meetings of the Member States' working groups at which the risk management measures are discussed.

Risk assessment: Members proposed that the European Chemicals Assessment process shall be carried out as part of a coordinated approach for all sectors concerned. In addition, evaluators shall integrate the assessment of cocktail effects into their work.

Studies, including test data, submitted by business operators in support of applications for authorisation shall be based on accessible scientific literature or comply with internationally recognised principles and good laboratory practice (GLP) principles. Data from a test commissioned but not registered shall not be used in a risk assessment.

To increase the effectiveness of the consultation, the consultation shall take place immediately after the studies submitted by industry included in an application for authorisation have been made public, under the transparency rules of this Regulation.

Organisation: the Board of Directors should be composed of members who ensure an optimal level of competence and commitment to the protection of health and the environment. It 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 maximum term of office for members would be 2.5 years.

Members of the Scientific Panels shall be appointed by the Management Board for a renewable 5-year term. The Executive Director, after consulting the Management Board, shall publish a call for expressions of interest in the Official Journal of the European Union, in the relevant scientific publications concerned and on the EFSA website, and inform the Member States accordingly. This call would set out the specific multidisciplinary expertise needed within each scientific group and indicate the number of experts required.

As 20% of the current national experts are British, the system shall be strengthened, while encouraging applicants to apply, in order to ensure that a sufficient pool of independent experts is available. In order to ensure the effectiveness of risk assessment, EFSA's staffing and financial resources shall be strengthened.

Lastly, using the model of the Board of Appeal of the European Chemicals Agency (ECHA), a Board of Appeal of EFSA shall be established by means of delegated acts.

## 2018/0088(COD) - 11/12/2018 Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 427 votes to 172, with 67 abstentions, amendments to the 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 and amending and amending eight sectoral legislative acts in terms of transparency and confidentiality.

The matter was referred back to the committee for interinstitutional negotiations.

As a reminder, the proposal for the revision of Regulation (EC) No 178/2002 on general food law (the GFL Regulation") aims to (i) strengthen the transparency rules applicable to the European Food Safety Authority (EFSA), (ii) increase the reliability, objectivity and independence of the studies on which EFSA relies for risk assessment and (iii) improve EFSA's governance and (iv) strengthen risk communication.

The main amendments adopted in plenary concern the following issues:

Risk communication: Members believe that risk management, risk assessment and communication actions shall be based in particular on the thorough application of the precautionary principle. To regain public confidence, they called for a transparent, independent, continuous and inclusive process of risk communication throughout the risk analysis, involving Union and national risk assessors and risk managers.

Parliament indicated that risk communication shall:

- provide information on how the risk management option chosen reflects the degree of uncertainty of the risk assessment, and the level of consumer and animal health and environmental protection it would achieve;
- foster public understanding of the risk analysis process, in particular by providing clear and consistent information on the respective tasks, powers and responsibilities of risk assessors and risk assessors;
- promote the balanced involvement of all interested parties, including economic operators in the food chain as well as consumers and civil society organisations;
- inform consumers about risk prevention strategies;
- combat the dissemination of false information and sources thereof.

In order to ensure transparent risk management, the Commission and the Member States shall be required to make public the draft risk management measures envisaged and the agenda and detailed minutes of the meetings of the Member States' working groups at which the risk management measures are discussed.

Risk assessment: Parliament proposed that the European Chemicals Assessment process shall be carried out as part of a coordinated approach for all sectors concerned. In addition, evaluators shall integrate the assessment of cocktail effects into their work.

Studies, including test data, submitted by business operators in support of applications for authorisation shall be based on accessible scientific literature or comply with internationally recognised principles and good laboratory practice (GLP) principles. Data from a test commissioned but not registered shall not be used in a risk assessment.

A Union register of studies commissioned by business operators seeking to obtain an authorisation or renewal under Union food law is hereby established. 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 immediately after the studies submitted by industry included in an application for authorisation have been made public, under the transparency rules of this Regulation.

Confidentiality: the amended text introduces a set of criteria for deciding what information may be considered confidential, such as the brand under which the substance will be marketed, and the trade name of the preparations, materials or articles in which it will be used, if any.

Except for information that is considered toxicologically, ecotoxicologically or environmentally relevant, the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by adequate and verifiable justification. The justification shall include verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual.

Organisation: the Management Board shall be selected in such a way as to secure the highest standards of competence and commitment to the protection of health and the environment and a broad range of relevant experience available amongst the representatives of the Member States, the European Parliament and the Commission.

It shall 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 maximum term of office for members would be 2.5 years.

Members of the Scientific Panels shall be appointed by the Management Board for a renewable 5-year term. The Executive Director, after consulting the Management Board, shall publish a call for expressions of interest in the Official Journal of the European Union, in the relevant scientific publications concerned and on the EFSA website, and inform the Member States accordingly. This call would set out the specific multidisciplinary expertise needed within each scientific group and indicate the number of experts required.

As 20% of the current national experts are British, the system shall be strengthened, while encouraging applicants to apply, in order to ensure that a sufficient pool of independent experts is available. In order to ensure the effectiveness of risk assessment, EFSA's staffing and financial resources shall be strengthened.

Lastly, using the model of the Board of Appeal of the European Chemicals Agency (ECHA), a Board of Appeal of EFSA shall be established by means of delegated acts.

## 2018/0088(COD) - 17/04/2019 Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 603 votes to 17, with 27 abstentions, a legislative resolution on the 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 Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EC) 2015/2283 and Directive 2001/18/EC.

The European Parliaments position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Risk communication

The proposed amending Regulation shall ensure transparent, continuous and inclusive risk communication throughout the risk analysis, involving Union and national risk assessors and risk managers.

Risk communication shall aim to:

- raise awareness and understanding of the specific issues under consideration, including in cases of divergences in scientific assessment, during the entire risk analysis process;
- ensure consistency, transparency and clarity in formulating risk management recommendations and decisions;
- provide a sound basis, including, where appropriate, a scientific basis, for understanding risk management decisions;
- improve the overall effectiveness and efficiency of the risk analysis;
- foster public understanding of the risk analysis, including of the respective tasks and responsibilities of risk assessors and risk managers to enhance confidence in its outcome;
- ensure appropriate involvement of consumers, feed and food businesses, the academic community and all other interested parties;
- ensure appropriate and transparent exchange of information with interested parties in relation to risks associated with the food chain;
- ensure the provision of information to consumers about risk prevention strategies; and
- contribute to the fight against the dissemination of false information and the sources thereof.

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

- ensure that accurate and all appropriate information is exchanged in an interactive and timely manner with all interested parties, based on the principles of transparency, openness, and responsiveness;
- 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, including information on how risk management decisions were reached and which factors were considered;
- take into account risk perceptions of all interested parties;
- facilitate understanding and dialogue amongst all interested parties; and
- be clear and accessible, including to those not directly involved in the process or not having a scientific background.

The Commission shall adopt, by means of implementing acts, a general plan for risk communication in order to achieve the objectives, in accordance with the general principles. The general plan shall establish appropriate mechanisms of coordination and cooperation between the risk assessors and risk managers at Union and national level involved in the risk analysis process, in particular where several Union agencies provide scientific outputs on the same or on related subject matters, to ensure coherent risk communication and an open dialogue amongst all interested parties.

Governance

Each Member State shall nominate a member and an alternate member as its representatives to the Management Board. The members and alternate members thus nominated shall be appointed by the Council and have the right to vote.

The Management Board would also include two full members appointed by the European Parliament with voting rights.

The selection of members of the Scientific Committee and Scientific Panels of the Authority by the EFSA Executive Director and their appointment by the Management Board shall be based on strict criteria ensuring the excellence and independence of the experts while ensuring the multidisciplinary expertise required for each Scientific Panel.

Experts appointed as members of the Scientific Panels shall be scientists who are also actively engaged in research and publish the results in peer-reviewed scientific journals, provided that they comply with the strict criteria of excellence and independence.

Pre-submission advice

The amended legislation also provides for the implementation of a new pre-submission advisory procedure that will allow EFSA to advise applicants on how to properly submit their application for authorisation, thus making the process more reliable.

Notification of studies

The Authority shall establish and manage a database of studies commissioned or carried out by business operators to support an application or notification in relation to which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion.

Business operators shall, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.

The Authority shall conduct its activities in the most transparent manner and make public a certain amount of information, including agendas, lists of participants and minutes of meetings of the Management Board, Advisory Forum, Scientific Committee and Scientific Panels and their working groups.

The disclosure of such information shall be without prejudice to any existing rules concerning intellectual property rights which set out limitations on certain uses of the disclosed documents or their content.

## 2018/0088(COD) - 06/09/2019 Final act

PURPOSE: to improve the transparency of scientific studies supporting marketing authorisation applications in the field of food safety.

LEGISLATIVE ACT: Regulation (EU) 2019/1381 of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

CONTENT: this Regulation amends Regulation (EC) No 178/2002 on General Food Law (GFL Regulation) and eight additional sectoral legislative acts relating to the food chain. Its objective is to make the scientific information on which risk assessment in the food chain and food

safety communication are based more transparent and accessible to citizens.

The Regulation originates from the European Citizens' Initiative on Banning Glyphosate and Protecting People and the Environment from Toxic Pesticides, which confirmed concerns about transparency with regard to studies commissioned by industry and submitted as part of authorisation procedures.

Improved risk communication

The Regulation shall ensure transparent, continuous and inclusive risk communication throughout the risk analysis, involving Union and national risk assessors and risk managers.

Risk communication shall aim to:

- raise awareness and understanding of the specific issues under consideration, including in cases of divergences in scientific assessment, during the entire risk analysis process;

- ensure consistency, transparency and clarity in formulating risk management recommendations and decisions;

- provide a sound basis, including, where appropriate, a scientific basis, for understanding risk management decisions;

- improve the overall effectiveness and efficiency of the risk analysis;

- foster public understanding of the risk analysis, including of the respective tasks and responsibilities of risk assessors and risk managers to enhance confidence in its outcome;

- ensure appropriate involvement of consumers, feed and food businesses, the academic community and all other interested parties;

- ensure appropriate and transparent exchange of information with interested parties in relation to risks associated with the food chain;

-ensure the provision of information to consumers about risk prevention strategies; and

- contribute to the fight against the dissemination of false information and the sources thereof.

The Commission shall adopt, by means of implementing acts, a general plan for risk communication in order to achieve the objectives.

Verification studies

The amending Regulation introduces the possibility for the Commission to request the European Food Safety Authority EFSA to commission scientific studies, in exceptional circumstances, to verify the evidence used in its risk assessment process. It also gives a more active role to Member States to help EFSA to encourage more and better scientists to participate in scientific panels.

Protection of confidentiality

Supporting data and information related to an application for authorisation shall be made public by EFSA after an assessment of the validity of the application, unless the applicant demonstrates that such publication could potentially harm his interests and requests confidential treatment by EFSA. The applicant may submit a confirmatory application if he/she disputes EFSA's assessment of confidentiality. In this case, the information shall not be made public until a final decision has been made.

Enhanced governance of the EFSA

The Regulation reinforces the role of the Member States and the efforts and commitment of all parties involved in the EFSA Management Board. In addition to the members and alternates, the Management Board shall comprise: (a) two members and two alternates appointed by the Commission, with the right to vote; (b) two members appointed by the European Parliament, with the right to vote; (c) four members and four alternates with voting rights, representing the interests of civil society and the food chain sector.

The selection of members of the Scientific Committee and Scientific Panels of the Authority by the EFSA Executive Director and their appointment by the Management Board shall be based on strict criteria ensuring the excellence and independence of the experts while ensuring the multidisciplinary expertise required for each Scientific Panel.

Pre-submission advice

The amending Regulation provides for the implementation of a new pre-submission advisory procedure that shall allow EFSA to advise applicants on how to correctly submit their application for authorisation, thus making the process more reliable.

Database and notification of studies

EFSA shall establish and manage a database of studies commissioned or carried out by business operators to support an application or notification in relation to which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion.

Fact-finding missions

Commission experts shall carry out fact-finding missions to Member States to assess the application by laboratories and other test facilities of the standards applicable to the performance of tests and studies submitted to the Authority in the context of a request.

Those fact-finding missions shall allow the Commission to identify, and to aim to correct, possible weaknesses in the systems and non-compliance and to provide an additional level of guarantees to reassure the general public on the quality of studies. Based on the conclusions of such fact-finding missions, the Commission may propose appropriate legislative measures aimed at improving compliance with the relevant standards.

ENTRY INTO FORCE: 26.9.2019.

APPLICATION: from 27.3.2021.