Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 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 (Text with EEA relevance)

REGULATION (EU) 2019/1381 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 June 2019

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

(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 Article 43(2), Article 114 and Article 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[(1)],

Having regard to the opinion of the Committee of the Regions[(2)],

Acting in accordance with the ordinary legislative procedure[(3)],

Whereas:

(1) Regulation (EC) No 178/2002 of the European Parliament and of the Council[(4)] lays down the general principles and requirements of food law, so as to form a common basis for measures governing food law at both Union and national level. It provides, inter alia, that food law is to 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.

(3) Risk communication is an essential part of the risk analysis process. The REFIT evaluation of the general food law (Regulation (EC) No 178/2002) of 2018 (‘Fitness Check of the General Food Law’) found that risk communication is not considered to be

effective enough overall. This has an impact on consumers' confidence in the outcome of the risk analysis process.

(4) It is necessary, therefore, to ensure transparent, continuous and inclusive risk communication throughout the risk analysis, involving Union and national risk assessors and risk managers. Such risk communication should strengthen citizens' trust that the risk analysis is underpinned by the objective of ensuring a high level of protection of human health and consumers' interests. That risk communication should also be capable of contributing to a participatory and open dialogue between all interested parties in order to ensure that the prevalence of the public interest, and accuracy, comprehensiveness, transparency, consistency and accountability are taken into account in the risk analysis process.

(5) Risk communication should place particular emphasis on explaining in an accurate, clear, comprehensive, coherent, appropriate and timely manner not only risk assessment findings themselves but also how such findings are used to help inform risk management decisions along with other legitimate factors, where relevant. Information should be provided on how risk management decisions were reached and on the factors, other than the results of the risk assessment, which were considered by the risk managers, as well as how those factors were weighed up against each other.

(6) Given the ambiguity in the public perception of the difference between hazard and risk, risk communication should endeavour to clarify that distinction and thereby ensure that such distinction is better understood by the general public.

(7) Where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health due to non-compliance resulting from intentional violations of applicable Union law perpetrated through fraudulent or deceptive practices, public authorities, identifying to the fullest extent possible the products concerned and the risk that they may present, should inform the public accordingly as soon as possible.

(8) It is necessary to establish general objectives and principles of risk communication, taking into account the respective roles of risk assessors and managers, while guaranteeing their independence.

(9) On the basis of the general objectives and principles, a general plan on risk communication should be established in close cooperation with the Authority and Member States, and following relevant public consultations. That general plan should promote an integrated risk communication framework for all risk assessors and risk managers at Union and national level on all matters relating to the food chain. It should also allow for the necessary flexibility and should not deal with situations specifically covered by the general plan for crisis management.

(10) The general plan on risk communication should identify the key factors to be taken into account when considering the type and level of risk communication activities needed, such as the different levels of risk, the nature of the risk and its potential impact on human health, animal health and, where relevant, the environment, who and what are directly or indirectly affected by the risk, the levels of exposure to a hazard, the level of

urgency and the ability to control risk, and other factors that influence risk perception, including the applicable legal framework and relevant market context.

(11) The general plan on risk communication should also identify the tools and channels to be used and should 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.

(12) Transparency of the risk assessment process contributes to greater legitimacy of the Authority being acquired in the eyes of the consumers and general public in the pursuit of 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 strengthen the confidence of the general public and other interested parties in the risk analysis underpinning the relevant Union law, and in particular in the risk assessment, including the transparency thereof as well as the organisation, functioning and independence of the Authority.

(13) It is appropriate to increase the role of Member States as well as the effort and engagement of all parties involved in the Management Board of the Authority (the 'Management Board').

(14) Experience shows that the role of the Management Board is focused 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, of the European Parliament and of the Commission as well as of civil society and industry organisations in the Management Board, while providing that those representatives should have experience and expertise not only in the fields of food chain law and policy, including risk assessment, but also in the fields of managerial, administrative, financial and legal matters and ensuring that they act independently in the public interest.

(15) The members of the Management Board should be selected and appointed in such a way as to secure the highest standards of competence and the broadest range of relevant experience available.

(16) 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 Authority's 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.

(17) To preserve the independence of the risk assessment from risk management and from other interests at Union level, it is appropriate that the selection by the Authority's Executive Director and the appointment by the Management Board of the members of the Authority's Scientific Committee and Scientific Panels be based on strict criteria

ensuring the excellence and independence of the experts while also ensuring the required multidisciplinary expertise for each Scientific Panel. It is essential to that end that the Executive Director, whose function is to defend the Authority's interests and in particular the independence of its expertise, have a role in the selection of those scientific experts. The Management Board should endeavour to ensure, to the largest extent possible, that experts appointed as members of the Scientific Panels are scientists who are also actively conducting research, and publishing their research findings in peer-reviewed scientific journals, provided that they comply with the strict criteria of excellence and independence. Proper financial compensation of the experts should be ensured. Further measures should also be put in place to ensure that scientific experts have the means to act independently.

(18) 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 Scientific Committee and the Scientific Panels. In particular, the Authority should organise the preparatory work supporting the tasks of the Scientific Panels, 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 those Scientific Panels. That should be without prejudice to the independence of the Authority's scientific assessments.

(19) Authorisation procedures are based on the principle that it is for the applicant or the notifier to prove that the subject matter of an application or notification complies with Union requirements. That principle is based on the premise that human health, animal health and, where relevant, the environment are better protected where the burden of proof is on the applicant or the notifier since it has to prove that the subject matter of its application or notification is safe prior to its placing on the market, instead of the public authorities having to prove that that subject matter is unsafe in order to be able to ban it from the market. In accordance with that principle and the applicable regulatory requirements, in support of applications or notifications under Union sectoral law, applicants or notifiers are required to submit relevant studies, including tests, to demonstrate the safety and, in some cases, the efficacy of a subject matter.

(20) Union law provides for the content of applications and notifications. It is essential that the application or notification submitted to the Authority for its risk assessment meet the applicable specifications to ensure the best quality scientific assessment by the Authority. Applicants or notifiers and in particular small and medium-sized enterprises do not always have a clear understanding of those specifications. It is thus appropriate that, where the Authority may be requested to provide a scientific output, it should provide advice to a potential applicant or notifier upon request, before an application or notification is formally submitted. Such pre-submission advice should relate to the rules applicable to, and the content required for, an application or notification and should not address the design of the studies to be submitted, as that remains the applicant's responsibility.

(21) Where the Authority may be requested to provide a scientific output, it should have knowledge of all studies performed by an applicant with a view to supporting an application under Union law. To that end, it is necessary and appropriate that, when business operators commission or carry out studies with a view to submitting an application or notification, they notify those studies to the Authority. The obligation to notify such studies should also apply to the laboratories and other testing facilities carrying them out. Information about the notified studies should be made public only once a corresponding application has been made public in accordance with the applicable rules on transparency. In order to ensure effective implementation of that obligation, it is appropriate to provide for certain procedural consequences in the event of non-compliance. The Authority should, in that context, lay down practical arrangements to implement that obligation, including procedures for requesting and making public the justifications for the non-compliance.

(22) In accordance with Directive 2010/63/EU of the European Parliament and of the Council[(5)], tests on animals should be replaced, reduced or refined. Therefore, within the scope of this Regulation, duplication of animal testing should be avoided, where possible.

(23) In the case of applications or notifications to request the renewal of an authorisation or an approval, the authorised or approved substance or product has already been on the market for several years. Experience and knowledge therefore already exist with regard to that substance or product. Where the Authority may be requested to provide a scientific output, it is appropriate for studies planned for supporting requests for renewals, including information on the proposed design, that have been notified by the applicant or the notifier to the Authority, to be submitted for consultation of third parties. The Authority should systematically provide advice to the applicants or to the notifiers on the content of the intended renewal application or notifications, as well as on the design of studies, taking into account the comments received.

(24) There are certain public concerns about the Authority's assessment in the area of authorisation procedures being primarily based on industry studies. It is of utmost importance that the Authority carry out 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 to ensure that the Authority can have access to all relevant scientific data and studies available on a subject matter of an application or a notification for an authorisation or a renewal of an authorisation or an approval, it is appropriate to provide for 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 or a notification are made public, under the applicable transparency rules. Where there is a risk that the results of a public consultation cannot be given proper consideration because of the applicable deadlines, it is appropriate to provide for a limited extension of those deadlines.

(25) Food safety is a sensitive matter of prime interest for all Union citizens. While maintaining the principle that the burden to prove compliance with Union requirements is on the industry, it is important to establish an additional verification tool, namely the commissioning of additional studies with the objective of verifying evidence used in the context of risk assessment to address specific cases of high societal importance where there are serious controversies or conflicting results. Considering that those verification studies would be financed from the Union budget and that the use of this exceptional verification tool should remain proportionate, the Commission, taking into account the views expressed by the European Parliament and by Member States, should be responsible for triggering the commissioning of such verification studies. Account should be taken of the fact that in some specific cases the verification studies commissioned may need to have a wider scope than the evidence at stake, for example, in cases where new scientific developments become available.

(26) 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 food chain, is not always perceived as being fully transparent. That is also partly due to the different transparency and confidentiality rules that are laid down in Regulation (EC) No 178/2002 and in other Union sectoral legislative acts. The interplay among those acts can have an impact on the acceptance of the risk assessment by the general public.

(27) The European citizens' initiative entitled ‘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 procedures.

(28) It is therefore necessary to strengthen the transparency of the risk assessment in a proactive manner. All scientific data and information supporting requests for authorisations or for approvals under Union law as well as other requests for scientific output should be made publicly available in a proactive manner and be easily accessible as early as possible in the risk assessment process. However, such disclosure to the public should be without prejudice to any rules concerning intellectual property rights or to any provisions of Union law protecting the investment made by innovators in gathering the information and data supporting relevant applications or notifications. It should be ensured that such disclosure to the public is not considered to be permission for further uses or exploitation, without jeopardising the proactive character of disclosure to the public and the easy public access to the disclosed data and information.

(29) To ensure the transparency of the risk assessment, a summary of the pre-submission advice should be made public only once a corresponding application or notification has been made public in accordance with the applicable rules on transparency.

(30) Where the opinion of the Authority is requested in relation to applications or notifications submitted under Union 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.

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

(32) With respect to the application or notification procedures provided for in Union law, experience gained so far has shown that certain items of information are generally considered sensitive and should remain confidential across the different sectoral procedures. It is therefore appropriate to lay down in Regulation (EC) No 178/2002 a horizontal list of items of information whose disclosure, as demonstrated by the applicant or the notifier, will potentially harm the commercial interests concerned to a significant degree and which should not therefore be disclosed to the public. Those items should include the manufacturing and production process, including the method and innovative aspects thereof, as well as technical and industrial specifications, such as impurities, inherent to that process other than information which is relevant to the assessment of safety. Only in very limited and exceptional circumstances relating to foreseeable health effects or, where an environmental assessment is required under Union sectoral law, to environmental effects, or where relevant authorities have identified urgent needs to protect human health, animal health or the environment, should such information be disclosed.

(33) For the purposes of clarity and to increase legal certainty, it is necessary to set out the specific procedural requirements to be followed by an applicant or by a notifier in respect of a request for information submitted to support an application or a notification under Union law to be treated in a confidential manner.

(34) It is also necessary to set out specific requirements with respect to the protection and confidentiality of personal data for the purposes of the transparency of the risk assessment process, taking into account Regulations (EU) 2018/1725[(6)] and (EU) 2016/679[(7)] of the European Parliament and of the Council. 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. In particular, for the purpose of ensuring the transparency and to avoid conflicts of interest, it is necessary to publish the names of the participants and observers in certain meetings of the Authority.

(35) For the purpose 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 formats should be developed.

(36) 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.

(37) Furthermore, in order to assess the effectiveness and efficiency of the different legal provisions applicable to the Authority, it is also appropriate to provide for a Commission evaluation of the Authority. That evaluation should, in particular, review the procedures

for selecting the members of Scientific Committee and Scientific Panels, for their degree of transparency, cost-effectiveness, and suitability to ensure independence and competence, and to prevent conflicts of interests.

(38) Studies, including tests, submitted by business operators in support of applications 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, such as those set by Directive 2004/10/EC of the European Parliament and of the Council[8] or those developed by the International Organization for Standardization, may arise in some cases and this is why international and national systems are in place to verify such compliance. It is therefore appropriate for the Commission to carry out fact-finding missions to assess the application by laboratories and other testing facilities of the relevant standards for carrying out tests and studies submitted to the Authority as part of an application. Those fact-finding missions would allow the Commission to identify, and to aim at correcting, 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 could propose appropriate legislative measures aimed at improving compliance with the relevant standards.

(39) 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 Regulations (EC) No 1829/2003[9], (EC) No 1831/2003[10], (EC) No 2065/2003[11], (EC) No 1935/2004[12], (EC) No 1331/2008[13], (EC) No 1107/2009[14], (EU) 2015/2283[15] and in Directive 2001/18/EC[16] of the European Parliament and of the Council should be amended.

(40) 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 against the rights of applicants or of notifiers, taking into account the specific objectives of sectoral Union law as well as experience gained. Accordingly, it is necessary to make specific amendments to Regulations (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC in order to provide for additional confidential items to those set out in Regulation (EC) No 178/2002.

(41) The rights on access to documents enshrined in Regulation (EC) No 1049/2001 of the European Parliament and of the Council[17] and, where environmental information is concerned, the rights enshrined in Regulation (EC) No 1367/2006[18] and Directive 2003/4/EC[19] of the European Parliament and of the Council are unaffected by this Regulation. The rights provided by those acts should not in any manner be limited by the provisions on proactive dissemination laid down in this Regulation and the relevant assessment of confidentiality request.

(42) In order to ensure uniform conditions for the implementation of Regulation (EC) No 178/2002 with regard to the adoption of a general plan for risk communication and the adoption of standard data formats, 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[(20)].

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

(44) Since the appointment of the members of the Scientific Committee and Scientific Panels depends on 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.

(45) 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[(21)],

HAVE ADOPTED THIS REGULATION:

(**1**) OJ C 440, 6.12.2018, p. 158.

(**2**) OJ C 461, 21.12.2018, p. 225.

(**3**) Position of the European Parliament of 17 April 2019 (not yet published in the Official Journal) and the decision of the Council of 13 June 2019.

(**4**) 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).

(**5**) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

(**6**) Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

(**7**) 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).

(**8**) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

(**9**) 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).

(**10**) 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).

(**11**) 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).

(**12**) 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).

(**13**) 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).

(**14**) 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).

(**15**) 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).

(**16**) 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).

(**17**) 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 (OJ L 145, 31.5.2001, p. 43).

(**18**) 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).

(**19**) Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).

(**20**) 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).

(**21**) 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).

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/1381 of the European Parliament and of the Council, Introductory Text.