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

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2019/1381 of the European Parliament and of the Council. (See end of Document for details)*

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.