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)

Article 1

Amendments to Regulation (EC) No 178/2002

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

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

4. Risk communication shall fulfil the objectives and respect the general principles set out in Articles 8a and 8b.;

(2) in Chapter II, the following Section is inserted:

Section 1a

Risk communication

Article 8a

Objectives of risk communication

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

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

(b) ensure consistency, transparency and clarity in formulating risk management recommendations and decisions;

(c) provide a sound basis, including, where appropriate, a scientific basis, for understanding risk management decisions;

(d) improve the overall effectiveness and efficiency of the risk analysis;

(e) 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;

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

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

(h) ensure the provision of information to consumers about risk prevention strategies; and

(i) contribute to the fight against the dissemination of false information and the sources thereof.

Article 8b

General principles of risk communication

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

(a) ensure that accurate 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;

(b) provide transparent information at each stage of the risk analysis process from the framing of requests for scientific advice to the provision of risk assessment and the adoption of risk management decisions, including information on how risk management decisions were reached and which factors were considered;

(c) take into account risk perceptions of all interested parties;

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

(e) be clear and accessible, including to those not directly involved in the process or not having a scientific background, while duly respecting the applicable legal provisions on confidentiality and protection of personal data.

Article 8c

General plan for risk communication

1 The Commission shall adopt, by means of implementing acts, a general plan for risk communication in order to achieve the objectives set out in Article 8a, in accordance with the general principles set out in Article 8b. The Commission shall keep that general plan updated, taking into account technical and scientific progress and experience gained. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2). When preparing those implementing acts, the Commission shall consult the Authority.

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

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

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

c establish appropriate mechanisms of coordination and cooperation in order to strengthen coherence of risk communication amongst risk assessors and risk managers; and

d establish appropriate mechanisms to ensure an open dialogue amongst consumers, food and feed businesses, the academic community and all other interested parties, and their appropriate involvement.;

(3) in Article 22(7), the second subparagraph is replaced by the following:

It shall act in close cooperation with the competent bodies in the Member States that carry out similar tasks to those of the Authority and, where appropriate, with the relevant Union agencies.;

(4) Article 25 is amended as follows:

(a) paragraph 1 is replaced by the following:

1. Each Member State shall nominate a member and an alternate member 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.;

(b) the following paragraphs are inserted:

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

a two members and two alternate members appointed by the Commission as its representatives, with the right to vote;

b two members appointed by the European Parliament, with the right to vote;

c four members and four alternate members with the right to vote as representatives of civil society and food chain interests, namely one member and one alternate member from consumer organisations, one member and one alternate member from environmental non-governmental organisations, one member and one alternate member from farmers organisations, and one member and one alternate member from industry organisations.

The members and alternate members referred to in point (c) of the first subparagraph shall be appointed by the Council in consultation with the European Parliament on the basis of a list which shall be drawn up by the Commission and sent to the Council. The list shall include more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament by the Council, together with the relevant background documents. As quickly as possible and at the latest within three months of the receipt of that list, the European Parliament may submit its views for consideration to the Council which shall then appoint those members.

1b The members and the alternate members of the Management Board shall be nominated and appointed on the basis of their relevant experience and expertise in the field of food chain law and policy, including risk assessment, whilst ensuring that there is relevant expertise in the

fields of managerial, administrative, financial and legal matters within the Management Board.;

(c) paragraph 2 is replaced by the following:

2. The term of office of members and alternate members shall be four years and may be renewed. However, the term of office of the members and alternate members referred to in point (c) of the first subparagraph of paragraph 1a may be renewed only once.;

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

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

(5) Article 28 is amended as follows:

(a) paragraph 5 is replaced by the following:

5. The members of the Scientific Committee who are not members of the Scientific Panels and the members of the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a five-year term of office, which may be renewed, following publication of a call for expression of interest in the *Official Journal of the European Union*, in relevant leading scientific publications and on the Authority's website. The Authority shall publish such a call for expression of interest after having informed the Member States about the necessary criteria and fields of expertise.

The Member States shall:

a publish the call for expression of interest on the websites of their competent authorities and of their competent bodies which undertake tasks similar to those of the Authority;

b inform relevant scientific organisations located on their territory;

c encourage potential candidates to apply; and

d take any other appropriate measures to support the call for expression of interest.;

(b) the following paragraphs are inserted:

5a. The members of the Scientific Committee who are not members of Scientific Panels and the members of the Scientific Panels shall be selected and appointed in accordance with the following procedure:

a on the basis of the applications received to a call for expression of interest, the Executive Director shall draw up a draft list of suitable candidates including at least twice the number of candidates necessary to fill the posts in the Scientific Committee and the Scientific Panels and send the draft list to the Management Board, indicating the specific multidisciplinary expertise needed in each Scientific Panel;

b on the basis of that draft list, the Management Board shall appoint the members of the Scientific Committee who are not members of the Scientific Panels and the members of the Scientific Panels and

draw up the reserve list of candidates for the scientific Committee and the Scientific Panels;

c the selection procedure and the appointments of the members of the Scientific Committee who are not members of the Scientific Panels and the members of the Scientific Panels shall be made on the basis of the following criteria:

(i) a high level of scientific expertise;

(ii) independence and absence of conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementation of that policy in respect of the members of the Scientific Panels;

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

d where candidates have equivalent scientific expertise, the Management Board shall ensure that the broadest possible geographical distribution is achieved in the appointments.

5b When the Authority identifies that specific expertise is missing in one or several Scientific Panels, the Executive Director shall propose to the Management Board, in accordance with the procedure laid down in paragraphs 5 and 5a, the appointment of additional members of the relevant Scientific Panels.

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

5d Member States and employers of the members of the Scientific Committee and of the Scientific Panels shall refrain from giving those members, or the external experts participating in the working groups of the Scientific Committee or the Scientific Panels, any instruction which is incompatible with the individual tasks of those members and experts, or with the tasks, responsibilities and independence of the Authority.

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

5f Each Scientific Panel shall include a maximum of 21 members.

5g Members of Scientific Panels shall have access to comprehensive training on the risk assessment.;

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

(b) the number of members in each Scientific Panel but no more than the maximum number provided for in paragraph 5f.;

(6) the following Articles are inserted:

Article 32a

Pre-submission advice

1 Where Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion, the staff of the Authority shall, at the request of a potential applicant or notifier, provide advice on the rules applicable to, and the content required for, the application or notification, prior to its submission. Such advice provided by the staff of the Authority shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Scientific Panels. The staff of the Authority providing the advice shall not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application or notification that is the subject of the advice.

2 The Authority shall publish general guidance on its website regarding the rules applicable to, and the content required for, applications and notifications, including, where appropriate, general guidance on the design of required studies.

Article 32b

Notification of studies

1 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.

2 For the purposes of paragraph 1, 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.

3 For the purposes of paragraph 1, laboratories and other testing facilities located in the Union shall also, without delay, notify the Authority of the title and the scope of any study commissioned by business operators and carried out by such laboratories or other testing facilities to support an application or a notification, its starting and planned completion dates, as well as the name of the business operator who commissioned such a study.

This paragraph shall also apply, *mutatis mutandis*, to laboratories and other testing facilities located in third countries insofar as set out in relevant agreements and arrangements with those third countries, including as referred to in Article 49.

4 An application or notification shall not be considered valid or admissible where it is supported by studies that have not been previously notified in accordance with paragraph 2 or 3, unless the applicant or notifier provides a valid justification for the non-notification of such studies.

Where studies have not been previously notified in accordance with paragraph 2 or 3, and where a valid justification has not been provided, an application or notification may be re-submitted, provided that the applicant or notifier notifies to the Authority those studies, in particular their title and their scope, the laboratory or testing facility carrying them out as well as their starting and planned completion dates.

The assessment of the validity or the admissibility of such re-submitted application or notification shall commence six months after the notification of the studies pursuant to the second subparagraph.

5 An application or notification shall not be considered valid or admissible, where studies that have previously been notified in accordance with paragraph 2 or 3 are not included in the application or notification, unless the applicant or notifier provides a valid justification for the non-inclusion of such studies.

Where the studies which have previously been notified in accordance with paragraph 2 or 3 were not included in the application or notification, and where a valid justification has not been provided, an application or notification may be resubmitted, provided that the applicant or notifier submits all the studies that were notified in accordance with paragraph 2 or 3.

The assessment of the validity or admissibility of such re-submitted application or notification shall commence six months after the submission of the studies pursuant to the second subparagraph.

6 Where the Authority detects, during its risk assessment, that studies notified in accordance with paragraph 2 or 3 are not included in the corresponding application or notification in full, and in the absence of a valid justification of the applicant or notifier to that effect, the applicable time limits within which the Authority is required to deliver its scientific output shall be suspended. That suspension shall end six months after the submission of all data of those studies.

7 The Authority shall make public the notified information only in cases where it received a corresponding application or notification and after the Authority has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e.

8 The Authority shall lay down the practical arrangements for implementing the provisions of this Article, including arrangements for requesting and making public the valid justifications in the cases referred to in paragraphs 4, 5 and 6. Those arrangements shall be in accordance with this Regulation and other relevant Union law.

Article 32c

Consultation of third parties

1 Where the relevant Union law provides that an approval or an authorisation, including by means of a notification, may be renewed, the potential applicant or notifier for the renewal shall notify the Authority of the studies it intends to perform for that purpose, including information on how the various studies are to be carried out to ensure compliance with regulatory requirements. Following such notification of studies, the Authority shall launch a consultation of stakeholders and the public on the intended studies for renewal, including on the proposed design of studies. Taking into account the received comments from the stakeholders and the public which are relevant for the risk assessment of the intended renewal, the Authority shall provide advice on the content of the intended renewal application or notification, as well as on the design of the studies. The advice provided by the Authority shall be without prejudice and non-committal as to the subsequent assessment of the applications or notifications for renewal by the Scientific Panels.

2 The Authority shall consult stakeholders and the public on the basis of the non-confidential version of the application or notification made public by the Authority in accordance with Articles 38 to 39e, and immediately after such disclosure to the public, in order to identify whether other relevant scientific data or studies are available on the subject matter concerned by the application or notification. In duly justified cases, where there is a risk that the results of the public consultation performed in accordance with this paragraph cannot be given proper consideration because of the applicable time limits within which the Authority is required to deliver its scientific output, those time limits may be extended for a maximum period of seven weeks. This paragraph is without prejudice to the Authority's obligations under Article 33 and does not apply to the submission of any supplementary information by the applicants or notifiers during the risk assessment process.

3 The Authority shall lay down the practical arrangements for implementing the procedures referred to in this Article and Article 32a.

Article 32d

Verification studies

Without prejudice to the obligation on applicants to demonstrate the safety of a subject matter submitted to a system of authorisation, the Commission, in exceptional circumstances of serious controversies or conflicting results, may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.;

(7) Article 38 is amended as follows:

(a) paragraph 1 is replaced by the following:

1. The Authority shall carry out its activities with a high level of transparency. It shall in particular make public:

a agendas, participant lists and minutes of the Management Board, the Advisory Forum, the Scientific Committee and the Scientific Panels and their working groups;

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

c scientific data, studies and other information supporting applications, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion, taking into account the protection of confidential information and the protection of personal data in accordance with Articles 39 to 39e;

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

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

f its scientific studies in accordance with Articles 32 and 32d;

g the annual report of its activities;

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

i a summary of the advice provided to potential applicants at pre-submission phase pursuant to Articles 32a and 32c.

Information referred to in the first subparagraph shall be made public without delay, with the exception of the information referred to in point (c) thereof, as far as applications are concerned, and in point (i) thereof, which shall be made public without delay once an application has been considered valid or admissible.

The information referred to in the second subparagraph shall be made public in a dedicated section of the Authority's website. That dedicated section shall be publicly available and easily accessible. That information shall be available to be downloaded, printed and searched through in an electronic format.;

(b) the following paragraph is inserted:

1a. The disclosure of the information referred to in points (c), (d) and (i) of the first subparagraph of paragraph 1 to the public shall be without prejudice to:

a any existing rules concerning intellectual property rights which set out limitations on certain uses of the disclosed documents or their content; and

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

The disclosure to the public of the information referred to in point (c) of the first subparagraph of paragraph 1 shall not be considered to be explicit or implicit permission or licence for the relevant data and information and their content to be used, reproduced, or otherwise exploited in breach of any intellectual property right or data exclusivity rules, and the Union shall not be responsible for its use by third parties. The Authority shall ensure that clear undertakings or signed statements are given to that effect by those who access the relevant information prior to its disclosure.;

(c) paragraph 3 is replaced by the following:

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

(8) Article 39 is replaced by the following:

Article 39

Confidentiality

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

2 Upon the request of an applicant, the Authority may grant confidential treatment only with respect to the following items of information where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree:

a the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;

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

c commercial information revealing sourcing, market shares or business strategy of the applicant; and

d quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety.

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

4 Notwithstanding paragraphs 2 and 3:

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

b information which forms part of conclusions of scientific outputs, including scientific opinions, delivered by the Authority and which relate to foreseeable effects on human health, animal health or the environment, shall nevertheless be made public.;

(9) the following Articles are inserted:

Article 39a

Confidentiality request

1 When submitting an application, supporting scientific data and other supplementary information in accordance with Union law, the applicant may request certain parts of the information submitted to be treated as confidential in accordance with Article 39(2) and (3). Such request shall be accompanied by verifiable justification that demonstrates how making public the information concerned significantly harms the interests concerned in accordance with Article 39(2) and (3).

2 Where an applicant submits a confidentiality request, it shall provide a non-confidential version and a confidential version of the information submitted in

accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall not include the information the applicant deems confidential on the basis of Article 39(2) and (3) and shall indicate the places where such information has been deleted. The confidential version shall contain all information submitted, including information the applicant deems confidential. Information requested to be treated as confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate the grounds on the basis of which confidentiality is requested for the different pieces of information.

Article 39b

Decision on confidentiality

1 The Authority shall:

a make public the non-confidential version of the application as submitted by the applicant without delay once that application has been considered valid or admissible;

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

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

d adopt a reasoned decision on the confidentiality request, taking into account the observations of the applicant, within 10 weeks of the date of receipt of the confidentiality request with respect to applications and without delay in the case of supplementary data and information; notify the applicant of its decision and provide information on the right to submit a confirmatory application in accordance with paragraph 2; and inform the Commission and the Member States, where appropriate, of its decision; and

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

2 Within two weeks of the notification of the Authority's decision on the confidentiality request to the applicant pursuant to paragraph 1, the applicant may submit a confirmatory application asking the Authority to reconsider its decision. The confirmatory application shall have suspensive effect. The Authority shall examine the grounds for the confirmatory application and shall adopt a reasoned decision on that confirmatory application. It shall notify the applicant of that decision within three weeks of submitting the confirmatory application and shall include in that notification information on the available remedies, namely an action before the Court of Justice of the European Union (the “Court of Justice”) against the Authority pursuant to paragraph 3. The Authority shall make public any additional data and information for which the confidentiality request has not been accepted by the Authority as justified, at the earliest two weeks after the notification of the Authority's reasoned decision on the confirmatory application to the applicant has taken place pursuant to this paragraph.

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

Article 39c

Review of confidentiality

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

Article 39d

Obligations with regard to confidentiality

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

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

3 If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of information as granted by the Authority in accordance with Articles 39 to 39e. The application shall be considered withdrawn as of the moment the written request to that effect is received by the competent body that had received the original application. Where the withdrawal of the application takes place before a final decision on the confidentiality request has been adopted by the Authority pursuant to, where appropriate, Article 39b(1) or (2), the Commission, the Member States and the Authority, shall not make public the information for which confidentiality has been requested.

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

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

regards Article 39b(2), the Authority shall ensure that appropriate separation of tasks is applied for the assessment of confirmatory applications.

Article 39e

Protection of personal data

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

a the name and address of the applicant;

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

c the names of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any other ad hoc group meeting on the subject matter.

2 Notwithstanding paragraph 1, disclosure of names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information shall be deemed to significantly harm the privacy and the integrity of those natural persons and shall not be made publicly available unless otherwise specified in Regulations (EU) 2016/679[(1)] and (EU) 2018/1725[(2)] of the European Parliament and of the Council.

3 Regulations (EU) 2016/679 and (EU) 2018/1725 shall apply to the processing of personal data carried out pursuant to this Regulation. Any personal data made public pursuant to Article 38 of this Regulation and this Article shall only be used to ensure the transparency of the risk assessment under this Regulation and shall not be further processed in a manner that is incompatible with these purposes, in accordance with point (b) of Article 5(1) of Regulation (EU) 2016/679 and point (b) of Article 4(1) of Regulation (EU) 2018/1725, as the case may be.

Article 39f

Standard data formats

1 For the purposes of point (c) of Article 38(1) and in order to ensure the efficient processing of requests to the Authority for a scientific output, standard data formats shall be adopted in accordance with paragraph 2 of this Article to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union law. Those standard data formats shall:

a not be based on proprietary standards;

b ensure interoperability with existing data submission approaches to the extent possible;

c be user-friendly and adapted for the use by small and medium-sized enterprises.

2 For the adoption of standard data formats referred to in paragraph 1, the following procedure shall be followed:

a the Authority shall draw up draft standard data formats for the purposes of the different authorisation procedures and relevant requests for a scientific output by the European Parliament, by the Commission and by the Member States;

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

c the Authority shall make the standard data formats, as adopted, available on its website;

d where standard data formats have been adopted pursuant to this Article, applications as well as requests for a scientific output, including a scientific opinion by the European Parliament, by the Commission and by the Member States, shall only be submitted in accordance with those standard data formats.

Article 39g

Information systems

The information systems operated by the Authority to store its data, including confidential and personal data shall be designed in a way that guarantees that any access to it is fully auditable and that the highest standards of security appropriate to the security risks at stake are attained, taking into account Articles 39 to 39f.;

(10) in Article 40(3), the second subparagraph is replaced by the following:

The Authority shall make public all scientific outputs including the scientific opinions issued by it and supporting scientific data and other information in accordance with Articles 38 to 39e.;

(11) Article 41 is amended as follows:

(a) paragraph 1 is replaced by the following:

1. Notwithstanding the rules on confidentiality provided for in Articles 39 to 39d of this Regulation, Regulation (EC) No 1049/2001 of the European Parliament and of the Council[3] shall apply to documents held by the Authority.

Where environmental information is concerned, Regulation (EC) No 1367/2006 of the European Parliament and of the Council[4] shall also apply. Directive 2003/4/EC of the European Parliament and of the Council[5] shall apply to environmental information held by Member States, notwithstanding the rules on confidentiality provided for in Articles 39 to 39d of this Regulation.;

(b) paragraph 2 is replaced by the following:

2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006 by 27 March 2020, ensuring as wide access as possible to documents in its possession.;

(12) Article 61 is replaced by the following:

Article 61

Review clause

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

2 By 28 March 2026, and every five years thereafter, the Commission shall evaluate the Authority's performance in relation to its objectives, mandate, tasks, procedures and location, in accordance with Commission guidelines. That evaluation shall also cover the impact of Article 32a on the functioning of the Authority with particular attention to the relevant workload and mobilisation of staff, and to any shifts in the allocation of the Authority's resources that may have taken place, at the expense of activities of public interest. That evaluation shall address the possible need to modify the mandate of the Authority, and the financial implications of any such modification.

3 In the evaluation referred to in paragraph 2, the Commission shall also evaluate whether the organisational framework of the Authority needs to be further updated with regard to decisions on requests for confidentiality and confirmatory applications, namely by setting up a specific Board of Appeal or by other appropriate means.

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

5 The Commission shall report to the European Parliament, to the Council and to the Management Board on the findings of its reviews and evaluations under this Article. Those findings shall be made public.;

(13) the following Article is inserted:

Article 61a

Fact-finding missions

Commission experts shall perform fact-finding missions in Member States to assess the application, by laboratories and by other testing facilities, of the relevant standards for carrying out tests and studies submitted to the Authority as part of an application, as well as compliance with the notification obligation set out in Article 32b(3), by 28 March 2025. By that date, Commission experts shall also perform fact-finding missions to assess the application of those standards by laboratories and other testing facilities located in third countries insofar as set out in relevant agreements and arrangements with those third countries, including as referred to in Article 49.

Non-compliance identified during those fact-finding missions shall be brought to the attention of the Commission, Member States, the Authority as well as the assessed laboratories and other testing facilities. The Commission, the Authority and Member States shall ensure the appropriate follow-up to such identified non-compliance.

The outcome of these fact-finding missions shall be presented in an overview report. On the basis of that report, the Commission shall submit a legislative proposal, if appropriate, as regards, in particular, any necessary control procedures, including audits..

(**1**) 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).

(**2**) 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).';

(**3**) 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).

(**4**) 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).

(**5**) 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).';

Status:
Point in time view as at 20/06/2019.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2019/1381 of the European Parliament and of the Council, Article 1.