QUESTIONS AND ANSWERS ON THE EFSA PRACTICAL ARRANGEMENTS

First publication: 30 March 2021

Last update: 28 August 2023

This document was first published on 30 March 2021 and updated on 28 August 2023. The updated version is intended as a guide for applicants submitting new applications and for applications for which the validity/admissibility check is still ongoing.

The document is republished using the new EFSA's logo and visual identity. A list of the changes introduced in this version is available in Annex 1. The main changes are highlighted in the document with a grey shading.

TABLE OF CONTENTS

QUESTIONS AND ANSWERS ON EFSA'S PRACTICAL ARRANGEMENTS

A. INTRODUCTION

Regulation (EU) 2019/1381,[1] the "Transparency Regulation" (TR), is applicable as of 27 March 2021. It amends Regulation (EC) No 178/2002,[2] the "General Food Law Regulation" (GFL), as well as eight other sectoral acts in the areas of genetically modified food and feed,[3] feed additives,[4] smoke flavourings,[5] food contact materials,[6] food improvement agents,[7] pesticides,[8] novel foods,[9] and genetically modified organisms.[10] As such, the new provisions introduced by the TR are not only relevant and applicable to the eight sectoral acts that were amended, but their impact is far greater: the new provisions of the GFL apply horizontally across all sectors covered by the latter, including for example the area of Health Claims.

The aim of the new regulation is to increase the transparency of risk assessment in the food chain, strengthen the reliability, objectivity and independence of the scientific studies submitted to EFSA, and ensure the long-term operational sustainability of EFSA. It was developed in response to a European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides" and the findings of the fitness check of the General Food Law Regulation that was completed in January 2018.

[1] 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 (OJ L 231, 6.9.2019, p. 1).

[2] Regulation (EC) No 178/2002 of the European Parliament and 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).

[3] 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)

[4] 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).

[5] 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).

[6] 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).

[7] 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).

[8] 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).

[9] 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).

[10] Directive 2001/18/EC 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).

Implementation of the TR – general observations

EFSA and DG SANTE have closely cooperated to ensure the proper implementation of the new Regulation in their respective fields of competence, ensuring the appropriate involvement of the EU Member States.

They have engaged stakeholders together on the basis of jointly agreed engagement principles: independence, transparency, openness, inclusiveness, flexibility, and non-duplication. Stakeholders have been informed about the implementation process through specific channels and meeting documents that were made public on the relevant dedicated webpages of EFSA and DG SANTE.

EFSA and DG SANTE have engaged through a number of dedicated meetings of a dedicated Sounding Board, Technical groups and the DG SANTE Advisory Group on the Food Chain and Animal and Plant Health, where information was shared and discussed and questions replied to where possible. In addition, EFSA has also engaged with stakeholders via a dedicated functional mailbox.

Implementation of the TR by EFSA

The TR empowers EFSA to develop detailed practical arrangements (i.e. binding rules) on how certain new provisions and procedures specified in the Regulation will operate in practice.

On 11 January 2021, EFSA published on its website[11] the following Practical Arrangements[12]:

- Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations;
- Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality;
- Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009

As prescribed by Article 39d(5) of the GFL that was amended by the TR, the Practical Arrangements concerning the confidentiality provisions were subject to a formal consultation with the European Commission, which delivered its opinion on 23 July 2020 (C(2020) 4836 final), representing the basis for the final version of the Practical Arrangements in question.

In accordance with the empowerment received under Articles 7(3) and 16(2) of Regulation (EC) No 1107/2009, EFSA consulted EU Member States on the draft Practical Arrangements concerning confidentiality through the section Phytopharmaceuticals – Pesticides Legislation of the Standing Committee on Plant Health, Animal Health, Food and Feed, in July, October, and December 2020.

EFSA also shared the draft Practical Arrangements with EU Member States and stakeholders for comments in November 2020, which were then discussed in November 2020 at the General Food

[11] https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements.

[12] In March 2020, EFSA already published Practical Arrangements on the processing of applications for access to documents and specifically implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006: https://www.efsa.europa.eu/sites/default/files/documents/wp200327-a2.pdf. The present document does not address questions concerning these EFSA Practical Arrangements.

Law Expert Group, the 2nd ad hoc DG SANTE Advisory Group meeting on the TR implementation, and the 3rd EFSA Sounding Board meeting.

Comments and questions received orally and in writing from stakeholders and Member States were taken into consideration during the finalisation, and before the sign off, of the Practical Arrangements.

This document provides answers to frequently asked questions (FAQs) by EU Member States and stakeholders that arose during the engagement process of the implementation of the TR. Questions on the interpretation of the provisions of the TR are out of the scope of this document which exclusively focuses on the EFSA Practical Arrangements.

The present FAQs do not offer any binding interpretation/position of EFSA and/or any other explanation as regards the provisions of the TR. The ultimate responsibility over the validity and interpretation of EU binding rules rests with the Court of Justice of the European Union.

EFSA portals that are of interest in this context are available here.

B. EFSA PRACTICAL ARRANGEMENTS ON PRE-SUBMISSION PHASE AND PUBLIC CONSULTATIONS

GENERAL ASPECTS

1. To which areas do the EFSA Practical Arrangements on pre-submission phase and public consultations apply?

The EFSA Practical Arrangements on pre-submission phase and public consultations (referred to as "EFSA Practical Arrangements" in Section B of the present document) aim at implementing Articles 32a, 32b and 32c of the GFL as amended by the TR. Regardless of whether and to what extent sectoral legislations have been amended by the Transparency Regulation, those Practical Arrangements are relevant for all areas which the different Transparency Regulation provisions apply to.

For instance, the provision of general pre-submission advice, outlined in Chapter II on General pre-submission advice, is available to potential applicants in all areas for which Union law contains provisions for the Authority to provide scientific output including a scientific opinion (e.g. Pesticides, MRLs, Feed Additives, Health Claims), with regard to potential applications for approvals or authorisations, for the renewal of approvals or authorisations, and also for the modification of the terms of approvals or authorisations when this is foreseen in applicable sectoral legislations. Conversely, again by way of example, the same provisions do not apply in the context of the authorisation at national level of plant protection products pursuant to Chapter III of Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ('Regulation (EC) 1107/2009') [13] since EFSA is not involved in such procedures.

[13] 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 (O) L 309, 24.11.2009, p. 1).

The same considerations apply to the EFSA Practical Arrangements implementing Articles 32b and 32c(1) (concerning applications for renewals only) and (2) of the GFL, as amended by the TR.

In some cases, the EFSA Practical Arrangements provide for specific rules applicable in the context of Regulation (EC) 1107/2009 and Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC ('Regulation (EC) No 396/2005').[14] Otherwise, the general provisions laid down in the EFSA Practical Arrangements apply to all other concerned areas/aspects.

As regards the re-evaluation by the Authority of the safety of food additives ('programme for the re-evaluation of food additives'), Commission Regulation (EU) No 257/2010 that sets up such a programme was recently amended by Commission Implementing Regulation (EU) 2021/148 to provide for levels of transparency and confidentiality in the context of this procedure that are comparable to those applicable in the context of the procedure for updating the Union list of approved food additives, while taking into account of the specificities of the re-evaluation procedure. As a consequence, the EFSA Practical Arrangements on pre-submission phase and public consultations apply to the extent that Commission Implementing Regulation (EU) 2021/148 refers to the provisions of the TR implemented by EFSA Practical Arrangements. This is particularly relevant as regards the provisions of new Articles 32a and 32c(2) of the GFL, implemented by Chapters II and V of EFSA Practical Arrangements respectively. Regarding the new Article 32b of the GFL, as a result of the adaptation of the procedure laid down in Commission Implementing Regulation (EU) 2021/148, only Articles 18-20 are relevant in the context of the re-evaluation of food additives.

2. As of when do the EFSA Practical Arrangements on pre-submission phase and public consultations apply?

In line with Article 11 of TR, the EFSA Practical Arrangements apply as of 27 March 2021. Moreover, in accordance with Article 10(1) of TR, the EFSA Practical Arrangements apply in the context of applications submitted on or after 27 March 2021.[15] For applications submitted before 27 March 2021 and their entire application lifecycle, this set of EFSA Practical Arrangements is not relevant.

In relation to the programme for the re-evaluation of food additives, Commission Implementing Regulation (EU) 2021/148 applies as of 27 March 2021 and to data and information submitted to EFSA or the Commission in relation to re-evaluation procedures launched and follow-up steps taken from that date. The EFSA Practical Arrangements are relevant insofar as Regulation (EU) 2021/148 applies.

3. What is intended by "potential applicant"?

The EFSA Practical Arrangements on pre-submission phase and public consultations defines "potential applicant" as any private or legal person that can profit from, or is subject to, pre-

[14] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (O) L 70, 16.3.2005, p. 1).

[15] Concerning the rules governing the renewal of approval of active substances, which have been revised in order to align them with the provisions of the TR, please check the website of the Commission here. The work programmes available there indicates to which substances Commission Implementing Regulation (EU) No 844/2012 continues to apply and to which substances new Commission Implementing Regulation (EU) No 2020/1740 applies. EFSA Practical Arrangements are relevant only for substances subject to Regulation (EU) No 2020/1740.

submission activities (which are in turn defined as activities foreseen in Chapters II, III, and IV of the EFSA Practical Arrangements).

The definition of "potential applicant" does not include "laboratories and testing facilities". This definition should therefore be intended as excluding laboratories and testing facilities in their role referred to in Article 32b of the GFL.

4. What falls within the definition of "study"?

The main objective of the notification obligation of commissioned/carried out studies pursuant to Article 32b of the GFL is to ensure that EFSA has prior knowledge of all studies performed by a business operator with a view to supporting an application under Union law. As a result, this goes beyond the studies conducted to demonstrate the safety of a substance or a product and includes all studies carried out for regulatory purposes and for which, pursuant to Union law, EFSA may or shall be requested to provide a scientific output, including a scientific opinion. EFSA must therefore ensure the effectiveness of this objective, while also taking into account the close links with the broader transparency requirement and the new Article 61a of the GFL on fact-finding missions, whereby the Commission is to verify compliance of the laboratories with the applicable standards and the notification obligation.

Given the above objective and the procedural consequences for non-compliance with the notification obligation of Article 32b of the GFL, to increase legal clarity the definition of study introduced in EFSA's Practical Arrangements is based on Directive 2004/10/EC on good laboratory practices[16] (GLP Directive). According to this definition, "study" means *an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data with respect to the properties and/or the safety of that test item, which is relevant for submission to appropriate regulatory authorities*.

By way of example, the definition includes stability, efficacy, and safety studies while more desk-oriented work such as literature research, bioinformatics studies and other studies not involving laboratories and testing facilities are excluded and, therefore, not subject to the provisions of Article 12 and Chapter IV of EFSA Practical Arrangements.

After two years' experience of implementation of the notification obligation of Article 32b of the GFL, as amended by the TR, it is understood that some analytical measurements should be exempted from the provisions of Chapters III and IV thereof: analyses to assess the identity/composition of a product, including the determination of its impurities and whole genome sequencing, and analyses to determine physico-chemical properties. Please note that for stability, as well as for studies to demonstrate absence from the product of viable cells and recombinant DNA of a production microorganism, a notification pursuant to Article 32b of the GFL is still required, even when submitted in the form of certificates of analysis and/or in the context of batch-to-batch variability analyses.

Moreover, with regard to method validation studies, these are not considered to fall within the definition of study laid down in the EFSA's Practical Arrangements, given that such studies are not meant to obtain data with respect to the properties and/or the safety of the test item.

[16] 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 (JO L 50, 20.02.2004, p. 40).

5. What is intended by "planned completion date of a study"?

The EFSA Practical Arrangements clarifies what is meant by the "planned completion date of a study", since this date must be indicated when submitting study notifications in the EFSA database. In particular, "planned completion date of a study" means the provisional date on which the study report is expected to be signed. In the specific case where the provisional date of the expected signature of the study report cannot be established, the planned completion date shall be determined as follows: (i) the planned completion date means the provisional date on which the study report is expected to be generated; (ii) if it is not possible to establish the provisional date of the generation of the study report and a laboratory analysis is generated, the planned completion means the provisional date of generating the final results. The second part of the definition can also be used in situations in which a formal study report is not foreseen (e.g. in case of in-house laboratory studies).

6. How does the registration of entities in the system developed by EFSA to support pre-submissions activities work?

Prior to initiating any pre-submission activities,[17] potential applicants and laboratories and testing facilities (insofar as they are subject to study co-notification obligations – see question 35) to which studies are commissioned, are required to register in the system developed by EFSA. The same goes for third parties representing such entities.

As regards multinational companies made up of several entities, any of these entities may register provided that the registered entity is recognised as having a separate legal personality under the national law of the country in which it has its registered office. As a general rule, there is no requirement indicating who should interact with EFSA as a potential applicant at pre-submission phase. However, with regard to the study notification (see question 35), the obligation falls on the business operator which has commissioned the study, although that obligation can be delegated to a third party authorised to represent the business operator having commissioned the study. Nevertheless, in both cases (i.e. the direct notification by the business operator or notification by a delegated third party), the business operator having commissioned the study must register in the system developed by EFSA.

Each registered entity is provided with one account associated to a contact. Up to six additional contacts can be added in relation to one account. Once this default limit of six additional contacts associated with a particular account is also reached, the possibility to create another further additional contact can be granted under particular circumstances e.g. each time that fifty study notifications are submitted in any given calendar month. A Detailed Guide for users on how to register is available on EFSA's website here.

7. How does the pre-application identification ('ID') work?

Prior to initiating any pre-submission activity, potential applicants must request EFSA to provide a pre-application identification ('ID'). Any pre-submission activity (e.g. a request for general pre-submission advice, the notification of the list of intended studies for renewal or the submission of a study notification) must be linked to a pre-application ID in order to be considered valid. The preapplication ID works as a folder in which all pre-submission activities undertaken by a potential applicant to support a future application are reported. As a minimum requirement, each

[17] Separate registrations are foreseen for the IT systems made available by the Commission or EFSA for the electronic submissions of applications (i.e. e-Submissions Food Chain Platform and IUCLID).

preapplication ID requested by potential applicants has to be linked to a specific regulated product in a given regulated product area. As a general rule, it is recommended to request no more than one pre-application ID relating to the same specific regulated product in a given regulated product area, although it is acknowledged that for certain procedures exceptions to this principle are possible.

Notwithstanding the abovementioned conditions, the system is sufficiently flexible to allow potential applicants to organise pre-submission activities, including study notifications, in the way they consider most appropriate within the applicable legal framework.

Pre-application IDs can be requested by a single potential applicant or by a potential applicant on behalf of a group of potential applicants. In both cases, it is possible to include, at a later stage, additional potential applicants under an already assigned pre-application ID.

Potential applicants jointly involved in pre-application activities under the same pre-application ID are not required, in principle, to request more than one pre-application IDs in relation to the same regulated product and regulated product area. However, should one of the potential joint applicants wish to seek general pre-submission advice separately or notify studies without sharing them with the other potential applicants jointly involved to avoid sharing confidential issues, they could activate an additional individual pre-application ID. When the joint application will be submitted, all the preapplication IDs need to be reported.

As regards the procedure for the renewal of approval of active substances pursuant to Commission Regulation (EU) No 2020/1740, it is recommended that potential applicants planning to request the renewal of approval of the same active substance act in a coordinated manner during the pre-submission phase. This is made possible by the fact that, following the notification of the list of the intended studies for renewal by one potential applicant (see questions 22, 23, 24), a public consultation will be carried out. In this way, the initiative of the potential applicant will be brought to the attention of other potential applicants interested in the renewal of approval of the same active substance, who will therefore be able to contact the first potential applicant and agree on future coordinated activities. The functionalities of the pre-application ID support such process.

When submitting the application through the IT system made available by the Commission or the EFSA for the submission of such applications, the applicant is required to indicate each pre-application IDs associated to the pre-submission activities carried out in relation to the specific regulated product. Depending on the approach followed by the applicant when notifying studies at pre-submission phase, one or more pre-application IDs will need to be indicated.

GENERAL PRE-SUBMISSION ADVICE

8. Do EFSA's Practical Arrangements apply to requests for pre-submission advice addressed to Member State competent authorities?

The Practical Arrangements on pre-submission phase and public consultations do not apply to requests for pre-submission advice addressed to Member State competent authorities. The Practical Arrangements regulate the procedures for requesting pre-submission advice, and the provision of such advice by EFSA staff in all areas for which Union law contains provisions for EFSA to provide a scientific output including a scientific opinion, with regard to potential applications for approvals or authorisations, for the renewal of approvals or authorisations but

also for the modification of the terms of approvals or authorisations when this is foreseen in applicable sectoral legislation or otherwise provided in Commission Implementing Acts.

As regards requests by potential applicants to EFSA for the provision of general pre-submission advice in the areas of Regulations (EC) No 1107/2009 and 396/2005, the EFSA Practical Arrangements also provide for the procedures according to which EFSA involves the relevant national competent authorities in the provision of the advice. However, the EFSA Practical Arrangements do not regulate the provision of pre-submission advice in the areas of Regulations (EC) No 1107/2009 and 396/2005, when this is requested by the potential applicants to the national competent authorities. In the latter case, the pre-submission advice is provided according to the procedures established at national level.

9. As of when can general pre-submission advice be requested?

For further details in this respect, reference may be made to the answer provided to question 2. As regards general pre-submission advice pursuant to Article 32a of the GFL and Chapter II of the EFSA Practical Arrangements, potential applicants are able to address to EFSA staff requests for general pre-submission advice as from 27 March 2021.

As of that date, potential applicants are free to request to EFSA general pre-submission advice at any time before the submission of the application/notification, provided that a pre-application ID has been requested. Based on past experience, EFSA recommends submitting the request at least six (6) months before the envisaged submission date of the application, since asking advice later could make it difficult for the potential applicant wishing to adapt the content of the application to the advice received. In any case, the advice shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the EFSA scientific panels, i.e. the advice is a recommendation which should by no means be considered as mandatory requirement for potential applicants.

10. On which aspects can EFSA provide general pre-submission advice?

In the context of general pre-submission advice, the questions addressed to EFSA must focus on the rules applicable to, and the content required for, the application (see recital (20) of TR which explains the rationale of Article 32a of the GFL). In this context, the general pre-submission advice service aims at explaining to the potential applicants the relevant requirements, located in the applicable rules or in guidance documents or guidelines and the advice provided cannot go beyond this scope. In particular, in accordance with Article 6(2) of the EFSA Practical Arrangements on pre-submission phase and public consultations, the general pre-submission advice shall not address the design of studies. Nevertheless, to a limited extent and an on exceptional basis, EFSA may provide general explanations about the design of studies only if and insofar as the study design is addressed in general guidance documents developed by the Authority. EFSA cannot provide advice on specific requests on how to develop and manage a study, hypothesis to be tested, etc. In addition, EFSA cannot comment on any proposed design, and cannot validate any protocol as this remains the applicant's responsibility. Furthermore, the assessment of the qualification of the specific regulated product under a given regulated product area remains the responsibility of the risk manager and related questions are out of the scope of the general pre-submission advice. The advice provided should be general and abstractly transposable to all potential applicants who intend to submit an application for the same regulated product under the same regulated product area. Questions which go beyond the admitted scope will be rejected following the administrative check. International guidelines as such are out of the scope of EFSA prerogatives when providing general pre-submission advice.

11. How can general pre-submission advice be requested?

As described earlier on in this document, prior to requesting general pre-submission advice, potential applicants must register in the system developed by EFSA to support pre-submission activities (see question 6) and obtain a pre-application ID (see question 7). When submitting a pre-submission advice request to EFSA, potential applicants must provide background information on the request and ensure that an exhaustive list of questions they would like the Authority to address is provided. The level of information expected to be provided is that which enables EFSA to understand the concerns/doubts of the potential applicants and to advise them as constructively as possible. The general pre-submission advice is a service provided by EFSA and the quality and usefulness of this service depends on the clarity and precision of the questions received. As best practice, EFSA suggests that the questions should be formulated in a concise and clear manner, be numbered, and make precise reference to the rules or guidance document which they concern.

Attention should also be paid to the fact that the questions addressed to EFSA should not concern aspects which are excluded from the permitted scope.

12. How many requests for general pre-submission advice can be addressed to EFSA?

As part of the empowerment given to EFSA by the TR for implementing Article 32a of THE GFL, EFSA had to strike a balance between the interest of the potential applicants to receive support to meet the applicable specifications and that of good administration. As a result, the EFSA Practical Arrangements set the number of requests for general pre-submission advice at a maximum of two per pre-application ID, providing that the same questions are not repeated at both requests. Nevertheless, if a request is rejected because for example does not fall within the permitted scope (see question 10), this will not be considered for the calculation of the afore-mentioned maximum number.

If, following a first request for general pre-submission advice, the potential applicant has follow-up questions or further new questions, these may be included in a second request, provided that they do not overlap with questions already submitted.

Separate measures will be in place to facilitate the access to general pre-submission advice for small and medium-sized enterprises.

13. Will EFSA provide a justification when rejecting requests for general pre-submission advice?

In order to maximise the service offered by the EFSA to potential applicants, in the event that certain elements of requests for pre-submission advice are rejected by EFSA, the Authority will outline the reasons behind such non-acceptance in a clear and concise manner.

14. On which basis will EFSA decide whether to reply in writing or to organise a meeting in response to a request for general pre-submission advice?

EFSA's decision whether to provide general pre-submission advice in writing or in the framework of a meeting (preferably by teleconference or video conference) will be taken on a case-by-case

basis. As explained above (see question 11), follow-up questions can be posed by way of a second request, providing that the maximum number of two requests has not yet been reached.

For small and medium-sized enterprises (SMEs), EFSA may opt to reply to their request preferably in a meeting, so as to provide closer support and to ensure that the potential applicants understand the requirements.

15. How long does EFSA take to provide general pre-submission advice?

Requests for general pre-submission advice first undergo an administrative check to verify that they have been submitted in accordance with the prescribed modalities and the related questions fall within the permitted scope. Potential applicants are informed about whether EFSA accepts or rejects a request within fifteen (15) working days from the receipt of the request. Clarification may be requested at this stage in case that additional information is needed to decide on the acceptability of a request. Subsequently, for requests or questions replied in writing, the general pre-submission advice is provided within fifteen (15) working days from the acceptance. In the case of requests or questions in response of which EFSA decides to organise a meeting, the general pre-submission advice is provided during the meeting which is held within twenty (20) working days from the acceptance. In practice, the whole process takes at the latest thirty (30) working days (for general pre-submission advice provided in writing) or thirty-five (35) working days (for general pre-submission advice provided during a meeting) from the receipt of the request.

16. Can EFSA consult EFSA Scientific Panels before providing general pre-submission advice?

As explained above (see question 10), EFSA can provide general pre-submission advice on the rules applicable to, and the content required for, the application. Therefore, consultation of Scientific Panels is neither necessary nor appropriate. It should also be borne in mind that, pursuant to Article 32a of the GFL, EFSA staff providing pre-submission advice cannot be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application that is the subject of the advice. Concerning the non-committal nature of the general pre-submission advice, please refer to question 21.

17. Which information will be included in the summary of the general pre-submission advice?

The summary of the general pre-submission advice provides a succinct overview of the advice provided to the potential applicant. As such, it does not contain any confidential information. Therefore, once drawn up, it is made available to the requester for information purposes only.

18. Will applicants be given the possibility to review the summary of the general pre-submission advice prior to its publication?

Potential applicants will receive the summary of the general pre-submission advice for information purposes only. The summary does not contain any confidential information and therefore confidentiality requests may not be submitted.

19. When is the summary of the general pre-submission advice made public?

The summary of the general pre-submission advice is made public without delay once a corresponding application has been submitted and considered valid or admissible. Before that moment, the summary will not be disclosed. As regards the general pre-submission advice itself and the information provided in the request, including the background information and the list of questions, these are not subject to proactive disclosure even after the corresponding application has been considered valid or admissible.

20. What about the general pre-submission advice provided in the areas of pesticides and MRLs?

The authorisation procedures in the areas of pesticides and maximum residues levels foresee the involvement of national competent authorities at different levels. It is therefore important that, in those areas, the general pre-submission advice is provided by EFSA in close cooperation with the relevant national competent authorities, e.g. in the area of MRLs either the Rapporteur Member State in the case of import tolerances or the Evaluation Member State (EMS) for all other MRL setting procedures.

In order to allow such a cooperation to take place, potential applicants are required to indicate which national competent authority should be involved. In the case of envisaged applications for renewal of approval of active substances pursuant to Commission Regulation (EU) No 2020/1740 (further information available here), EFSA is required to inform the designated rapporteur Member State of the request and to decide jointly with that national competent authority whether the designated co-rapporteur Member State is also required to participate in providing the general pre-submission advice. As a result, EFSA can only accept requests for general pre-submission advice for active substances for which the renewal procedure has been already allocated to a rapporteur Member State/co-rapporteur Member State. Moreover, should the potential applicant fail to indicate the rapporteur Member States/co-rapporteur Member State, the request for general pre-submission will be rejected.

The timelines for the provision of general pre-submission advice are slightly adjusted to allow for the necessary interaction between EFSA and the national competent authority concerned. The administrative check will be completed within fifteen (15) working days at the latest, and the general pre-submission advice will be provided within twenty (20) working days of acceptance both for requests or questions replied in writing and for requests or questions in response to which EFSA decides to organise a meeting.

21. What is the significance of the fact that the general pre-submission advice is not committal?

First, the general pre-submission advice is non-committal for the applicants in the sense that they can decide to draw up an application fully or partially deviating from the advice received by EFSA or by EFSA in collaboration with relevant national competent authority.

Moreover, the general pre-submission advice is non-committal for EFSA and its Scientific Panels and, when applicable, the Member States with regard to the subsequent assessment of the applications. This means that EFSA or the Member States will not be bound by what was advised during the pre-submission phase when assessing the application.

Despite the non-committal nature of the general pre-submission advice, the system is organised in such a way as to allow the entities responsible to assess the validity/admissibility of the application and subsequently to perform the risk assessment to get access to the advice provided by EFSA staff during the pre-submission phase. This is possible thanks to the fact that, when submitting an application, the applicant is required to indicate each pre-application ID associated to any pre-submission activities carried out by the applicant in relation to the specific regulated product which is the subject of the application.

INTENDED APPLICATIONS FOR RENEWAL

22. From when will the new provisions on intended applications for renewal apply?

The new provisions laid down in Article 32c(1) of the GFL and the corresponding rules laid down in EFSA's Practical Arrangements (i.e. Chapter III) specifically concern the intended application for renewals and are not relevant for other types of applications. Reference should be made to the answer provided to question 2. These provisions apply from 27 March 2021. This means that a potential applicant seeking the renewal of an authorisation or approval will be subject to those provisions only if, on or after 27 March 2021, still intends to commission or carry out a new study in support of a future renewal. If a study has been commissioned or started before 27 March 2021, there is no obligation to notify it as an intended study, even if on 27 March 2021 is still ongoing. If no new studies are planned to support the renewal application, Article 32c(1) of the GFL does not apply.

The above provisions do not anyway apply to applications for renewal submitted before 27 March 2021 and this is valid for their entire application life cycle.

22b. What is meant by an "intended study"?

"Intended study" means a study that the business operator plans to conduct to support a potential application for the renewal of an approval or authorisation, which has not yet started or commissioned to a laboratory/external testing facility.

23. How do potential applicants notify the list of intended studies?

As described earlier on in this document, prior to notifying the intended studies for renewal, potential applicants must register in the system developed by EFSA (see question 6) and obtain a pre-application ID (see question 7) if this has not yet been done for the purpose of other pre-submission activities linked to the same intended application for renewal.

The notification of the intended studies for renewal consists of the submission by the potential applicant of a complete list of studies it intends to perform for the purpose of supporting an application for renewal. This must be done in the form of a single submission per pre-application ID in a dedicated section of EFSA database ('List of intended studies for renewals' section).

The notification of the intended studies is instrumental to the provision by EFSA of renewal pre-submission advice for the benefit of potential applicants for renewals. In this context, unlike the general pre-submission advice, EFSA is mandated to provide advice not only on the content of the intended renewal application but also on the design of the studies. To enable EFSA to provide the best possible service, it is necessary that the concerned potential applicants, for each of the studies included in the list, submit information related to certain data requirements (see Annex I

to EFSA Practical Arrangements). The tool developed by EFSA for implementing the notification of intended studies is structured through data elements and dropdown menus almost identical to the Article 32b notification to facilitate the selection of the mandatory information and potential consequent notification according to article 32b of the GFL. The more accurate the information provided, the better the service provided to the potential applicant.

With specific reference to the study design, it is mandatory to indicate either the study guideline/guidance document followed by the study from the provided pick list or, if the intended study does not follow any study guideline available in the pick list, additional reference guidance documents or the description of the design of the study including the hypothesis to be specified in the study design description field. In addition, EFSA recommends potential applicants to also submit the detailed proposed study protocol intended as detailed information and further elaborating methodology, statistical considerations, and organisation of the study. The protocol can also give the background and *rationale* of the study. The information about the proposed study protocol is optional, however if provided it contributes to a more precise and accurate renewal pre-submission advice.

For what concerns the intended applications for the renewal of approval of existing active substances pursuant to Commission Implementing Regulation (EU) No 2020/1740, when submitting the list of intended studies, the potential applicant is required to indicate the designated rapporteur Member State. This, because this Regulation states that the pre-submission advice by EFSA pursuant to Article 32c(1) of the GFL is be provided with the participation of the rapporteur Member State and the co-rapporteur Member State. Therefore, the process cannot start before the rapporteur Member State and the co-rapporteur Member State are designated by the Commission. Please refer to question 20 also.

24. When does the list of intended studies for renewal have to be submitted?

There is no legal requirement imposing a specific timeline. However, the EFSA Practical Arrangements recommend that potential applicants for renewal notify all intended studies at least five (5) months before the date of the intended commissioning of such studies to a laboratory/external testing facility (for commissioned studies) or intended starting date (for studies carried out in in-house laboratory/testing facility).

In the relation to intended applications for the renewal of approval of existing active substances, the potential applicant must wait for the designation of the rapporteur Member State/co-rapporteur Member State.

25. What happens following the notification of the intended studies for renewal pursuant to Article 32c(1) of the GFL?

Following the notification by the potential applicant of the intended studies for renewal, as outlined in Article 32c(1) of the GFL and Chapter III of the EFSA Practical Arrangements, EFSA takes the necessary steps to carry out the consultation of the stakeholders and the public (see question 26) and to provide the renewal pre-submission advice (questions 27, 28, 29 and 30).

Nevertheless, as provided for in Article 32c(1) of the GFL and Article 16 of the EFSA Practical Arrangements, the renewal pre-submission advice is a service for the potential applicant and noncommittal neither for EFSA, nor for the potential applicant itself. Therefore, the potential applicant can either wait for the renewal pre-submission advice before taking any other step, or

proceed with the commissioning/initiation of the same studies, notifying them in the EFSA database pursuant to Article 32b of the GFL, without waiting for the renewal pre-submission advice.

26. How does the public consultation at pre-submission phase work?

Upon receipt of the list of the intended studies for renewal and the information notified in relation to each study included in the list, EFSA carries out an administrative check, which is normally completed within ten (10) working days. This step consists of a check on the completeness/clarity of the information provided by the potential applicant before this information is exposed to third parties for consultation. If need be, EFSA can request the potential applicant to submit any missing information within a deadline which is established case-by-case depending on the type/amount of elements the potential applicant is required to provide.

Upon conclusion of the administrative check, EFSA launches the public consultation which lasts three (3) calendar weeks, highlighting the concerned regulated product and indicating that comments received which are relevant for the risk assessment of the specific renewal sought will be taken into account by EFSA when providing renewal pre-submission advice. In this timeframe, third parties (stakeholders and the general public) can submit comments.

Subsequently, following the closure of the consultation, all comments received by stakeholders and the public are made public by EFSA without delay after the closing date of the consultation. Upon request, the identity of individuals who submitted comments in their personal capacity will not be disclosed.

The purpose of the public consultation is to allow EFSA and, ultimately the potential applicant, to benefit from the experience and knowledge which already exist due to the fact that the regulated product in question has already been on the market for several years. In this sense, EFSA reviews the comments received from stakeholders and the general public and takes them into consideration when providing renewal pre-submission advice insofar as they are relevant for the risk assessment of the intended renewal application. Whether a comment is to be considered relevant or not is the result of a case-by-case assessment. The results of the public consultation, meaning the explanation how relevant comments have been considered and if not, the reasons why, are reported in the summary of renewal pre-submission advice drawn up by EFSA.

27. How is the renewal pre-submission advice organised?

After the review of the comments received from stakeholders and the public and the identification of those which are considered relevant, EFSA provides advice to the potential applicant. Unlike the context of the general pre-submission advice, the specific pre-submission advice for renewals focuses not only on the content of the intended application but also on the design of studies proposed by the potential applicant. The working procedures are similar to those foreseen for the provision of the general pre-submission advice (see question 14): the default option is that the advice is provided in writing while meetings (preferably by tele-conference or video-conference) are organised only if EFSA considered this necessary.

All pre-submission activities, including those foreseen in Article 32c(1) of the GFL and Chapter III of the EFSA Practical Arrangements, have to be undertaken in association with a pre-application ID previously obtained by the potential applicant. As explained (see question 7), the latter can be requested by a single potential applicant or by a potential applicant on behalf of a

group of potential applicants. In both cases, it is possible to include, at a later stage, additional potential applicants under an already assigned pre-application ID. The renewal pre-submission advice is provided by EFSA either to the individual potential applicant or to the group of potential applicants.

28. How long does it take for EFSA to provide renewal pre-submission advice?

Following the receipt of the list of intended studies, EFSA carries out an administrative check which is usually completed within ten (10) working days, unless it is found that certain information is missing. The launching of the public consultation takes approximately additional ten (10) working days. The public consultation lasts 3 calendar weeks. Subsequently, in both cases (advice provided in writing or pre-submission advice meetings), EFSA provides advice within thirty (30) working days after the closure of the public consultation. Unless there is the need for further information from the potential applicant in the context of the administrative check, the process takes sixty-five (65) working days from the receipt of the notification of the list of intended studies.

28b. In which circumstances the pre-submission activities related to the renewal pre-submission advice can be interrupted by EFSA?

The activities described under Chapter III of the EFSA Practical arrangements will be interrupted by EFSA in the following cases:

- the notified list of intended studies for renewal actually contains only studies that can no longer be considered as "intended" because they have already started or been commissioned to a laboratory;
- the corresponding renewal application has been submitted.

In such cases, the public consultation on the intended studies for renewal will not be launched and/or the subsequent renewal pre-submission advice will not be provided.

29. How is the renewal pre-submission advice organised in the area of pesticides?

Similarly to the provision of general pre-submission advice in the areas of pesticides (see question 20), also the renewal pre-submission advice in the context of intended applications for the renewal of approval of existing active substances is to be provided by EFSA in close collaboration with the national competent authorities, meaning the designated rapporteur Member State/co-rapporteur Member State.

To facilitate this collaboration, the potential applicant is requested to indicate the designated rapporteur Member State when requesting advice through the IT tool. For what concerns the recommendation that potential applicants planning to request the renewal of approval of the same active substance act in a coordinated manner during the pre-submission phase, reference may be made to question 7.

The advice provided by EFSA under Article 32c(1) of the GFL and Chapter III of the EFSA Practical Arrangements is without prejudice to any advice requested by the potential applicant for renewal of approval of existing active substance to the designated rapporteur Member State/co-rapporteur Member State. The latter falls outside the scope of the afore-mentioned provisions.

30. What about the involvement of external experts in providing renewal pre-submission advice?

If EFSA decides, due to the specificity and scientific complexity of a particular case, to involve external experts for the provision of renewal pre-submission advice, their selection will be done in accordance with the procedures in place for the selection of scientific experts. If EFSA decides to use external experts, the concerned potential applicants will be informed and their involvement will be reflected in the summary of the renewal pre-submission advice.

31. What happens following the receipt of the renewal pre-submission advice?

Following the receipt of the renewal pre-submission advice, the potential applicant could proceed with commissioning/starting the studies it intends to perform, if not yet done (see question 25). It should be noted that the renewal pre-submission advice (likewise the general pre-submission advice) is noncommittal for EFSA or the Member States (see question 21) but also for the potential applicant itself. The latter is therefore free to decide which studies to commission/start and according to which design, irrespective of the advice received by EFSA.

Nevertheless, when the potential applicant commissions the studies to laboratories or carries them out in its testing facility, it would be required to notify such studies in the EFSA database pursuant to Article 32b of the GFL and Chapter IV of the EFSA Practical Arrangements (see question number 35).

Moreover, if following the receipt of the renewal pre-submission advice, the potential applicant considers that it is necessary to carry out new studies not initially included in the list notified to EFSA pursuant to Article 32c(1) of the GFL and Chapter III of the EFSA Practical Arrangements, those new studies will have to be notified in the EFSA database pursuant to Article 32b of the GFL and Chapter IV of the EFSA Practical Arrangements, without triggering again the specific process for the intended studies for renewal.

32. How does the notification of intended studies for renewal work for applications which are due for submission soon after the entry into application of the Transparency Regulation?

This answer has been removed from the revised version of this document as the question relates to a situation which can no longer arise.

NOTIFICATION OF STUDIES

33. As of when do the Article 32b notification obligations apply?

As regards this question, reference may be made to the answer provided to question 2.

In particular, in line with Article 10(1) of the TR, the obligation to notify studies pursuant to Article 32b of the GFL and Chapter IV of the EFSA Practical Arrangements does not apply in the context of an application submitted to EFSA **before 27 March 2021** and for the entire life-cycle of such application. This means that if, for example, during the assessment of the validity/admissibility of that application or during the risk assessment, the applicant submits a new study, this study is not subject to the obligations of Article 32b of the GFL, even if it has been commissioned or initiated on or after 27 March 2021.

In the context of applications submitted on or after 27 March 2021, studies completed or ongoing on this date are not subject to the Article 32b notification obligations. In order to be considered an ongoing study on 27 March 2021, a study carried out by a potential applicant using its own test facilities must already have been started before this date. In the event that the relevant study is commissioned to an external laboratory or testing facility, the study must have been commissioned before 27 March 2021 to be considered an ongoing study on this date.

As regards studies commissioned or carried out to support applications for the renewal of approval of active substances in the pesticides area, reference should be made to the rules governing the renewal of approval of active substances and in particular to the transition measures laid down in Article 17 of Commission Implementing Regulation (EU) No 2020/1740. Further information can be found here, where the work programmes updated for each active substance are available

34. In which cases do the Article 32b notification obligations apply?

Reference should be first made to the answer provided to question 4 concerning the definition of "study". Only studies which satisfy the definition of "study" laid down in Article 2, letter (c) of the EFSA Practical Arrangements are subject to the Article 32b notification obligations. Moreover, only studies commissioned or carried out by business operators in order to support an application in relation to which Union law contains provisions for EFSA to provide a scientific output, including a scientific opinion, are subject to the Article 32b notification obligations. As a result, it is not necessary to notify to EFSA studies not conducted for the purpose of supporting an application (e.g. studies conducted for research purpose only). With regard to studies which, according to the applicant, have not been notified or notified with delay since (initially) conducted for research purposes only, these justifications will not be considered acceptable by EFSA for studies conducted according to OECD test guidelines and/or according to GLP (e.g. toxicity studies). In addition, studies conducted to support an application for which Union law does not contain any provisions for EFSA to provide a scientific output (e.g. applications for the approval of plant protection products pursuant to Chapter III of Regulation (EC) 1107/2009) do not need to be notified to EFSA, unless they may be submitted at a later point in time in the context of an EU regulatory process requiring EFSA to provide a scientific output, i.e. applications in the context of approval or renewal of approval of active substances and/or MRL setting.

With regard to studies initially conducted for a purpose other than supporting an application in relation to which Union law contains provisions for EFSA to provide a scientific output, it should be noted that the verification of compliance with study notifications is carried out following the receipt of the application. In this context, the inclusion in the application of a study which has not been previously notified needs to be justified by the applicant. Please also refer to question 41.

35. To whom do the Article 32b notification obligations apply?

The obligation to submit information on studies is imposed on potential applicants that have either commissioned such studies to a laboratory or external testing facility or have opted to carrying out such studies in their own in-house testing facilities.

In situations whereby a study is commissioned to a laboratory or external testing facility, in addition to the potential applicant having commissioned the study, the laboratory or external testing facility is also required to notify the study to EFSA in line with Article 32b(3) of the GFL. This co-notification is necessary only when the relevant external laboratory or external testing

facility is located in the EU or in a third country with an agreement or arrangement within the meaning of Article 32b(3), second paragraph, of the GFL[18]. With regard specifically to the impact of the withdrawal of the United Kingdom from the European Union, at present, the Protocol on Ireland/Northern Ireland to the EU-UK Withdrawal Agreement makes the GFL applicable also to and in the United Kingdom in respect of Northern Ireland. As a consequence, laboratories or external testing facilities located in Northern Ireland are subject to the co-notification obligations of Article 32b(3) of the GFL whereas laboratories and external testing facilities located in Great Britain are not subject to those obligations.

In order to streamline the notification process and to increase coordination between potential applicants and laboratories and to avoid double notifications of the same study, a co-notification process has been developed. This allows the laboratory or external testing facility reported in a study notification by a potential applicant to be alerted and confirm the notified information. In this way, the study is associated to one individual study identification, avoiding duplications. The system also allows the laboratory or external testing facility to be the first entity to notify a study. In such cases, the same process applies, and the potential applicant will be requested to confirm the information notified by the laboratory or external testing facility. The potential applicant should proceed with the co-notification in order to comply with its notification obligation outlined in Article 32b(2) of the GFL.

In the specific case of multisite studies, as defined in Article 2, letter (d) of the EFSA Practical Arrangements, in accordance with Article 18(3) of those Practical Arrangements, the testing site at which the person responsible for overseeing the study (e.g. the study director) is located shall be responsible for the submission of information to be reported in the database. In situations whereby a multisite study to be notified to EFSA is commissioned to an external laboratory or other external testing facility subject to the notification obligations outlined in Article 32b (3) of the GFL, a notification is to be submitted to EFSA notwithstanding the fact that testing site at which the person responsible for overseeing the study may not be based in the EU or a third country with an agreement or arrangement within the meaning of Article 32b(3), second paragraph, of the GFL.

36. Do Article 32b notification obligations influence the choice of the potential applicant of which laboratories to commission the study to?

It should be noted that the Article 32b notification obligations binding laboratories and external testing facilities do not interfere in any way with the potential applicant's choice of the laboratory/testing facility to which commission the study.

37. When do studies have to be notified under Article 32b of the GFL?

In line with Articles 32b(2) and (3) of the GFL, potential applicants and laboratories or external testing facilities to which studies are commissioned must submit study notifications to EFSA "without delay".

The EFSA Practical Arrangements highlight that the reference to "without delay" is intended as a reference to the moment the European Union becomes a potential market for the regulated product to which a particular study is related.

[18] The three EEA EFTA States (Iceland, Liechtenstein, and Norway).

Then, the EFSA Practical Arrangements provide indications on when each study notification has to be submitted in the database. In particular, the information related to studies need to be notified in the database before the starting date of the study. In this connection, the definition of the "starting date of a study" can be found in Article 2, letter (e) of the aforementioned EFSA Practical Arrangements.

Notwithstanding the above, the EFSA database will not block delayed notifications, submitted after the starting date of the study. This holds true for Article 32b study notifications submitted in the database in connection to studies already completed. For example, this could happen because certain studies may have originally been commissioned or carried out by business operators without the intention of using them to support an application for the European Union market. Such already ongoing or completed studies may subsequently need to be notified in the database due to a change of commercial strategy resulting in the European Union becoming a potential market. However, when submitting a corresponding application, the applicant will be required to present a justification for any given delay (see question 42), including documentary evidence to demonstrate the initial purpose for the performance of such studies (e.g. proof of an earlier submission of these studies to another regulatory agency).

38. Which information about studies has to be notified?

As outlined in Recital 21 of the TR, the objective of Article 32b of the GFL is to ensure that EFSA is aware of all studies being carried out in support of applications with regard to which the Authority shall provide a scientific output. To this end, the Article 32b notification obligations are accompanied by procedural consequences imposed on the applicant, following the submission of a corresponding application, in cases of non-compliance with Article 32b of the GFL. To ensure that those procedural consequences are applied by EFSA or the other entities responsible to verify the compliance with notification obligations in a correct, fair and proportionate manner, clear links need to be identified between the notified information and the studies included in the application. In this connection, it should be borne in mind that the receipt of precise information in the database facilitates the process of assessing compliance with notification obligations, which may in certain situations necessarily result in procedural consequences having to be applied. The information required by EFSA, as outlined in Annex II to the EFSA Practical Arrangements serves this purpose.

39. Can Article 32b study notifications be modified in/withdrawn from the EFSA database?

Each Article 32b study notification submitted in the EFSA database is assigned a unique study identification ('ID'). Potential applicants, laboratories and other testing facilities as well as any third party entity contracted by such organisations to perform notifications on their behalf may modify the individual study notifications which they submit until the submission of the corresponding application. All fields of the notification are editable at any time before the planned completion date of the study indicated in the notification. It should be noted that, if and once the notified information will be made public in accordance to Article 32b(7) of the GFL and the EFSA Practical Arrangements concerning transparency and confidentiality, all modifications will be also made public.

The withdrawal of Article 32b study notifications is also possible, when for example the related study is cancelled or interrupted. The record of the withdrawal remains available in the database. Nevertheless, a withdrawal of a notification is conceptually equivalent to the non-

inclusion of a study previously notified. In this respect, in accordance with Article 20(4) of the EFSA Practical Arrangements, a study notification can be withdrawn by the potential applicant(s) having submitted the relevant notification before the planned completion date of the study. However, at application submission phase, the applicant will need to provide justifications for this withdrawal (see question 42).

It is also reminded that, in accordance to Article 3(3) of the EFSA Practical Arrangements, registered entities are required to ensure that all information provided, including information notified in the database, are reported accurately and kept up-to-date.

40. How is the confidentiality of the notified information stored in the database ensured?

Article 17(3) of the EFSA Practical Arrangements indicates that, with respect to the accessibility of the database, adequate levels of privacy and information security are ensured. In this regard, a distinction should be made between accessibility before and after a corresponding application is received. As long as the application has not been submitted, EFSA has anyway access to the database due to its role of managing such system, pursuant to Article 32b(1) of the GFL. However, until a valid/admissible corresponding application is received, EFSA will not assess or otherwise use the notified information beyond the need to manage the database.

Each contact/user under the same registered organisation has the same access privileges. During the pre-submission phase, potential applicants and laboratories/testing facilities under the obligation to co-notify a study – registered in the system - have access to the individual study notifications which they have submitted in the database or in which they are indicated as business operators or laboratories/testing facilities.

Concerning third parties contracted by a potential applicant, their access to the EFSA database can be controlled by the contracting entity. A contracting entity can grant access to a third party to already created pre-application IDs or already created studies notifications. For instance, if access is granted at a specific pre-application ID level, the third party will have access to information related to all pre-submission activities performed under that pre-application ID, from the moment the access is granted. Notifications performed before that moment will not be accessible by the third party. If the potential applicant grants the concerned third party access only to specific notifications, this third party will only have access those studies notifications. Third parties can also create new pre-applications ID and perform all pre-submission activities under that pre-application ID on behalf of the contracting entity. A contracting entity automatically has full rights on the pre-submission activities performed by the third party.

The contracting entity can remove access to the third party at any time from the pre-application IDs or notifications for which access was granted.

A third party that was granted access by a contracting entity, cannot further delegate another third party.

In the event that no corresponding application is eventually submitted, the information notified will remain stored in the database but not be disclosed, according to the access rules specified above.

Once a given application is received, as a general principle, the information stored in the database will not be disclosed until the notified information is made public in accordance to

Article 32b(7) of the GFL and the EFSA Practical Arrangements concerning transparency and confidentiality (see Section C of the present document). Nevertheless, the applicant should expect that the entities in charge of assessing the validity or admissibility of the application are put in a position to verify the compliance with study notification obligations. Accordingly, where under Union law the responsibility to decide on the validity of the application in question lies with the Authority exclusively or jointly with the Commission, EFSA uses the information stored in the database to verify that the application is compliant with study notification obligations pursuant to Article 32b(4) and (5) of the GFL and Articles 22 and 23 of the EFSA Practical Arrangements. (see also question 42). In cases where Union law provides for the Commission or a Member State to decide exclusively on the validity or admissibility of an application, access to specific relevant notified information is granted by EFSA, strictly on a need-to-know basis.

41. For which sectors is EFSA responsible for assessing the validity of an application exclusively or jointly with the Commission and for which sectors are the Member States responsible?

The individual roles of each relevant institutional actor in all areas concerned is governed by the pertinent sectoral legislation, which represents the official legal text applicable in each case. Nevertheless, the principal workflows of the relevant regulatory frameworks in which EFSA is involved are outlined for information purposes only by food sector area on the EFSA website at the following online location: https://www.efsa.europa.eu/en/applications. For further information regarding the specific involvement of the competent authorities of EU Member States and the European Commission, interested parties may refer to the website of the European Commission, which can be accessed by following this link: https://ec.europa.eu/food/overview_en.

In addition, as an additional service to business operators, an indicative list of sectors for which EFSA has the responsibility to decide on the validity of the application exclusively or jointly with the Commission, provided for informational purposes only, has been made available below for ease of reference:

Exclusive EFSA competence to validate applications

Genetically modified food and feed - Articles 6(3) and 18(3) of Regulation (EC) No 1829/2003 on genetically modified food and feed;

Smoke flavourings – Article 8(3) of Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods;

Feed additives - Article 8(3) of Regulation (EC) No 1831/2003 on additives for use in animal nutrition;

Food contact materials - Article 10(3) of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

Shared competence with the European Commission in validating applications

Food improvement agents (food additives, food enzymes and flavourings) - Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, and Article 12(2) of Commission Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008.

Novel foods – Article 10 of Regulation (EU) 2015/2283 on novel foods and Article 6(2) of Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283.

Novel foods – Article 14 of Regulation (EU) 2015/2283 on novel foods and Article 7(2) of Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283.

Novel foods – Article 16 of Regulation (EU) 2015/2283 on novel foods and Article 8(2) of Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283.

42. How will EFSA carry out the verification of compliance with Article 32b notification obligations?

As a reminder, EFSA is responsible for verifying compliance with the Article 32b notification obligations where, under Union law, the responsibility to decide on the validity of the application in question lies either exclusively with EFSA or jointly with the Commission. Where the responsibility to decide on the validity or admissibility of the application in question lies exclusively with the Commission or a Member State, the assessment of compliance with the Article 32b notification obligations is carried out by those entities. (see question 41).

Pursuant to Article 21 of the EFSA Practical Arrangements, when submitting the application, the applicant is requested to provide study notifications submitted in the database in support of the application (i.e. pre-application IDs and study IDs generated by the database). Moreover, the applicant has to provide justifications explaining:

1) the non-notification in the database of studies that have been included in the application;
2) why study notifications were submitted after their starting date, including when the study was notified after its termination, since a delayed notification is conceptually treated as a non-notification of a study;
3) the non-inclusion in the application of studies notified in the database;
4) why a study notification submitted in the database was subsequently withdrawn, since the withdrawal of a study notification is conceptually treated as a non-inclusion of a study previously notified.

The presentation of accurate and objective justifications is a key step to avoid procedural consequences being applied in case of deviations from the applicable rules and process.

Upon receipt of the afore-mentioned information, EFSA assesses the compliance with the study notification obligations by verifying whether the application contains all studies that have been previously notified, and whether the application contains no additional studies apart from those previously notified, and assessing the validity of any justifications submitted by the applicant. This assessment is carried out on a case-by-case basis, taking into consideration all relevant factual elements as well as any additional elements of justification or clarification, which may be requested at any time during the analysis.

This is done not only on the basis of the elements provided by the applicant in accordance with Article 21 of the EFSA Practical Arrangements but also, where considered appropriate, using

information retrieved from the database as outlined in Article 22(2) of the EFSA Practical Arrangements.

43. What about studies commissioned or carried out by other business operators?

The Article 32b notification obligations only concern studies commissioned or carried out by the potential applicant in support of its own future application. In this case, the potential applicant is responsible for notifying the studies in question in the EFSA database, or for having other business operators/delegated third parties notify the studies on its behalf.

This notwithstanding, in situations where a study commissioned or carried out by a business operator is used to support an application submitted by another business operator, the latter, having submitted the relevant application (and being considered the applicant), would need to justify the non-notification of the study in question, in accordance with Article 21(b)(i) of the EFSA Practical Arrangements. No procedural consequences will be applied if the applicant is able to demonstrate that it did not commission or carry out the concerned study.

44. In which cases will procedural consequences apply when an application is declared non-valid?

As a result of the verification of compliance with the Article 32b notification obligations, the application is considered valid if compliance with notification requirements is verified or, in case of non-compliance, the justifications presented by the applicant are considered valid by EFSA. In these two cases, the procedural consequences envisioned in Article 32b(4) and (5) of the GFL and Article 23 of the EFSA Practical Arrangements are not applied.

It should also be noted that the procedural consequences of Article 32b(4) and (5) of the GFL are applicable only in the circumstances laid down in those articles, i.e. only in the event that an application is not considered valid on the grounds of failure to comply with the relevant notification of studies obligations. As a consequence, if an application is considered non-valid on other grounds, these procedural consequences will not apply.

Nevertheless, attention should be paid to the case in which, during the assessment of the validity of the application, EFSA requests from the applicant additional information or clarification within an assigned deadline. This request as such does not trigger any procedural consequence linked to notification of studies obligations. However, if the applicant, in response to this request, presents a new study, which was not included in the application initially, the applicant is required to provide information on the study notification and, if necessary, appropriate justifications for any deviations from notification obligations. If EFSA concluded that the new study has not been previously notified in accordance with the applicable rules and process and no valid justification was given in this respect, the procedural consequences of Article 32b(4) of the GFL would apply.

45. How can decisions applying the procedural consequences related to Article 32b notification obligations be challenged?

Where the possibility of an administrative review is provided for in the applicable sectoral acts, business operators may submit a request for an administrative review of a particular EFSA decision of non-validity of application in accordance with the appropriate administrative review clauses. As regards the possibility for business operators to seek judicial review of decisions of non-validity of applications, actions for annulment of EU acts may be submitted to the European

Court of Justice in accordance with Article 263 of the Treaty on the Functioning of the European Union, provided that the relevant criteria outlined in that legal provision are met.

46. How do Article 32b notification obligations apply in the context of the risk assessment?

In accordance with Article 32b(6) of the GFL, specific provisions apply if, during its risk assessment, EFSA detects that studies previously notified in the database and included in the application have not been included in full. In this case, the applicant will be asked to provide justifications for the missing data and will be informed that the risk assessment is suspended until such justifications are provided. Upon receipt of the justifications provided by the applicant, EFSA will assess them. If these justifications are considered valid by EFSA, the risk assessment will resume. If not, the applicant will be asked to submit the missing data and will be informed that the risk assessment will remain suspended for six (6) months following the submission of the missing data.

PUBLIC CONSULTATION ON SUBMITTED APPLICATIONS

47. What will be subject to public consultation?

In accordance with Article 32(c)(2) of the GFL, EFSA shall consult stakeholders and the public on the non-confidential version of the application or notification made public by EFSA in accordance with Articles 38 to 39e of the GFL. As a result, only information contained within a particular submitted application or notification will be subject to the public consultation, which EFSA must carry out in application of Article 3(c)(2). It should also be noted that public consultation obligations do not apply where the Commission does not request the opinion of the Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 on novel foods, and to notifications for traditional foods under Article 14 of Regulation (EU) 2015/2283 on novel foods, as EFSA is not consulted at this stage but only subsequently when applications under Article 16 of this regulation are submitted for traditional foods.

In addition, as regards Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, in cases where the opinion of EFSA is not sought in accordance with Article 3(2) of that regulation, public consultation obligations are not applicable either.

48. At what stage of the process will the submitted application undergo public consultation?

In accordance with Article 27(1) of the EFSA Practical Arrangements, the consultation of stakeholders and the public on the submitted application is launched by EFSA immediately after the application is found valid or admissible and the non-confidential version of the dossier (including scientific data, studies and other information part of, or supporting, the submitted application) is made public.

Without prejudice to applicable Union law, if the applicant, when submitting the application, requests that certain parts of the submitted information are treated as confidential, the consultation of third parties shall take place on the basis of the version of the application made public

by EFSA following the implementation of the confidentiality decision-making ('final non-confidential version').[19]

Nevertheless, if the applicant decides to bring an action for annulment before the Court of Justice of the European Union[20] against EFSA's confirmatory decision on confidentiality and, in this context, is granted the suspension of the publication of the final non-confidential version,[21] the consultation of third parties will be carried out on the basis of the non-confidential version of the information submitted by the applicant in accordance with Article 39a(2) of the GFL.

49. When will the comments received be made public?

In accordance with Article 28 of the Practical Arrangements, when a public consultation is carried out by EFSA, any submission made in response to that public consultation must be made public unless the specific party submitting their input has requested non-public disclosure of their comments. The comments to be published will be made available immediately after the closure of the relevant public consultation, while the results of the public consultation, i.e. the general explanations regarding how certain comments received were or were not taken into account by EFSA, will be published together with the pertinent scientific output issued by EFSA.

50. How will comments received during public consultation be used?

All comments received in the context of a public consultation carried out by EFSA will need to be assessed on a case-by-case basis, taking into consideration all the relevant elements arising during the risk assessment phase. The results of all public consultations, in the sense of general explanations regarding how the comments received were or were not taken into account by EFSA in its assessment, will be made publicly available together with the corresponding scientific output in application of Article 28(2) of the EFSA Practical Arrangements.

51. Who is responsible to assess the comments received in the public consultation in the context of pesticides and MRLs?

The comments received by way of public consultations carried out in the pesticides area will be taken into consideration by the relevant Member State in its initial assessment.

[19] Where the Authority is entrusted with the assessment of confidentiality, the implementation of the Authority's confidentiality decision-making is carried out in accordance with Articles 6(2) and 13 of the Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality.

[20] Under Article 263 of the Treaty on the Functioning of the European Union ('TFEU').

[21] Under Article 278 of TFEU.

C. EFSA PRACTICAL ARRANGEMENTS CONCERNING TRANSPARENCY AND CONFIDENTIALITY

SUBJECT MATTER, SCOPE AND DEFINITIONS

1. What is intended by "applications"?

The scope of the Practical Arrangements concerning transparency and confidentiality is defined in Article 2 of the Practical Arrangements, which clarifies that they apply to all scientific data, studies and other information listed in Article 38(1) of the GFL.

Conversely, the chapter of the Practical Arrangements concerning confidentiality requirements specifically applies to all confidentiality requests accompanying the submission of scientific data, studies and other information, including supplementary information, the assessment of which is entrusted to the Authority pursuant to the applicable Union provisions.

Therefore, the Practical Arrangements in question adopt a pragmatic approach of considering as applicants not only persons submitting application dossiers but also:

- those who submit scientific data and information for evaluation to the Authority pursuant to established sectoral Union law procedures;
- those who submit information voluntarily to the Authority upon which the Authority is expected to base its scientific outputs within the meaning of Article 38(1)(d) of the GFL; as well as
- any natural or legal person who has produced information supporting a request from the European Parliament, the Commission and the Member States for a scientific output and therefore has a direct interest with respect to the closed list of information items for which confidentiality treatment can be requested, as laid down in the Annex.

It follows that the concept of "application" is not needed to define the scope of the present Practical Arrangements.

To the extent this is necessary, Article 2(2) also lists processes to which the Practical Arrangements concerning transparency and confidentiality do *not* apply, namely:

a) confidentiality requests submitted to, and assessed by, the national competent authorities, under Article 25 of Directive 2001/18/EC;
b) confidentiality requests submitted in accordance with Article 63 and assessed by the national competent authorities under Article 7 of Regulation (EC) No 1107/2009;
c) confidentiality requests submitted in the context of Regulation (EC) No 1331/2008, where an opinion by the Authority is not required in accordance with Article 3(2) thereof;
d) confidentiality requests submitted in the context of Regulation (EU) 2015/2283 with regard to notifications of traditional foods pursuant to Article 14, as well as applications of novel foods for which the Commission does not request the opinion of the Authority in accordance with Article 10(3) thereof;
e) confidentiality requests submitted in the context of Article 7a of Commission Regulation (EU) No 257/2010 setting up a programme for the re-evaluation of approved food additives, where the Authority is not requested to take further steps.

2. What is intended by "applicant" in the context of the Practical Arrangements concerning transparency and confidentiality?

Article 39 of the GFL, as amended by the TR, gives the possibility of submitting confidentiality requests to "applicants". This means that legal or natural persons not falling under this concept are not allowed to claim confidentiality on information they may share with EFSA.

For the limited purpose of the Practical Arrangements concerning transparency and confidentiality, the definition of applicant is now defined in Article 3(1)(a) of the Practical Arrangements, according to which "applicant" means:

1. any natural or legal person submitting an application or notification under Union law;
2. any natural or legal person submitting scientific data and information for evaluation to the Authority pursuant to established sectoral Union law procedures;
3. where permitted under sectoral Union law procedures and/or in the absence thereof, any natural or legal person submitting information voluntarily to the Authority upon which the Authority is expected to base its scientific outputs within the meaning of Article 38(1)(d) of the GFL;
4. any natural or legal person that has produced information supporting a request from the European Parliament, the Commission and the Member States for a scientific output and therefore having a direct interest with respect to the closed list of information items for which confidentiality treatment can be requested, as laid down in the Annex.

The same provision also clarifies that this definition does not include the European Commission, the European Parliament, other Union institutions, bodies, offices or agencies, Union Member States, or third countries' public authorities as such. However, when these institutions, bodies, offices or agencies put forward requests for scientific outputs supported by scientific information and studies put forward by legal or natural persons, the latter would qualify as applicants to request confidentiality treatment for that information.

The rather inclusive concept of "applicant" adopted by EFSA in these Practical Arrangements is meant to provide a mechanism ensuring the protection of legitimate interests of all natural or legal persons captured by the definition, and ensure the appeal of contributing to the Union specific evaluation processes. In turn, this provides a clear and level playing field and regulatory framework applicable to those in a position to provide information and data to EFSA, by clarifying the applicable procedural steps and the available rights.

PROACTIVE TRANSPARENCY

3. Which items are subject to public disclosure?

Article 38(1) of the GFL lists all the elements for which mandatory proactive publication by EFSA is required. These elements are further detailed in Articles 5 and 6 of EFSA's Practical Arrangements concerning transparency and confidentiality. For each item included in Articles 5 and 6 above, the moment of online publication by EFSA is indicated, together with the clarification on whether the item may be, directly or indirectly, subject to a confidentiality request, and as such its content may be partially or entirely withheld from public disclosure.

The submission of a confidentiality request is no guarantee that the information for which it was submitted will be withheld from public disclosure, as this depends on the outcome of the applicable confidentiality decision making process assigned to EFSA, the Commission or the

responsible Member State authority, depending on the applicable legal framework (in this regard, see also the reply to question no. 9 below).

For items that are not given confidential status, their proactive dissemination by EFSA may be prevented by withdrawing the application dossier that contains them, if one has been submitted.

The possibility for an applicant to withdraw its application is reflected in Article 11(3)(a) and Article 15 of these Practical Arrangements.

Pursuant to Article 11(3)(a), an applicant may decide to withdraw its application during a two-week consultation period, to which it is entitled concerning the draft decision on confidentiality, and before the latter is signed and notified. Withdrawal at this moment will prevent the dissemination of any information claimed confidential by the applicant.

Pursuant to Article 15, an applicant is entitled to withdraw its application also after this moment, with the consequences set out in this Article, which vary depending on the moment when the withdrawal is triggered. If the withdrawal is received by EFSA before the information claimed confidential by the applicant is disseminated, EFSA will not disseminate information claimed confidential. If the withdrawal is received by EFSA after the information claimed confidential by the applicant is disseminated, EFSA will delete this information from its website at the conditions set out in Article 15.

Proactive disclosure requirements are without prejudice to the applicability of Regulation (EC) No 1049/2001 or Regulation (EC) No 1367/2006 on elements or documents not made proactively available by EFSA pursuant to Article 38(1) of the GFL. In practice, this means that even if a document is given confidential status under Articles 39-39e of the GFL, or one of the relevant sectoral provisions, it may still be subject to a request for access to documents under one of the two regulations above. These requests, if received, are processed by EFSA in accordance with the relevant legal framework and case law.

4. In which way will relevant items be disclosed?

EFSA will make publicly available items listed under Articles 5 and 6 of the Practical Arrangements concerning transparency and confidentiality either on its website, on its OpenEFSA portal, on IUCLID or in EFSA's scientific journal. The application dossiers will be made available on the OpenEFSA portal. Technically, this is an autonomous portal linked to EFSA's website and capable of handling the considerable number of documents that will have to remain available to the public.

The OpenEFSA portal will make available to the public documents, information or data deemed not confidential by the applicant, or by the Rapporteur Member State, the Commission or EFSA, depending on the applicable legal framework and the different stages of the confidentiality assessment process, pursuant to Articles 39-39e of the GFL. Users of the OpenEFSA portal will be allowed to get access to the documents, information or data supporting application dossiers after accepting EFSA's terms of reference in compliance with Article 38(1a) of the GFL. In view of the well-defined empowerment set out in Article 38 and Article 39d(5) of the GFL, EFSA is not in a position to run identity or background checks, pursue law enforcement actions or issue sanctions for the unauthorised re-use of information or data made available on its OpenEFSA portal in breach of Intellectual Property Rights or data exclusivity rules. This implies that no verification, or traceability, of the identities or internet protocol of users will be ensured by EFSA.

In terms of applicable standards, pending the adoption of standard data formats pursuant to Article 39f of the GFL, EFSA does not have the legal empowerment to put in place a mandatory scheme that would be binding for applicants. For this reason, Article 4(5) of the Practical Arrangements concerning transparency and confidentiality recommends to applicants to submit structured as well as unstructured data.

EFSA acknowledges that the TR has not altered existing data submission requirements set out in relevant sectoral Union law. This notwithstanding, documents made publicly available must be downloadable, printable, and searchable in an electronic format.

5. What about materials disclosed by EFSA and subject to Intellectual Property Rights?

Pursuant to Article 38(1)(c) of the GFL, as well as Article 6 of the Practical Arrangements concerning transparency and confidentiality, EFSA is required to make proactively available all information and studies submitted by applicants to support their respective dossiers. This includes 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 scientific outputs, including scientific opinions, taking into account the protection of confidential information and the protection of personal data in accordance with Articles 39 to 39e of the GFL.

In addition to the Practical Arrangements concerning transparency and confidentiality, sector specific information is made available in sectoral administrative guidance documents developed by EFSA to support the submission of applications in the sectors most directly impacted by the implementation of the Transparency Regulation.

EFSA shall make publicly available information and studies that are not considered confidential pursuant to Articles 39-39e of the GFL. Intellectual Property Rights owned by the applicant cannot be relied upon, *per se,* to prevent public disclosure in accordance with Article 38(1)(c) of the GFL.

Applicants may also consider supporting their applications by relying on scientific publications available to the public (e.g. upon payment of a fee). Where applicants may not have or may not be able to obtain the necessary IPRs by the rightful owner (e.g. scientific journals) for the reproduction of those publications on the OpenEFSA portal (for public dissemination purposes), they will have the possibility of providing instead the full bibliographic references allowing the correct identification of the publication by the public. Due attention should be paid to the fact that this option is available exclusively for existing publications in scientific journals, or comparable publications.

Moreover, users of the OpenEFSA portal will be allowed to get access to the documents, information or data supporting application dossiers only after having accepted EFSA's terms of reference complying with Article 38(1a) of the GFL. Indeed, Article 38(1a) of the GFL clearly prescribes that such disclosure shall be without prejudice to pre-existing rights and that disclosure under this provision is not meant as 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 Rights or data exclusivity rules.

In view of the well-defined empowerment set out in Article 38 and Article 39d(5) of the GFL, EFSA is not in a position to run identity or background checks, pursue law enforcement measures or issue sanctions for the unauthorised re-use of information or data made available on its OpenEFSA portal. This implies that no verification or traceability of the identities or internet protocols of users will be ensured by EFSA.

EFSA is very much aware that its Practical Arrangements concerning transparency and confidentiality may not waive its liability pursuant to Article 340 TFEU, and acknowledges that its behaviour and actions are subject to the jurisdiction of the Court of Justice at the terms and conditions set out in the Treaties and relevant case law. For this reason, EFSA is fully committed to implement in a sound, proportionate and reasonable manner the duties assigned to it by the TR, including the operation of proactive disclosure and the related confidentiality decision making process.

6. How will personal data be handled?

Pursuant to Article 39e(1) of the GFL, EFSA shall make publicly available the name and address of the applicant; the names of authors of published or publicly available studies supporting such requests; and 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.

By way of contrast, in accordance with Article 39e(2) of the GFL, EFSA may not make publicly available names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information.

Other personal data will be disclosed by EFSA if they fall under one of the items listed in Article 38(1) of the GFL, which is considered by EFSA as a legal basis requiring the Authority to disclose all information contained therein, including personal data, in view of a public interest pursuant to Article 5(1)(a) of Regulation (EU) 2018/1725. This shall be the case unless applicants submit a request specifying the reasons based on which such data should not be disclosed to the public, and EFSA supports the request with the adoption of a positive decision. Against this background, it is possible for applicants to prevent the dissemination of specific personal data not mentioned under Article 39e(2) of the GFL, such as the name of a director of a study, under the circumstances outlined above.

For this purpose, Article 4(5) of EFSA's Practical Arrangements concerning transparency and confidentiality prescribe that the *non-confidential* version of application dossiers, information, documents and data submitted in order to comply with related proactive disclosure requirements must not contain personal data, with the exception of the name and address of the applicant, where applicable, and the names of authors of published or publicly available studies. The same provision indicates that applicants must ensure the absence, sanitisation or anonymisation, as appropriate, of information relating to identified or identifiable persons from non-confidential versions of dossiers, information, documents and data.

Personal data made public pursuant to EFSA's Practical Arrangements concerning transparency and confidentiality must only be used to ensure the transparency of the risk assessment processes managed by the Authority, and may not be further processed in a manner that is incompatible with this purpose, in accordance with point (b) of Article 4(1) of Regulation (EU) 2018/1725.

7. How will EFSA handle disclosure of confidential information where urgent action is essential for the purposes of protecting human health, animal health or the environment?

Pursuant to Article 39c of the GFL, where EFSA identifies information that forms part of the conclusions of its scientific outputs relating to foreseeable effects on animal health, human health or the environment, and confidentiality decisions awarding confidential status to that information were already issued by EFSA, it must review these previous confidentiality decisions to verify whether information that has been previously accepted as confidential must nevertheless be made public.

In this case, EFSA must comply with the full procedure set out in Article 39b of the GFL and further implemented by Article 13 of the Practical Arrangements concerning transparency and confidentiality. This means that the applicant will have the opportunity to comment on a draft decision prior to its signature in accordance with Article 39b(1) of the GFL, and to submit a confirmatory application pursuant to Article 39(b)(2) of the GFL.

After the notification of a decision on their confirmatory application, the applicant may challenge the decision on the confirmatory application pursuant to Article 263 TFEU within two months and ten days of its receipt. Alternatively, the applicant may submit to the Ombudsman a complaint for alleged maladministration in accordance with Article 228 TFEU within two years from the moment when they became aware of the facts. Prior to lodging a complaint with the European Ombudsman, the applicant must first have contacted EFSA in an endeavour to resolve the matter.

CONFIDENTIALITY

8. To which areas of the food chain are the Practical Arrangements concerning Transparency and Confidentiality applicable? Are they applicable to processes that have not been amended by the TR?

The TR brought about a targeted amendment of the GFL and of eight sectoral acts. Nevertheless, the actual impact of the TR is much broader: due to the scope of the GFL, the TR does not only affect the processes of the sectoral acts it amends, but also all processes to which the amended or newly introduced provisions of the GFL apply.

For example, Regulation (EC) No 1924/2006 on nutrition and health claims on food was not amended by the TR. However, the general provisions of the GFL, including those relating to transparency and confidentiality, do apply, as more specific ones may not be found in Regulation (EC) No 1924/2006. Accordingly, confidentiality requests submitted with regard to applications supporting the request for authorisation of a health claim that is received by EFSA as of 27 March 2021, is subject to the new provisions of Articles 38 and 39-39e of the GFL. The same holds true for MRL applications submitted pursuant to Regulation (EC) No 396/2005 as of this date and, more generally, for acts falling under the scope of the GFL, unless they include specific provisions on transparency and confidentiality requirements.

Moreover, proactive disclosure requirements, and consequently also the related confidentiality decision making process, apply not only to information submitted to support an application dossier, but extend also to any request to EFSA for a scientific output from the Commission, the EU Member States or the European Parliament as indicated in Article 38(1)(c) of the GFL, as well

as to information on the basis of which EFSA develops any of its scientific outputs as per Article 38(1)(d) of the GFL. This implies that the Practical Arrangements concerning transparency and confidentiality apply to *all sectors* falling under EFSA's remit with regard to scientific data, studies and other information that may be transmitted to EFSA for the purposes of an EFSA scientific output in accordance with the GFL or relevant sectoral legislation. This includes all information transmitted to EFSA in support of requests from the European Parliament, the Commission and the EU Member States for an EFSA scientific output, and all information on which EFSA bases its scientific outputs (on this point, see also replies to questions no. 1-3 above).

9. In which areas does confidentiality decision-making remain under the responsibility of Member States or the Commission? How is consistency ensured?

In most of the sectors, EFSA is responsible for confidentiality decision-making whenever scientific data, studies or other information are transmitted to EFSA for the purposes of an EFSA scientific output in accordance with the GFL and/or sectoral legislation.

However, in some processes, the responsibility for confidentiality decision making is assigned to the Commission or a competent national authority.

Confidentiality decision-making under the responsibility of the Member States (MSs)

This is the case for:

(i) data and information supporting dossiers for approval of new active substances for use in pesticides pursuant to Article 7 of Regulation (EC) No 1107/2009; and
(ii) information supporting notifications under Directive 2001/18/EC ('GMO Directive').

In areas where an EFSA scientific output is eventually adopted (dossiers for approval of new pesticide active substances) or may be adopted (notifications under GMO Directive), the confidentiality decision-making remains within the purview of the Member States. However, as regards notifications under the GMO Directive, should EFSA be requested to issue a scientific opinion in accordance with Article 28 of the GMO Directive, and where information that was previously considered confidential forms part of the conclusions of that opinion relating to foreseeable effects on human health, animal health or the environment, EFSA shall review the Member State's confidentiality decision in accordance with Article 39c of the GFL, with a view to publishing that information. If the conditions set out in Article 39(4)(b) of the GFL are met, pursuant to Article 63(2b)(e)(ii) of Regulation (EC) No 1107/2009, EFSA shall also review previous confidentiality decisions concerning data and information supporting dossiers for approval of new active substances for use in pesticides.

There are a number of safeguards to ensure consistency between confidentiality decision-making of Member States and EFSA in the field of pesticide active substances. Here, consistency is guaranteed, first and foremost, through identical lists of items of information for which confidential treatment may be requested and, second, by a set of Practical Arrangements concerning confidentiality pursuant to Articles 7 and 16 of Regulation EC No 1107/2009, which ensures the application of comparable procedural and substantive requirements.

By closely aligning the procedural and substantive criteria applicable to confidentiality assessments concerning approval dossiers (carried out by the Rapporteur Member State, RMS) and renewal dossiers (performed by EFSA), the Practical Arrangements concerning

confidentiality pursuant to Articles 7 and 16 of Regulation (EC) No 1107/2009 reduce the likelihood of mismatches between confidentiality decisions regarding the same active substance. Moreover, an additional tool to achieve consistency is provided by Article 7(6) of the Practical Arrangements, which mandates the RMS to consult with EFSA prior to finalising its confidentiality decision, thereby allowing for the development of common approaches.

Confidentiality decision-making under the responsibility of the Commission

The Commission is empowered to take confidentiality decisions for:

- information supporting applications for authorisation of food additives, food enzymes or food flavourings submitted under Regulation (EC) No 1331/2008, where an EFSA opinion is not required in accordance with Article 3(2) thereof;
- information supporting notifications of the intention to place traditional foods from third countries on the Union markets pursuant to Article 14 of Regulation (EU) 2015/2283;
- information supporting applications for authorisation of novel foods where an EFSA opinion is not required in accordance with Article 10(3) of Regulation (EU) 2015/2283;
- information related to the re-evaluation of a food additive, including information submitted under a call for data, considered by EFSA pursuant to Article 4 of Commission Regulation (EU) No 257/2010, where EFSA is not requested to take further steps in accordance with Article 7a(1) thereof.

10. How to submit confidentiality requests?

In accordance with Article 9(3) of the Practical Arrangements concerning transparency and confidentiality, and Article 5 of the Practical Arrangements concerning confidentiality pursuant Articles 7 and 16 of Regulation (EC) No 1107/2009, the following procedural arrangements apply to the submission of confidentiality requests:

Confidentiality requests may be made when:

a) submitting scientific data, studies or other information supporting applications under relevant Union law provisions, including supplementary information upon request by EFSA;
b) submitting scientific data and information to EFSA for evaluation pursuant to established procedures under Union law;
c) submitting, as permitted under established sectoral Union law procedures, or on a voluntary basis, scientific data and information upon which EFSA is expected to base its scientific outputs within the meaning of Article 38(1)(d) of the GFL. This includes submissions made in response to public calls for data, other than those covered by point b) above;
d) submitting scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, pursuant to Article 38(1)(c) of the GFL.

Depending on the sector in which the dossier is submitted, an applicant must use one of the following IT tools:

- **The updated version of FSCAP called 'e-submission food chain' platform**: for most of the sectors requiring the submission of dossiers,[22] confidentiality requests concerning scientific data and information mentioned under the above points a), b) and c) other than information supporting pesticide dossiers (approval, renewal and MRL applications) must be submitted via the e-submission platform managed by the Commission, 'e-submission food chain' platform, which is the updated version of 'Food System Common Authorisation Procedure' ('FSCAP');
- **IUCLID**: with regard to approval of basic substances, new pesticide active substances and renewal of approvals of pesticide active substances under Regulation (EC) No 1107/2009, and of MRL applications under Regulation (EC) No 396/2005, confidentiality requests are to be submitted by means of the digital submission platform 'International Uniform ChemicaL Information Database' ('IUCLID')
- **Portalino**: confidentiality requests regarding scientific data and information referred to in point c) and d) above that are not to be submitted under the 'e-submission food chain" platform (formerly known as FSCAP) nor to IUCLID are to be introduced via the dedicated IT platform interface nicknamed by EFSA 'Portalino'.

Confidentiality requests may be submitted only with respect to **items included in the closed and positive lists** in Article 39(2)(a) to (d) of the GFL, or in Article 30(2) of Regulation (EC) No 1829/2003, Article 18(3) of Regulation (EC) No 1831/2003, Article 20(2) of Regulation (EC) No 1935/2004, Article 12(3) of Regulation (EC) No 1331/2008, Article 63(2) of Regulation (EC) No 1108/2009, Article 23(4) of Regulation (EC) 2015/2283, or Article 25(3) of Directive 2001/18/EC (A comprehensive table of all sector-specific closed positive lists is available in the Annex to the Practical Arrangements on transparency and confidentiality).

However, applicants must provide a **verifiable justification** demonstrating compliance with Article 10 (substantive requirements) of the Practical Arrangements on transparency and confidentiality, laying down the substantive requirements applicants must meet when submitting confidentiality requests.

Applicants may not modify or proactively complement already submitted requests, unless EFSA requests clarifications.

11. Which items of information may be claimed confidential?

Pursuant to Article 9(4)(a) of the Practical Arrangements on transparency and confidentiality, confidentiality requests may only be submitted with regard to information falling within the scope of the items of information listed in Article 39(2)(a) to (d) of the GFL, as supplemented by additional items of information laid down in sectoral Union law, namely Article 30(2) of Regulation (EC) No 1829/2003, Article 18(3) of Regulation (EC) No 1831/2003, Article 20(2) of Regulation (EC) No 1935/2004, Article 12(3) of Regulation (EC) No 1331/2008, Article 63(2) of

[22] Food additives; Food enzymes; Food flavourings; Smoke flavourings; Feed additives; GMO food and feed (Regulation (EC) 1829/2003); Deliberate release into the environment of GMOs other than higher plants (Directive 2001/18/EC); Deliberate release into the environment of GM higher plants (Directive 2001/18/EC); Substances other than potable water used to remove surface contamination from products of animal origin, according to Article 3(2) of Regulation (EC) 853/2004; Infant formulae & follow-on formulae (IF&FOF) manufactured from protein hydrolysates; Food allergens; Nutrient sources; Health claims; Novel foods; Traditional food notification; Food contact materials (Regenerated cellulose film; Substance to be used in plastic materials; Recycling processes; Active and intelligent materials).

Regulation (EC) No 1108/2009, Article 23(4) of Regulation (EC) 2015/2283, and Article 25(3) of Directive 2001/18/EC. A comprehensive table of all sector-specific lists is available in the Annex to the Practical Arrangements on transparency and confidentiality). This is an essential procedural requirement that applicants must comply with. Otherwise, EFSA shall reject their confidentiality requests as inadmissible.

For instance, the item 'DNA sequence' may be subject to a confidentiality request only under Regulation (EC) No 1829/2003 and Directive 2001/18/EC. In the absence of a closed positive list in the sectoral legal act, the positive list set out in Article 39(2) of the GFL applies (e.g. Health Claims Regulation, MRL Regulation).

Requests for confidential treatment cannot, under any circumstances, be made regarding items of information beyond those expressly set out in the closed list of the GFL, as supplemented by additional items of information in sectoral legislations. For instance, submission of a confidentiality request on an item not included in one of the positive lists solely by reference to the fact it is subject to Intellectual Property Rights s will result in a decision rejecting the request. Indeed ('IPRs' *per se* do not constitute an item of information in relation to which a confidentiality request can be submitted. That does not mean, however, that confidentiality requests made on items benefiting from Intellectual Property Rights may not be subject to a positive assessment of relevant confidentiality requests, if they fall within the information items that could profit from confidentiality treatment (positive lists) and provided that compliance with Article 10 (substantive requirements) of the Practical Arrangements on transparency and confidentiality is demonstrated.

Applicants may also consider supporting their applications by relying on scientific publications available to the public (e.g. upon payment of a fee). Where applicants may not have or may not be able to obtain the necessary Intellectual Property Rights by the rightful owner (e.g. scientific journals) for the reproduction of those publications on the OpenEFSA portal (for public dissemination purposes), they will have the possibility of providing instead the full bibliographic references for the purpose of public disclosure, and thereby allowing the correct identification of the publication by the public. Due attention should be paid to the fact that this option does not exempt the applicants from the need to secure the right for regulatory use of these publications in accordance with the applicable IPR law (i.e. provision of copies of those scientific publications in the dossier to facilitate risk assessment by risk assessors), and the option is available exclusively for publications in scientific journals, or comparable publications.

Due attention should be paid to the fact that the scope of application of EFSA's Practical Arrangements concerning transparency and confidentiality is limited to the empowerment received under Article 39d(5), and as such does not include closed lists of items of information for sectors where EFSA is not in charge of confidentiality decision-making, e.g. regarding notifications under the GMO Directive (without prejudice to Article 28 of the GMO Directive).

12. What is the minimum content of confidentiality requests?

In order to submit a successful confidentiality request, pursuant to Article 39 of the GFL, an applicant must provide a verifiable justification with regard to each item, or bit of information, the disclosure of which by EFSA would potentially harm its interests to a significant degree.

EFSA's Practical Arrangements concerning transparency and confidentiality further clarify of which elements this justification should be composed. In the respective e-submission platform, which may be either IUCLID, the e-submission food chain platform or the 'Portalino', depending

on the sector, an applicant is required to provide the following elements for each confidentiality request:

1. The relevant legal basis, or grounds, under which the confidentiality request is submitted

   In accordance with Article 39(2) of the GFL, the applicant may request certain parts of the information submitted to be treated as confidential in accordance with the provisions of Article 39(2) and (3) of the GFL. The closed positive lists are set out in the abovementioned Article 39(2), as well as in Article 30(2) of Regulation (EC) No 1829/2003, Article 18(3) of Regulation (EC) No 1831/2003, Article 20(2) of Regulation (EC) No 1935/2004, Article 12(3) of Regulation (EC) No 1331/2008, Article 63(2) of Regulation (EC) No 1108/2009, Article 23(4) of Regulation (EC) 2015/2283, and Article 25(3) of Directive 2001/18/EC, which are referenced in the Annex to EFSA's Practical Arrangements on transparency and confidentiality.

   The applicant shall specify under which of these items and provision the confidentiality request is submitted.

2. The relevant justification, pursuant to Article 10 of EFSA's Practical Arrangements concerning transparency and confidentiality. In this regard, the applicant must clarify

   i. that public disclosure of the relevant parts of the information would potentially harm their interest to a significant degree. In this regard, the applicant must clarify if
      a. the information on which the request is made is worthy of protection. In order to verify whether or not the interests liable to be harmed by disclosure are objectively worthy of protection, the applicant should confirm that the information for which the confidentiality treatment is requested was legally acquired. In case no confirmation is provided in the confidentiality request, the applicant must justify why the confidentiality request should be accepted nonetheless.
      b. the harm that may be caused by the disclosure of the information for which the request is filed amounts to at least 5% of the gross annual turnover/income for the relevant year.

      The relevant year is the financial year preceding the calendar year of the submission of the confidentiality request. This means that the indicative percentage of the expected loss must be calculated with regard to the last budget or last tax declaration submitted to the competent authorities.

      For the concept of turnover, regard should be had to the definition set out in Article 2(5) of Directive 2013/34/EU, paying due attention to the fact that EFSA's Practical Arrangements ask applicants to submit the statement of turnover regarding the legal or natural person for the benefit of which the application is submitted.

      The applicant is allowed to calculate the potential harm caused by the disclosure in a cumulative manner by considering confidentiality requests concerning the same or different documents, provided these are linked logically or functionally. By way of example, different confidentiality requests on different documents belonging to the manufacturing process may be considered in a cumulative manner, for the purpose of meeting the 5% threshold.

If the applicant cannot establish that the harm that may be caused by disclosure reaches at least 5%, it must provide appropriate justification demonstrating why in that specific case the harm that would be caused would still be significant.

ii. Whether the information concerned has been finalized[23] more than 5 years ago (novelty test). If it is older than five years, the justification as to why public disclosure of that information would still potentially harm its interests to a significant degree must be provided;
iii. whether there is a direct causal link between the harm sustained and disclosure of the information concerned;
iv. whether the information concerned falls under the definition of "environmental information" in accordance with Article 2(1)(d) of Regulation (EC) No 1367/2006 ("the Aarhus Regulation").

13. What is intended by "harm to the interests of the applicant to a significant degree"?

In accordance with Article 11 of EFSA's Practical Arrangements concerning transparency and confidentiality, the applicant must provide explanation or evidence that the harm that may be caused by the disclosure of concerned information harms the interests of the applicant to a significant degree. This translates in a rebuttable presumption that the information can be disclosed if the harm that may be caused by the disclosure of the information concerned does not amount to at least 5% of the gross annual turnover/income for a year or if the information concerned is older than 5 years. As a consequence, the applicant must provide adequate and verifiable justification to rebut these presumptions in case they consider the presumptions are not applicable in their specific case.

EFSA verifies whether the applicant provided a specific reason as to why they consider that disclosure would nonetheless potentially harm their interests to a significant degree taking into account the specificities related to each case, including the size of the legal person, or the earnings of the natural persons, their positioning on the respective market in relative and absolute terms as well as local and sectoral conditions, or socio economic factors, insofar as relevant.

EFSA does not exclude the possibility of considering on a case by case basis and upon receipt of supporting and verifiable justification related to each confidentiality request, that cumulative harm concerning different items functionally or logically connected one to another may be considered as contributing to meeting the indicative threshold of 5%. EFSA equally does not exclude a priori the cumulative effect that the disclosure of different items could have on the financial situation of the applicant. However, this needs to be asserted and supported by adequate reasoning and it will be assessed on a case by case basis.

Please also refer to question 12.

[23] For the purposes of documents, finalized information should be taken to refer to documents which were published or formally approved/adopted. As concerns data, finalized information shall refer to validated data only.

14. Which are possible examples of information eligible for legal protection and has not acquired in an unlawful manner?

The Practical Arrangements on transparency and confidentiality are not intended to provide possible examples but to lay down practical arrangements concerning transparency and confidentiality. The Practical Arrangements constitute binding means to interpret and implement the legal framework provided by the Transparency Regulation and by specifying the details for the implementation of required processes commit EFSA to the application of the Transparency Regulation.

A concrete example of information acquired in a legitimate manner may be that of studies for which the applicant secured necessary rights for regulatory use with the owner of the study by means of a Letter of Access or by means of specific contractual arrangements of some sort, or again, as a consequence of a merger or acquisition of the study owner.

For what concerns the concept of information eligible for legal protection and that has not been acquired in an unlawful manner, EFSA intends to accept at face value the confirmation provided by the applicants, without seeking the submission of documentary evidence. This is without prejudice to the possibility that EFSA may receive evidence of fraudulent actions or declarations from the applicant and decide to take the appropriate measures.

15. Why is it requested to demonstrate that information on which confidentiality is requested is not "environmental information"?

In accordance with Article 10 of the Practical Arrangements on transparency and confidentiality, applicants must either confirm that the information which is claimed confidential falls under the definition of "environmental information" pursuant to Article 2 of Regulation (EC) 1367-2006 ("the Aarhus Regulation"), or provide a text explaining comprehensively and in plain language the reason(s) why the document, information or data for which confidential status is requested does not fall under such definition.

Pursuant to recital 8 of the Practical Arrangements on transparency and confidentiality, documents, information or data falling under the definition of environmental information should be subject to higher transparency standard in view with the legitimate interest of the public at large to be in a position to gradually gain access to information that relates to the environment in which we all live. Article 2(1)(d) of the Aarhus Regulation provides an accurate definition of "environmental information" and EFSA is not empowered to provide further definitions as this would go beyond the empowerment it received under Article 39d(5) of the GFL regulation.

Pursuant to Article 1(b) of the Aarhus Regulation the objective of this requirement is to ensure that environmental information is progressively made available and disseminated to the public in order to achieve its widest possible systematic availability and dissemination in recognition of the public interest served by disclosure.

Article 4 of the Aarhus Regulation prescribes that Union institutions, agencies and bodies must organise the environmental information which is relevant to their functions and which is held by them, with a view to its active and systematic dissemination to the public, in particular by means of computer telecommunication and/or electronic technology. In accordance with Article 6 of the Aarhus Regulation exceptions to disclosure must be interpreted in a restrictive way, taking into account the public interest served by disclosure.

Due attention should be paid to the fact that only the established case law of the Court of Justice represents a binding authority providing the definitive interpretation of relevant Union law.

16. Are there other criteria EFSA will consider when assessing confidentiality requests?

No, the criteria that EFSA will use to assess confidentiality requests are those set out in its Practical Arrangements and already outlined in the previous replies. Every confidentiality assessment will be carried out on a case by case basis taking into account all relevant specific circumstances applicable to particular confidentiality requests and brought to EFSA's attention by the applicant.

EFSA is empowered to award confidential treatment only to the information items included in the closed positive lists set out in Article 39(2)(a), (b), (c), (d) (e) of the GFL, Article 30(2) of Regulation (EC) No 1829/2003, Article 18(3) of Regulation (EC) No 1831/2003, Article 20(2) of Regulation (EC) No 1935/2004, Article 12(3) of Regulation (EC) No 1331/2008, Article 63(2) of Regulation (EC) No 1108/2009, Article 23(4) of Regulation (EC) 2015/2283, Article 25(3) of Directive 2001/18/EC and Annex I of EFSA's Practical Arrangements on transparency and confidentiality.

This implies that the Authority may not add additional information items on which confidentiality requests may be submitted that go beyond those already set out in the positive lists recalled above. In turn, this means that the breach of an IPR that may be, or that is caused, by the disclosure of the information or document that is claimed confidential is not, in its own right, a sufficient justification for the award of confidential status. Nonetheless, if an applicant provides a justification demonstrating that such breach harms them to a significant degree in accordance with Article 10 of EFSA's Practical Arrangements on transparency and Confidentiality, and the request concerns one of the items on the closed positive lists, EFSA may award confidential status to the information with regard to which the request has been submitted (e.g. DNA sequence provided in the context of a request for authorisation for a GM Food – which is also IPR protected – may get confidential status by means of being listed in the closed positive lists and the applicant has demonstrated that public disclosure of this information would potentially harm its interests to a significant degree).

Applicants may also consider supporting their applications by relying on scientific publications available to the public (e.g., upon payment of a fee). Where applicants may not have or may not be able to obtain the necessary IPRs by the rightful owner (e.g., scientific journals) for the reproduction of those publications on OpenEFSA portal (for public dissemination purposes), they will have the possibility of providing instead the full bibliographic references allowing the correct identification of the publication by the public.

Due attention should be paid to the fact that this is not part of the confidentiality decision making process and that this option does not exempt the applicants from the need to secure the right for regulatory use of these publications in accordance with the applicable IPR law (i.e. provision of copies of those scientific publications in the dossier to facilitate risk assessment by risk assessors), and it is available exclusively for publications in scientific journals, or comparable publications.

17. Can confidentiality requests be made on additional or supplementary information provided by applicants?

Yes, it is possible for applicants to submit confidentiality requests also with regard to additional information or data, or clarifications, submitted in the context of the scientific evaluation performed by EFSA (or by a national authority in a multi-layered scientific evaluation involving also EFSA).

In accordance with Article 6(1)(c) of the Practical Arrangements on transparency and confidentiality, non-confidential versions submitted by applicants of scientific data, studies and other information part of, or supporting, an application, including additional or supplementary information supplied by applicants, shall be made public by EFSA without delay, once a valid or admissible application has been received. Non confidential versions submitted by applicants of any additional or supplementary information supplied by the applicant at the request of EFSA in relation to a submitted application shall be made public by EFSA, without delay, upon receipt.

Confidentiality requests regarding data submitted during the scientific evaluation process are submitted by the applicant through the appropriate tools, namely the E-submission Food Chain platform (formerly known as FSCAP), IUCLID for pesticides or EFSA's "Portalino".

In accordance with Article 11(5) of the Practical Arrangements on transparency and confidentiality, EFSA shall decide upon confidentiality requests concerning additional or supplementary information provided once the submission has been considered complete, and in a single decision. All confidentiality requests are grouped together and kept on hold until the scientific output has been adopted/approved/endorsed. Once the scientific output has been adopted/approved/endorsed, EFSA processes the confidentiality request by analysing the confidentiality requests in their entirety, including the merits of the verifiable justification submitted by the applicant in accordance with Article 10 of the Practical Arrangements on transparency and confidentiality. This means that the decision making on confidentiality requests concerning additional or supplementary information submitted during the scientific evaluation process commences after the scientific evaluation is complete.

18. How does EFSA decide about confidentiality requests?

EFSA first verifies compliance of the confidentiality requests with the procedural requirements for the submission of confidentiality requests set out in Articles 9 of the Practical Arrangements on transparency and confidentiality. Then EFSA performs an individual assessment of the confidentiality requests pursuant to Article 11 of the Practical Arrangements on transparency and confidentiality considering compliance with substantive requirements set out in Article 10 thereof.

More specifically, this implies that EFSA verifies that the requests have been:

1) submitted by using the correct tool;
2) made on one or more of the items listed in the Annex to the Practical Arrangements concerning transparency and confidentiality;
3) submitted with verifiable justification;
4) submitted with a justification proving compliance with the substantive requirements set out in Article 10 of the Practical Arrangements, namely:
    a) a clear identification of the relevant parts of the submitted information that, in their opinion, qualify for confidential treatment, accompanied by a link to and a detailed

reference to the exact paragraph, page, line or part thereof as appropriate, where this information is located, in a sufficiently precise manner so as to exclude any information that is not subject to the confidentiality request;

b) a text explaining the reason(s) why the information should be granted confidential status.

As part of the latter check, EFSA assesses that the following requirements have been satisfied, and if this is the case, to which extent:

(i) the document, information or data for which confidential status is requested is not publicly available or is known only to a limited number of persons;

(ii) the public disclosure of the document, information or data for which confidential status is requested may potentially harm the interests of the applicant to a significant degree;

(iii) the applicant provided explanation or evidence demonstrating to the satisfaction of the Authority that the harm that may be caused is of a significance corresponding at least to 5% of the gross annual turnover for legal persons, or the gross annual earnings for natural persons, for the financial year preceding the calendar year of the submission of the confidentiality request.
If the harm is quantified as not reaching this percentage, or the applicant is unable to calculate its impact on their turnover/earnings, the applicant shall provide a specific reason as to why they consider that any public disclosure would potentially harm their interests to a significant degree;

(iv) the document, information or data for which confidential treatment is requested is eligible for legal protection and has not been acquired in an unlawful manner;

(v) the document, information or data for which confidential status is requested does, or does not, fall under the definition of "environmental information" pursuant to Article 2 of the Aarhus Regulation;

(vi) the document, information or data for which confidential status is requested has been finalised in the form in which it was submitted to the Authority up to five (5) years prior to the submission of the confidentiality request. If the document, information or data for which confidential status is requested is older than five (5) years, the applicant shall provide (a) specific reason(s) as to why public disclosure of that information would still potentially harm its interests to a significant degree.

If EFSA confirms compliance with these elements, it awards confidential status to the relevant piece of information by confirming the validity of the confidentiality requests and of the public version of the document or information on which they have been submitted.

Conversely, in case EFSA concludes that one or more of the elements above is not provided, or not provided to the required extent, or that the justification provided to justify departure from the rebuttable presumptions is not credible or does not justify such departure, it adopts a wholly negative, or partially negative, confidentiality decision, depending on the case.

19. What is the administrative procedure for reviewing previous confidentiality decisions?

In accordance with Article 39b(2) of the GFL, the applicant may file a confirmatory application asking EFSA to reconsider its decision adopted under Article 11 or Article 14 of its Practical Arrangements concerning transparency and confidentiality. Without prejudice to the possibility

to provide clarifications at EFSA's request, the confirmatory application shall be limited to the review of the contested decision and shall not result in new confidentiality requests which were not part of the original confidentiality request subject to the confirmatory application.

The applicant shall submit a confirmatory application on a previous negative decision via the relevant tool within two (2) calendar weeks of the notification of the contested decision to the applicant. In the absence of a tool, the confirmatory application shall be sent via email to confidentialityconfirmatoryapplication@efsa.europa.eu.

Upon receipt of a confirmatory application, EFSA shall put on hold the implementation of its confidentiality decision with respect to which it has received the application.

Following an examination of the grounds set out by the applicant, EFSA shall issue a reasoned decision on the confirmatory application and notify the applicant thereof not later than three (3) calendar weeks from its receipt via the relevant tool.

The notification of the reasoned confirmatory decision, or the decision itself, shall indicate the possibility for the applicant to withdraw its application as well as the legal remedies available to the applicant, namely the possibility to bring an action challenging the legality of the confirmatory decision under Articles 263 and 228 TFEU.

20. How does EFSA implement confidentiality decisions?

EFSA implements its confidentiality decisions in line with Article 13 of the Practical Arrangements on transparency and confidentiality. This is done through the 'sanitisation', or redaction, of information as defined under Article 3(1)(c) of the Practical Arrangements on transparency and confidentiality as the process of masking or unmasking of scientific data, studies and other information in accordance with a confidentiality request or with a confidentiality decision, including the masking of personal data in accordance with Article 39e(2) of the GFL.

The applicant is responsible for submitting a confidential and a non-confidential version of application dossiers to EFSA. The non-confidential version shall not include any information which the applicant deems confidential, including personal data, and for which a confidentiality request has been submitted to EFSA.

In the non-confidential version, the items deemed confidential by the applicant must be permanently masked (not removed). Technically, it can be achieved by using a redaction tool which ensures that the redacted information is irreversibly blocked out.

In line with Article 6(1) of the Practical Arrangements on confidentiality and transparency, EFSA will publish the non-confidential versions of scientific data, studies and other information part of, or supporting, an application without delay once a valid or admissible application has been received.

Equally, EFSA will publish without delay the non-confidential versions of any additional or supplementary information submitted by the applicant upon receipt.

EFSA aims to share the documents which were sanitised by EFSA in line with its confidentiality decision prior to its dissemination with the applicant in line with Article 13(3) of the PA with the sole purpose to further verify the consistency between the confidentiality decisions and the way in which they have been implemented by EFSA. This additional and optional verification is not meant

to introduce new confidentiality requests or to reopen confidentiality decisions that were already taken.

Any potential verification with the applicant will be subject to a very short deadline for the applicant to reply in order to allow EFSA to assess feedback on the factual correctness of the sanitization, and to possibly incorporate it in a revised sanitised version.

The publication of any data and information for which the confidentiality request has not been accepted as justified by EFSA will take place on the OpenEFSA portal by two weeks after the notification of the confidentiality decision (in the absence of a confirmatory application).

If a confirmatory application is submitted, the publication of any data and information for which the confidentiality request has not been accepted by EFSA as justified will take place on the OpenEFSA Portal within two weeks after the notification of the decision on the confirmatory application to the applicant.

21. How can EFSA decisions on confidentiality be challenged?

In accordance with Article 12(6) of the Practical Arrangements on transparency and confidentiality EFSA's decisions can be challenged pursuant to Article 263 of the TFEU, by lodging an action contesting its legality before the General Court of the European Union within two months and ten days of its receipt.

In the alternative, if the applicant believes that maladministration was committed by EFSA in processing the confidentiality request, it has the right to lodge a complaint to the European Ombudsman pursuant to Article 228 of the TFEU within two years as of the moment they became aware of the facts that would amount to maladministration. Prior to lodging a complaint with the European Ombudsman, the applicant must first have contacted EFSA in an endeavour to resolve the matter.

22. What if the applicant withdraws the application?

In accordance with Article 39b(1) of the GFL as amended by the Transparency Regulation, the applicant may withdraw its application within two weeks of the date on which it was notified of EFSA's draft decision. This is also reflected in Article 11(3)(a) of the Practical Arrangements concerning transparency and confidentiality. However, this by no means implies that the applicant is deprived of the possibility of withdrawing the application after this moment.

This is clarified also in Article 15 of the Practical Arrangements concerning transparency and confidentiality. Pursuant to Article 15(1) of the Practical Arrangements concerning transparency and confidentiality where an applicant withdraws its application prior to the adoption of a confidentiality decision, the Member States, the Commission and EFSA shall not make public the information for which confidentiality has been requested pursuant to Article 9 and Article 10 of the Practical Arrangements.

The same holds true also in case the applicant withdraws the application before the confidentiality decision in question is implemented, or before the sanitised document or data is disseminated by EFSA.

EFSA shall likewise not make public the information that has been granted confidential status by EFSA pursuant to Articles 11, 12 and 14 of the Practical Arrangements concerning transparency and confidentiality if the application is withdrawn after the adoption of a confidentiality decision,

and the same principles apply also to decisions on confirmatory applications and to documents on which these decisions are implemented.

Importantly, if the withdrawal notice from the applicant reaches EFSA *after* the relevant confidentiality decision is implemented, and after the documents or data sanitised accordingly are disseminated to the public, the Authority commits to deleting the relevant information or data without delay on receipt of the notice.

23. How will EFSA ensure confidentiality of information which has been granted confidentiality status?

Elements granted confidential status by EFSA, the Commission or the national competent authority, depending on the applicable legal framework, are not subject to proactive disclosure. Furthermore, standards of professional secrecy referred to in Article 17 of EFSA's Practical Arrangements concerning transparency and confidentiality apply to all such information, which is also not shared with the Commission or Member States authorities unless this is required by law or upon their explicit request.

These obligations last during the term of office, service or appointment of the concerned professionals and shall continue after their duties have ceased with respect to the information and knowledge acquired during the term of office, service or appointment. EFSA ensures that individuals handling or processing confidentiality requests and decisions dispose of the necessary professional background and expertise and shall develop, also by of training, a corporate culture of regulatory awareness conducive to the adoption of legally sound and well-reasoned decisions.

It should be noted that the above is without prejudice to reactive transparency requirements under Regulation (EC) No 1049/2001 on public access to documents held by Union institutions and Regulation (EC) No 1367/2006, or to the need to disclose relevant document or data in the context of auditing and other *ex post* controls, as well as with sharing with Commission or Member States authority upon request, or when so required by law. In practice, this means that even if a document is awarded confidential status under Articles 39-39e of the GFL, or one of the relevant sectoral provisions, it may still be subject to requests for access to documents under one of the two regulations above. These requests, if received, are processed by EFSA in accordance with the relevant legal framework and case law.

24. When will the Practical Arrangements concerning transparency and confidentiality be reviewed?

In accordance with recital 20 of EFSA's Practical Arrangements concerning transparency and confidentiality, EFSA commits to review this decision every five years following its entry into force, meaning by January 2026, and every five years thereafter.

D. EFSA PRACTICAL ARRANGEMENTS CONCERNING CONFIDENTIALITY IN ACCORDANCE WITH ARTICLES 7(3) AND 16 OF REGULATION (EC) NO 1107/2009

1. Which legal framework applies to confidentiality requests in the areas of pesticides and MRLs?

The legal framework applicable to confidentiality requests submitted with regard to new active substances is set out exclusively in Articles 7 and 63 of Regulation (EC) No 1107/2009, Commission Implementing Regulation (EU) 2021/428 and in EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation (EC) No 1107/2009. Article 7(3) of Regulation (EC) No 1107/2009 prescribes that the Rapporteur Member State (RMS) shall be responsible for issuing confidentiality decisions on requests submitted on dossiers for new pesticides active substances. It is the duty of the RMS to consult with EFSA on a draft decision, prior to its finalisation. This is reflected in Article 7 of EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation (EC) No 1107/2009. These Practical Arrangements set out minimum procedural and substantive requirements that the RMS must assess in their confidentiality decision.

The empowerment laid down in Articles 7 and 16 of Regulation (EC) No 1107/2009 concerns the adoption of Practical Arrangements aimed at ensuring the consistency of confidentiality decisions of the RMS with those adopted by EFSA. However, it does not go so far as empowering EFSA to achieve a complete harmonisation of the confidentiality decision making performed by RMS. In any event, EFSA is committed to continuously improve these set of Practical Arrangements, and does not exclude the possibility of developing in the future more detailed working instructions, or guidance documents, for the RMS to follow in their confidentiality decision making processes.

The legal framework applicable to confidentiality requests submitted with regard to renewal dossiers is set out exclusively in Articles 16 and 63 of Regulation (EC) No 1107/2009 and Commission Implementing Regulation (EU) 2020/1740, implemented by EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation (EC) No 1107/2009. According to Article 4 of these Practical Arrangements, however, these confidentiality requests are processed by EFSA in accordance with its Practical Arrangements concerning transparency and confidentiality, except for a few exceptions, set out therein.

Finally, the legal framework applicable to confidentiality requests submitted with regard to MRL applications under Regulation (EC) No 396/2005 may be identified in Articles 39-39e of the GFL. This is implemented by the Practical Arrangements concerning transparency and confidentiality.

In practical terms, this means that the confidentiality decision making processes managed by EFSA are *de facto* regulated by the Practical Arrangements concerning transparency and confidentiality, while decisions by the RMS are to be issued pursuant to EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation (EC) No 1107/2009.

2. How are confidentiality requests submitted?

According to Article 63 of Regulation (EC) No 1107/2009 and Article 39 of the GLF, transparency is the rule, and confidentiality is the exception. Furthermore, pursuant to Article 63 above, and EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7 and 16 of Regulation (EC) No 1107/2009, a confidentiality request must be submitted by applicants on every element whose confidentiality is requested.

Applicants must submit in IUCLID confidentiality requests for applications concerning new active substances, amendments to the conditions of an approval, confirmatory information renewal applications approval of basic substances and MRLs. As a rule, information inserted in IUCLID fields is automatically disclosed by EFSA when the application is deemed admissible, unless a confidentiality request is submitted by the applicants in IUCLID fields where this is permitted[24]. For what concerns confidentiality requests for new active substances and renewal applications, these fields are based on the items listed in Article 63(2)(a) to (g) of Regulation (EC) No 1107/2009 on which confidentiality may be requested. Instead, confidentiality requests on MRL applications must concern one or more of the items part of the closed positive list set out in Article 39(2) of the GFL.

The confidentiality request, if submitted, is assessed in accordance with the abovementioned Practical Arrangements.

Applicants must remove from the public version of the dossier personal data information not meant to be published (Article 39e of the GFL), such as personal data of names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information, along with information claimed to be confidential, in accordance with the abovementioned filter rules. The nonconfidential version of the dossier is then made available on IUCLID via the OpenEFSA Portal.

Applicants are advised to pay particular attention to the filtering feature in IUCLID. Dossier filtering is an automated process and it is independent of the text provided in a certain field. Therefore, in order to avoid the accidental dissemination of information not meant to be published, it is important for IUCLID users to review their dossier before submission via the dissemination preview feature.

Applicants should take note of the fact that a revised version of the dossier will be made available via the OpenEFSA Portal if the RMS or EFSA disagree with one or more confidentiality requests initially submitted. More comprehensive information on confidentiality request submission is made available in IUCLID user manuals.

3. How are confidentiality requests handled and according to which timeline?

The timelines reflected in EFSA's Practical Arrangements concerning transparency and confidentiality pursuant to Articles 7 and 16 of Regulation (EC) No 1107/2009 reflect those laid down in Articles 3939b of the GFL and are meant to provide for a level playing field with applicants submitting their dossiers under the latter provisions, or in sectoral legal acts referring to those (e.g., Regulation (EC) No 1829/2003; Regulation (EC) No 1831/2003).

[24] I.e. if the information may come under any of the items referred to in Article 63 (2) of Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2019/1381, that may be claimed confidential.

An outline of all relevant timelines that may be found in EFSA`s Practical Arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009 insofar as the processing of the confidentiality request is concerned is presented below:

Timelines for confidentiality requests submitted for the renewal of approval of an active substance (Article 4), and for the data or documents submitted under Regulation EC No 396/2005 (MRL regulation)

- A confidentiality request is submitted.
- EFSA may request the applicant to provide clarifications on the confidentiality request - clarifications must be submitted within 5 working days. If there is no response within the deadline, the Confidentiality Request is rejected as unjustified.
- The applicant may submit comments on EFSA`s draft decision regarding the confidentiality request or withdraw the application within two weeks from the notification of the draft decision.
- Having taken into account the applicant`s comments (if any), the Authority issues a decision no later than 10 calendar weeks from the receipt of the confidentiality request.
- The applicant may submit a confirmatory application within two calendar weeks from the notification of the final decision on the confidentiality request.
- The Executive Director issues a decision on the confirmatory application within three calendar weeks from its receipt.
- The decision is implemented within the timeline foreseen for its adoption. EFSA may share with the applicant the sanitised documents. Pending the modification of IUCLID to allow the direct intervention of EFSA on the applicant's dossier, the implementation of the decision may be delegated to applicant.
- The sanitised documents are published on EFSA`s website / OpenEFSA Portal at the latest two weeks from the notification of the relevant decision.

Timelines for Confidentiality Requests submitted for the approval of an active substance

- A confidentiality request is submitted.
- No later than four calendar weeks after the receipt of a complete confidentiality request and prior to finalising its confidentiality decision, the RMS consults with EFSA by sharing the draft decision.
- EFSA provides its comments on the draft decision no later than 10 working days from its receipt.
- Having taken into account EFSA`s comments, the RMS shares a draft decision with the applicant, for the latter to submit comments.
- The applicant may comment within 1 calendar week from the notification of the draft decision to it.
- Having taken into account the applicant`s comments, the RMS shall issue a decision within 4 calendar weeks from the time it received EFSA`s comments.
- The RMS notifies its decision to the applicant.
- The RMS implements the decision within 1 calendar month from the notification of the decision to the applicant. Pending the modification of IUCLID to allow the direct intervention of EFSA on the applicant's dossier, the implementation of the decision may be delegated to applicant.

- The sanitised documents are published on EFSA`s website / OpenEFSA Portal by one month from the notification of the relevant decision.

Timeline for review of previous confidentiality decisions

- EFSA shares the draft decision with the applicant.
- The applicant may submit comments on EFSA`s draft decision within 2 weeks from its notification.
- Having taken into account the applicant`s comments (if any), the Authority issues a decision within 20 working days from the adoption of the concerned scientific output.
- The applicant may submit a confirmatory application within two calendar weeks from the notification of the final decision on the confidentiality request.
- The Executive Director issues a decision on the confirmatory application within ten working days from its receipt.
- The decision is implemented within the timeline foreseen for its adoption.
- The sanitised documents are published on EFSA`s website within two 2 from the notification of the relevant decision.

4. Is coordination envisaged between EFSA and the RMS in confidentiality decision-making?

Several arrangements have been put in place to achieve consistency between confidentiality decisions taken by EFSA and the RMS.

The timelines set out in the Practical Arrangements for RMS confidentiality decision making correspond to, and reflect, those granted to EFSA for its own decisions. This is meant to contribute to achieving the purpose of the Practical Arrangements, which is to ensure consistency between EFSA's and RMS' confidentiality assessments.

Furthermore, these timelines also contribute to ensuring that confidentiality decision making does not delay the public consultation to be performed pursuant to Article 32c(2) of the GFL, which in turn could delay the risk assessment and peer review process.

Similarly, the substantive and procedural criteria that applicants are expected to comply with under Article 6 of EFSA's Practical Arrangements concerning confidentiality under Articles 7 and 16 of Regulation (EC) No 1107/2009, correspond exactly to those laid down in Articles 9 and 10, respectively, of EFSA's Practical Arrangements concerning transparency and confidentiality regulating EFSA's own confidentiality decision making process.

In this regard, the mandatory consultation that each RMS has to perform on its draft confidentiality decisions by seeking EFSA's comments provides an extra layer of security and a concrete means for the Authority to verify compliance with its Practical Arrangements, and therefore also with its substantive screening criteria. Over time, this commenting phase is likely to become a source of authoritative interpretation of the Practical Arrangements, thereby mitigating to a large extent the risk of an inconsistent application of the applicable regulatory framework.

ANNEX 1 - LIST OF MAIN CHANGES INTRODUCED IN THE UPDATED VERSION OF 28 AUGUST 2023 OF THE QUESTIONS AND ANSWERS ON THE EFSA PRACTICAL ARRANGEMENTS' DOCUMENT

Front page	A new sentence on the temporal applicability of the updated version is added.
PART B	
Question 4	The sentence referring to studies performed for development purposes is removed, while the concept is further elaborated in Question 34. A new paragraph is included to clarify which analytical measurements are exempted from notification of study obligations as of the date of the publication of the updated version of the Q&A document. A sentence is also added to clarify that method validation studies are not considered to fall within the study definition.
Question 6	The number of additional contacts that can be added to an account is increased (from two to six, or more in certain cases) with regard to the registration of entities in the Connect.EFSA platform.
Question 11	It is specified that background information should be provided when requesting general pre-submission advice.
Question 14	It is clarified that a closer support may be given to SMEs, by providing the answer to the general pre-submission advice preferably in a meeting.
Question 15	A sentence is added to indicate that EFSA can request for a clarification before deciding on the acceptability of a general pre-submission advice request.
Question 19	Information is added to clarify which parts of a general pre-submission advice request is not subject to proactive disclosure.
Question 22b	A new question is added to clarify what is meant by an intended study.
Question 28b	A new question is added to clarify in which circumstances the pre-submission activities related to a renewal pre-submission advice can be interrupted by EFSA.
Question 32	The former answer is removed as the question relates to a situation which can no longer arise.
Question 34	A sentence is added to clarify which studies cannot be considered being conducted for research purposes only, in the context of notification of study obligations. Information is added to clarify at which stage the notification of study obligations would apply for applications that have been submitted in the context of Regulation (EC) No 1107/2009.
Question 35	Information is added to complement the information on the co-notification process to reflect the behaviour of the system.
Question 37	A sentence is added to clarify which type of documentary evidence is expected to be provided in case of studies that were initially performed for other purposes than for the European Union market and that have been notified with delay.

The main changes are highlighted in the document with a grey shading. Minor and editorial changes are not listed above.