DECISION
LAYING DOWN THE PRACTICAL ARRANGEMENTS ON PRE-SUBMISSION PHASE AND PUBLIC CONSULTATIONS

THE EXECUTIVE DIRECTOR OF THE EUROPEAN FOOD SAFETY AUTHORITY,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Charter of Fundamental Rights of the European Union,

Having regard to 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,[1] and in particular Articles 32b(8) and 32c(3) thereof,

Whereas:

(1) Regulation (EC) No 178/2002 ('GFL Regulation'), as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council[2] aims at increasing the transparency of the EU risk assessment in the food chain, on strengthening the reliability, objectivity and independence of the studies used by European Food Safety Authority ('the Authority'), and revisiting the governance of the Authority in order to ensure its long-term sustainability.

(2) To this end, *inter alia*, the GFL Regulation provides for measures to guarantee that applications or notifications[3] submitted to the Authority meet the applicable specifications in order to ensure the best quality scientific assessment. To increase the understanding of those specifications by applicants, in particular small and medium-sized enterprises, Article 32a(1) of the GFL Regulation foresees that, where the Authority may be requested to provide a scientific output, the staff of the Authority, at the request of a potential applicant or notifier,[4] shall provide pre-submission advice on the rules applicable to, and the content required for, the application, prior to its submission ('general pre-submission advice'). However, such general pre-submission advice should not address the design of the studies to be submitted, which remains the applicant's responsibility.

(3) In the case of applications to request the renewal of an authorisation or an approval, the authorised or approved substance or product has already been on the market for several years. Experience and knowledge therefore already exist with regard to the substance or

[1] OJ L 31, 1.2.2002, p. 1.

[2] 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).

[3] For ease of reference, the term "application or notification" referred to in the GFL Regulation will be referred to as "application" throughout the entirety of these practical arrangements.

[4] For ease of reference, the term "applicant or notifier" as referred to in the GFL Regulation will be referred to as "applicant" throughout the entirety of these practical arrangements.

product. In this context, Article 32c(1) of the GFL Regulation foresees that, where Union law provides that an approval or authorisation may be renewed and the Authority may be requested to provide a scientific output, studies planned for supporting requests for renewals, including information on the proposed design, shall be notified to the Authority by the potential applicant and submitted for consultation of third parties. Following this consultation, and taking into account the comments received, the Authority shall systematically provide specific pre-submission advice to the potential applicant on the content of the intended renewal application, as well as on the proposed design of the studies ('renewal pre-submission advice').

(4) The GFL Regulation also provides for measures enabling the Authority to have knowledge of all studies commissioned or carried out by potential applicants with a view to supporting applications under Union law, which places the Authority in the position to perform its risk assessment responsibilities in the most effective and efficient manner possible. To this end, the establishment and management of a database of studies commissioned or carried out by business operators (hereinafter "database of study notifications" or "database") is of pivotal importance both for potential applicants as well as for the Authority. Indeed, business operators commissioning or carrying out studies at pre-submission phase are required to notify to the Authority certain specific information related to those studies. The same obligation applies to the laboratories and other testing facilities carrying out those studies, located in the EU as well as in third countries insofar as set out in relevant agreements and arrangements with those countries, including as referred to in Article 49 of the GFL Regulation. Furthermore, to ensure the effective implementation of the legal obligations related to the notification of studies laid down in Article 32b(2) and (3) of the GFL Regulation, certain procedural consequences are triggered as a result of non-compliance.

(5) In addition, the GFL Regulation provides for measures ensuring that the Authority can have access to all relevant scientific data and studies available on a subject matter of an application for an authorisation/approval or a renewal thereof. To this end, Article 32c(2) of the GFL Regulation provides for the consultation of third parties on the submitted scientific data and studies in order to identify whether other relevant data or studies are available. The consultation shall take place on the basis of the non-confidential version of the application made public by the Authority following the implementation of the confidentiality decision-making ('final confidential version'), immediately after such disclosure to the public.

(6) For the purposes of implementing the procedures outlined in Articles 32a and 32c of the GFL Regulation, the Authority is required to adopt practical arrangements to that effect, pursuant to Article 32c(3) of the GFL Regulation.

(7) For the purposes of implementing the provisions outlined in Article 32b of the GFL Regulation, including arrangements for requesting and making public valid justifications, the Authority is required to adopt practical arrangements to that effect, pursuant to Article 32b(8) thereof.

(8) Given that this decision implements certain provisions of Regulation (EU) 2019/1381, which applies from 27 March 2021, this Decision should apply from the same date.

(9) It may become appropriate to refine certain elements of this Decision based on the experience gained in the implementation of Regulation (EU) 2019/1381. To this end, the Executive Director should review this Decision every five years following its entry into force.

HAS ADOPTED THE FOLLOWING DECISION,

CHAPTER I

GENERAL PROVISIONS

Article 1
Scope

1. With regard to the provision of pre-submission advice, this Decision:

(a) establishes the procedures for the provision of general pre-submission advice referred to in Article 32a(1) of the GFL Regulation and, in the context 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[5] ('Regulation (EC) 1107/2009 on plant protection products') 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 on MRLs),[6] the specific modalities to be followed by future applicants, the Authority and the Member State national competent authorities;

(b) establishes the procedures for the provision of renewal pre-submission advice referred to in Article 32c(1) of the GFL Regulation and the relevant modalities to be followed by future applicants, the Authority, as well as the national competent authorities in the context of Regulation (EC) 1107/2009 on plant protection products. With a view to the provision by the Authority of the renewal pre-submission advice, this decision also establishes:

(i) the obligation for the potential applicant for the renewal to notify the Authority of the studies it intends to perform for that purpose, including information on the proposed design;

(ii) the procedures for launching the consultation of stakeholders and the public on the intended studies for renewal; and

(iii) shall not apply to requests for pre-submission advice submitted to the national competent authorities or originating from the competent authorities of a Member State outside the framework of Articles 32a(1) and 32c(1) of the GFL Regulation.

2. With respect to the notification of studies referred to in Article 32b of the GFL Regulation, this Decision:

(a) shall apply to:

(i) the establishment and management by the Authority of the database of notifications of studies commissioned or carried out to support an application in relation to which Union law contains provisions for the Authority to provide a scientific output as referred to in Article 32b(1) of the GFL Regulation (study notifications);

(ii) the obligation for business operators to notify the Authority of information of studies commissioned to a laboratory or testing facility or carried out by them in an in-house laboratory or testing facility to support an application as provided for in Article 32b(2) of the GFL Regulation, as well as the obligation for laboratories and other testing facilities being commissioned or carrying out those studies to notify study-related information, as provided for in Article 32b(3) of the GFL Regulation;

[5] 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).

[6] 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 (OJ L *70,* 16.3.2005, p. 1).

(iii) the assessment of the validity of applications, by the Authority exclusively or jointly with the Commission, in accordance with Article 32b(4) and (5) of the GFL Regulation and the implementation of any resulting procedural consequences;

(iv) the detection of the absence of necessary information during the Authority's risk assessment in accordance with Article 32b(6) of the GFL Regulation and the implementation of any resulting procedural consequences.

(b) shall not apply to the public disclosure of the notified information referred to in Article 32b(7) of the GFL Regulation and of the valid justifications, where received in line with Article 32b(4) to (6) of the GFL Regulation, which is addressed, respectively, by Article 6(1)(f), (g) and (h) of Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality.

3. This Decision establishes the procedures followed by the Authority for launching the consultation of stakeholders and the public referred to in Article 32c(2) of the GFL Regulation and accounting for all relevant results in the process of delivering the Authority Scientific Output.

Article 2
Definitions

For the purpose of this Decision, and without prejudice to any relevant Union law provisions, the following definitions shall apply:

(a) "Regulated product" means the claim, process, product, substance, active ingredient or organism which is the subject matter of an intended or submitted given application for which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion.

(b) "Regulated product area" means the legal framework under which the potential applicant intends to submit or has submitted an application for a regulated product.

(c) "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.

(d) "Multisite study" means any study conducted at more than one testing site, including when more than one laboratory or testing facility are partnering to carry out the same study. Work subcontracted by the laboratory or testing facility to which the study was commissioned to other testing facilities shall not be considered for the purpose of this definition.

(e) "Starting date of a study" means the experimental starting date, that is to say, the date on which the first study-specific data are expected to be collected; in the specific case where the experimental starting date is difficult to estimate, the starting date of a study is determined as follows:

(i) for studies conducted according to an established protocol, the starting date of a study means the date of signature of this protocol;

(ii) for studies not conducted according to an established protocol, the starting date of a study means the date of definition of the study plan.

(f) "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 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 date means the provisional date of generation of the final results.

(g) "Laboratory or testing facility" means the natural or legal persons carrying out the study as defined in letter c).

(h) "Pre-submission activity or activities" means one or more of the activities foreseen in Chapters II, III and IV.

(i) "Potential applicant" means any private or legal person that can profit from or is subject to pre-submission activities. This definition does not include "laboratories and testing facilities" as defined in letter g).

Article 3
Registration

1. In order to initiate a pre-submission activity, a potential applicant or a laboratory or testing facility to which a study has been commissioned shall first register in the system developed by the Authority to support pre-submission activities, following the instructions of the user guide made available on the Authority's website.

2. Third parties authorised to represent one or more entities referred to in paragraph 1 shall also register in the Authority system supporting pre-submission activities, in accordance with the instructions of the user guide. For the purpose of this decision, references to entities referred to in paragraph 1 shall be read as including third parties authorised to represent those entities, where applicable.

3. Registered entities shall ensure that all information provided is reported accurately and kept up-to-date.

Article 4
Pre-application identification

1. Prior to initiating any pre-submission activity, potential applicants shall request the Authority to provide a pre-application identification ('ID'), which links all pre-submission activities undertaken by a potential applicant to support a future application related to a specific regulated product in a given regulated product area.

2. The pre-application ID may be requested by a potential applicant on behalf of a group of potential applicants in relation to all the pre-submission activities which are envisioned to support a future joint application related to a specific regulated product in a given regulated product area. To this effect, potential applicants involved in joint pre-submission activities under the same pre-application ID shall:

(a) agree among themselves on the allocation of all responsibilities and decide which potential applicant is to formally represent the group of potential applicants involved in the joint pre-submission activities;

(b) be responsible for ensuring that the interests of each potential applicant involved in the joint pre-submission activities are respected in a fair and appropriate manner.

(c) note that potential applicants involved in the joint pre-submission activities under the same pre-application ID are strongly recommended not to request any other pre-application ID in relation to the same regulated product and regulated area.

3. Where more than one potential applicant is planning to request renewal of the approval of the same active substance pursuant to the Commission Implementing Regulation (EU) 2020/1740 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) 844/2012,[7] the Authority strongly recommends these potential applicants to request a pre-application ID jointly in accordance with paragraph 2.

Article 5
Requirements in relation to the submission of applications

When submitting an application through the IT system made available by the Commission or the Authority for the submission of such applications, applicants shall also indicate each pre-application ID associated to any pre-submission activities carried out in relation to the specific regulated product which is the subject of that application.

CHAPTER II
GENERAL PRE-SUBMISSION ADVICE

Article 6
Scope and general provisions

1. The general pre-submission advice, provided by the staff of the Authority upon receipt of a request from a potential applicant in areas for which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion, shall, in accordance with Article 32a(1) of the GFL Regulation, be limited to the rules applicable to, and the content required for, an application. In particular, any input provided by the staff of the Authority shall relate exclusively to the relevant requirements set out in the applicable rules and guidance documents or guidelines. Aspects going beyond the information available in the rules and guidance documents or guidelines applicable to applications shall be out of the scope of the general pre-submission advice provided pursuant to Article 32a(1) of the GFL Regulation.

2. The advice referred to in paragraph 1 shall not address the design of studies, unless the advice concerns guidance documents developed by the Authority in which study design is addressed. Similarly, questions related to hypotheses to be tested or risk management shall be out of the scope of the general pre-submission advice pursuant to Article 32a(1) of the GFL Regulation.

3. Any general pre-submission advice pursuant to Article 32a(1) of the GFL Regulation with regard to applications for approval of new substances and renewal of approval of existing substances under Regulation (EC) 1107/2009 on plant protection products and applications for maximum residue levels of pesticides under Regulation (EC) No 396/2005 on MRLs shall be provided by the Authority together or in close collaboration with the national competent authorities, in accordance with the rules laid down in Article 10.

[7] OJ L 392, 23.11.2020, p. 20.

4. The Authority shall undertake all measures necessary to ensure that the staff of the Authority providing general pre-submission advice pursuant to Article 32a(1) of the GFL Regulation are not involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application that is the subject of the advice.

Article 7
Requests for general pre-submission advice

1. Potential applicants may request general pre-submission advice at any time before submitting the corresponding envisaged application, with respect to both intended applications for new authorisations or approvals and for renewals of existing authorisations or approvals. The Authority recommends submitting the request at least six (6) months before the envisaged submission date of the application.

2. Requests for general pre-submission advice shall be submitted to the Authority by filling in the dedicated general pre-submission advice online form ('general pre-submission advice form') available on the Authority's website. Potential applicant(s) shall link requests to the individual or joint pre-application ID referred to in Article 4, provided by the Authority in relation to the specific regulated product and regulated product area for which the advice is requested.

3. Potential applicant(s) shall provide all necessary information regarding the potential application, including an exhaustive list of questions, as specified in the general pre-submission advice form.

4. In order to reconcile the interests of individual potential applicants with those of good administration, each potential applicant shall submit questions in the form of one single request per pre-application ID; however, up to two requests may be submitted for the same pre-application ID, providing that the same questions are not repeated in both requests.

5. The Authority shall put in place separate measures facilitating the access to general pre-submission advice for small and medium-sized enterprises.

Article 8
Administrative checks

1. Following the receipt of the general pre-submission advice form, the Authority shall verify that the related questions fall within the scope outlined in Article 6 and that the request has been submitted in compliance with Article 7.

2. Within 15 working days from the receipt of the general pre-submission advice form, the Authority shall inform the requester(s) as to whether the submitted request is accepted or rejected. Rejected requests shall not be considered for the calculation of the maximum number of general pre-submission advice requests referred to in Article 7(4).

Article 9
Provision of general pre-submission advice

1. The Authority shall decide upon the most appropriate manner to address the questions posed through the general pre-submission advice form of a request which has been duly accepted in accordance with Article 8(2) by implementing the following working procedures:

(a) where possible, the Authority shall answer the questions in writing;

(b) if the Authority considers that a discussion with the potential applicant(s) might be useful to clarify specific aspects of the request, a meeting shall be organised. This meeting shall be conducted preferably by teleconference or video conference, however, in exceptional circumstances, the Authority may decide to organise physical meetings should the Authority consider that no other viable solution is available.

2. The Authority shall provide the requester(s) with its advice in accordance with the following timelines:

(a) for requests, or questions included in a request, in response to which the Authority has decided to reply in writing, the written advice shall be provided within 15 working days as of the date of the acceptance of the request;

(b) for requests, or questions included in a request, in response to which the Authority has decided to organise a meeting, the meeting shall be organised within 20 working days as of the date of the acceptance of the request. The advice shall be provided during the meeting.

3. The Authority shall draw up a summary proving a succinct overview of the advice and shall send this summary to the relevant requester(s) for information purposes only. The summary shall be made available to the relevant requester(s) in accordance with the timeline laid down in paragraph 2, letter a) or after the meeting referred to in paragraph 2, letter b).[8]

Article 10

Special and exceptional provisions applicable to the area of plant protection products and maximum residue levels of pesticides

1. This Article shall apply to requests for general pre-submission advice received by the Authority in the context of intended applications for approval of new substances and renewal of approval of existing substances under Articles 7 and 14 of Regulation (EC) 1107/2009 on plant protection products, and applications for maximum residue levels of pesticides under Regulation (EC) No 396/2005 on MRLs.

2. By way of derogation from Article 9, the Authority shall provide the requester(s) with its advice in close cooperation with the following national competent authorities:

(a) for intended applications for approval of new active substances under Article 7 of Regulation (EC) 1107/2009 on plant protection products, the Member State to which the application is going to be submitted ('intended rapporteur Member State') and, where applicable, the intended co-rapporteur Member State;

(b) for intended applications for maximum residue levels of pesticides under Article 6(1) of Regulation (EC) No 396/2005 on MRLs, the Member State to which the application is going to be submitted ('intended evaluating Member State');

(c) for intended applications for renewal of approval of existing substances under Article 14 of Regulation (EC) 1107/2009 on plant protection products and intended applications for import tolerance under Article 6(4) of Regulation (EC) No 396/2005 on MRLs, the designated rapporteur Member State/co-rapporteur Member State.[9]

[8] The public disclosure of the summary of general pre-submission advice shall be carried out in in accordance with Article 5(2)(f) of the Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality.

[9] Rapporteur Member States for renewal of approval of active substances are designated by the Commission and laid down in Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes

3. To this end the requester(s) shall provide the following information in the general pre-submission advice form:

(a) for intended applications for approval of new substances referred to in paragraph 2, letter a), the indication of the intended rapporteur Member State and, where applicable, the intended co-rapporteur Member State;

(b) for intended applications for maximum residue levels of pesticides referred to in paragraph 2, letter b), the indication of the intended evaluating Member State;

(c) for intended applications for renewals of existing substances and intended applications for import tolerance referred to in paragraph 2, letter c), the indication of the designated rapporteur Member State and, where applicable, the co-rapporteur Member State.[10]

Should the requester(s) fail to provide the information under paragraph 3, letter a) and b), the Authority shall provide the general pre-submission advice in accordance to Article 9. In this case, the Authority may not be held liable for any divergences between the general pre-submission advice provided by the Authority and that possibly provided separately by the relevant national competent authorities. Should the requester(s) fail to provide the information under paragraph 3, letter c), the request for general pre-submission advice shall be rejected pursuant to Article 8.

4. Notwithstanding the specific provisions applicable in the area of pesticides laid down in this Article, the ordinary provisions regarding requests for general pre-submission advice outlined in Article 7 shall apply.

5. Upon receipt, the request for general pre-submission advice shall be transmitted to the relevant national competent authorities referred to in paragraph 2. The Authority shall perform the administrative check referred to in Article 8 pursuant to the timeframe laid down therein.

6. Following the administrative check, the Authority shall inform the relevant national competent authorities whether the request for general pre-submission advice is accepted and whether it will be replied to in writing or in the context of a meeting.

7. If the request for general pre-submission advice relates to an intended application for renewal of an existing substance, and where agreed with the designated rapporteur Member State, the Authority shall involve the co-rapporteur Member State.

8. The general pre-submission advice shall be provided according to the following modalities and timelines:

(a) for requests, or questions included in a request, in response to which the reply shall be provided in writing:

(i) the Authority shall prepare the written advice and the related summary, in close cooperation with the relevant national competent authorities; if, the relevant national competent authorities disagree with the Authority on one or more replies, the written advice and the summary shall reflect both opinions. In any event, the Authority may not provide general pre-submission advice outside the scope outlined in Article 6(1) and (2).

(ii) within 20 working days as of the date of the acceptance of the request, the written advice and the related summary shall be provided to the requester(s).

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of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest (OJ L 200, 27.7.2012, p.5). The reference to rapporteur Member State also includes a group of Member States jointly assuming the role of the rapporteur Member States as set out in the fourth column of Part B of the Annex to Implementing Regulation (EU) No 686/2012, where appropriate.

[10] Rapporteur Member States for renewal of approval of active substances are designated by the Commission and laid down in Commission Implementing Regulation (EU) No 686/2012. The reference to rapporteur Member State also includes a group of Member States jointly assuming the role of the rapporteur Member States as set out in the fourth column of Part B of the Annex to Implementing Regulation (EU) No 686/2012, where appropriate.

(b) for requests, or questions included in a request, in response to which the Authority has decided to organise a meeting:

(i) the Authority shall prepare the meeting in close cooperation with the relevant national competent authorities;

(ii) the meeting shall be organised within 20 working days as of the date of the acceptance of the request; both the Authority and the relevant competent authorities shall attend;

(iii) the advice shall be provided during the meeting. In this context, the Authority may not provide general pre-submission advice outside the scope outlined in Article 6(1) and (2);

(iv) after the meeting, the Authority shall prepare a summary in close cooperation with the national competent authorities. If, the relevant national competent authorities disagree with the Authority on one or more replies provided to the requester(s) during the meeting, the summary shall reflect both opinions. The summary shall be sent for information to the requester(s).

9. The Authority shall share the written advice, the summary referred to in paragraph 8, letter a) and the summary referred to in paragraph 8, letter b) with the competent authorities of all Member States for information.

10. Following the submission of the application for which general pre-submission advice was requested, in order to allow for the public disclosure of the summary referred to in paragraph 8, letter a) and b), the relevant national competent authorities shall inform the Authority without delay of any positive conclusion as regards the admissibility of that application.[11]

11. The national competent authorities shall take the necessary measures so that information received by them under this Article are kept confidential.

12. The Authority is committed to providing the most helpful support possible by way of general pre-submission advice in close cooperation with the relevant national competent authorities. However, in situations whereby the relevant national competent authorities do not consent to such collaboration, the Authority may not be held liable for any divergences between the general pre-submission advice provided by the Authority and the one possibly provided separately by the relevant national competent authority.

Article 11
Non-committal nature of general pre-submission advice

1. The general pre-submission advice provided under this Chapter by the staff of the Authority shall be without prejudice and non-committal as to any subsequent assessment of applications by the Authority and the Member States.

2. The general pre-submission advice provided under this Chapter by the staff of the Authority shall be without prejudice and non-committal as to the assessment of the qualification of the specific regulated product under a given regulated product area, which remains the responsibility of the Commission or the relevant Member States when validating the application.

3. The potential applicant shall not be bound by any general pre-submission advice received under this Chapter.

[11] The public disclosure of the summary of the renewal pre-submission advice shall be carried out in accordance with Article 5(2)(f) of the Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality.

CHAPTER III

PROVISIONS APPLICABLE TO INTENDED RENEWAL APPLICATIONS

Article 12
Notification of intended studies for renewal

1. This Article shall apply to the notification by a potential applicant seeking the renewal of an authorisation or approval of the studies it intends to perform for that purpose, including information on how the various studies are to be carried out to ensure compliance with regulatory requirements.

2. The notification obligation laid down in Article 32c(1) of the GFL Regulation, which shall apply as of 27 March 2021, includes all situations whereby a potential applicant seeking the renewal of an authorisation or approval intends to perform new studies for that purpose, in areas for which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion.

3. The notification of the intended studies for renewal referred to in paragraph 1 shall be carried out by the potential applicant in a dedicated section of the database referred to in Article 17, specifically provided by the Authority for that purpose. In particular, the potential applicant shall submit a complete list of studies it intends to perform for the purpose of supporting an application for renewal, including information on how the various studies are to be carried out to ensure compliance with regulatory requirements. For each study included in that list, the potential applicant shall provide the information related to the data requirements listed in Annex I to these practical arrangements. The Authority recommends that information submitted concerning the design of the studies is accompanied by the detailed proposed study protocols.

4. All information described in paragraph 3 shall be submitted all together by the potential applicant at the same time in the form of a single submission per pre-application ID.

5. The Authority recommends potential applicants for renewal to notify all intended studies for renewal at least five (5) months before the date of the intended commissioning of such studies to a laboratory or testing facility as this facilitates the timely production of the advice referred to in Articles 14 and 15 to the benefit of the potential applicant.

6. The notification of intended studies for renewal referred to in this Chapter is without prejudice to the notification obligations laid down in Section 1 of Chapter IV.

Article 13
Public consultation on the intended studies for renewal

1. Upon receipt of the information notified by the potential applicant pursuant to Article 12, the Authority shall perform an administrative check of the notified information in view of its submission for consultation of stakeholders and the public ('consultation of third parties'). This administrative check shall be completed within 10 working days from the date of the receipt of the notified information.

2. If during the administrative check referred to in paragraph 1 it is found that certain information requirements outlined in Article 12 have not been fulfilled, the Authority shall request the potential applicant to submit, within a set deadline, any missing information in order to complete the administrative check. In this case, the administrative check shall be completed by the Authority within 10 working days from the receipt of the requested missing information.

3. Within 10 working days from the completion of the administrative check referred to in paragraph 1, the Authority shall launch the consultation of third parties on the intended studies for renewal, including on the proposed design of the studies. To this end, the information notified

by the potential applicant pursuant to Article 12 shall be made available on the Authority's website. This information shall be accompanied by a description of the regulated product concerned by the intended application, and by an explanation that the comments received, where related to the risk assessment of the particular renewal sought, shall be taken into account by the Authority when providing the renewal pre-submission advice on the content of the intended renewal application, as well as on the design of the studies, as provided for in Article 14.

4. The consultation of third parties shall remain open for a period of three (3) calendar weeks.

5. Following the closure of the consultation, all comments received by stakeholders and the public shall be made public by the Authority without delay. By way of derogation from this general principle, upon receipt by the Authority of a request for anonymity submitted by an individual having submitted comments in a personal capacity, the identity of that individual shall not be disclosed.

6. After the closure of the consultation, the Authority shall review the comments received from the stakeholders and the public which are relevant for the risk assessment of the intended renewal.

7. The results of the consultation of third parties referred to in this Article shall be inserted in the summary of the renewal pre-submission advice referred to in Articles 14(5) and 15(6).

Article 14
Provision of renewal pre-submission advice

1. After the review of the comments received from stakeholders and the public pursuant to Article 13(6), the Authority shall provide renewal pre-submission advice to the potential applicant, taking into account those comments that are related to the risk assessment of the intended renewal.

2. The Authority shall decide on the most appropriate manner to provide renewal pre-submission advice, by implementing the following working procedures:

(a) where possible, the Authority shall provide advice in writing;

(b) if the Authority considers that a discussion with the potential applicant is required to clarify some of the aspects to be addressed in the advice, a meeting shall be organised. This meeting shall be conducted preferably by tele-conference or video-conference. The Authority may organise physical meetings in exceptional cases, where the physical presence of the concerned individuals is deemed to be necessary for the discussion of the topic subject to the advice.

3. The Authority shall provide the potential applicant for renewal with its advice according to the following timelines:

(a) if the Authority has decided to provide the renewal pre-submission advice in writing, the written advice shall be provided within 30 working days after the closure of the consultation of third parties referred to in Article 13;

(b) if the Authority has decided to organise a meeting, the meeting shall be organised within 30 working days after the closure of the consultation of third parties referred to in Article 13; the advice shall be provided during the meeting.

4. Owing to the highly technical character of the assessment of the design of studies, the Authority may decide to consult external experts with specific expertise in order to provide an informative and scientifically sound advice to the potential applicant for renewal.

5. The Authority shall draw up a summary of the renewal pre-submission advice and send it to the potential applicant for information, according to the timelines laid down in paragraph 3, letter a) or after the meeting referred to in paragraph 3, letter b).[12]

Article 15

Special and exceptional provisions applicable to the area of plant protection products

1. This Article shall apply to intended applications for the renewal of the approval of existing active substances as provided for in Regulation (EC) 1107/2009 on plant protection products and Commission Implementing Regulation (EU) 2020/1740.

2. By way of derogation from Article 14, the Authority shall provide the potential applicant for renewal with its advice with the participation of rapporteur Member State(s) and the co-rapporteur Member State. To this end, the relevant national competent authorities shall be:

(a) provided with the information notified by the potential applicant pursuant to Article 12 and the comments received during the consultation of third parties referred to in Article 13;

(b) informed whether the Authority intends to provide the advice in writing or in the context of a meeting.

3. The following modalities and timelines shall apply:

(a) if the Authority has decided to provide the renewal pre-submission advice in writing:

(i) the Authority shall prepare the written advice and the related summary, in close cooperation with the rapporteur Member State and the co-rapporteur Member State. If the rapporteur Member State and the co-rapporteur Member State disagree with the Authority in connection with one or more aspects, the written advice and the summary of the advice shall reflect both opinions;

(ii) within 30 working days after the closure of the consultation of third parties referred to in Article 13, the written advice and the related summary, agreed by the Authority, the rapporteur Member State and the co-rapporteur Member State, shall be provided to the potential applicant.

(b) if the Authority has decided to organise a meeting:

(i) the Authority shall prepare the meeting, in close cooperation with the rapporteur Member State and the co-rapporteur Member State;

(ii) the meeting shall be organised within 30 working days after the closure of the consultation of third parties referred to in Article 13; the Authority, the rapporteur Member State and the co-rapporteur Member State shall attend and the advice shall be provided during the meeting;

(iii) after the meeting, the Authority shall prepare a summary in close cooperation with the rapporteur Member State and the co-rapporteur Member State. If the rapporteur Member State and the co-rapporteur Member State disagree with the Authority in connection with one or more aspects, the summary of the advice shall reflect both opinions.

4. the Authority shall share the written advice and the summary referred to in paragraph 3, letter a) and the summary referred to in paragraph 3, letter b) with the competent authorities of all Member States for information.

[12] The public disclosure of the summary of renewal pre-submission advice shall be carried out in in accordance with Article 5(2)(f) of the Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality.

5. Following the submission of an application for which renewal pre-submission advice was provided, in order to allow the public disclosure of the summary referred to in paragraph 3, letters a) and b), the rapporteur Member State shall immediately inform the Authority of any positive conclusion as regards the admissibility of that application.[13]

6. The national competent authorities shall take all necessary measures to ensure that information received by them under this Section are kept confidential.

Article 16
Non-committal natural of renewal pre-submission advice

1. The renewal pre-submission advice provided under this Chapter shall be without prejudice and non-committal as to any subsequent assessment of applications for renewal by the Scientific Panels of the Authority or the Member States.

2. The renewal pre-submission advice provided under this Chapter shall be without prejudice and non-committal as to assessment of the qualification of the specific regulated product under a given regulated product area, which remains the Commission's or the Member States' responsibility when validating the application.

3. The potential applicant shall not be bound by the renewal pre-submission advice received under this Chapter.

[13] The public disclosure of the summary of the renewal pre-submission advice shall be carried out in accordance with Article 5(2)(f) of the Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality.

CHAPTER IV
NOTIFICATION OF STUDIES

SECTION 1
Submission of study notifications

Article 17
Database of study notifications

1. As envisioned in Article 32(b)(1) of the GFL Regulation, the Authority has established a database of studies commissioned or carried out by business operators to support an application in relation to which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion.

2. To identify each study notification, the database shall assign a unique study identification ('ID').

3. With respect to the accessibility of the database, adequate levels of privacy and information security, pursuant to Article 39g of the GFL Regulation shall be ensured. Concretely, only potential applicants and laboratories and testing facilities subject to the obligations of notifications referred to in Article 32b(2) and (3) of the GFL Regulation and any third party entity contracted by such organisations to perform notifications on their behalf may submit individual study notifications. Those entities shall have access only to the study notifications which they have submitted or in which they are indicated.

4. 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 shall be granted by the Authority, strictly on a need-to-know basis.

5. Additional information security measures shall also be introduced in the form of a system audit trail which tracks each entry into the database as well as every modification, pursuant to Article 39g of the GFL Regulation.

Article 18
Obligations to submit study notifications

1. The obligation to submit information on studies commissioned or carried out by business operators to support a future application in relation to which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion, applies to the following actors:

(a) potential applicants having commissioned to a laboratory or external testing facility or carrying out such studies in in-house testing facilities;

(b) laboratories and other external testing facilities located in the Union – and those located in third countries insofar as set out in relevant agreements and arrangements with those third countries – having carried out studies commissioned by the potential applicants referred to under paragraph 1, letter a).

2. Any study notification submitted by the potential applicants referred to under paragraph 1, letter a) shall be associated with all pre-application IDs requested by those potential applicants for the specific regulated product and the regulated product area to which the study notification relates.

3. By way of derogation from paragraph 1, letter b), in the case of multisite studies, the test facility 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.

4. Studies submitted by an applicant after the submission of an application, either during the assessment of the validity or admissibility of the application or in relation to risk assessment, shall also be subject to study notification obligations. In the event that no pre-application activities were carried out before the submission of an application, studies submitted by an applicant after the submission of such an application in relation to risk assessment are not required to be associated to any pre-application ID.

5. The user guide referred to in Article 3 shall provide detailed information on how to submit study notifications in the database.

Article 19
Timelines

1. Obligations of Article 32b(2) and (3) of the GFL Regulation shall apply to studies that are commissioned or carried out as of 27 March 2021.
2. The terminology "without delay" referred to in Articles 32b(2) and (3) of the GFL Regulation shall refer to the moment the European Union becomes a potential market for the regulated product to which a study is related.
3. All study notifications shall be submitted before the starting date of the study.
4. For any study notification submitted after the starting date of the study, when submitting the application, the applicant shall provide justifications for the delay. The procedural consequences foreseen in Article 32b(4) of the GFL Regulation for failing to notify studies shall apply if the justifications provided by the applicant are not considered valid by the Authority, after the assessment of Article 22.

Article 20
Information to be notified

1. All study notifications shall be submitted in the database referred to in Article 17.

2. To submit a study notification, information regarding the data requirements listed in Annex II to these practical arrangements shall be provided by the potential applicants and laboratories and other testing facilities subject to the obligations of Article 18(1).

3. The information provided pursuant to paragraph 2 in relation to a study notification can be modified by the potential applicants and the laboratories or testing facilities having submitted this information at any time before the planned completion date of the study. Records of these

modifications shall be kept by the Authority and shall form part of the notified information made public in accordance with Article 32b(7) of the GFL Regulation.[14]

4. A study notification submitted in accordance with this Section can be withdrawn by the potential applicants having submitted this notification before the planned completion date of the study. Any corresponding study notification concerning the same study by the relevant laboratory or testing facility shall also be considered withdrawn if the potential applicant withdraws information previously submitted by the business operator and the record of the withdrawal shall remain available in the database. At application submission phase, the applicant shall provide justifications for this withdrawal. The timing of the withdrawal shall be taken into consideration by the Authority when assessing the validity of the justification. The procedural consequences foreseen in Article 32b(5) of the GFL Regulation for the non-inclusion of studies previously notified but withdrawn from the database shall be applied if the justifications provided by the applicant are not considered valid by the Authority after the assessment of Article 22. In this case, the applicant shall also submit all data delivered by the relevant laboratory or testing facility even without the study having been completed.

Article 21

Information to be provided by the applicant in relation to the assessment of the validity or admissibility of the application

Without prejudice to the requirements laid down in Union law for the submission of applications, when submitting an application or new studies requested during the assessment of the validity or admissibility of the application, the applicant shall provide the following information:

(a) the study notifications submitted in the database in support of the application. This shall be carried out by indicating:

  (i) all pre-application IDs provided to the applicant, in accordance with Article 4, which are associated to the study notifications supporting the application; and

  (ii) study IDs generated by the database for each study submitted in the application.

(b) if necessary, the following justifications, linked, where applicable, to the study ID:

  (i) justifications explaining the non-notification in the database of studies that have been included in the application;

  (ii) justifications explaining the non-inclusion in the application of studies notified in the database;

  (iii) justifications for the withdrawal of a study notification submitted in the database in support of the application, as referred to in Article 20(4);

  (iv) justifications for the delayed submission of a study notification in support of the application in question after the starting date of the study, as referred to in Article 19(4);

  (v) justifications explaining any other deviation from the process outlined in Section 1.

[14] Information notified pursuant to Article 32b of the GFL Regulation shall be made public by the Authority in accordance with Article 6(1)(f) of Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality.

Section 2

Verification of compliance with study notification obligations

Subsection 1

Verification of compliance under the responsibility of EFSA in the context of the assessment of the validity of the application

Article 22

Procedure

1. This Article shall provide the procedural steps for the verification of compliance with study notifications of Article 32b(2) and (3) of the GFL Regulation to be followed by the Authority 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.

2. Upon receipt of the information referred to in Article 21, the Authority shall assess the compliance with the study notifications of Article 32b(2) and (3) of the GFL Regulation, as outlined in Section 1. This assessment shall be carried out on the basis of the elements provided by the applicant in accordance with Article 21. In addition, and where it is considered appropriate, the Authority shall carry out research in the database to retrieve any relevant information, particularly in relation to the specific regulated product which is the subject of the application.

3. In particular, the Authority shall verify that the following requirements are met:

(a) the application contains all studies that have been previously notified in accordance with Section 1, and

(b) the application contains no additional studies apart from those previously notified in accordance with Section 1.

4. The Authority shall also assess the validity of any justifications submitted by the applicant in accordance with Article 21, letter b).

5. At any time during the assessment, the Authority may request the applicant to provide additional elements of justification or clarification.

Article 23

Procedural consequences on the validity of applications

1. This Article shall outline the procedural steps for the application of the procedural consequences of Article 32b(4) and (5) of the GFL Regulation, to be followed 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.

2. With respect to the obligations of study notifications laid down in Article 32b(2) and (3), the application shall be considered valid, provided that the requirements of Article 22(3) are met or a valid justification is provided for any procedural deviations.

3. In the event that the application is not considered valid the applicant shall be:

(a) invited to re-submit the application in accordance with Section 1 and contextually provide the identification of the application which was previously not considered valid;

(b) required to notify in the database the studies which have not previously notified or to submit the studies which were previously notified in the database;

(c) in the specific case of an application which is not considered valid as a result of an unjustified withdrawal of a notification of a study, required to submit, where existing, the data delivered by the relevant laboratory or testing facility even without having the study completed;

(d) informed that the assessment of such a re-submitted application shall commences six (6) months after the re-submission of the application.

4. The conclusions referred to in paragraph 2 shall form part of the outcome of the overall assessment of validity of the application carried out by the Authority. The applicant shall be informed of those conclusions and, as necessary, of the procedural consequences referred to in paragraph 3 either by the Authority (where, under Union law, the responsibility to verify the validity of the application in question lies with the Authority exclusively) or by the Commission (where, under Union law, the responsibility to verify the validity of the application in question is shared between the Authority and the Commission). This communication shall be done according to the timeline foreseen for the communication of the outcome of the overall assessment of the validity of the application.

5. The Authority shall promptly inform the Commission and the competent authorities of the Member States of the procedural consequences applied in the relation to a given application in accordance with this Section.

Subsection 2
Verification of compliance under the exclusive responsibility of the Commission or the Member States

Article 24
Information

1. Where under Union law, 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 the compliance with the obligations of study notifications laid down in Article 32b(2) and (3) shall be carried out by those entities, according to the applicable rules in place.

2. The Authority shall provide those entities with all the relevant elements required for this assessment, as set out in Section 1, strictly on a need-to-know basis and for the period necessary to complete the assessment.

3. The Commission or the national competent authorities shall inform the Authority about the outcome of the assessment of compliance referred to in paragraph 1, in particular with regard to the justifications which have been considered valid in view of their public disclosure.[15]

[15] The public disclosure of the summary of the renewal pre-submission advice shall be carried out in accordance with Article 6(1)(g) of the Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality.

Subsection 3

Verification of compliance in the context of the risk assessment carried out by the Authority

Article 25

Detection during the risk assessment of notified studies not submitted in full

1. If during the risk assessment, following a more extensive verification of the data submitted by the applicant, the Authority detects that the studies previously notified in accordance with Article 32b(2) and (3) of the GFL Regulation are not included in the submitted application in full, it shall request the applicant to provide justifications regarding any missing data. The applicant shall also be informed that the time-limits within which the Authority is required to deliver its scientific output shall be suspended, pending the provision of valid justifications by the applicant.

2. The Authority shall assess the justifications provided by the applicant pursuant to paragraph 1. If the justifications are considered valid, the risk assessment process shall resume, and the applicant informed accordingly.

3. If the justifications provided by the applicant are not considered valid, the applicant shall be requested to submit the missing data. The applicant shall also be informed that the risk assessment process will remain suspended until six (6) months after the submission of any missing data relating to any supporting studies.

4. The Authority shall promptly inform the Commission and the competent authorities of the Member States of the procedural consequences applied in the relation to a given application in accordance with this Section.

CHAPTER V

PUBLIC CONSULTATION ON SUBMITTED APPLICATIONS

Article 26

Scope of public consultations on applications

Where the relevant Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion,[16] in order to ensure that the Authority can have access to all relevant scientific data and studies available on the subject matter concerned by an application for an approval or an authorisation or a renewal of an approval or an authorisation, the Authority shall consult stakeholders and the public ('consultation of third parties') on the scientific data, studies and other information part of, or supporting, the submitted application to identify whether other scientific data or studies are available.

[16] This includes situations whereby the application of Union law results in the mandatory consultation of the Authority, providing that certain specific circumstances occur. See for example Article 28(1) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106 of 17.4.2001, p. 1).

Article 27

Procedure for carrying out publication consultations on application

1. Immediately after the scientific data, studies and other information part of, or supporting, the submitted application are made public,[17] the Authority shall launch the consultation of third parties on the submitted application.

2. Unless otherwise specified in sectoral Union law, the consultation and its supporting information, including the opening and closing date for submitting a comment, shall be made available on the Authority's website.

3. 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 the Authority following the implementation of the confidentiality decision-making ('final confidential version').[18]

By way of derogation from the first subparagraph, if the applicant decides to bring an action for annulment before the Court of Justice of the European Union[19] against the Authority's confirmatory decision on confidentiality and, in this context, is granted the suspension of the publication of the final confidential version,[20] the consultation of third parties shall 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 Regulation.

4. The launch of the consultation of third parties shall be accompanied by a description of the regulated product to which the application relates and by an explanation that the consultation aims at identifying whether other relevant scientific data or studies are available on the subject matter concerned by the application and that relevant comments shall be taken into account in the related risk assessment.

5. The consultation with third parties shall remain open for a period of three (3) calendar weeks, unless otherwise specified in sectoral Union law.

6. Upon the closure of a public consultation, all comments received by stakeholders and the public shall be made publicly available by the Authority. By way of derogation from this general principle, upon receipt by the Authority of a request for anonymity submitted by a particular party having submitted comments, the identity of the latter shall not be disclosed.

Article 28

Use and disclosure of the results of public consultation

1. After the closure of a public consultation, the Authority shall review all comments received and provide them to the relevant actors involved in the scientific evaluation of the concerned regulated product for consideration during the risk assessment.

2. The results of the consultation of third parties referred to in this Section shall be made public by the Authority together with the relevant scientific output adopted on the submitted

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[17] The scientific data, studies and other information part of, or supporting the submitted application are made public by the Authority in accordance with Article 6(1), letter c) of Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality.

[18] 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.

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

[20] Under Article 278 of TFEU.

application.[21] The corresponding scientific output shall address the relevant comments received from the third parties during the risk assessment.

3. By way of derogation from paragraphs 1 and 2, in the context of applications for approval of new substances and renewals of approvals of existing substances under Regulation (EC) No 1107/2009 on plant protection products, and of applications for maximum residue levels of pesticides under Regulation (EC) No 396/2005 on MRLs, the Authority shall provide the comments received by stakeholders and the public to the rapporteur Member State/co-rapporteur Member State, and to the evaluating Member State, which shall take them into consideration during the related scientific assessment.

Article 29
Entry into force

This Decision shall enter into force the day following its signature and shall apply from 27 March 2021.

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Bernhard Url

Executive Director of the European Food Safety Authority

[21] The public disclosure of the results of the public consultation shall be done pursuant to Article 6(1), letter d) and (2) of the Decision of the Executive Director of the Authority laying down the practical arrangements concerning transparency and confidentiality.

ANNEX I

Data requirements in relation to the notification obligations laid down in Article 12

The following data requirements relate to Article 12 (provisions applicable to intended renewal applications). Data requirements marked with the symbol "*" shall be mandatory.

1. **Study Title*** shall report the title of the study. If the original title is not in English, an English translation shall also be provided.
2. **Potential applicant(s)*** is a repeatable field containing the information to identify the organisations that intend to submit an application for the renewal of the authorisation or approval.
3. **Former application id*** shall contain the identifier of the application to be renewed.
4. **Study scope*** section shall comprise of the following information elements:
   - **Intended study area*** shall report the regulated product area of the future application or notification for renewal that the study is meant to support.
   - **Study type*** shall report the type of the study.
   - **Study objective*** shall report the narrative where the objective shall be described.
   - **Test item*** shall report the identification of the study test item related to the regulated product that is subject of the application under renewal. Depending on the type of the test item, information on its components shall also be provided.
5. **Study Design***
   - **Study guideline*** shall report the guideline or guidance document followed by the study, if any; or, if the intended study does not follow any study guideline, the **Study Design description*** shall contain the description of the design of study including the hypothesis.
   - **Study detailed protocol (optional)** shall contain more detailed information and further elaborating methodology, statistical considerations, and organization of a study. The protocol usually also gives the background and rationale for the study.

ANNEX II

Data requirements in relation to the notification obligations laid down in Article 20

The following data requirements relate to Article 20 (submission of study notifications – information to be notified). Data requirements marked with the symbol "*" are mandatory.

1. **Study Title*** shall report the title of the study. If the original title is not in English, an English translation shall also be provided.
2. **Study Starting Date*** shall reports the starting date of the study as defined in Article 2, letter e).
3. **Study Planned Completion Date*** shall report the study planned completion date as defined in Article 2, letter f).
4. **Potential applicant(s)*** is a repeatable field containing the information to identify the organisation(s) that commissioned or carried out the study.
5. **Laboratories*** is a repeatable field containing the information to identify the laboratory or testing facility carrying out the study commissioned by the business operator(s).
6. **Study scope*** section comprises of the following mandatory information elements:
    - **Intended Study area*** shall report the regulated product area of the future application that the study is meant to support. More than one area can be indicated.
    - **Study type*** shall report the type of the study.
    - **Study international standard certification*** shall report the standard certification of the study.
    - **Study objective*** shall report the narrative where the objective is to be described.
    - **Test item*** shall report the identification of the study test item related to the regulated product that is subject of the future application. Depending on the type of the test item, information on its components shall also be provided.
    - **Study internal reference id assigned by the business operator/laboratory or testing facility (optional)** shall report the identifier of the study as assigned by the business operator/laboratory or testing facility.