European Crop Protection

POSITION PAPER
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ECPA key questions on implementation of Commission proposal on *transparency and sustainability of EU risk assessment model*

Background

On 11 April 2018, the Commission published the legislative proposal (COM(2018)179) to amend the General Food Law (GFL)[1] and 8 other pieces of sectorial legislation including Regulation 1107/2009. Following completion of the ordinary legislative procedure in June 2019, the final legislative text is expected to be published in early September 2019 and after an 18 month transition period, should officially apply as from March 2021.

ECPA is supportive of the overall Commission proposal and its objective to increase transparency and consumer confidence in the risk assessment process, but note that it will entail key changes[2] to the procedures for the evaluation of active substance under Regulation 1107/2009 and Regulation 844/2012 (renewals). This paper describes the key questions we have identified where we would welcome further clarity on how these provisions will be applied in practice. The questions are intended to provide constructive input into the implementation process and where possible we have also offered proposals to address these points.

ECPA's questions on key provisions of Commission proposal

Pre-submission advice, Article 32a

Key questions: Pre-submission advice
- When is the earliest time point prior to dossier submission that pre-submission advice can take place?
- How will pre-submission advice be managed for renewals in cases of multiple Applicants?
- How will coordination be ensured between EFSA and the RMS in the pre-submission advice provided to Applicants and in the subsequent evaluation by the RMS of the dossier submitted?
- Will Applicants be given the opportunity to review and comment on the **summary** of the pre-submission advice prior to this being made public by EFSA under Article 38(2) (at the time "application" is considered admissible)?

- To ensure that dossiers meet the required standards and include all the necessary data to complete the risk assessment, pre-submission advice should be available several times during the pre-submission phase, e.g. early to ensure that proposed testing programmes are acceptable and then again in advance of dossier submission to discuss any initial study results and the proposed follow up testing.
- For most applications under Regulation 1107/2009 and Regulation 844/2012, first pre-submission advice should ideally take place 4½-5 years before dossier submission. This is essential to allow sufficient time for Applicants to discuss the list of intended studies (renewals) under Article 32c prior

[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

[2] These relate mainly to: pre-submission advice, the notification of studies to the database of studies to be established by EFSA, the submission of a list of intended studies (renewals) and subsequent public consultation on this list, the establishment of standard data formats, the assessment of confidentiality, the making of the complete dossier public (except informational considered confidential) and the subsequent public consultation on the dossier.

to submitting this to EFSA and for the consultation of stakeholders and the public to take place well in advance of dossier submission. Applicants will need to have the relevant advice from EFSA on the list and then to have the necessary time to undertake their testing programmes and to compile their dossiers prior to the required submission date. The opportunity for subsequent further pre-submission advice should be available, e.g. for Applicants to discuss with EFSA the results of initial testing programmes and the nature of the planned further studies. There may be cases where the ideal 4½-5 year timeframe recommended above is not always possible, for example for candidates for substitution which are limited to a 7 year approval period and for applications for MRLs/Import Tolerances submitted under Regulation 396/2005. In all cases the early assignment of the RMS or the EMS (MRL/IT applications) is critical.
- Coordination and alignment between EFSA and the RMS on the pre-submission advice will be essential to ensure that dossiers meet the necessary regulatory requirements, and to reduce the risk of issues being raised after dossier submission.
- In cases of multiple Applicants, to increase efficiency and to reduce unnecessary workload, the RMS with EFSA's support should facilitate coordination between Applicants in relation to pre-submission advice. This coordination could be to organise combined pre-submission meetings for all Applicants and/or other steps to actively promote taskforce formation. Ensuring coordination between Applicants at the early stage of pre-submission advice would assist with the later processes under the GFL proposal (submission of list of intended studies, submission of dossier and related public consultations) and where coordination between Applicants would facilitate the procedures. Clearly for any confidential information this will need to be discussed separately with each Applicant.
- Applicants should be given the opportunity to review and comment on the summary of the pre-submission advice prior to this being made public by EFSA under the provisions of Article 38(2) (at time application considered admissible).

List of intended (planned) studies (renewals), stakeholder and public consultation on list, Article 32c(1)

Key questions: List of intended studies
- What level of detail will be required to be notified to EFSA for the list of intended studies? What is meant by "study design", e.g. a descriptive sentence or a full protocol ? How will intellectual property be handled, which might be in the study design?
- How will the list of intended studies be managed to take into account the complex tiered testing strategies of Applicants where the selection of higher tier studies is dependent on the results of initial studies?
- When would the public consultation on the list of intended studies take place within the procedures of Regulation 844/2012 and what would be the duration of the consultation? Will EFSA manage this consultation in the same manner as the existing consultation on the RMS Draft Assessment Report/Renewal Assessment Report where a response to comments and summary on the consultation are prepared?
- How will cases of multiple Applicants be managed? Will there be separate consultations on the lists submitted by each Applicant or can coordination be facilitated leading to a combined consultation?
- What would be the timeframe within which EFSA provides feedback to Applicants on the list of intended studies, including the proposed study design?
- How will EFSA ensure coordination with the RMS on any advice provided on the design of studies following the consultation on the list of intended studies? [EFSA is required to provide the advice to Applicants, but under Regulation 844/2012 the RMS is responsible for assessing dossier admissibility and preparing the Renewal Assessment Report].

- While Article 32c(1) of the GFL proposal provides some guidance, further clarification would be useful on exactly what level of detail will be required to be provided to EFSA on the list of intended studies, e.g. what constitutes a "study" and the level of information required to be provided.

- The list should be managed in a way that takes into account the complexity of tiered testing approaches whereby the decision on exactly which higher tier or follow up studies are performed is based on the results of initial studies. The nature of the likely higher tier studies should ideally be discussed with EFSA and RMS in pre-submission advice, both before and after the public consultation under Article 32c(1) has taken place.
- For most applications under Regulation 1107/2009 and Regulation 844/20012, the consultation on the list of intended studies should ideally take place 4-4½ years before dossier submission. EFSA should provide feedback on the list of intended studies including proposed study design within 3 months from the end of the public consultation. This timeframe is necessary to allow the consultation and advice to take place well in advance of dossier submission so that Applicants can finalise their testing programmes (taking into account the EFSA advice), perform the required studies and prepare their dossiers ahead of the submission due date.
- The duration of the public consultation is not prescribed in the Commission proposal. Given the nature of the consultation (on a list of intended studies), 30 days would appear an appropriate timeframe.
- In cases of multiple Applicants to increase efficiency the RMS with EFSA's support should facilitate coordination between Applicants related to the submission of the list of intended studies. The subsequent consultation could then be coordinated and take place at one time period, rather than multiple consultations on the lists submitted by each Applicant. Any confidential information will need to be discussed separately with each Applicant.
- EFSA should apply a pragmatic and workable approach in taking into account the comments received during the public consultation. Article 32c(1) refers to EFSA taking into account comments "*which are **relevant for the risk assessment** of the intended renewal"*[3]*.*

Stakeholder and public consultation on dossier, Article 32c(2)

Key questions: stakeholder and public consultation on dossier
- What will be the duration of the consultation on the dossier made available under Article 38(1)(c)? Will EFSA manage this consultation in the same manner as the existing consultation on the RMS Draft Assessment Report/Renewal Assessment Report where a response to comments and summary on the consultation are prepared?
- How will the consultation be managed in cases of multiple Applicants? Will a separate consultation be opened for each Applicant or will the consultations be coordinated?
- How will coherence be ensured between EFSA and the RMS? [EFSA is responsible for launching the consultation, the RMS is responsible for preparing the Draft Assessment Report/Renewal Assessment Report taking into account the comments received during the consultation].

- The stated objective of the public consultation launched at the time the dossier *("scientific data, studies and other information supporting applications"*) is made public under Article 38(1)(c), is "*to identify whether other relevant scientific data or studies are available on the subject matter concerned by the Applicant'.* The consultation is not intended to comment on the dossier itself.
- Article 6(4) of Regulation 844/2012 requires Applicants to take *"all reasonable steps"* to submit their dossiers jointly. However, in cases where there are multiple Applicants and where more than one dossier is submitted, it would appear preferable to coordinate the consultations so that there is one opportunity where stakeholders and the public can provide input to identify "*other relevant scientific data or studies"* relevant to all any of the respective dossiers.
- The duration of the public consultation is not prescribed in the Commission proposal. A duration of 30 days would appear appropriate, which would be consistent with our proposed timeframe for the public consultation on the list of intended studies (mentioned above).
- Our assumption is that following the close of the consultation EFSA will collate the comments received and this will be provided to RMS to take into account when preparing the Draft Assessment

[3] Article 32c(1): *"…Taking into account the received comments which are **relevant for the risk assessment** of the intended renewal, the Authority shall provide advice on the content of the intended renewal application, as well as on the design of studies. …"*

Report/Renewal Assessment Report. It would be useful to understand if, when and how this report will be made available including to Applicants.

Notification of studies commissioned or carried out, Article 32b

Key questions: notification of studies
- ECPA's interpretation of the notification requirements is that this is an ongoing requirement as each study is commissioned or carried out, that there is no fixed deadline for notification, and that a transitional process will be required to notify all studies existing leading up to and at the time of official application of the GFL proposal. Is this interpretation shared by EFSA?
- During the conduct of studies, initial results may have an impact leading to a change in for example, the study scope or timelines. Will such changes be managed in a pragmatic way?
- What procedures and systems will EFSA employ for the notification and database of studies (e.g. an electronic database accessible by Applicants and laboratories)?
- What will be the process for applying the notification provisions to dossiers submitted under the AIR4 and AIR5 renewal programmes (Regulation 844/2012) which will be concurrently ongoing at the time GFL provisions officially apply (March 2021)?
- How will the notification requirements between Applicants and laboratories be managed? Would EFSA accept coordinated notifications between the two parties?
- How will the obligations related to notification of studies be managed in cases of multiple Applicants? Our assumption is that the original study owner will be required to notify all existing studies (transitional arrangements) and then after the official application date of the GFL provisions as each new study is commissioned or carried out. The notification requirements would not apply to other Applicants which are not the data owner but which have negotiated access to those studies (letter of access). Is this interpretation correct?
- How will coherence be ensured between EFSA and RMS? [EFSA would manage the database of studies, the RMS assesses admissibility of the dossier]

- ECPA's interpretation is that the notification is an ongoing requirement and is required as new each new study is commissioned or carried out, i.e. that there will be no fixed deadline for notifications and that this is a parallel process to the consultation on the list of intended studies (renewals). Studies can only be notified once a testing facility has been found and contracts signed, and therefore typically will take place after the submission of the list of intended studies. However, we anticipate that a transitional process will be required to notify all studies which already exist or which have already been commissioned leading up to and at the date of official application of the GFL proposal (i.e. and which will support Applications submitted after this date). We would welcome the opportunity of a meeting to discuss particularly this requirement to ensure clarity on this critical point.
- The notification requirements should be as workable and pragmatic as possible, i.e. an electronic system (database) accessible by Applicants and laboratories where those elements required under Article 32b(1a) can easily be entered (*"…title and the scope of the study, the laboratory or testing facility carrying out the study, and the starting and planned completion dates of any study commissioned or carried out … to support an application…"*). Also, if during the conduct of studies, initial results lead to in a change in the study scope or timelines, these should be managed in a pragmatic and workable manner, e.g. Applicants should be able update the notification accordingly.
- ECPA would support the concept of a coordinated notification between Applicant and laboratory (EU and non-EU laboratories) which would reduce workload and help ensure coherence and efficiency, i.e. the Applicant should assume the lead responsibility in submitting the notification, which is confirmed to EFSA by the respective laboratory. We would highlight that for pesticides Applicants are usually developing active substances for worldwide use and therefore studies are often performed outside of Europe including for import tolerance applications where residue studies are conducted in exporting countries (e.g. Latin America, Asia) is part of the data requirements.
- To ensure clarity, ECPA would also welcome confirmation on how the obligations related to the notification of studies will be managed in cases of multiple Applicants (question above). In addition

we would also highlight that the data owner can be an individual company or jointly as a taskforce involving several different companies.
- Coherence will need to be ensured between EFSA and RMS. EFSA will establish and manage the database of studies, but the RMS is responsible for assessing admissibility of the dossier and will therefore need to review the details in the database when making this evaluation.

Making public, Article 38 and confidentiality, Article 39 and 39(a)

Key questions: making public
- While Article 38(2) provides some guidance on how dossiers (*"scientific data, studies and other information supporting applications…"*) will be made public under Article 38(1)(c), what will be the system and procedures established by EFSA to disclose this information? What safeguards will be put in place to prevent commercial including regulatory mis-use of the information in the EU and worldwide?
- Will Applicants be allowed to submit the (non-)confidential versions of the dossier with watermarks on each page highlighting that the content may be subject to copyright and other IP protection and that mis-use for commercial, including regulatory purposes is prohibited worldwide?
- Will EFSA maintain a register of persons seeking access to the studies in order to identify the person, so that in cases where the studies have been mis-used without permission, an Applicant is able to enforce its rights?
- Will the undertakings mentioned in the text of the GFL revision contain a legal note that the person accessing the studies consents to the data submitter/owner pursuing effective remedies in court for mis-use of information?
- When submitting a request for confidentiality does a reasoning for each item of confidential information need to be submitted by the Applicant? In which format should such requests be submitted and to what level of detail?
- Is ECPA's understanding correct that personal data can be redacted and that this redaction applies to all studies submitted and is not limited to confidential information or vertebrate studies?
- Is a difference expected in the procedure for the assessment of confidentiality requests between new applications and renewal applications?

- The Commission proposal states that EFSA shall make public the information listed under Article 38(1)(c) (dossier) "*on a dedicated section of the Authority's website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print and search through in an electronic format"*. The detailed procedures for exactly how the information will be made available are to be defined by EFSA, although Article 38(2) further clarifies that: "*The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be used, reproduced, or otherwise exploited in breach of any intellectual property right or data exclusivity rules and its use by third parties shall not engage the responsibility of the European Union. The Authority shall ensure that* ***clear undertakings or signed statements are given to that effect by those accessing the relevant documents, prior to their disclosure****."*
- While facilitating legitimate public access to the relevant studies, the exact procedures of disclosure must also aim to prevent mis-use of the information for commercial purposes by competitors in the EU and globally[4].
- Attachment 1 contains a non-exhaustive list of points which should be considered in relation to the procedures for disclosure. To avoid the loss of data compensation[5] in regions outside the EU and to comply with the EU's international obligations (e.g. the TRIPS agreement), it is important to

[4] Under WTO rules, the EU has agreed to protect legitimate commercial interests, including CBI, and to protect undisclosed data submitted to regulatory authorities from unfair commercial use. Article 39(2) of the TRIPS agreement states that *"Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use"*

[5] Data compensation is a process applicable particularly in the US whereby the data owner of a study is financially compensated by a separate Applicant who wishes to have access to the study for the purposes of supporting an application for authorisation.

highlight the distinction between the “publication” and “disclosure” of information; information should be made available via a mechanism of **controlled disclosure**, and **not** published.
- Critical to reduce the risk of mis-use is that studies should be available individually rather than the whole dossier itself being able to be downloaded.
- We would also highlight the existing procedures established by the European Medicines Agency (EMA) in implementing policy 0070 for making clinical trial data publicly available[6]. There are many similarities in the objectives and structures necessary to support the disclosure of information under the GFL proposal with those already established by EMA. We would therefore encourage EFSA to review the EMA systems and procedures as template.
- Article 39(2) of the GFL proposal with the proposed amendments to Article 63(2) of Regulation 1107/2009 will list those items for which confidential treatment can be granted; Article 39(a) of the GFL proposal with the proposed amendments to Article 39(2)(a) and 39(2)(b) of Regulation 1107/2009 will provide a general framework for Applicants to submit requests for confidentiality. Further guidance or clarification would be useful to understand what the requirements for these requests will be.

Standard data formats, Article 39f

Key questions: standard data formats
- What transition period does EFSA envisage for any changes in the standard data format for applications under the new GFL provisions?
- What will be the overall scoping of implementation of a standard format? Are complex assessment and calculations included? Existing databases as used in other regulations can only cover those in an unstructured document based way and will need significant adaptations.
- Would a unique identifier be created in the database of notified studies for each notified study of an active substance? This would ensure traceability in the dossier and related assessment reports as the identifier could be the key reference for a study instead of the study author.

- ECPA would welcome further clarity on the anticipated changes to the standard data formats used to support pesticide active substance dossier submissions. We would also highlight that for active substances there is an extensive and continuous renewal programme (AIR). Consequently, Member State and Applicants alike will need significant time and resources to adapt to any changes in the standard data formats to support applications according to the new GFL provisions.
- As much as possible any future formats should also be aligned internationally (i.e. OECD) and with the format submitted to other agencies (e.g. JMPR for MRL applications/import tolerance requests).
- A unique identifier for referenced documents used consistently in a study register and data format is key for consistency and clarity in the evaluation process

Application and transitional measures, Article 10

Key questions: application and transitional measures
- Will a clear implementation process (involving transitional measures) be developed for applying the new GFL provisions to substances in the AIR4 and AIR 5 renewal programmes, particularly where dossier submission will be shortly after March 2021?
- Given the complexity of applying the new GFL provisions to the ongoing renewal programmes, will ECPA be consulted during the development of the implementation procedures?

[6] www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf

- Article 10(1) (transitional measures) of the GFL proposal states that: *"The provisions of this Regulation shall not apply to applications […] under Union […] law … submitted to the Authority prior to [general date of entry of application:18 months after its entry into force]"*
- If published in the Official Journal in September 2019, the GFL provisions will officially apply to "applications"[7] submitted after March 2021. At this time the AIR4 and AIR5 renewal programmes will be concurrently ongoing with applications and subsequently dossiers being due for submission leading up to and after this date. The preparation of dossiers due to be submitted around this period are well underway and have been for some time (e.g. studies to support those submissions have already been agreed with the respective RMS and are currently being commissioned).
- A clear process will need to be established which sets out the transitional measures for applying the new GFL provisions leading up to and shortly after the official application date (March 2021). For example, the list of intended studies (renewals) and the related stakeholder consultation on this list and the notification of studies to the database of studies, are both processes that should take place well in advance of dossier submission. The database of studies will therefore need to be established before March 2021 to allow Applicants and laboratories sufficient time to populate this database for applications which are due for submission shortly after March 2021. For the list of intended studies and the subsequent consultation, is it feasible that this process takes place for applications submitted shortly after March 2021? As these processes should already have taken place for applications which are now only approximately 18 months from submission. As discussed above, for most applications ideally the list of intended studies and subsequent consultation should take place 4-4½ years in advance of dossier submission to allow agreement on testing programmes and for the related studies to be conducted and the dossier prepared accordingly.
- We would note term "application" referred to in Article 10 (transitional measures) of the GFL proposal. For pesticide active substances an "application" is defined in Articles 7 and 15 of Regulation 1107/2009 and Article 2 of Regulation 844/2012 and is not the dossier itself which is defined in Article 8 of Regulation 1107/2009 and Article 7 of Regulation 844/2012. Clarification is needed to avoid confusion between the two processes.

Key questions: application and implementation in relation to Regulation 396/2005 (MRLs/Import Tolerances)

- How will the GFL provisions be applied to applications for MRLs or Import Tolerances submitted under Regulation 396/2005 and to the subsequent procedures to develop an EFSA reasoned opinion?
- How will the provisions related to pre-submission advice, notification of studies, disclosure of studies and the respective public consultations be managed for MRL and IT applications?

- As an EFSA reasoned opinion on an MRL or Import Tolerance application under Regulation 396/2005 constitutes an EFSA "scientific output", ECPA's understanding is that these applications, and the subsequent process to develop the reasoned opinions, will also be subject to the new GFL provisions. It would be useful to have further clarity on exactly how the provisions will be applied to the procedures under Regulation 396/2005 and to understand if there may be differences in implementation for these processes compared with those for Regulations 1107/2009 and 844/2012. For example, for MRL/Import Tolerance requests how will the provisions related to pre-submission advice, notification of studies, disclosure of studies and the respective public consultations be managed?

[7] Applications as defined in Article 7 of Regulation 1107/2009 and Article 2 of Regulation 844/2012.

Attachment 1

ECPA considerations: procedures for disclosure of studies under Commission initiative on transparency & sustainability of the EU risk assessment model (COM (2018)179)

Article 38, Commission proposal COM (2018)179

Article 38 of the Commission proposal states that:

"Those items referred to in the first subparagraph shall be made public on a dedicated section of the Authority's website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print and search through in an electronic format.

…

1a. The disclosure of the information mentioned in points (c), (d) and (i) of paragraph 1 to the public shall be without prejudice to:
(a) any existing rules concerning intellectual property rights which set out limitations on certain uses of the disclosed documents or their content; and,
(b) any provisions set out in Union law protecting the investment made by innovators in gathering the information and data supporting relevant applications for authorisations ('data exclusivity rules').

The disclosure to the public of the information mentioned in paragraph (1)(c) shall not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be used, reproduced, or otherwise exploited in breach of any intellectual property right or data exclusivity rules and its use by third parties shall not engage the responsibility of the European Union. The Authority shall ensure that clear undertakings or signed statements are given to that effect by those accessing the relevant documents, prior to their disclosure."

Process of making public under controlled disclosure

ECPA supports the objectives of the Commission's amendments to the General Food Law (GFL), including those aimed at increasing transparency and consumer confidence in the current risk assessment process. We also need to ensure that intellectual property and proprietary data is protected against unfair commercial use. ECPA would therefore make the following recommendations regarding the practical procedures for the public disclosure of regulatory data contained within pesticide dossiers submitted for EU evaluation:

- While access to the entire content of the dossier (except CBI) must be ensured to meet the objectives of the Commission initiative, the ability to consult, print and download information should ideally be according to each individual study rather than the complete dossier itself.
- Proper procedures must be put in place to prevent commercial misuse of studies for regulatory purposes in the EU and globally.
- A standard undertaking should be signed by those wishing to access the relevant documents ("Users"). There must be a mandatory "Terms of Use" which Users have to have "read and accepted", by ticking a box on a web form, before they receive access. In absence of this acceptance, access should not be provided. The Terms of Use should include wording such as, *"By making a request to receive study documents the User confirms that he/she is neither directly nor indirectly engaged nor has the intent to become engaged in the commercialisation of crop protection products nor is acting on behalf or to the benefit of any third party being directly or indirectly engaged in the commercialisation of crop protection products. The User is not permitted to use study documents for any regulatory or commercial purposes, which includes, without limitation, any use by the User and/or any third party that could reasonably be understood to be for or in support of the creation of profit".* Other suggested terms can be found in EMA policy 0070[8] which could be adapted for these purposes.
- Enforcement of the Terms of Use (noted above) by the data submitter must also be facilitated. Therefore, the standard undertaking needs to be backed up by the availability of legal remedies. The Terms of Use should expressly enable direct enforcement by the data submitter against unfair commercial use by Users (see for example EMA Policy 0070). In addition, the User accessing

[8] https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf

the documents expressly consents to the jurisdiction of a specified court or tribunal, agreeing to an anti-misuse provision with wording such as *"The User consents to the data submitter pursuing effective remedies before a national court in order to seek recourse for misuse of information, including but not limited to injunctive relief and/or damages to the full extent provided by law*". .

- The standard Terms of Use (noted above) must be backed up by a system for accurately identifying the identity of the User. Otherwise, "phantom" requests could be made and enforceability of the undertaking becomes practically impossible. This could be achieved by requiring at a minimum a full name (person or name of organisation) **and** valid email address and preferably a scan of a valid ID card or passport. The IP address(es) of the computers used for accessing the documents should also be recorded and this fact can be indicated. It is however, clear that in any case the applicable rules on protection of personal data need to be respected and complied with when setting up such a system. Therefore the Terms of Use may need to obtain express consent for such processing. As data submitters may also need access to the information to enforce their rights against unfair commercial use, provision should also be made to release this information to data submitters where required for investigative or litigation purposes.
- Include watermarks on each page of the relevant documents, clearly forbidding use for commercial purposes and showing the identity of the data submitter (data owner) and the source of the documents. The text of these watermarks should be drafted and included by the data submitter. Included below is the possible text of such a watermark: *"This document has been retrieved from* [EFSA online system] *and is owned by* [data submitter/data owner]. *Please note that the content of this report could be subject to copyright and other IP rights. Any use for commercial purposes is prohibited worldwide"*