QUESTIONS & ANSWERS
02/04/2021 - Q&A/21/LO/33684

Transparency Regulation living Q&A document

Version 1.4

The purpose of this living document is to capture key and/or most frequent questions raised by applicants in the PPP and GMO sectors regarding the implementation of the Transparency Regulation 1381/2019, as well as responses when available.

The information provided in this document is indicative and sources for responses are cited when possible. The documentation from the European Commission and EFSA (if/when available) takes precedence and are available from:

- EFSA https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation
- European Commission https://ec.europa.eu/food/safety/general_food_law/implementation-transparency-regulation_en

The document is structured with the following format:

Q	**Type**: General/PPP/GMOs	**Category** Pre-submission advice Renewal Notification of studies Confidentiality Other	**Question**
A	**Response date**	**Response source**	**Answer**

Changelog

- V1.4 – Update following publication of EFSA Q&A document (link): A3, A6, A7, A9, A11, A14, A15, A16, A17, A18, A22, A23, A26, A27, A29, A32, A38, A39, A41, A43, A44, A45, A46, A50, A53, A55, A56, A57, A58, A63.
- v1.3 – Update of A11, A26 and A57
- v1.2 – Update of A62
- v1.1 – Typos corrected

Pre-submission advice			
Q1	General	Pre-submission advice	***When is the earliest time point prior to dossier submission that pre-submission advice can take place?***
A1	11-Jan-21	Practical Arrangements - notification	There is no earliest timepoint to request pre-submission advice. Please note Article 7 of the Practical Arrangement which states that: *Potential applicants may request general pre-submission advice at any time before submitting the corresponding envisaged application (...). The Authority recommends submitting the request for pre-submission advice at least six (6) months before the envisaged submission date of the application.*
Q2	PPP	Renewal notification & consultation	***How will pre-submission advice and renewal notification advice be managed in cases of multiple applicants?***
A2	11-Jan-21	Practical Arrangements - notification	No details have been provided to manage the situation with multiple applicants working independently. Article 4 of the practical arrangements however provides some basic advice on the process to follow for any joint pre-submission activities involving multiple applicants. Also, Regulation 2020/1740 states in Article 4(2) encourages cooperation: *2.Where several potential applicants request general pre-submission advice, the Authority shall suggest that they submit a joint application for renewal and disclose their contact details to each other for that purpose.*
Q3	PPP	Pre-submission advice	***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?***
A3	2-Mar-21	Practical Arrangements - notification Regulation 2020/1740 EFSA FAQ B20	Regulation 2020/1740 states in Article 3(2) that: *2.The pre-submission advice by the Authority pursuant to Article 32c(1) of Regulation (EC) No 178/2002 shall be provided with the participation of the rapporteur Member State and the co-rapporteur Member State, taking into account any existing experience and knowledge relevant for the active substance, including, where appropriate, available studies from the earlier approval or renewal of approval.* EFSA FAQ: *EFSA can only accept requests for general pre-submission advice for active substances for which the renewal procedure has been already allocated to a rapporteur Member State/co-rapporteur Member State. Moreover, should the potential applicant fail to indicate the rapporteur Member States/co-rapporteur Member State, the request for general pre-submission will be rejected. The timelines for the provision of general pre-submission advice are slightly adjusted to allow for the necessary interaction between EFSA and the national competent authority concerned. The administrative check will be completed within fifteen (15) working days at the latest, and the general pre-submission advice will be provided within twenty (20) working days of acceptance both for requests or questions replied in writing and for requests or questions in response to which EFSA decides to organise a meeting.*

Q4	PPP	Pre-submission advice	***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?***
A4	2-Mar-21	Practical Arrangements - notification Regulation 2020/1740	For renewal notification feedback, Article 14 of the Practical Arrangement states that: *The Authority shall draw up a summary of the renewal pre-submission advice and send it to the potential applicant for information…* There is no reference to making this information public at this stage. However, Article 10(10) states that the pre-submission advice can be made public after dossier submission: 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.*
Q5	PPP	Pre-submission advice	***Does possible EFSA pre-submission advice apply only to renewal of AS, or also to application for new AS?***
A5	2-Mar-21	General knowledge	The system of pre-submission advice applies to all applications. It is the decision of the applicant whether or not they want to request such pre-submission advice (it should however be noted that the renewal notification and 3rd party consultation and the EFSA advice in that context is for renewals only and does not apply to new ASs).
Q6	PPP	Pre-submission advice	***Will this pre-submission advice will be rather: is this study triggered or not? or will EFSA also go into detail and interpretation of the study?***
A6	11-Jan-21	Practical Arrangements – notification EFSA FAQ B10	Article 6(10 of the Practical Arrangement provides some further information. We would in particular highlight the last sentence of Article 6(1), which states: *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.* *EFSA FAQ: Nevertheless, to a limited extent and an on exceptional basis, EFSA may provide general explanations about the design of studies only if and insofar as the study design is addressed in general guidance documents developed by the Authority. EFSA cannot provide advice on specific requests on how to develop and manage a study, hypothesis to be tested, etc.*
Notification of studies			

Q7	GEN	Late notification of studies - justifications	***Is there a deadline by which a study may be entered in the EFSA database as a 'commissioned study' without triggering the need for a valid justification of non-compliance?***
A7	11-Jan-21	Practical Arrangements – notification EFSA FAQ B37	Article 19 of the Practical Arrangement states that: *>> 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.* The Practical Arrangement does however appear to be stricter in its definition compared with the legislation, as Article 32b(2) states that business operators should notify '*without delay*', but no specific reference is made to the need to notify before the starting date. EFSA FAQ: *Notwithstanding the above, the EFSA database will not block delayed notifications, submitted after the starting date of the study. This holds true for Article 32b study notifications submitted in the database in connection to studies already completed. For example, this could happen because certain studies may have originally been commissioned or carried out by business operators without the intention of using them to support an application for the European Union market. Such already ongoing or completed studies may subsequently need to be notified in the database due to a change of commercial strategy resulting in the European Union becoming a potential market. However, when submitting a corresponding application, the applicant will be required to present a justification for any given delay (see question EFSA FAQ 42).*
Q8	GEN	Late notification of studies - justifications	***What will be considered as a valid justification? And will it apply per submission or per individual study?***
A8	11-Jan-21	Practical Arrangements - notification	Article 23 (2) of the Practical Arrangement clarifies that: *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.*
Q9	GEN	Late notification of studies - justifications	***Art. 32b para. 4 to 6 refer to valid justification in case (1) studies have not been notified or (2) notified studies have not been included in the application or (3) studies notified are not provided in full as part of the application. What can be considered as a valid justification? How and when the assessment of the justification will be performed?***
A9	2-Mar-21	General knowledge	No specific guidance has been provided to define what can be considered as a 'valid justification'.

		EFSA FAQ B42	*EFSA's assessment is carried out on a case-by-case basis, taking into consideration all relevant factual elements as well as any additional elements of justification or clarification, which may be requested at any time during the analysis. This is done not only on the basis of the elements provided by the applicant but also, where considered appropriate, using information retrieved from the database as outlined in Article 22(2) of the EFSA Practical Arrangements.*
Q10	GEN	Late notification of studies - justifications	***In case of discrepancies between the list of notified studies and the list of studies considered in an application or in case the justification (for including or excluding a particular study) is not considered valid, will EFSA consult the applicant before applying the 6-month penalty?***
A10	11-Jan-21	Practical Arrangements - notification	Article 23(3) of the Practical Arrangement clarifies that: *In the event that the application is not considered valid the applicant shall be: 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; 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; 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; informed that the assessment of such a re-submitted application shall commences six (6) months after the re-submission of the application.*
Q11	GEN	Notification of studies	***Can a study whose report is already available be entered in the EFSA database as a 'commissioned study'?***
A11	2-Mar-21	General knowledge EFSA FAQ B33	For applications submitted after 27 March 2021, all studies initiated after this date will need to be included. Where a notification has (mistakenly) not been made before the initiation of the study, it is advisable to notify as soon as the oversight is identified. EFSA FAQ: *In particular, in line with Article 10(1) of the TR, the obligation to notify studies pursuant to Article 32b of the GFL and Chapter IV of the EFSA Practical Arrangements does not apply in the context of an application submitted to EFSA before 27 March 2021* ***and for the entire life-cycle of such application****. This means that if, for example, during the assessment of the validity/admissibility of that application or during the risk assessment, the applicant submits a new study, this study is not subject to the obligations of Article 32b of the GFL, even if it has been commissioned or initiated on or after 27 March 2021.*
Q12	GEN	Notification of studies	***Will there be an interface to electronically submit the notifications information in bulk as required and in a structured format?***
A12	2-Mar-21	General knowledge	Not in place at the moment

Q13	GEN	Notification of studies	***Is it confirmed that laboratories of the business owner (independent of site, or different legal entity) do not need to co-notify?***
A13	2-Mar-21	Regulation 178/2002	No, Article 32b requires: *(i) applicants to notify studies commissioned or carried out by them; and (ii) laboratories to notify studies commissioned by business operators.* This wording (studies carried out by business operators) implies that for studies conducted by a company lab, a notification from the applicant will be sufficient while for studies conducted by independent labs two notifications are needed.
Q14	GEN	Notification of studies	***For OECD multi-site GLP studies (e.g. a residue study which contains a field part and an analytical part) where several CROs may be involved , are there specific requirements in the notification process?***
A14	11-Jan-21	Practical Arrangements – notification EFSA FAQ B35	The Practical Arrangement states in Article 18(2) that: 3....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. EFSA FAQ: *In situations where a multisite study is commissioned to an external laboratory / testing facility subject to the notification obligations, a notification is to be submitted to EFSA notwithstanding the fact that testing site at which the person responsible for overseeing the study may not be based in the EU or a third country with an agreement or arrangement within the meaning of Article 32b(3).*
Q15	GEN	Notification of studies	***What is the "study" definition for the purposes of notification of studies (Art. 32b)? There is information submitted by the applicant in the format of reports that are not studies per se and therefore fall outside of the scope of the notification provision.***
A15	11-Jan-21	Practical Arrangements notification EFSA FAQ B4	Article 2(c) of the Practical Arrangement clarifies that: *"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.* EFSA's FAQ further explains that the definition goes beyond the studies conducted to demonstrate the safety of a substance or a product and includes all studies carried out for regulatory purposes and for which EFSA may provide a scientific output, including a scientific opinion. Desk-oriented work such as literature research, bioinformatics studies and other studies not involving laboratories and testing facilities are excluded from notification. Studies which are commissioned/carried out for development reasons as part of R&D and which are not relevant for submission to appropriate regulatory authorities do not fall within the definition of study.
Q16	GEN	Notification of studies	***Art. 32b para. 7 provides that the Authority shall make public the notified information in case where it received a corresponding application. Which notified information will be made publicly available?***

A16	2-Mar-21	General knowledge EFSA FAQ B40	No specific guidance is available at the moment. FAQ suggests that the information stored in the database will be once the notified information has been made public in accordance to Article 32b(7) of the GFL.
Q17	GEN	Notification of studies	***What if a laboratory or testing facility notifies a study not meant to support an EU application? Can the business operator indicate that the notification is not relevant (i.e. veto to the notification) at the step of "co-notification"?***
A17	2-Mar-21	EFSA FAQ B39	The withdrawal of Article 32b study notifications is also possible, when for example the related study is cancelled or interrupted. The record of the withdrawal remains available in the database. Nevertheless, a withdrawal of a notification is conceptually equivalent to the non-inclusion of a study previously notified. In this respect, in accordance with Article 20(4) of the EFSA Practical Arrangements, a study notification can be withdrawn by the potential applicant(s) having submitted the relevant notification before the planned completion date of the study. However, at application submission phase, the applicant will need to provide justifications for this withdrawal (see question EFSA FAQ 42).
Q18	GEN	Notification of studies	***What is the process when a business operator commissions a study in support of an application that will be submitted by another business operator?***
A18	2-Mar-21	EFSA FAQ B43	FAQ: In situations where a study commissioned or carried out by a business operator is used to support an application submitted by another business operator, the latter, having submitted the relevant application (and being considered the applicant), would need to justify the non-notification of the study in question. No procedural consequences will be applied if the applicant is able to demonstrate that it did not commission or carry out the concerned study.
Q19	GEN	Notification of studies	***Will there be a possibility of including the same intended study in two different lists of intended studies (by the same applicants or by different applicants)?***
A19	2-Mar-21	General knowledge	This should be possible but no specific guidance has been identified.
Q20	GEN	Notification of studies	***In case information that needs to be updated on a regular basis is in the scope of the notification process, it can happen that a study listed as intended in the context of a renewal application is conducted and completed in the context of a pending or new application before the applicant gets EFSA's advice on the intended studies for the renewal. How will EFSA deal with such situation?***

A20	2-Mar-21	General knowledge	It is expected that EFSA will provide advice on the need for any additional data that may be needed. While there is no specific advice available, it is assumed that EFSA will recognise the additional data that has already been generated and provide advice that is more focused on any need for new data to complete the submission package.
Q21	GEN	Notification of studies	***Would there be consequences if an item is selected from the drop-down list that was not the best fit to describe the study type/ international standard/etc as some items seem overlapping (e.g. acute toxicity vs Acute Toxicity: Oral vs Animal Studies)?***
A21	2-Mar-21		No information
Q22	GEN	Notification of studies	***Can notified information for commissioned studies deviate from the final report information (e.g. small differences in title, (planned) completion date)?***
A22	2-Mar-21	EFSA FAQ	The entries in the database can be edited until the time of actual submission of an application referring to those studies. Changes are tracked and will also be made public.
Q23	GEN	Notification of studies	***What is the step of the study triggering the notification? The signature of the study plan? The signed quote? The first part experiment? What is the deadline to notify a study after the trigger step?***
A23	2-Mar-21	General knowledge EFSA FAQ B37	While this is not clearly defined, the following references should provide a response to the key points: >> Article 32b(2) states that business operators should notify 'without delay' >> Article 19(30 of the Practical arrangement states that *'3. All study notifications shall be submitted before the starting date of the study.'* Additional information from FAQ: *The EFSA database will not block delayed notifications, submitted after the starting date of the study. EFSA provides an example of studies that may have originally been commissioned or carried out without the intention of using them to support an EU application. But due to a change of commercial strategy resulting in the European Union becoming a potential market they are submitted. When submitting a corresponding application, the applicant will be required to present a justification for any given delay.*
Q24	GEN	Notification of studies	***Is this study pre-notification a "formal step", or is EFSA allowed to give a no-go to proceed with the notified study?***
A24	2-Mar-21	General knowledge	This is a notification database only - not a permission system. EFSA therefore have no role in deciding if the study can or cannot be carried out. Of course, vertebrate data permissions should be in place well before this timeline.
Q25	GEN	Notification of studies	***I understand there will be an obligation to disclose to the labs the kind of submission intended. Can you confirm?***

A25	2-Mar-21		The information provided to the EFSA database will be visible to the laboratory when the study is carried out in the EU. It is however likely that the laboratory will already have this information as it will be required to carry out the actual study.
Q26	GEN	Notification of studies - Date related	***Will studies commissioned before 27 March 2021 and included in applications submitted after 27 March 2021 fall outside the scope of the notification provision?***
A26	16-Feb-21	16 Feb 21 - EFSA webinar Practical Arrangements – notification EFSA FAQ B33	There is no need to notify studies generated before 27 March 2021 and when that are submitted after that date. The practical arrangement states in Article 19.1 that: *"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."* FAQ clarifies that the obligation to notify studies does not apply in the context of an application submitted to EFSA before 27 March 2021 and for the entire life-cycle of such application. This means that if the applicant submits a new study for applications submitted before 27 March 2021, this study is not subject to the obligations of Article 32b of the GFL, even if it has been commissioned or initiated on or after 27 March 2021.
Q27	GEN	Notification of studies - EU relevant	***Is there any easy way to check which non-EU countries have signed an agreement with EU where the CROs/laboratories based in those third countries will also notify studies to the EFSA database?***
A27	2-Mar-21	General knowledge	There is currently no way to check if such an obligation applies to third countries. Such a legal obligation requires a specific mention in an international agreement. **The only international agreement that currently can easily address this aspect is the EEA agreement** (concerns Iceland, Liechtenstein, Norway). Whenever an EEA-relevant legal act such as the GFL is amended, a corresponding amendment is made to the EEA Agreement, the process takes some time but it is almost automatic. Other international agreements would require a formal amendment. The Protocol on Ireland/Northern Ireland to the EU-UK Withdrawal Agreement makes the GFL applicable also to and in the United Kingdom in respect of Northern Ireland. As a consequence, laboratories or external testing facilities located in Northern Ireland are subject to the co notification obligations of Article 32b(3) of the GFL whereas laboratories and external testing facilities located in Great Britain are not subject to those obligations.
Q28	GEN	Notification of studies (confidential)	***For a study on a non-relevant impurity for renewal or similar wholly CBI study – does this bypass the 32c1 "intended studies for renewal" list and go straight to 32b? Do I need to justify? Is there a confidential checkbox in the system? 32c1 list contains "test item" which would be CBI.***

A28	2-Mar-21	General knowledge	There is no 'bypass' of study notification. All relevant studies will need to be notified as individual studies (32b) and for renewal notification (32c). It is not possible to seek confidentiality for the information entered in the EFSA database of notified and commissioned studies, but it is possible to use a company code to identify the test item in the notification of intended studies and commissioned studies, thereby avoiding disclosure of the chemical structure of the non-relevant impurity.
Q29	GEN	Notification of studies (Co-notification)	***Does the obligation for a laboratory to co-notify commissioned studies apply to laboratories (independent from the applicant) located in the EU?***
A29	2-Mar-21	Regulation 178/2002 EFSA FAQ B35	Yes, this is a clear obligation in Article 32b of the Transparency Regulation. EFSA FAQ: The laboratory or external testing facility is also required to notify the study to EFSA when it is located in the EU.
Q30	GMO	Notification of studies	***In case different applicants (business operators) collaborate (i.e. GM stack applications), one applicant might depend on studies notified by another. Would the system allow to assign one notified study to more than one application?***
A30	2-Mar-21	Notification of studies working group discussion	Yes
Q31	PPP	Notification of studies	***How will EFSA manage the relationship between the list of studies intended for renewal and the list of notified studies?***
A31	16-Feb-21	16 Feb 21 - EFSA webinar	The EFSA notification database will create a link between the list of studies for a renewal notification and the individual studies notifications.
Q32	PPP	Notification of studies	***What happens if an applicant decides to cancel a study or it needs to be repeated for technical/other reasons?***
A32	11-Jan-21	Practical Arrangements – notification EFSA FAQ B39	In the practical arrangement *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.... At application submission phase, the applicant shall provide justifications for this withdrawal.* Article 21(b)(ii) states that it is possible to provide: *'justifications explaining the non-inclusion in the application of studies notified in the database'.* EFSA FAQ: Applicants can withdraw study notifications for example when the related study is cancelled or interrupted. The record of the withdrawal remains available in the database. A withdrawal of a notification is conceptually equivalent to the non-inclusion of a study previously notified. A study notification can be withdrawn before the planned completion date of the study, but at

			application submission phase, the applicant will need to provide justifications for this withdrawal.
Q33	PPP	Notification of studies	***Will there be clarifications on how to handle studies being submitted in more than one process (e.g. AIR process of one or more substances, MRL application)?***
A33	2-Mar-21	General knowledge	No specific clarification have been provided for such cases. Further experience can be gained when full details of the functioning of the notification database are available.
Q34	PPP	Notification of studies	***Will notified information remain open for updating (beyond the planned completion date) as reports can be reopened after finalization to capture amendments (which can be on request of EFSA)?***
A34	2-Mar-21	General knowledge	So provisions are in place to update the study notification beyond the planned completion date.
Q35	PPP	Notification of studies	***What about the studies intended to be presented in formulated PPP dossier? Should the testing facilities also notify them? What about the particular case of residues studies that are present in both active and product dossiers?***
A35	2-Mar-21	Regulation 178/2002	In line with Article 32b, for all studies to be used in any future EU submissions, these should be notified by the applicant and EU-based CROs. No notification is required where studies are generated only for PPP dossiers and will not be included in a future EU AS dossier.
Q36	PPP	Notification of studies	***In the case of a Task Force application, does each member company have to notify the study or can it be notified by a Task Force Manager on behalf of all companies?***
A36	16-Feb-21	16 Feb 21 - EFSA webinar	It is expected that all the companies being owners of the study will be listed, with multiple lines provided for that field within the database. The details are to be confirmed.
Q37	PPP	Notification of studies	***What about the notification of studies to the EFSA database in case of category 4 studies?***
A37	2-Mar-21		Yes, most Category 4 studies will need to be notified. Where the studies are likely to be used in the next AS renewal process, they should be notified to the studies database when conducted.
Q38	PPP	Notification of studies	***If there are studies found by literature search, do they need to be additionally notified?***
A38	2-Mar-21	EFSA FAQ B4	NO! The obligation to notify new studies is for studies commission and/or carried out by the applicant. There is no requirement for the applicant to notify studies carried out by any third party, this applies also to studies found in the literature search.

			EFSA FAQ confirms that desk-oriented work such as literature research, bioinformatics studies and other studies not involving laboratories and testing facilities are excluded from notification.
Q39	PPP	Notification of studies	***If the study in conducted in EU lab but will not be used in EU will it be required to be notified?***
A39	2-Mar-21	EFSA FAQ B4 EFSA FAQ B34	Notifications are only required if the study is to be submitted in Europe. There is no notification requirement for a study carried out in the EU for use exclusively in third countries. EFSA FAQ: The notification applies to studies performed by a business operator with a view to supporting an application under Union law. It is not necessary to notify to EFSA studies not conducted for the purpose of supporting an application (e.g. studies conducted for research purpose only) or conducted to support an application for which, however, Union law does not contain any provisions for EFSA to provide a scientific output (e.g. applications for the approval of plant protection products pursuant to Chapter III of Regulation (EC) 1107/2009).
Q40	PPP	Notification of studies	***Any fees linked with notifications ?***
A40	2-Mar-21		There are currently no fees for the process of study notifications to the EFSA database.
Q41	PPP	Notification of studies	***If during a study, an amendment (which would modify the title or the scope of the study) is generated, will be it necessary to notify it?***
A41	2-Mar-21	EFSA FAQ B39	Potential applicants, laboratories and other testing facilities as well as any third party entity contracted by such organisations to perform notifications on their behalf may modify the individual study notifications which they submit until the submission of the corresponding application. All fields of the notification are editable at any time before the planned completion date of the study indicated in the notification. Once the notified information will be made public, all modifications will be also made public.
Q42	PPP	Notification of studies	***For studies initially generated to support Art 33 and 43 submissions and which will likely also be included in the next EU renewal dossier, do these studies need to be notified?***
A42	2-Mar-21		Yes, all studies likely to be included in <u>any future EU renewal procedure</u> should be notified.
Q43	PPP	Notification of studies - Date related	***Regulation 844/2012 applies for substances where the dossier was submitted before 27 March 2021, and GFL procedures don't apply. If a study is conducted after this date for such a substance, should it be notified in the database e.g. if it would be submitted in a stop the clock period, which would be after 27 March 2021?***

A43	2-Mar-21	Regulation 178/2002	Article 32b.1 refers to *"...studies commissioned or carried out by business operators to support an application or notification in relation to which Union law contains provisions for the Authority to provide a scientific output…"*. It is the date of the study that is important. In this case, the study should be notified as it is [a] conducted after 27th March 2021, and [2] is required in the EU approval process.
Q44	PPP	Notification of studies - Date related	***What about new studies (ED studies for example) that would be requested by EFSA after March 21 for an ongoing AS renewal dossier? Should they be notified/ included in EFSA database?***
A44	2-Mar-21	General knowledge EFSA FAQ B33	All studies initiated after 27th March 2021, and which will be included in a **future** EU level dossier, will need to be notified to the EFSA database. This includes ED studies for the AS renewal process. EFSA FAQ clarifies that the obligation to notify studies does not apply in the context of an application submitted to EFSA before 27 March 2021 and for the entire life-cycle of such application.
Q45	PPP	Notification of studies - Efficacy	***Are the GEP trials also concerned by the notification?***
A45	2-Mar-21	General knowledge EFSA FAQ B4	The legislation requires the notification of studies that will be submitted to support an EU level application. As efficacy trials are not submitted nor evaluated at the EU level, there is no requirement to notify these studies in the EFSA database. EFSA FAQ: *studies which are commissioned or carried out for development reasons as part of the innovation process and which are not relevant for submission to appropriate regulatory authorities do not fall within the definition of study retained in the EFSA Practical Arrangements.*
Q46	PPP	Notification of studies - EU relevant	***Do applicants need to notify all early studies on all potential development candidates in order to allow later evaluation of such early studies (e.g. mechanistic studies to elucidate mode of action of a specific new chemical structure in research phase) while it is not known yet if or if not they will be used in the EU to support applications? Or can industry consider studies relevant for notification under GFL from the date when a first positive decision is taken by the applicant that the development of a new active substance is striving for an application for use in EU?***
A46	2-Mar-21	Practical Arrangements – notification EFSA FAQ B34	EFSA FAQ: *It is not necessary to notify to EFSA studies not conducted for the purpose of supporting an application (e.g. studies conducted for research purpose only) or conducted to support an application for which, however, Union law does not contain any provisions for EFSA to provide a scientific output (e.g. applications for the approval of plant protection products pursuant to Chapter III of Regulation (EC) 1107/2009).* This question is partly answered in the Practical Arrangement. Article 19.2 states that *"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." It can be interpreted that notification under GFL are needed from the date when a first positive decision is taken by the applicant that the development of a new active substance is striving for an application for use in the EU.
Renewals			
Q47	GEN	Renewal notification & consultation	***When and how will inputs received during the public consultation be made publicly available by EFSA?***
A47	11-Jan-21	Practical Arrangements - notification	Article 13 (4)(5) of the practical arrangement states that: *The consultation of third parties shall remain open for a period of three (3) calendar weeks. 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.*
Q48	PPP	Notification of studies - renewal & 3rd party consultation	***Is it possible to add studies to a renewal dossier notification as data development is in progress? What will happen in case a notified study later triggers new higher Tier studies that have not initially been notified?***
A48	2-Mar-21	General knowledge	The aim of the renewal notification is to provide information on all studies generated (or to be generated) to support that submission. There are no specific provisions in EFSA's practical arrangement to deal with this situation.
Q49	PPP	Renewal notification & consultation	***What will be the duration of the consultation on the dossier made available under Article 38(1)(c)?***
A49	2-Mar-21	Practical Arrangements - notification	Article 27.5 of the practical arrangement states that: *"The consultation with third parties shall remain open for a period of three (3) calendar weeks, unless otherwise specified in sectoral Union law".*
Q50	PPP	Renewal notification & 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?***

A50	2-Mar-21	EFSA FAQ B51	The comments received by way of public consultations carried out in the pesticides area will be taken into consideration by the relevant Member State in its initial assessment.
Q51	PPP	Renewal notification & consultation	***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].***
A51	2-Mar-21	General knowledge	The role of the RMS and EFSA in the renewal process are set out in Regulation 2020/1740 (updated AIR Regulation), which the obligations remaining largely consistent with that in place under the previous AIR Regulation.
Q52	PPP	Renewal notification & consultation	***For AIR submission in 2021, is there also an obligation to make a renewal notification? When will renewal notifications become compulsory?***
A52	11-Jan-21	Practical Arrangements - notification	There are currently no legal timelines for the renewal dossier pre-notification. The only reference to a timeline is in Article 12(5) where it states: '*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...*' There are no transitional periods for the implementation of this measure.
Confidentiality			
Q53	GEN	Public access; confidentiality	***What safeguards will be put in place to prevent commercial including regulatory misuse of the information in the EU and worldwide?***
A53	2-Mar-21	EFSA FAQ C5	No specific safeguards. Users of the OpenEFSA portal will be allowed to get access to the documents, information or data supporting application dossiers after accepting EFSA's terms of reference (see also A55 below).
Q54	GEN	Public access; confidentiality	***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 misuse for commercial, including regulatory purposes is prohibited worldwide?***
A54	2-Mar-21	General knowledge EFSA FAQ C16	It is understood that watermarks will be accepted in the non-confidential versions of the dossier.
Q55	GEN	Public access; confidentiality	***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 person accessing the studies be required to give consent that the data submitter/owner may pursue effective remedies in court for misuse of information? What safeguards will EFSA put in place to prevent misuse of the information in the EU and/or other regions?***

A55	2-Mar-21	EFSA FAQ C5	No verification, or traceability of the identities or internet protocol of users will be ensured by EFSA. Users of the OpenEFSA portal will only have to accepted EFSA's terms of reference (i.e. disclosure is not meant as permission to be use data in breach of IPRs). Where applicants don't have the necessary IPRs by owners for public dissemination of copyrighted studies they have the possibility of providing instead the full bibliographic references.
Q56	GEN	Public access; confidentiality	***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?***
A56	2-Mar-21	Practical Arrangements - general confidentiality and PPP confidentiality EFSA FAQ C12	Applicants have to provide verifiable justification for each item that disclosure would potentially harm interests to a significant degree. The level of details (minimum content) is specified in Article 10 of the general PAs or Article 6 of the PPP PAsThe format for the justification are expected to be in line with the process already in place, further details are however expected..
Q57	GEN	Public access; confidentiality	***Can personal data be redacted in all studies submitted in line with GDPR, and it is not limited to confidential information or vertebrate studies?***
A57	11-Jan-21	Regulation 178/2002 Practical Arrangements - general confidentiality EFSA FAQ C6	EFSA's Q&A The current understanding is that personal data can be removed except for: *(a) the name and address of the applicant;* *(b) the names of authors of published or publicly available studies supporting such requests; and* *(c) the names of all participants and observers in meetings of the Scientific Committee and the* *Scientific Panels, their working groups and any other ad hoc group meeting on the subject matter.* EFSA will sanitize names and addresses of people involved in testing on vertebrate animals or in obtaining toxicological information. As regards all other personal data such as authors of other studies, applicants need to provide adequate reasons for non-disclosure. Applicants are advised to completely redact all personal data from the non-confidential versions of dossiers, with the exception of the few pieces which should be always published ex Art 39e.
Q58	GEN	Public access; confidentiality	***On confidentiality claims, on which parameter will the potential damage to a significant degree be assessed (Art 39(2))?***
A58	2-Mar-21	Practical Arrangements - general confidentiality and PPP confidentiality	Article 10 of the General PAs and Article 6 of the PPP PAs provide some additional information on the potential harm to the interests of the applicant to a significant degree. The FAQ Document specifies that the main parameters are the rebuttable presumption that the information can be disclosed if the harm that may be caused by the disclosure of the information concerned does not amount to at least 5% of the gross

		EFSA FAQ C13	annual turnover or if the information concerned is older than 5 years. The applicant must provide adequate justification to rebut these presumptions in case they consider that the presumptions do not apply in the specific case.
Q59	PPP	Public access; confidentiality	***Is a difference expected in the procedure for the assessment of confidentiality requests between new applications and renewal applications?***
A59	2-Mar-21	Practical Arrangements - general confidentiality and PPP confidentiality	Assessments for renewals are carried out exclusively by EFSA in accordance with the General PAs and following the procedure outlined in Articles 39 to 39e of Regulation 178/2002 (this procedure is also followed for MRLs and GMOs applications). Member States lead the assessment of claims included in new AS applications in line with Article 7 of the PPP PAs. The RMS, prior to finalising its confidentiality decision, needs to consult EFSA which is thus responsible for final check. This procedure also follows different timelines (e.g. applicants may state its views or withdraw the application within one week from notification of RMS position. For renewals applicants are given two weeks from notification of EFSA's decision).
Q60	PPP	Public access; confidentiality	***Is it necessary to indicate whether data qualify as environmental information under the Aarhus Regulation in new AS applications?***
A60	2-Mar-21	Practical Arrangements - PPP confidentiality General knowledge	Uncertain. This requirement is not incorporated into the Practical Arrangements - PPP confidentiality (applicable to new AS applications and amendment of approvals) but still mentioned in a recital. It was indicated in an EFSA webinar that the requirement should apply also to new AS.
Q61	GMO	Public access; confidentiality	***How many users can access dossiers submitted to the e-submission food chain platform by the main company contact? What is the process of granting access to full dossiers in FSCAP to other company representatives?***
A61			No information
Q62	GMO	Public access; confidentiality	***Will there be any support e.g. HelpDesk available for applicants when submitting via the e-submission food chain platform?***
A62		EFSA Webinar 25-03	Not clearly specified yet. The E-Submission Food Chain platform will be operational as of Monday 29 March 2021 at 08:00 CET the final link will be communicated on that date on the Commission webpage (link) servicedesk@efsa.europa.eu is the address to contact EFSA on technical aspects
Q63	GMO	Public access; confidentiality	***What is the process of claiming personal data confidential in the e-submission food chain platform? Will it be conducted by the applicant or EFSA? Will applicants need to provide justification for each name redaction and for each study report?***

A63		EFSA FAQ C6	Applicants can prevent dissemination of personal data by providing adequate reasons for non-disclosure (see also A57 above). It seems that applicants would need to provide justification for each redaction (applicants may "*prevent the dissemination **of specific personal data***") but this aspect remains unclear.
Other questions			
Q64	GMO	Standard data formats, Article 39f	***What will be the timing and overall scoping of implementation of a standard data format?***
A64	2-Mar-21		No information
Q65	GMO	Standard data formats, Article 39f	***Which standard data formats is EFSA considering for GMO submissions?***
A65	2-Mar-21		No information
Q66	GEN	Other elements	***Will the EFSA own commissioned studies be notified in the database and will there be consultation on the protocol or mandate before?***
A66	2-Mar-21		No information
Q67	PPP	IUCLID	***Should submission of data gaps identified following the MRL Art.12 evaluation (i.e. MRL confirmatory data) be in IUCLID format?***
A67	2-Mar-21	General knowledge	After 27 March 2021, all submissions will be in IUCLID format. However, for any additional/confirmatory data there may be some flexibility. A check with RMS would be recommended for all such submissions.
Q68	PPP	IUCLID	***Regarding the IUCLID format, it is clear the upcoming regulation on renewals for PPPs will include a provision asking formally the format for future renewals. What about submissions for new active substances and MRL (new, renewal, Import tolerances)? Which document will formalize this obligation and as from when will it apply ? Does the March 27th effective date apply to the IUCLID requirement for these dossiers?***
A68	2-Mar-21	Regulation 2020/1740	The obligation to submit in IUCLID for renewal dossiers in set out in Article 7 of Regulation 200/1740. A separate legislative requirement is in place requiring IUCLID format for all new submissions for new ASs and MRLs, to be submitted after 27 March 2021.