EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Food chain science and stakeholder relations

AD HOC MEETING OF THE ADVISORY GROUP ON THE IMPLEMENTATION OF THE TRANSPARENCY REGULATION

18 NOVEMBER 2020, 09H30-15H30

Summary Record

1. WELCOME AND OPENING BY MS ANASTASIA ALVIZOU, DEPUTY HEAD OF UNIT, SANTE D1, FARM TO FORK STRATEGY

SANTE Deputy Head of Unit D1, Anastasia Alvizou, chaired and opened the virtual meeting and welcomed the participants and EFSA representatives. The Chair informed stakeholders that the meeting is a follow-up meeting to the ad hoc meeting held on 5 June, with the purpose to discuss specific aspects of the implementation process and on providing stakeholders with the latest state of play.
The Chair presented the agenda, explaining that the morning session would be dedicated to the draft EFSA practical arrangements, which were shared with stakeholders for comments/questions. The Chair indicated that COM/EFSA would try to address the comments/questions already received, which would be grouped in clusters/themes, indicating also that the ultimate responsibility for the interpretation of the EU law remains with the Court of Justice of the European Union. She further informed stakeholders that the deadline to send comments had been extended to 20 November 2020. However, the Chair stressed that the practical arrangements would need to be finalised by the end of 2020 and urged participants to limit comments to inconsistencies/non-appropriate issues and to be mindful of the time constraints. The Chair assured stakeholders that no questions would be left unanswered and that training sessions, seminars and manuals would be provided to prepare all interested parties for the entry into application on 27 March 2021. She informed stakeholders that the afternoon session would focus on the IT side of the implementation, more specifically on the IT tools used for the notification of studies and for the submission of the dossiers.
The Chair concluded by informing stakeholders that as part of the introduction to the meeting, the meeting agenda would start with a short update on the revision of certain Commission implementing acts.

2. STATE OF PLAY ON THE REVISION OF CERTAIN IMPLEMENTING ACTS

COM presented a brief state of play on the Revision of certain Commission Implementing Acts (IAs).

The Chair added that the Implementing Act concerning Article 8 of Regulation 1925/2006 on the addition of vitamins, minerals and other substances to foods, was still under preparation. Once the draft is finalised, it would also be subject to a public consultation and that stakeholders would have the possibility to provide feedback.

Questions and comments raised

No comments and questions raised.

Before moving onto the next item on the agenda, the Chair reminded participants that the Transparency Regulation is a targeted revision of the General Food Law (GFL) and eight other sectoral acts. Nevertheless, the impact of the Transparency Regulation is much broader; it does not only affect the processes of the acts it amends, but also all processes to which the GFL applies. For example, Regulation 1925/2006 on the addition of vitamins and minerals and other substances to foods was not amended by the TR per se; however, the general provisions of the GFL do apply and therefore the relevant IA concerning Article 8 of the latter Regulation would need to be amended. This also applies to health claims: in the area of health claims, the Regulation had no specific confidentiality rules. Accordingly, confidentiality requests in the context of the health claims had been assessed under the general provisions of the GFL and as of 27 March 2021, under the new provisions of Articles 38 and 39 of the GFL as amended by the TR. Therefore, the general practical arrangements on new Articles 38/39 of the GFL as well as the relevant new provisions on the pre-submission phase and public consultations (Articles 32a/32b and 32c of the GFL) would be applicable in the area of health claims. The same is the case to MRLs: whenever the GFL applies, relevant provisions would also need to be adapted.

As regards Articles 38/39 of the GFL, as amended by the GFL, the Chair explained that confidential information could solely be requested on the basis of the closed positive list of information items. Additionally, any request for confidentiality treatment would need to be substantiated and the applicant should demonstrate that public disclosure of the relevant parts of information would potentially harm its interest to a significant degree. There is a general positive list of information items in the GFL for which confidentiality treatment may be requested. Nevertheless, whenever legislators considered that additional items were required, an additional complementary closed positive list was created in the relevant sectoral act.

With respect to smoke flavourings, no additional complementary positive list was introduced in the Smoke Flavourings Regulation, as the co-legislators considered that the general positive list in the GFL sufficed. The Chair stressed that the positive lists are closed and that they could only be adapted by means of the ordinary legislative procedure (ex co-decision).

Finally, the Chair underlined that the new rules did not infringe on IP rights and emphasised that IP rights cannot be used as a means to prevent public disclosure. She stressed that EFSA was not an enforcer of IP rights. Neither EFSA nor COM are responsible for any misuse in breach of IPRs of the publicly disclosed documents by people accessing those. EFSA's only obligation is to communicate/make the person accessing the documents understand that any further exploitation/use cannot breach any existing IP rights.

Questions and comments raised

EU specialty Food Ingredients enquired about the legal base of the IA on food additives. EU Specialty Food Ingredients questioned the legal base of this decision, which in their view was not captured by the TR. It further asked to elaborate on the legal background and to clarify what has motivated this political decision.

The Chair explained that the confidentiality provisions of the 2010 IA on food additives were not in line with the Transparency Regulation and had to be aligned to comply with the General Food law after the entry into application on 27 March 2021. Moreover, certain adaptations with regard to Articles 32a, 32b and 32c of the GFL would need to be included in the IA. The Chair said that the draft IA was discussed with MSs in the context of the PAFF Committee on 17 November 2020. The vote on the IA had taken place by written procedure and MSs did not oppose.

FEFANA commented on the public disclosure mechanism and expressed concern that the draft PAs did not address how COM/EFSA would obtain confirmation from people, accessing the documents, that they would not breach IP rights. FEFANA understood that COM/EFSA should not be responsible, nevertheless, it emphasised that more action should be undertaken to prevent illegal use of these documents.

The Chair reiterated that EFSA was not an enforcer of IP rights and that it could not undertake any action to prevent illegal use, except passing a message to the user (e.g. by use of cookies) that the accessed document(s) cannot be used to breach IP rights. She stressed that EFSA's responsibility stops at that point.

The Chair then passed the floor to EFSA for the first item on the agenda.

3. PRESENTATION OF THE DRAFT PAS ON ARTICLES 38 AND 39 OF THE GFL REGULATION (TRANSPARENCY/CONFIDENTIALITY)

EFSA elaborated on the progress made and on the timeline for adoption of the draft practical arrangements in general.

EFSA presented the draft PAs on Articles 38 and 39 of the GFL, related to transparency and confidentiality and addressed as many stakeholder questions/comments as possible while discussing the specific points of the PAs.

Questions and comments raised

Client Earth enquired about the composition of the Expert Group of GFL.

The Chair replied that it is composed of experts representing all MSs and is chaired by the Commission.

CEFIC said that it would provide its comments before the extended deadline of 20 November, but already wanted to raise two comments:

- Firstly, as regards the Aarhus Regulation, even though the text of the draft PAs mentions environmental information, the Aarhus Regulation refers to a much more limited set of information, more specifically to 'emissions into the environment'. CEFIC referred to a court case in November 2016 in the Court of Justice, which specified the definition of 'emissions into the environment'. Therefore, CEFIC suggested that the wording needs to be adapted.
- Secondly, CEFIC drew attention to Article 7 on the limited reuse of disclosed data and the fact that EFSA is not an enforcer of IPRs. Article 7.2 is not in line with Art. 340 of the Treaty on the functioning of the EU. CEFIC commented that putting it on the website with an asterisk is not sufficient and that the Treaty should be taken into account. The mandate by the secondary legislation does not waive EFSA's responsibility.

On IPRs, the Chair replied that IPRs do not grant an absolute protection. Whenever there is an overriding public interest, there is a balancing of interests and the information is disclosed. This is reflected in Regulation 1049/2001 on Access to

Documents. In the TR, the balance of interest has already taken place: if the information is relevant for the assessment of safety, confidentiality cannot be claimed and the information will be disclosed. The Chair said that CEFIC's comment is duly noted, but reiterated that the balance of interest is already incorporated and that items on which confidentiality can be claimed can either be IPR protected or not.

On CEFIC's comment regarding the emissions into the environment, EFSA replied that COM/EFSA already looked into it and confirmed that it has taken note of the mention of emissions into the environment with regard to the application of exceptions concerning requests for access to environmental information. However, in this case, it concerns public disclosure, which is also requirement under Art. 4 of the Aarhus Regulation. Both recital 15 and article 6 would clarify that they apply specifically for the request for information.

On the reuse of disclosed documents, EFSA said that COM already covered the question, but explained that EFSA – as a decentralised agency of the EU –has only the powers and the tasks vested in it by the legislation. EFSA emphasised that the legislation is clear: EFSA should proactively publish certain sets of documents and shall not be held liable for misuse by third parties. IPRs and data protection clauses are maintained; the information to be publicly disclosed cannot be used without prior agreement of rights holders. EFSA underlined that regarding concerns/issues going beyond EFSA's limited empowerment, it is not in a position to address these concerns.

FEFANA asked for a clarification on the withdrawal of applications, notably Article 15. The applicant's reason for withdrawal is the rejection of confidentiality treatment for certain information. If this request is done before EFSA's decision, this request should have immediate effect to avoid disclosure of this information. The decision to keep this information publicly available for six months, seems arbitrary and is not specified in the TR.

EFSA replied that if the withdrawal notice is received prior to the confidentiality decision, it has immediate effect and will also stop the risk assessment that is undergone in parallel. What remains publicly available online, is simply the non-confidential version that was originally submitted by applicant and does not include confidential information. EFSA stressed that the withdrawal notice takes immediate effect and ensures complete protection.

Consequently, EFSA addressed/summarised the key stakeholder questions that were not included in the specific slides.

- EFSA received several concerns regarding the possibility that proactive disclosure of this quantity of data would have interested parties or common citizens approaching the EFSA dissemination portal. EFSA said it took good note of these concerns, but was convinced that the effect of possible data-washing would be avoided due to the fact that – at least for application dossiers – they would be structured. Nevertheless, the application dossiers would still be sizeable in quantity and complex in content. Interested parties would be able to access the relevant application dossier and follow the structure that was followed by the applicant. EFSA said that it would not restructure the data submitted by the applicant to make it more readable and stressed that it does not have the power to do so with the exception of items sanitised according to the confidentiality decision.

- EFSA received a comment concerning the need to avoid abuse of the system to grant applicants the possibility to submit confidentiality requests. EFSA replied that it was convinced that the PAs would guarantee proportionate and sound confidentiality procedures in accordance with the terms of the TR.
- EFSA further received comments regarding concerns for the applicants' need for resources in order to request confidentiality. EFSA took note of these concerns and highlighted that already under the existing regime confidentiality requests were being submitted. EFSA acknowledged that some requirements would have to be adapted and be more sophisticated, but applicants would have at their disposal electronic submission tools to facilitate submissions of these requests.
- EFSA said it received comments regarding the scope of the practical arrangements, but referred to the Chair's opening remarks, in which these comments had already been addressed.
- EFSA received comments regarding the definition of applicants, notably the reasons for not having the same definition in the different sets of PAs, and especially in the PA on PPP confidentiality. EFSA explained that the PA on PPP confidentiality is only applicable to that specific sector, while for the PA on Articles 38 and 39 of the GFL, the concept is much broader. It also has to cover business operators who share information in context of calls for data and requests for information from the Commission, the European Parliament and the Member States. EFSA emphasised that it is in EFSA's and COM's interest to have the broadest and most complete data sets available to complete the RA and scientific evaluations.
- EFSA received a comment about the disclosure of documents after the confidentiality decision-making process. EFSA underlined the difference between the concept of results of public consultations versus the comments/specific input received by EFSA in this context. By law, the latter will be made available immediately after the closure of the public consultation. However, the results of any public consultations during the risk assessment process would only be made available at the end of the scientific evaluation process.
- Lastly, EFSA confirmed that contractual reports would be disclosed as they fall in the category of scientific or verification studies, outsourced by EFSA, or in the category of information on which EFSA bases its scientific outputs.

<u>Questions and comments raised</u>

FEFANA asked to clarify the meaning of 'sanitisation'. It also asked further clarification on the withdrawal of applications. In the event that there would be a disagreement on confidentiality and EFSA would decide to disclose, FEFANA asked why this information would be consequently be available on the website for a period of six months and not, e.g. six days. FEFANA added that this decision seems arbitrary.

On the withdrawal of applications, the Chair replied that, in case of a disagreement, this disagreement would not be shared with the outside world. She further explained that the draft Practical Arrangements only regulate the fate of the 'non confidential' versions already available. More concretely, – according to the presented draft Practical Arrangements as they stood at the time of the meeting– if a withdrawal takes place before EFSA makes a confidentiality decision, only the non-confidential version, as submitted by the applicant, would remain public. However, if the withdrawal takes place after the adoption of the confidentiality

decision, such a withdrawal could be for various reasons other than a potential disagreement on the confidentiality request between the applicant and EFSA. Withdrawal of an application stops the risk assessment process and has immediate effect.

EFSA clarified that sanitisation referred to the process by which EFSA applies its confidentiality decision and the IT process, namely the 'redaction' or 'data protection' in some cases and means the impossibility for a third party to review the information that has been sanitised/redacted/anonymised. On the question of who does what, EFSA said that, under the PAs on Articles 38 and 39 of the GFL, the sanitisation/redaction would be ensured by EFSA. EFSA would examine the dossiers and either lift the confidentiality/blackening applied by the applicant, or retain the confidentiality request. Initially this would be a human intense procedure, however, EFSA was looking to automate this process in the future.

EUROPABIO supported FEFANA's comments on data disclosure and withdrawal of applications. As regards pending standard data formats, EUROPABIO asked whether there is harmonisation for the sectors and how applicants can comply with these requirements. It further commented that scientific papers published in journals can be submitted as part of the dossiers. Nevertheless, these can be subject to copyright. EUROPABIO asked who would be responsible for potential copyright breaches.

FSE requested a clarification regarding the withdrawal of applications. FSE understood that once EFSA has taken a decision, the information will be disclosed, regardless of whether the applicant has withdrawn the dossier or not. Nevertheless, FSE emphasised that some information should be protected/not be accessible outside of the EU. After the confirmatory application, the applicant should be able to withdraw the application in order to prevent publication of the information in the public domain. FSE asked EFSA/COM to confirm.

The Chair replied that withdrawal is not the only means to prevent disclosure. She explained that the applicant has the possibility for a confirmatory application, asking EFSA to review its original decision. Furthermore, the applicant also has the possibility to go to the European Court of Justice to request an interim measure not to disclose the information until a final decision on confidentiality is made. While this process is ongoing, the RA and the public consultation will continue.

In reply to EUROPABIO's question on standard data formats, EFSA highlighted the importance to differentiate between sectors.

- For pesticides renewals, the standard data format is provided by IUCLID (as prescribed in the relevant IAs to be soon adopted);
- For other sectors, COM had not yet adopted standard data formats. Nevertheless, depending on the sector, a table of content and structure of the dossier will be made available/published to facilitate the submission of application dossiers via FSCAP. This is supposed to support dossiers on non-active substances as well.
- For OECD Harmonised Templates (OHT), the correct forum to suggest improvements/request changes is the OHT Working Group, managed by OECD.
- EFSA said it expected IUCLID to become the standard data format for new active substances prior to April 2021, but this was subject to confirmation from COM.

- Dossiers that should be submitted in FSCAP, will follow a table of content/structure that will be disclosed by EFSA/COM. These were at that time being fine-tuned, but were expected to be released in January 2021. EFSA/COM will jointly draw up the standard data formats in accordance with Article 39f.

As regards the question concerning copyrights of published scientific articles, EFSA underlined that it was the responsibility of the applicant to ensure compliance with existing rights. EFSA would not be breaching any rights, because there is an explicit legal basis for the proactive disclosure of scientific studies, mentioned explicitly in Art. 38§1c of the GFL, as amended by the TR. Compliance concerning existing rights is a matter for the applicant and not EFSA's responsibility. The applicant will also have to highlight the obligation for disclosure to the publisher. Parts of studies may be confidential. However, if it is relevant for the RA process and scientific evaluation, it has to be disclosed.

EDE supported FSE's comments.

Concerning the six-month period proposed for maintaining the already made public non confidential versions following a withdrawal, EFSA explained that this was considered a proportionate timeline after withdrawal to ensure transparency. As mandated by the TR, EFSA opted for a timeline of 6 months. However, this may be reconsidered.

FSE commented on COM's reply that it was more drastic for SMEs to have information published, which if obtained by competitors, can result in putting them out of business. FSE asked EFSA to reconsider as regards the consequences of a withdrawal in terms of public disclosure given the dilemma of withdrawal or going to Court to object EFSA's confidentiality decision.

The Chair replied that it would be for the applicant to make the decision that preserves its best interest: withdrawal or go to court. Both have advantages and disadvantages. The Chair said she had taken good note of FSE's concerns.

Except for FSE, several other stakeholders expressed concern about the withdrawal, more specifically FEFANA, EuropaBio, EDE, FoodDrinkEurope and EU Specialty Food Ingredients.

4. PRESENTATION OF THE DRAFT PAS ON THE CONSISTENCY OF CONFIDENTIALITY ASSESSMENTS IN THE CONTEXT OF THE PLANT PROTECTION PRODUCTS (ART 7 AND 16 OF THE PPP REGULATION)

The Chair gave a short introduction, explaining that the objective of these PAs is to ensure consistency of confidentiality in the area of PPPs. She further explained that the system for PPPs is semi-decentralised and that - for new approvals - confidentiality is assessed by MSs, whereas in the area of renewals it is assessed by EFSA.

EFSA presented the draft PAs on Confidentiality (Articles 7 and 16 of Regulation (EC) No 1107/2009), elaborating on the scope, decision-making for new active substances, decision-making for renewals and the substantive screening criteria.

Questions and comments raised

No comments or questions raised.

EFSA reminded stakeholders of the extended deadline for written comments (20 November 2020).

5. PRESENTATION OF THE DRAFT PAS ON ARTICLES 32A (GENERAL PRE-SUBMISSION ADVICE), 32B (NOTIFICATION OF STUDIES) AND 32C (SPECIFIC PRE-SUBMISSION ADVICE ON RENEWALS / PUBLIC CONSULTATION OF SUBMITTED STUDIES)

The Chair gave a brief introduction, explaining the objectives of Articles 32a, 32b and 32c and passed the floor to EFSA.

EFSA gave a comprehensive presentation on the PAs on the pre-submission phase and public consultations, addressing:

- ✓ General aspects
- ✓ General pre-submission advice (GPSA)
- ✓ Intended renewal applications
- ✓ Notification of studies
- ✓ Public consultation on submitted applications.

The Chair thanked EFSA and explained that EFSA would first address the questions received in clusters/themes before taking questions from the floor.

She further addressed a question received from FEFANA - in the context of the specific feedback mechanism on IA on feed additives - on the transitional aspects of the renewals. FEFANA asked how the date for entry into application (27 March 2021) would interact with the compliance with notification of intended studies for renewals (Art. 32c(1) and notification of commissioned studies (Art. 32b) of the GFL). The Chair said this question was not only limited to renewals for feed additives, but it was also pertinent for all areas where renewals of authorisations/approvals are foreseen in the legislation for which a submission would have to be made within a specific timeline prior to the expiry of the existing authorisation/approval. In reply to the question on how to comply with both Art. 32c(1) and Art. 32 b of the GFL, the Chair explained that the obligation of Art 32c(1) would only come into play if on 27 March 2021, a potential applicant would still intend to commission a study. If a study had already been commissioned prior to 27 March 2021, this would not be applicable. The same is true for the notification of studies. For example, if an applicant would realise on 27 March 2021 that an additional study is needed, the study would need to be notified in accordance with Art. 32c(1). If the timeline would not allow the applicant to wait until the pre-submission advice by EFSA is received and the window of opportunity would be missed, there would be a parallel process and the applicant would be allowed to proceed with the commissioning of the study. The Chair stressed the importance of ensuring compliance with Art. 32b because of the procedural consequences in case of non-compliance, which would result in the non-renewal of the application.

EFSA addressed/summarised the key stakeholder questions that were not included in the presentation:

- EFSA received enquiries about the timeline for operators to test the system and gain a better understanding of how it works. EFSA informed stakeholders that it had set up a training plan to be carried out between January and March 2021 to cover all systems. It has also created a dedicated webpage with training materials and tutorials. EFSA said that more information would follow in the afternoon session.

- As regards the transition period, EFSA highlighted the importance of how Article 10 of the TR will work with in relation to the notification of studies and notification of intent studies.
- EFSA clarified the division of competencies for the assessment of validity/admissibility of an application/notification:
    - ✓ EFSA is responsible for the assessment of validity/admissibility in relation to GM food and feed, smoke flavourings, feed additives and food contact materials.
    - ✓ EFSA/COM share competence in the areas of food additives/enzymes/flavourings and novel foods.
    - ✓ MSs are competent in the areas of health, claims, GMO Directive, pesticides andMRLs.
- EFSA received questions on how it would treat studies that are intended for non-EU markets. EFSA emphasised the importance for the applicant to comply with Art. 32b of the GFL. The applicant will have the possibility to decide on the strategy and to provide justifications.
- Concerning the general pre-submission advice (GPSA) and EFSA's treatment of multiple applicants, EFSA explained that the system is flexible. There is no limitation: the applicants can interact with EFSA as a group or individually. If the applicants decide to request a jointly application ID, the difficulty for EFSA is to dispatch the advice to all applicants and to ensure that all applicants are invited to the meetings.
- On decentralised systems and EFSA-RMS coordination, EFSA said that it was addressed in the presentation and reiterated that the aim is to avoid diverging views between EFSA and RMS. This was covered in the process.
- EFSA received many questions on why Art. 32a on GPSA excludes advice on the design of studies. EFSA stressed that this is not a tailor-made advice and that EFSA is bound by the limits of Art. 32a of the TR.
- As regards the possibility to discuss international test guidance, in particular OECD, EFSA repeated that the boundaries of Art. 32a are EU rules and EU test guidelines.
- EFSA received comments regarding the limitations of two requests in the context of the GPSA. EFSA explained the logic during the presentation and added that the idea is to respond in the interest of the potential applicant and to ensure that EFSA applies a proportionate effort.
- EFSA further received questions regarding the possibility of a follow-up by phone in the context of RPSA. EFSA replied that presently, it was not foreseen that applicants could request clarifications on RPSA, but said it had taken good note and would consider it in the future.
- EFSA received many questions on renewals, with one question in particular on pesticides. In certain cases, the applicant may have already agreed the study plan with the RMS. EFSA highlighted the importance of the timeline of Art. 10 on transitional measures and how this would apply in the context of Art. 32c(1).

Questions and comments raised

SNE enquired about the use of a study that would be discovered during the preparation of the application, but would not have been notified, because it was not specifically made for the application.

EU Specialty Food Ingredients asked how the PA will apply in a case that is neither an application or a renewal. Regarding the planned completion date of a study, i.e., the date of expected study signature of the study report, EU Specialty Food Ingredients commented that in case of an in-house lab study, there is not always such a formal study report.

AMFEP commented that in its view, the definition of study was not operational and would lead to hundreds of notifications per dossier. It suggested restricting it to those studies, which would really affect the safety evaluation of products. As regards the issue of valid justifications, AMFEP said that, when developing an application, there is a preliminary phase with many studies and it is only when everything is concluded, that it is decided whether or not to use those studies for the application. AMFEP asked COM/EFSA to confirm if this can be used as a valid justification as to why a study was not notified immediately.

The Chair replied that this relates to the TR provision. Art. 32b applies to all studies supporting an application and not only to those relating to safety. From the moment a study is commissioned with a view to support an application, it falls within the scope. The definition of study used in the draft Practical Arrangements is the one in the GLP Directive, taking into account the objective of Art. 32b of the GFL. Art. 32b of the GFL has the objective to ensure there are no hidden studies meant to support an application. The link with the GLP Directive is important, because there is also Art. 61a on fact-finding missions to laboratories, pursuant to which a verification with the applicable standards (including GLP) and with the notification requirement by the relevant laboratory would be carried out. The Chair emphasised the importance of consistency. She further stressed that EFSA did not have the power to limit the broad scope determined by the legislators.

EFSA added that it took the GLP definition as a starting point, but adapted it slightly to cover everything that may be included in an application. EFSA underlined that it would be up to the participant to assess the risk of not notifying and that EFSA will assess the justifications on a case-by-case basis.

EFFA asked about the public consultation in relation to the notification of studies.

The Chair said EFSA will come back to this question later during the meeting.

EFSA addressed/summarised the key stakeholder questions on notification of studies in themes/clusters:

- EFSA confirmed that the modification of existing authorisations were covered by the scope of the notification of studies obligation.
- EFSA elaborated on what would happen to the notification stored in the database, in case an application is withdrawn. EFSA said that the information will not be deleted and highlighted that, until a connected application is submitted, the notified information will remain confidential and will not be disclosed, in accordance with Art. 32b.
- However, a notification under Art. 32c(1) will be subject to public consultation.
- EFSA received the question why the draft PAs require a justification regarding the reason of withdrawing a study from the NoS database. EFSA explained that it cannot allow the use of unjustified withdrawal of a study notification as a

way to by-pass the need for compliance with Art. 32b; this is the reason behind the request for a justification on this front.

- In reply to the question until when it would be possible to amend notified information, EFSA replied that there was no limitation and that all information can be amended until the end. Nevertheless, EFSA drew attention to the fact that once the confidentiality assessment is finalised, the information in the NoS database will be made public, together with the valid justifications.
- As regards the possibility for EFSA to waive the submission of toxicological studies. EFSA replied that in the PAs procedural consequences are only foreseen for studies inserted in the application or requested in the context of the assessment of the validity/admissibility of the application, not in the context of studies requested during the RA process.

Questions and comments raised

EFFA asked if an applicant could initiate studies only after the public consultation and feedback from EFSA and how much time this will take. If an applicant would start the study immediately, would he/she need to wait for positive feedback from the public consultation. EFFA also enquired how potential objections from the public consultation will be addressed and whether this will cause delays.

The Chair replied that the public consultation, done in the context of renewals, leads to the tailor-made renewal pre-submission advice from EFSA. This advice is non-committal and the applicant may disregard it or follow it. It is also non-committal for EFSA. An overlap may be possible in 2021-2022. It is up to the applicant to decide on the timeline. Nevertheless, the applicant may profit from EFSA's recommendations and tailor-made pre-submission advice on renewals, taking into account the public consultation. It may reassure the applicant that the prepared studies are appropriate to support the application.

EFSA added that the default system is for the applicant to wait for the RPSA in accordance to Art. 32c(1) and said it had taken note of the issue regarding applications that are due for submission early.

ECCA raised concern regarding non-notified studies with a justification. It explained that for pesticides dossiers, it was confronted with a number of studies, both in and outside of the EU. MSs ask for many studies. ECCA said that it foresaw future problems with regard to studies that were not notified in the system. ECCA asked whether EFSA had the ultimate decision whether or not to accept a justification or whether there would be possibilities for an appeal.

The Chair reminded ECCA that, for pesticides, the decision regarding admissibility lies with the MSs. The reporting MS will take the decision.

FSE asked whether compositional data on a product is covered by the definition of study and would need to be notified. ECCA further asked what would be the procedure followed by EFSA, during the assessment of the application, to check whether studies have been notified. In this respect, ECCA noted that, there are studies for which study notifications are present in the EFSA database but which were not included in the application, because these studies were notified by other parties than the applicant and the applicant was unaware of those studies. In this case, would the applicant be requested to re-submit the application, because the applicant will not have access to these studies?

The Chair clarified that this was not part of the notification of studies. She emphasised that the notification of studies only concerns studies commissioned

by the applicant for its own submission and not studies commissioned and therefore notified by others.

As regards studies on compositional data, EFSA replied that they will be covered under the definition of studies and will fall within the obligations of Article 32b.

EFSA confirmed that if the studies are commissioned by someone else and are not included in the submission, Article 32b will not be applicable.

EUROPABIO asked to clarify Article 20 §4 relating to EFSA's request for data for non-completed studies. As regards GLP studies, the final report would need to be approved, however, if the study is incomplete, the study report would not be available and consequently, the data would not be available. EUROPABIO further asked to elaborate on the criteria and definition/meaning of studies not submitted in full. Finally, Europabio asked if a review of the PA on pre-submission phase and public consultations is foreseen.

On non-completed studies, EFSA replied that it understands that no final report can be provided, however, EFSA would require a justification that the withdrawal of the study is justified and to check if data was generated.

As regards a review, EFSA said that the Transparency Regulation did not foresee a possibility for confirmatory application on the decision on compliance with notification of studies obligation.

The Chair clarified that for studies not submitted in full, a valid justification is needed, e.g. for studies on feed additives, a full study might not always be relevant. Nevertheless, the Chair stressed the importance of a strongly argued justification, because of the potential consequences of non-compliance. She added that this could also be clarified in the GPSA on a case-by-case basis.

FEFANA commented on the notification of intended studies for renewal and expressed concern that the deadline to notify studies at least five months in advance is very long and puts extra burden on companies.

The Chair explained that under Article 32c(1), the notification of intended studies by applicants is mandatory, but that it also foresees a public consultation, which results in tailor-made advice and a recommendation of which the applicant can profit. It will allow applicants, especially SMEs, to receive the necessary support and information. In light of this, the Chair replied that it should not be viewed as a burden, but as an opportunity for more robust and strengthened studies and as a service to the potential applicants.

EFSA stressed that the RPSA is a recommendation and that it will never refuse a notification of intended studies for non-compliance with this recommendation. Nevertheless, a shorter timeline is non-negotiable. EFSA has designed the process according certain timelines. These will remain in place and start from the moment EFSA receives the list of intended studies.

6. UPDATE OF EFSA'S GUIDANCES

EFSA presented an update on EFSA's guidances, providing an overview of the 27 updated guidance documents and elaborating on the update flows for administrative/scientific guidance documents and the estimated timeline for publication.

Questions and comments raised

EPBA enquired whether the main guidance on regulated products will be part of the set that will be published late January – February 2021.

EFSA said it did not expect further delays. The timing is linked to the adoption of the adoption of the PAs by the end of December 2020. EFSA confirmed it expected to respect the set timeline for the guidance documents, which will need to take into account procedures foreseen for their endorsement.

7. PRESENTATION OF THE NOTIFICATION OF STUDIES DATABASE

EFSA gave a comprehensive presentation of Notification of Studies database, explaining the process for new applications (Article 32b) and renewals (Article 32c1). In addition, EFSA also shared a demo video of the database.

Questions and comments raised

FEFANA enquired whether the video would be disseminated.

EFSA replied that it will be discussed internally and that it may prepare a more professional version (now available here). EFSA further informed stakeholders that a webinar will take place on 19 November 2020 where a complete overview of all IT tools will be presented and where a training program for external participants will be announced. For those stakeholders not able to participate, all information will also be made available on the EFSA website[1].

ECPA supported the dissemination of the video as it is. As regards training material and the opening of the system in February/March 2021, ECPA said that is already too late and pushed for any type of beta testing as soon as possible, even if the system is still under development.

IBMA, Europabio, FEFANA and AMFEP supported the request for immediate beta testing.

EFSA replied that it has tested the system with external users of Technical Group on Notification of Study Database.

ECPA further asked for more details on how registration to the system will take place, more specifically whether there would be a limitation on logins for applicants.

EFSA replied that it has ensured a sufficient number of licenses to satisfy the need of the organisations.

8. PRESENTATIONS OF E-SUBMISSION SYSTEMS FSCAP AND IUCLID

COM gave a comprehensive presentation on the implementation of FSCAP, the IT tool for the electronic submission for applications in all domains, with the exception of PPPs and MRLs for which IUCLID will be used. In the presentation, COM addressed the progress made, how FSCAP works and interacts with EFSA's systems and supporting materials. COM further shared a demo on the FSCAP Dossier submission system to give stakeholders a preview of what the system will look like.

EFSA presented a comprehensive update on IUCLID implementation and hypercare.

Questions and comments raised

[1]Following the webinar taking place on 19 November 2020, the relevant information will be available at https://www.efsa.europa.eu/en/events/event/webinar-implementing-transparency-regulation-requirements-tools-and

ECPA said it would comment officially, however, already gave a first feedback on the filtering rules, which it found cryptic and difficult to check from the applicants' side. ECPA asked if such filtering function fits the sanitisation process.

EFSA acknowledged that the process is complex and said that in case of difficulties/questions, applicants can contact EFSA for clarifications.

ECPA further asked if and by when it would receive more details on the EFSA dissemination portal and what it would look like.

EFSA said it takes note of ECPA's request.

EU Specialty Food Ingredients enquired whether in cases not related to new or renewal applications (e.g. EFSA calls for scientific data) industry or other interested parties will have to us the FSCAP IT tool.

The Chair replied that FSCAP is used for authorisation processes. For the re-evaluation of food additives, COM had to wait for the adoption of the IA. COM could not reply at that moment, but will come back with a further refinement. All other processes (non-authorisation processes) relate to the dissemination of information on which EFSA bases its opinion. This would be a different process and would be for EFSA to address.

Europabio asked if the demo video on FSCAP would be shared and when the training materials would be made available. Europabio further asked if the login for FSCAP and the NoS database would be the same to ensure synergies between the systems.

On training materials, COM replied that the training was foreseen in steps. The first video would be available before the end of 2020 and would contain more details than the video presented. A more detailed video would be made available and other more specific modules will be provided. Different videos will be provided step-by-step.

As regards the logins, COM replied that there would be two different logins: one for FSCAP and one for NoS database. For FSCAP an EU login is necessary. Nevertheless, if the email address for this EU login is recognised in the EFSA system, a link can be made.

The Chair added that COM would keep stakeholders informed on the availability of training materials/seminars/modules through the Advisory Group.

FEFANA asked if COM foresees a future meeting to discuss further details of the PAs.

The Chair said she would address this question in the concluding remarks.

9. WRAP UP AND CLOSURE

The Chair thanked participants for a constructive meeting and for their active participation and interesting questions/comments, which proved very helpful in the assessment of the effectiveness of the new provisions of the TR.

The Chair indicated that EFSA and COM tried to answer as many questions as possible, however, there may be a need to come back to stakeholders regarding any questions left unanswered.

The Chair reminded participants that the deadline for comments on the PAs had been extended until 20 November 2020. She further stressed the importance of finalising the PAs by the end of December 2020. The Advisory Group will continue to serve as a discussion forum for other items of the TR, e.g. risk communication. EFSA may develop Q&As.

The Chair encouraged stakeholders to be aware of the IT tools and reiterated that COM/EFSA will keep stakeholders informed on future trainings, seminars and materials.

She concluded by thanking EFSA and SANTE colleagues for their work and input and closed the meeting.

10. NOTE AFTER THE MEETING

The Practical arrangements on Transparency and Confidentiality; on Confidentiality in accordance with the Plant Protection Products Regulation; and on Pre-submission phase and public consultations have been adopted by EFSA on 23 December 2020 and are available on the EFSA website at https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements