EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Food chain science and stakeholder relations

PLENARY MEETING OF THE ADVISORY GROUP ON THE FOOD CHAIN AND ANIMAL AND PLANT HEALTH

7 MAY 2019

Summary Record

1. WELCOME AND OPENING BY MR MATTHEW HUDSON, ACTING DIRECTOR, DIRECTORATE FOOD CHAIN: STAKEHOLDER AND INTERNATIONAL RELATIONS

SANTE Acting Director of Directorate D (Food Chain: stakeholder and international relations) opened the meeting and expressed his pleasure at the opportunity to chair the Advisory Group meeting. He informed the Group that following Michael Scannell's move to DG AGRI in December 2018, he took over the position as Director for Stakeholder and International Relations and that in the past he has already been actively involved in developing stakeholder relations and stakeholder dialogue and consultation. Chair mentioned that the agenda is quite extensive due to many specific requests from members of the Advisory Group and acknowledged the importance of a balance between responding to the issues that members are raising and the issues that COM would like to put forward to the Group as a reflection of the two-way relationship between the Advisory Group and COM.
In conclusion, he explained that he would not preview all the items on the agenda but would immediately move on to the first item.

2. REVISION OF REGULATION (EC) NO 178/2002 ON GENERAL FOOD LAW: TRANSPARENCY AND SUSTAINABILITY OF THE EU RISK ASSESSMENT IN THE FOOD CHAIN – NEXT STEPS

COM presented the current state of play, starting with a brief overview and the changes since the proposal was first introduced. The Fitness Check of the General Food Law was a long but successful exercise with both positive and negative results. The main finding is that the system is working well with room for improvement in certain areas, namely transparency, long-term sustainability of EFSA to maintain high quality risk assessment and more efficient risk communication by all actors. In parallel with the Fitness Check exercise finishing in autumn 2017, there was the European Citizens' Initiative "Ban glyphosate". It was a successful initiative and COM consequently decided to take action. In its reply, COM addressed concerns raised in the initiative, similar to the concerns raised in the Fitness Check, namely transparency and the public's perception of risk assessment and risk communication, as well as the quality of scientific studies.

COM further reminded participants of the consultation in early January 2018 and the adoption of the proposal by the Commission on 11 April 2018. COM emphasised that it was a targeted revision on the General Food Law with the objective of having

the proposal still negotiated and adopted in this legislative term and thanked the stakeholders for their good cooperation.

Following the Commission's adoption of the proposal in April, discussions started between the Council and the Parliament and an agreement was reached on 11 February 2019. COM informed the participants that after adoption by the Parliament and the Council, publication in the Official Journal can be expected early September 2019.

COM further explained that legislators maintained the main structure with the four pillars and presented an update on each of the pillars.

1. Quality and reliability of studies: the first pillar comprises a set of small but important measures, the first of which is pre-submission advice. The main issue with this measure is that it is at the request of the potential applicants, but it should not be to such an extent that EFSA could be perceived as co-author of the studies and there should be a limit to how far EFSA can go in giving advice. The second measure deals with notifications of Commission studies by both applicants and laboratories. There is also a provision for third countries, but always on the basis of international or bilateral agreement, as COM does not have legislative power beyond the EU. The third measure concerns public consultations, where a distinction should be made between renewals and new substances. There is an additional public consultation for the renewal of planned studies. All these consultations aim to provide EFSA with the broadest range of facts to base its risk assessment on. The fourth measure are the fact-finding missions, which were initially referred to as 'audits' in the proposal. It was COM's idea that these would be a regular exercise, however, mainly at the request of Member States, this has been changed to fact-finding missions with a time limit and a report. If the report concludes that action is necessary, e.g. if laboratories do not comply with the standards, COM shall provide legislative proposals. The fifth measure pertains to the commissioning of verification studies. The concept remains the same as in the proposal: in exceptional or controversial cases, COM might ask EFSA to commission verification studies.

2. Transparency of risk assessment: this pillar builds upon the measures mentioned in the previous pillar, i.e. the reliability of studies. COM emphasised the importance of transparency in terms of helping EFSA acquire greater legitimacy in pursuing its mission, increasing consumers' confidence in EFSA's work and ensuring that EFSA is accountable to the EU citizens. As regards transparency, the changes do not only concern GFL, but also eight sectoral acts. The impact however reaches further than the nine amended acts and also concerns acts that are not directly amended, but are applicable through the GFL, e.g. health claims. COM further outlined the measures under this pillar, starting with the core measure, i.e. all studies and data supporting any request for a scientific output, including applications for authorisations, will be made public proactively and automatically through EFSA's website. COM drew special attention to the proactive character and to the fact that this shall be done early in the risk assessment process, before EFSA delivers its scientific opinion. Nevertheless, this proactive public disclosure will not impeach on existing intellectual property rights and data exclusivity rules. COM emphasised that the new rules stipulate that people accessing the disclosed information will have to provide clear undertakings and signed statements to indicate their awareness that this access does not equal permission to exploit the disclosed information. Nevertheless, this provision should not interfere with the proactive character of

the public disclosure. Another aspect is that standard data formats for applications are to be developed by means of implementing acts. Regardless, duly justified confidential information will continue to be protected. The new rules define closed positive lists of information that may be treated as confidential, upon verifiable justification provided by the applicant, proving significant harm to commercial interests in case of disclosure of the information. There is one general confidentiality list set out in the GFL plus lists in seven sectoral acts (smoke flavourings being an exception). Confidentiality assessments are currently carried out by COM, but will in the future be done by EFSA, when delivering a scientific opinion. There are some exceptions e.g. in the PPP area and GMO directive, where the assessment is done by MS and for the exceptional cases for which EFSA does not deliver a scientific opinion in the areas of novel foods and food additives,where the confidentiality assessment is done by the COM. The new rules outline a procedure on how to assess confidentiality and how disclosure is to be made, whilst taking into account the rights of the applicant. COM emphasised that there is a possibility of a confirmatory application within EFSA in order to review the assessment in case of a disagreement with the applicant. Even in case of duly justified confidential information, there are two exceptions where disclosure in the general interest is required, i.e. when there is an urgent need to protect public health, animal health and environment and for parts of conclusions of scientific opinions related to foreseeable effects on public health, animal health and environment. COM underlined that these exceptions are already included in the current GFL. The final measure covers the protection of personal data. COM stressed that the new rules do not prejudice the regulation on access to documents nor the "Aarhus Convention".

3. Risk communication: the Fitness Check clearly indicated that risk communication was not working efficiently and could be improved. COM therefore decided to elaborate the risk communication aspect in the GFL by defining general objectives and principles of RC. Based on these, the Commission will adopt a general plan on risk communication by means of an Implementing Act and in consultation with MS and EFSA. COM further outlined the objectives of the IA and emphasised again the importance of risk communication. COM trusts that the new measures will strengthen RC and put more emphasis on the added value of the risk analysis principle.

4. Sustainability and governance of EFSA: there are no major changes (as compared to the COM proposal) in the fourth pillar. The main issue remains the discussion about the level of involvement of MSs in sourcing the pool of experts from which EFSA constitutes the expert panels and the scientific committee. The agreement between legislators and parties concerned is that MS will have an active involvement in finding experts, whilst respecting the criteria for independence and quality.

5. COM stressed that the legislation is not retroactive and will only apply when the new rules enter into application. COM further informed the participants that publication in the OJ will likely happen early September 2019 and the new rules will enter into application around March 2021 (18 months after publication). The new MB will take over as from 1 July 2022. There are two already existing review clauses: COM shall review the effectiveness of the GFL Regulation as well as EFSA's performance. As regards budget, no decision has been taken yet, but there is an understanding between MS and MEPs that EFSA should receive

appropriate resources. However, negotiations on the MFF are still ongoing. COM then outlined the preparatory work to be carried out by EFSA and COM as listed in the presentation.

Comments and questions raised

Chair commented that AG meeting comes at an opportune time to give a full update on the outcome of the process. He stressed the importance of the issue, which affects everyone present.

EPBA welcomed the steps towards the transparency of studies of risk assessment, but raised a question on the relationship with FTAs, e.g. CETA. He referred to Art. 20(30) "Protection of data related to plant protection product" in which the EU and Canada agree to give applicants ten years of data protection for tests and study reports supporting the authorisation of new active ingredients. It was also agreed to notify trade partners of new regulations that affect the FTA: were the Canadians notified and did they react to this transparency approach?

ECCA expressed surprise at the introduction of fact-finding missions to inspect if laboratories are compliant with GLP, especially in the context of risk perception. Taking into account that the GLP system carries out very thorough inspections on an international level, the introduction of fact-finding mission sends the message that no one knows what is going on in laboratories.

FEFAC referred to an observation it already shared before, namely its concern about the EFSA's lack of direct engagement in risk assessment work carried out by CODEX and other bodies and requested clarification on how the shared coordination of risk assessment of SANTE/EFSA would work in practice.

EU Specialty Food Ingredients raised a question about the transitional measures: does the date of 1 January 2021 apply to studies to be carried out in future applications e.g. 4 years later or does it apply to applications already made by that time.

FEFANA asked if, as an outcome of a public consultation, a stakeholder would like to add additional studies to the risk assessment of EFSA, should these studies adhere to the same standards as the studies the applicants bring in, i.e. should they be pre-notified.

In response to EPBA, COM underlines that data protection in this case refers to data exclusivity rules and should not be confused with personal data protection. In essence, data submitted by one applicant, even when made public, cannot be used for the benefit of a subsequent applicant in another application. Secondly, COM explained that there were bilateral presentations made to the Canadians both on the proposal and the outcome, but that this has no direct impact: the new rules do not impeach on data exclusivity rules.

On EU Specialty Food Ingredients' question concerning the transitional measures, COM confirmed that a certain flexibility will be taken into account with regards to the pre-submission phase, e.g. for applications submitted on 2 March 2021, based on studies commissioned 2 years ago when the rules were not yet in place, and that this will be specified in EFSA's practical arrangements. Specific requirements will be taken into account in the transitional period.

In answer to FEFANA's question, COM explained that the requirement of notification of studies when commissioned only relates to the applicant. The purpose of a public consultation is to give EFSA access to the broadest evidence

base possible. Therefore, relevant studies should be flagged to EFSA, who in turn will check their relevance. Under the new rules, the outcome of a public consultation will be explained in EFSA's opinion.

On ECCA's remarks on the fact-finding missions, COM assured that the objective of fact-finding missions is to strengthen the public's trust that the laboratories comply with the rules and not to undermine this trust or create suspicion.

Regarding EFSA's involvement and coordination with international bodies such as Codex and OIE, COM stressed that EFSA is very much involved already, albeit often in the background and that EFSA is an independent body with its own policy on international cooperation. COM's position is that no closer cooperation is needed.

Chair endorsed this position and explained that EFSA, as a RA body, provides a lot of information to support work in Codex and OIE. He stressed that it is a team effort to elaborate EU positions and an important part of the EU system. COM also emphasised that in food safety, maintaining credibility is extremely important. He then referred to the audits carried out by Directorate F in Grange: the audits are part of the process of maintaining a high level of trust in the system in a transparent manner.

FEFANA came back to their earlier question and asked to further elaborate on the standards of the quality of data submitted by a stakeholder following a public consultation: should it comply with the same high standards as data submitted by an applicant, e.g. if laboratories should be compliant with GLP, should data brought by a stakeholder be of an equal scientific level.

COM pointed out that GLP compliance is not always required and that EFSA is not closed to non-GLP standards. EFSA should assess the quality of the study and the relevance to the subject matter and make sure that pertinent and reliable evidence is taken into account. If this is not the case, EFSA needs to provide justifications as to why the requirements of quality were not met.

EU Specialty Food Ingredients enquired when the negotiations on the MFF are expected to finish and if there is a calendar for the adoption.

Europabio requested an update on the timeline and expectations regarding the implementation of the risk communication plan.

In answer to EU Specialty Food Ingredients, the chair informs the participants that the MFF will not be resolved before the change of legislature. Overall, the chair expressed optimism that, in light of the clear alignment of the three institutions on this proposal, it is likely that EFSA will receive the requested resources.

On the risk communication plan, COM assures Europabio that even though the two year provision was deleted, it does not mean that it is not a priority. The aim is to start working on it after publication in order to adopt the plan as soon as possible. The main objective is to have good rules in place, which work and make sense.

FSE raised the question whether EFSA will have a structured procedure to implement all the measures it needs to take in terms of consultations, timing, transparency, etc.

COM expresses the expectation that EFSA will develop a structured plan to implement the different measures, but said it can not share yet details of such a plan. EFSA, in turn, confirmed that it is taking a structured approach and that it is in the process of developing a plan in liaison with DG SANTE colleagues.

3. UPDATE ON COMMISSION LEGISLATIVE STEPS IN RELATION TO ALLOWING INSECT PAP IN FEED

COM gave a short update on the legislative steps in relation to the introduction of insect proteins into animal feed. COM's approach is to acknowledge all the efforts undertaken in the EU to improve the situation concerning BSE in general and to have a more proportionate approach to the current feed ban as laid down in Regulation (EC) 999/2001. Currently, the main issue is the discussion with MSs about opening the use of pig protein in poultry feed and at simultaneously opening the use of insect protein in poultry feed. Discussions with MSs are only in the early stages and it will most likely take until the end of the year to reach a conclusion on the file. Nevertheless, the preliminary discussions with MSs were positive. As regards insect protein, there was a clear demand from MSs to extend the authorisation to pig feed. However, due to the complexity of the control methods in pig feed, the authorisation will be limited to poultry feed in a first stage. There are still different issues to address, namely the authorisation of the proteins and the necessity to bring in a possible tolerance with regard to cannibalism in order not to overburden the MSs' control resources. In conclusion, COM explained that careful discussion with MSs is necessary and that this will take time.

Comments and questions raised

FVE asked how the planning would fit in with the Official Controls Regulation and whether a tertiary legislation will be drafted.

FEFAC agreed with the necessity to be cautious regarding the method of controls based on experience with the re-authorisation of PAPs in fish feed, but also in view of public acceptance. FEFAC asked whether COM considers a stakeholder consultation beyond the set-up of the AG.

AVEC requested more information on the timeline for the re-authorisation for poultry feed in light of COM's remark that this will not be for 2019. AVEC reiterated its position that if pig protein in poultry feed is authorised, this should also be the case for poultry protein in pig feed.

BEUC expressed reservation with regard to relaxing the feed ban and enquired whether COM would consider labelling requirements if pig protein will be re-authorised in poultry feed.

EFPRA asked if COM has more information on the level of threshold it is working on to make this workable for the industry.

IPIFF commented that it shares the will to advance on the authorisation of insect proteins in poultry feed and that it took note of the concerns to do so cautiously. As regards the issue of detection methods, IPIFF informed COM that it is collaborating with a European Reference Laboratory to ensure that the method in place when applied to insect proteins enables to detect the presence of unauthorised materials. The sector has also published a guide on good hygiene practices in food and feed. This is currently still a draft, but will be discussed with MSs in the next months. IPIFF also kindly offered to provide any information that COM may require. In conclusion, on the matter of public acceptance, IPIFF mentioned that many studies on insects as feed have been developed and that it is happy to provide this information.

On the link with OCR, COM replied that the text that was drafted in the context of the framework of the OCR is nearly finished and will be published in approximately two weeks. The text on the subject of processed animal proteins will be

incorporated in the framework of the Regulation on TSE. COM stressed that these are two separated works.

On FEFAC's comment about control methods, COM stressed that it is attentive to this issue and that it is the reason for a split approach: first focus on pig proteins in poultry feed, possibly followed by poultry protein in pig feed. Due to control obligations, it might be necessary to determine different methods of analysis than the ones currently available in order to make a distinction between acceptable and non-acceptable materials. In answer to FEFAC's question about a public consultation, COM informed the stakeholders that there will be a consultation for feedback when COM has completed the internal consultations between different services. Whether there will be an additional consultation of the stakeholders remains to be determined.

Concerning the timeline, COM does not expect an outcome before the end of 2019, mainly because of the change of COM. COM also reiterated that it will proceed with the re-authorisation of pig proteins in poultry feed, but that poultry protein in pig feed will come at a later stage for the earlier mentioned reasons.

In reply to BEUC, COM stated that it has no intention to implement additional labelling requirements at this point in order not to create discrimination between EU poultry producers and third country poultry producers. Currently, there is no international regulation on BSE for non-ruminant material. Trade partners therefore have no obligation to prohibit the use of these proteins in animal feed before exporting the products obtained from these animals. COM's position was that there is no reason to introduce labelling requirements.

As regards EFPRA's question, COM informed the stakeholders that the issue of thresholds has not been discussed yet with the MSs or even in the COM internally. COM then explained that there are two thresholds to be considered. The first threshold would be related to cannibalism, i.e. can some level of poultry material be tolerated in poultry feed and pig material in pig feed. The second threshold would be related to the tolerance of ruminant material in poultry and pig feed. In third countries, non-ruminants can be fed non-ruminant as well as ruminant proteins. In the EU however, this is not the case. COM stressed that these are sensitive issues and that the principle of allowing such thresholds is yet to be discussed. Moreover, if a tolerance level would be introduced, there is still the matter of deciding what level would be acceptable. COM said that it is in favour of such thresholds, but reiterated that there have been no discussions on this matter so far.

COM welcomed IPIFF's comments and said it would be happy to receive any information on public acceptance. COM's position is that there is no major issue with the public acceptance of insect protein in poultry feed. There is one issue that is connected to religion is the acceptance of pig material in poultry feed. However, COM stated that this is not for COM and that religious issues should be addressed outside the BSE regulation.

Chair suggested, in view of the interest for this topic and the number of unresolved issues, to schedule another update for the next meeting in November 2019.

FEFAC had one more question regarding a meeting on waste it attended the day before where a reference was made to the re-authorisation of the use of swill as pig feed. In view of outbreaks of some serious diseases such as ASF that can be linked to swill, FEFAC asked if this issue has been discussed.

COM answered to have no knowledge of this and that this issue pertains to animal health rather than to public health.

COM also remarked that it is important to use quality proteins.

4. HORIZON EUROPE, THE NEXT EU RESEARCH AND INNOVATION FRAMEWORK PROGRAMME

COM presented an overview of Horizon Europe, the EU Research and Innovation Programme that will cover the period 2021 to 2027 taking over from Horizon 2020. The Commission has proposed for Horizon Europe an ambitious budget of EURO 100 billion, which will need to be confirmed as part of the forthcoming discussions on the next EU multi-annual financial framework. Horizon Europe is considered an evolution of Horizon 2020, with new opportunities to foster research to address key challenges facing the EU and beyond. Of particular interest for DG SANTE's related policies will be the Pillar regarding Global Challenges, and in particular its Clusters on "Food, Bioeconomy, Natural Resources, Agriculture and Environment" and on "Health". There will be opportunities to finance research via classic research projects, research and innovation Partnerships and the newly introduced Missions. Furthermore, the European Innovation Council and the European Institute of Technology can further stimulate innovation in the food chain. The co-design spirit of Horizon Europe calls for all stakeholders to engage in defining future research priorities, and to that end a Public Consultation will be launched (note that this is now open until 8 September). Furthermore, the European Research and Innovation Days, taking place in Brussels between 24 and 26 September, will be another opportunity to debate and shape the future EU research and innovation landscape. COM will keep the Advisory Group members informed about the details of these and other future activities in order to foster their engagement in Horizon Europe.

Comments and questions raised

Advisory Group Members welcomed the presentation on the progress of Horizon Europe and acknowledged the key contribution of research and innovation to support EU food safety and related policies.

EPBA asked whether there would be changes to the open science policy and if this aspect will be strengthened. Digital agriculture will change the landscape of food production. If public money is spent, it is the expectation to end up with public code and public annotated image databases to train the AI systems and this would require that open science standard is expanded to take into account important issues when training AI systems.

EUROCOMMERCE expressed their appreciation for the presentation and the fact that there is a dedicated sector on food. There is a lot of innovation taking place in retail and wholesale and the reference to linking research results to market applications is therefore very important to the sector, which is present across the range of innovation topics. EUROCOMMERCE also voiced the concern that they might not have enough resources to follow up on the different policy papers and suggested an alternative set-up, e.g. a workshop where stakeholders can give their input in a concentrated timeframe.

FOODDRINKEUROPE requested more clarity about the scope of the mission and when the call for membership for the mission boards will be launched. Additionally, what type of expertise does COM require in applicants.

COM thanked EUROCOMMERCE for their positive feedback and mentioned that the open public and SH consultation will be a way to signal this. COM further referred to

the context of the Food 2030 R&I Initiative where certain elements related to retail are included in the scope of the initiative.

On the open policy question, COM explained that in Horizon 2020 the open policy was translated into the program with the option for projects for which the finance was granted, to participate in an open data pilot. It is COM's objective to no longer make this optional. Regardless, it remains to be seen what the Council and Parliament will conclude.

On FOODDRINKEUROPE's question, COM replied that it is still very early to say what the coverage will be. Nevertheless, the expertise that will be sought for the mission boards will include elements related to soil and food, but priorities still need to be defined and there is nothing definitive yet regarding the type of expertise required for the mission boards.

In conclusion, Chair emphasised that Research is a very important area to which the EU devotes a large budget including important food and health topics.

5. PLANT PROTECTION PRODUCTS – REGULATION 1107/2009 –GENERAL UPDATE

COM gave a brief update on on-going activities, including an update on guidance documents, as a follow-up of a dedicated WG meeting of this Advisory Forum held in September 2018. At the last PAFF Committee in March 2019, a draft Commission Notice on technical guidelines on data protection was endorsed. Even though it is not yet published in the OJ, Stakeholders were consulted in September and comments were received.

Another endorsed document is EFSA's Administrative guidance on submission of dossiers for approval or renewal of active substances and in parallel a series of updates to existing guidance documents of SANTE were made to be in line with the EFSA guidance document. The updated SANTE documents have been published and are available on the website.

COM further outlined a series of guideline documents that are under development. Work on these is currently ongoing.

As regards the EFSA Bee Guidance document published in 2013, COM proposed a stepwise implementation. Following discussions with the MSs, COM sent a mandate to EFSA in March 2019 to review the Bee Guidance document. Linked to this BG document, there is the need to amend the uniform principles concerning the point on bees. As regards this amendment, COM informed the stakeholders that a feedback mechanism is expected to launch shortly.

COM then informed about the of the new endocrine disrupter criteria applicable since November 2018. EFSA and MS are applying these criteria for the peer reviews and draft assessment reports. All new dossiers from November 2018 onwards need to be in line with these new ED criteria.

As for co-formulants, a draft act is currently under discussion in the PAFF Committee and a feedback consultation will be launched soon.

With regard to data requirements on chemicals, COM received the stakeholder comments following the consultation, but added that presently the file is on hold due to resources. COM further added that it is at a very early stage with discussions for the update of data requirements for microorganisms.

Furthermore, COM has started discussions in the PAFF Committee on risk mitigation and has compiled a first list of risk mitigation measures in MSs and in

different guidance documents, which can be consulted by the PAFF Committee when taking decisions or by EFSA/MS during the peer review or, once published, by applicants submitting a file.

COM further informed the stakeholders that it has initiated the process to better define specific protection goals, needed for the guidelines for environmental risk assessment for pesticides. COM stressed that it will follow a stepwise approach and desires an early engagement of stakeholders. COM outlined a tentative timeline of the process. There are 3 workshops planned: in June with MSs, in September with stakeholders and depending on the outcome of these first two, another workshop will be organised in January with COM/EFSA/MSs/Stakeholders. Next step is to send an invitation to the AG stakeholders who express interest. The invitation will also be extended to stakeholders who are not represented in the AG, but have an interest in environmental risk assessment of pesticides.

COM presented an update on REFIT, an ex-post evaluation with the objective to assess if pesticide legislation is fit for purpose. COM Report and the accompanying Staff Working document. The evaluation is focusing on Regulation (EC) 1107/2009 on the approval of active substances and authorisation of PPPs and the Regulation (EC) 396/2005 on PPP residues. The exercise does not cover Directive 2009/128/EC on sustainable use. COM then listed the different evaluation steps and findings of the REFIT and highlighted one important finding from the Overview Report on Audits, more specifically that there are significant delays in the regulatory process.

Comments and questions raised

EPBA asked to clarify the methodology used for the list of risk mitigation measures, whether data is collected on the effectiveness of these measures and whether MSs are capable of ensuring compliance. It also commented that in terms of clearly defining protection goals, the goals should be the same in different regulatory areas. Lastly, EPBA questioned whether the REFIT will also assess if the system is fit for purpose to accomplish the protection goals.

FRESHFEL asked more information on the scope of the guidance document under development on zonal assessments and mutual recognition and requested to elaborate on the next steps for the REFIT evaluation and more specifically what to expect after September.

ENA commented that plant health legislation is becoming better at preventing the spread of plant pests and diseases, especially for plants for planting. However, EU nurseries are obliged to deliver healthy plants, but the number of PPPs available is decreasing, so in this respect the rules are not working well.

PAN Europe asked whether COM agreed to work on specific protection goals or whether this will depend on the assessment of the level of interest following the workshops. It also asked to clarify if this will be a political process or if there will be a validation stage by independent experts.

ECPA raised concern with regard to the slide showing a steady increase in active substances between 2011 and 2018. While factually correct, under the current regime there is a steady increase in basic active substances, a slow increase in microorganisms and a steady decrease in conventional chemicals. ECPA asked COM to highlight these nuances, which are important to the farmers.

In reply to EPBA, COM confirmed that effectiveness and compliance are key issues. COM emphasised that the list is compiled of existing measures that are already implemented in different MSs and are brought together on EU level. On the question

of whether protection goals should be the same in different areas and on a harmonised approach, COM stressed that these are the key questions for the project.

In answer to PAN Europe's question, COM confirmed that it will work to better define specific protection goals, but has not yet decided on how to proceed, hence the stepwise approach. COM wants to ensure all parties have the same understanding of the proposed EFSA method. The question whether a validation stage is necessary can also be raised during the workshops. COM confirmed that scientists will also be involved.

COM said it took note of the comments regarding the REFIT in particular ECPA's comment on active substances. The question on protection goals as regards health and environment, while not on the slide, will be addressed in the report that will be published soon.

On FRESHFEL's question on next steps, COM stated that next steps will depend on the change of Commission.

In response to ENA, COM acknowledged the issue raised.

On FRESHFEL's enquiry as to the scope of the guidance documents, COM replied that it is unable give the full scope at present, but that it will be an update of existing documents and that stakeholders will be consulted.

In conclusion, Chair commented that the presentation provided a very good outline of the current state of play. He further reminded the stakeholders that they will have the opportunity to discuss these matters in more detail in the workshops.

6. UPDATE ON THE DRAFT COMMISSION NOTICE ON THE APPLICATION OF ARTICLE 26(3) OF REGULATION (EU) N° 1169/2011, RELATED TO ORIGIN INFORMATION

COM gave an update on the draft Commission notice on the application of Article 26(3) of Regulation (EU) N° 1169/2011 related on origin information. This document has been drafted at the request of the MSs in the context of the adoption of the Implementing Regulation (EU) 2018/775 on the modalities of how the information on the primary ingredient as requested by Article 26(3) should be provided.

COM highlighted that the guidance document is still in the draft stage and outlines elements related to the provisions in the basic act Regulation (EU) N° 1169/2011, also called the FIC Regulation, and the Implementing Regulation (EU) 2018/775. Following discussions with the MSs and contributions received from stakeholders, COM has identified elements/problems that need clarification in order to apply Article 26(3). COM provided replies based on the experience of the MSs and on the results of studies requested by COM in the context of the impact assessment of the FIC Regulation.

The guidance document reflects the outcome of aforementioned discussions and consists of four chapters: the scope of Article 26(3), the definition of the primary ingredient and two chapters linked to the Implementing Regulation.

COM invited stakeholders to give their views and to share elements they may consider important for the application of Article 26(3) that have not been addressed yet in the draft guidance document.

COM further informed the stakeholders of the tentative timeline: adoption of the guidance document six months before the date of application of the Implementing

Regulation, probably October/November 2019. SANTE would like to launch an inter service consultation by mid-June.

Chair suggested doing a round of questions by chapter, starting with Chapter 2.

Comments and questions raised

FOODDRINKEUROPE welcomed the COM initiative and stressed the importance of such guidance document to business operators. Nevertheless, it expressed concern about the timeline for adoption. October/November is not sufficiently timely. Operators would already have to change the labels at present, therefore it is necessary to have clarity at an earlier stage. FOODDRINKEUROPE enquired if COM can provide more transparency before the official adoption and asked if COM could share the impact assessment with stakeholders. Another concern is the difficulty COM has to find a balance/flexibility between the legal framework and what is pragmatic for operators. FOODDRINKEUPOPE also gave some examples of this. At present, in order to indicate the origin of the primary ingredient, there is only the default option EU and non-EU. FOODDRINKEUROPE questioned whether consumers are informed to a sufficient level. Another issue is the repetition of the indication that the origin of the primary ingredient is different. FOODDRINKEUROPE suggested that there could perhaps be a more pragmatic solution. Country codes cannot be used to indicate origin labelling. FOODDRINKEUROPE drew attention to the fact that, since origin labelling is voluntary, companies have stated that they will remove this information from the product if it proves too difficult to do so. FOODDRINKEUROPE emphasised the necessity for a pragmatic approach and a harmonised interpretation across all the MSs. As a third point, FOODDRINKEUROPE expressed their concern about the terminology used in a Q&A about single ingredients products, which refers to 'raw material" rather than the ingredient, even though the Implementing Regulation refers to the 'primary ingredient'. In certain third countries, it is required to add a 'made in' declaration that is not an origin declaration, but a technical requirement used in exports. If you have a multipack for several countries, it would automatically trigger the origin indication according to the current interpretation of the Q&A, whereas FOODDRINKEUROPE believes this has nothing to do with origin indication. In conclusion, FOODDRINKEUROPE reiterated that more clarity and a more pragmatic approach (within legal boundaries) is necessary soon.

Chair stressed that it is important to keep in mind that this guidance document was requested in the context of the adoption of tertiary legislation and is intended to assist the implementation and application of this legislation. It cannot change the law. EU laws are the result of a process (stakeholder consultations and involvement of MSs, etc.) that leads to provisions that place certain restraints. COM's duty is to implement these within the parameters of the law.

BEUC regretted not having more time to review the guidance document as COM sent it rather last minute and asked if there would be an opportunity to give written feedback to COM by a predetermined deadline. It also stated that as a consumer organisation, it believes that their members could provide useful feedback on the document. BEUC further stated that at first glance, the document reflects the spirit and intention of the Implementing Regulation, which BEUC believes is weak in terms of answering consumers' demands of knowing the origin of products. BEUC also asked COM about national trials on mandatory origin labelling for various types of food and whether there are currently discussions at EU level to extend the list of food products for which mandatory origin labelling applies.

EUROCOMMERCE expressed support for FOODDRINKEUROPE's comment on the provisional timing of the adoption and stressed that it is important to receive possible updated versions of the document in order to be aware of any major changes.

PFP asked how to get clarifications on topics not included in the Q&A, referring specifically to the declaration of the origin if not the same for the primary ingredient and the food. As the Implementing Regulation grants some flexibility, PFP asked how to know if a statement is acceptable within the remit of the regulation.

UECBV also asked for the possibility to send written feedback and to set a deadline for comments.

Chair confirmed that written comments can be submitted by 22 May 2019.

In response to FOODDRINKEUROPE's comment on a more harmonised approach, COM replied that Article 26(3) has a case-by-case assessment. There are various aspects to take into account (consumers' perception can vary in different MSs, the product itself, etc.) which make a 100% harmonised approach impossible. There can be some principles/instructions enforced by the MSs, but it is inevitable that consumers in different MSs will have a different understanding/assessment. However, on the framework, COM agreed that MSs need the same tools and follow the same procedures with regard to assessing the labels.

On the question referring to the phrase 'made in' as an origin indication, COM stressed that the replies given in the guidance document do not apply to all cases and that whilst providing the general principles and approach and the framework, MSs can individually fill in this framework based on their experience and on the consumers perception.

COM further asked to send written comments as soon as possible.

As regards BEUC's question on national trials, COM explained that it is waiting for the reports of participating MSs in order to analyse them, but stressed that with the change of Commission it is impossible to predict what decision will be made. Nevertheless, COM will share the outcome of the reports with stakeholders and launch the reflection process.

FOODDRINKEUROPE expressed concern about COM's reply about the case-by-case approach and different understanding in the MSs. This different interpretation of MSs will prove challenging for companies to sell their goods in various MSs and the role of the EU should be to ensure that MSs allow free movement of goods. FOODDRINKEUROPE further suggested continuing assessing the implementation of the IR in the COM WGs.

Chair replied that continued exchanges in the committees are standard practice. Chair further commented that even though products are the same, when placed in different markets, presentation often differs for varied reasons and reiterated COM's position that complete harmonisation is impossible to achieve.

On FOODDRINKEUROPE's question regarding raw material, COM said that it will reflect on it and possibly revise the text.

Chair assured the stakeholders that their comments and the issues raised will be given careful consideration, even if COM cannot provide an immediate response.

In reaction to FOODDRINKEUROPE's comment on repetition of origin indication, COM said that this has been subject to a long discussion. COM stated that often food

operators accentuate the origin, because they want to attract consumers with this information. Therefore, COM asks for repetition of the origin indication in order to create more transparency and clarity with regard to the labels.

Chair emphasised COM's intention to finalise the text within the next month and launch an inter service consultation. He further ensured stakeholders that they will be informed of possible updates.

EPBA reiterates its favourable position on mandatory labelling of country of origin on honey because the sector faces many cases of fraudulent imports and mislabelled products. It is an existential issue for professional beekeepers in the EU.

In response, COM requested clarification stating that legislation of DG AGRI requires the origin indication of honey.

Referring to FOODDRINKEUROPE's earlier statement, EPBA explained that this labelling indicates 'EU' or 'non-EU', which does not give the consumer much information. EPBA is in favour of introducing country of origin labelling in order of the quantity and has presented this idea on numerous occasions.

Chair acknowledged the validity of the point, but stated that this is an issue for DG AGRI.

AVEC endorsed UECBV's comment and confirmed that it will send comments by 22 May 2019.

7. ORGANISATION OF AG MEETINGS

Chair requested feedback from the stakeholders regarding their preference for the AG agenda: do stakeholders prefer a wider variety of topics or fewer items with more time dedicated to each topic.

EUROCOMMERCE suggested that COM indicates the timing on the agenda in order to have a better idea of the level of preparation required for each topic and that it is more specific about what is expected from the stakeholders.

FVF commented that even though it is helpful to receive documents/presentations in advance, it would be better to receive them sooner in order to prepare better and have time to ask feedback from members.

BEUC endorsed FVF's comment and expressed appreciation for the broad diversity of topics.

Chair thanked stakeholders for their useful feedback and said that with their cooperation, COM will consider these remarks for the organisation of future meetings.

8. UPDATE ON THE NEW REGULATIONS ON VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEED

COM presented an update on the new EU Regulation on veterinary medicinal products, starting with the timeline. Publication date was 7 January 2019 and application will be in January 2022. That may seem long, but there are some 27 delegated and implementing acts (DA/IAs) to be prepared to make the Regulation applicable.

COM outlined the main objectives of the new regulations on veterinary medicines and medicated feed and stressed that due to the extensive time it took to develop

and adopt, the new Regulations will apply for the next decade. COM mentioned that it is happy with what has been achieved, with the help of MSs and Parliament. COM has obtained agreement on a number of concrete measures to strengthen the fight against AMR (listed in the slides). These measures remain to be implemented, but the direction is clearly set out.

For the work on the implementing measures in the coming years, COM has identified a provisional timeline for the different stages. There are 4 packages of IA/DA foreseen according to the different start dates and end dates. COM explained that several consultation phases are foreseen for each act. The first package of measures is currently in the first phase, more specifically the scientific advice phase with the involvement of the experts of the European Medicine Agency (EMA) and the launch of a working group in the European Food Safety Authority (EFSA) on residues limits of 24 antimicrobials. Stakeholders and MSs will be involved throughout the process, from the scientific advice stage up to the draft acts. COM showed the different phases of the legislative process for both DA and IA. The main difference is that for the IA, a vote in the Standing Committee is necessary.

COM referred to the content of the first package as listed in the slides. COM highlighted one of the most difficult items, namely the design and development of the Veterinary Product Database in which all available products in the EU should be encoded. COM explained that for the first package EMA experts are currently preparing their advice and that EFSA established a dedicated working group including experts from EMA to address the issue of residues of 24 antimicrobials

At present, COM is starting to develop the second package (items listed in the slides). As regards the state of play, the drafting of the mandates and preparatory work is currently ongoing and will be discussed with MSs and EMA in June. A targeted stakeholder consultation may be launched separate from the MS Consultation as well as a general public consultation.

COM outlined the involvement of the MSs and stakeholders and concluded by informing the stakeholders of a dedicated website where they can find the latest updates of the work on the Regulations and the text of the mandates that were sent to EMA and EFSA.

Chair emphasised the importance of this implementation period.

<u>Comments and questions raised</u>

EGGVP requested more information on the possible targeted stakeholder consultation.

BEUC asked for clarification on the distinction between the ban for promoting growth and the ban for increasing yield, which according to the presentation will be reinforced under the new regulation. In relation to the application of the rules to third countries, BEUC also enquired if COM is optimistic that third countries will be willing to cooperate with the EU to ensure that the provisions of the new regulation are correctly enforced.

FVE said it welcomes the new regulation and informed COM that it developed an infographics, available on the FVE website, to explain the main changes of the new regulation to consumers and colleagues. Furthermore, FVE prepared two position papers to be shared with COM: the first paper on the product and pharmacovigilance database and the second paper setting up the criteria for

antimicrobials specific for human diseases. FVE asked COM to consider consulting them before the public consultation is launched.

Regarding medicated feed, FEFAC asked COM to advise on the right moment to bring forward an updated code of good manufacturing practice to enforce the new Regulation.

ANIMALHEALTHEUROPE endorsed EGGVP and FVE's comments with regard to the targeted stakeholder consultation and expressed the wish to be consulted at the present stage. As regards the timeline, ANIMALHEALTHEUROPE asked to clarify if the individual IA and DA, will also be notified separately to the EU SPS Committee.

In answer to the EGGVP, FVE and ANIMALHEALTHEUROPE's remarks regarding the stakeholder consultation, COM replied to be open to specific stakeholder input and recommendations.

On BEUC's question on growth promotion, COM referred to 2006 when all antibiotics were banned in the EU as feed additives for growth promotion. The new regulations now extend the prohibition of antibiotic growth promoters via feed

- to all antimicrobials (not only antibiotics),
- to their use explicitly for increasing yield and
- toachieve these intended uses via veterinary medicinal products.

In reply to BEUC's question about the cooperativeness of third countries, the regulation includes a provision whereby third countries have to observe two main rules: firstly not to use antimicrobials for growth promotion and increasing yield and secondly, not to use for animals antimicrobials reserved for humans. Third countries have to observe these rules when exporting products to the EU, but how to enforce them is for the implementing measures establishing detailed rules. There have been discussions with third countries to explain the plans and measures where COM promised to continue this transparency towards third countries along the process of developing the measures, so in that respect COM is indeed optimistic.

In reply to FEFAC, COM stated to be pleased to have succeeded in increasing the coherence between medicated feed and veterinary medicinal products. As regards the code of good manufacturing practice, COM advised to start with the preparatory work for the update of the code as soon as possible in order to allow its formalisation well in advance of the application date of the Regulation.

On SPS notifications, COM replied to ANIMALHEALTHEUROPE that only measures bearing a specific impact on trade have to be notified to the SPS Committee.

EUROGROUP for ANIMALS asked what package will include the IA based on Article 93 on good manufacturing practice and asked more information on the timeframe for later packages.

FVE commented that there is plenty of scientific evidence in the EU of good use and improvement of antimicrobials in the veterinarian sector compared to the human sector.

COM replied to ANIMALS for EUROPE that the IA on GMP is included in the fourth package because there is no time limit foreseen.

9. PLANT HEALTH LAW AND THE IMPLEMENTING AND DELEGATED ACTS

COM gave a brief presentation on the state of play of the implementation of the new Plant Health Law. COM reminded stakeholders that an act on formats of plant passports has already been adopted and that two more acts on plant passports are in progress. The first act, a delegated act on the criteria to be fulfilled by authorised operators to issue plant passports, has been adopted by COM and has been submitted to the Parliament and the Council for the scrutiny period that expired on 13 May 2019. The date of application will be December 2020, because the expert group requested an extra year in order to better prepare the operators for the new rules. COM will also adopt an implementing act on exceptions for final users in protected zones and technical rules on traceability codes. A stakeholder consultation will be launched in the second quarter of 2019.

COM also adopted a list of high risk plants in December 2018, which will be applicable in December 2019. At present, these plants are provisionally listed while the risk assessment is being carried out. The Commission Regulation 2018/2018 on procedures for the full risk assessment of high risk plants by EFSA was adopted in December 2018.

As regards a delegated act on priority pests, COM is currently launching internal COM procedures and has drafted a provisional list based on the input of the expert groups and on the methodology carried out by EFSA and JRC. A stakeholder consultation is foreseen for June 2019.

COM highlighted the adoption of the implementing act on the update of pests and measures, which will reflect the existing Annexes I to V of Directive 2000/29/EC. COM is currently finalising the text and a stakeholder consultation is foreseen for the second half of 2019. In parallel, COM will submit the act for notification to the international SPS Committee because it concerns import measures. This is the most important act and it has to be adopted before the end of the year.

COM adopted a delegated act on movement of scientific material, which is foreseen to enter into force in May 2019. Application is foreseen for December 2019.

A complementary implementing act outlining the conditions for the release of material from quarantine stations, will be drafted. Stakeholder feedback is expected in the second half of 2019 with the objective to get a vote in the PAFF Committee in the third quarter of 2019.

COM further stressed that the new Plant Health Regulation will cover all aspects, including travellers' luggage. COM is currently preparing an implementing act outlining how to provide this information travellers and clients of postal services. A stakeholder consultation is foreseen for the third quarter of 2019.

Under the OCR, COM has adopted in an IA designating EU Reference Laboratories for pests and plants for particular categories of pests. This was adopted in March 2019 and did not require a Standing Committee vote, but was directly adopted by the College of the COM.

In January 2019, COM adopted another act in relation to the OCR, namely the implementing act on minimum frequencies for plant health checks.

Beyond the regulatory work, COM has created, in collaboration with the MSs, an EU Plant Health Awareness Expert Group, whose objective is to foster knowledge sharing between MSs for the implementation of national and regional awareness about plan health rules/campaigns/risks.

COM further drew attention to the increased responsibilities for professional operators in order to detect/notify/eradicate pests found on their premises under the new regulation. In addition, there are information campaigns for the public. Extra resources both on national and regional level will be required in order to achieve this.

Chair emphasised that the plant health regime is moving forward and that it does not only involve professional operators. Pests and diseases do not distinguish between commercial, private or public plants and the new Plant Health Regulation is a further broadening of the EU's approach to plant health.

Comments and questions raised

Regarding the DA on authorised operators to issue plant passports, ARCHE NOAH welcomed the COM proposal to have an electronic guidance document that will be issued by MSs, but asked whether MSs have accepted. Furthermore, the date of application for this act is foreseen for December 2020, but ARCHE NOAH asked to clarify what will happen after 19 December 2019 when professional operators have to issue plant passports without knowledge of the criteria to follow in order to become a registered plant passport issuer. As regards travellers and in view of article 75 of the PHR, which allows the possibility to adopt an act that would define exceptions for travellers' luggage for small quantities of particular plants, ARCHE NOAH asked whether COM plans to include this in the IA. ARCHE NOAH further welcomed the creation of an expert group on awareness raising, but asked whether the developed material will be available to stakeholders. As regards the extra resources, ARCHE NOAH enquired about budget lines and cost benefit analysis.

As many of the new pieces of legislation imply additional procedures for the nurseries, ENA requested that COM shares the ongoing drafts with stakeholders, especially those related to plant passports and traceability

In relation to the update of annexes I to V, FRESHFEL requested to receive the comments on the new update as soon as possible. With regard to the implementation of the previous update of the annexes which was approved in March, FRESHFEL asked whether COM already has feedback from third countries on upcoming notifications, especially with regard to changes to the wording of annex IV under option d and whether third countries that have already notified the use of this option, should update their notification.

EPBA enquired whether there is a preliminary list of harmful organisms available and whether organisms harmful to the beekeeping sector are on COM's radar. In addition, EPBA asked about liability if plants imported for commercial reasons are harmful to other businesses, for instance the beekeeping business.

In reply to ARCHE NOAH's question about the DA, COM preferred to have the date of application in December 2019, but the majority of MSs in the expert group were in favour of a one-year delay, because they felt not prepared to issue the necessary guidelines and for operators to implement these guidelines. COM does not foresee this gap to be a problem as operators are already knowledgeable on the basic rules and COM will set out the requirements in the IA. However, COM recognised that the sooner the complete system of conditions is set up, the better for all parties involved. On the question on travellers, COM replied to ARCHE NOAH that presently

the adoption of an act listing the exceptions is not a priority. However, any exceptions that might be introduced under article 75 will be reflected in the act that will be adopted under article 45 with information for passengers.

On the awareness raising expert group, COM took note of ARCHE NOAH's request to share conclusions with the stakeholders. It also noted the point made on cost benefit analysis and said that extra budget will be allocated, especially at national level.

In reply to ENA's question to share new measures, COM referred to the slides, which include the indicative timing for the stakeholder consultation for each act.

As regards FRESHFEL's question on the update of annexes I to V, COM replied that the stakeholder consultation can be expected in the summer. As for FRESHFEL's question on SPS notification, COM said it will share the contact details of the person in DG SANTE who is responsible for this particular file.

COM informed EPBA that from a technical point of view, pests harmful to bees are not part of this legislation, unless these pests are also harmful to plants. The new list with all pests covered will be available to stakeholders in the summer. On liability, COM stressed that liability for plant health is not regulated on EU but on national level.

EPBA asked if COM is aware of any other regime that can protect the beekeeping sector from harmful organisms in the same manner the Plant Health Regulation does for plants or if there is a possibility to bypass this technicality and address the problems these pests cause for the beekeeping sector.

Chair assured EPBA that their comments are noted.

EUROPATAT asked whether the MSs' guidelines for professional operators will be collected by COM and published. As regards the stakeholders' consultation on the IA, EUROPATAT requested that COM highlights the parts that are new and the parts taken from previous legislations in order to facilitate the work for the stakeholders and their members.

ENA emphasised the importance of the implementing acts on plant passports and traceability code. Nurseries are already compliant, but will have to adapt the internal procedures and make changes to computer systems, so it is important to get the text as soon as possible.

ESA commented on the update of annexes I to V and asked for clarification regarding the procedures for plants that do not require a plant passport at present, but might do so in the future.

COM replied to EUROPATAT that MSs' guidelines will indeed be shared with stakeholders when COM is notified, but this is foreseen for a later stage. COM said that it will be discussed with SANTE colleagues how best to facilitate the stakeholders' work on the IA.

On plant passports and traceability codes, the text will be shared with stakeholders in the summer, so operators will know what to expect. However, COM stressed that the scope of this act will be very narrow and that its adoption will not have a big impact for ENA.

In answer to ESA's question, COM replied that some MSs have asked for a transitional period and that COM will examine this internally with the legal service.

10. UPDATE ON OFFICIAL CONTROLS REGULATION

COM presented a state of play of the forthcoming entry in application of the new regulation on Official Controls. The regulation is in place since 2017 and the rules will be applicable from December 2019.

COM gave a brief overview of the elements that should complement the legislation. The regulation aims at establishing rules on official controls and other official activities along the food supply chain addressing risks related to public health, animal and plant health and animal welfare. The regulation contains a series of provisions, which build upon requirements in existing legislation and take a more coherent approach.

The focus point for 2019 was to ensure the smooth transition from the current system to the new legal framework. COM's main priority are import controls.

COM has advanced well on the delegated and implementing acts.

A delegated act on the addition of composite products, hay and straw to goods to be checked at BCP, was already adopted and published in March 2019.

Delegated acts related to the training of BCP staff and derogations from BCP requirements have been adopted and transmitted to Council and EP. The objective of the derogations is to adjust the burden on MSs. These acts will now be translated and formally adopted.

As regards the act on prior notification of consignments, there is nothing new compared to the current legislation.

COM pointed out that the work program for 2019 is quite comprehensive and listed the technical elements still to be finalised for the new rules to be in place by December 2019 (see slide). All these elements are linked to the broader topic of entry of consignments into the EU.

COM informed stakeholders that discussions with MS are close to finalisation for details on physical/identity/documentary checks at BCP and the derogation of identity and physical checks at control points.

Discussions are still ongoing for the frequencies of identity and physical checks.

COM further outlined discussions to be launched in the future.

COM informed participants of an upcoming AG Working Group on OCR on 28 May 2019 and of the next deadline for delegated acts to be transmitted to the EP, more specifically 18 July 2019. COM further thanked stakeholders for feedback received following consultations.

COM emphasised the workload ahead and stressed that the next months are crucial in order to have the new regulation enter in application in December and concluded by informing the participants of two upcoming conferences, namely a Conference on official controls on e-commerce from 24-26 June in Berlin and a Conference on OCR on 13 December in Brussels.

<u>Comments and questions raised</u>

FVE commented that they expect acts on meat inspection that have been sent to the Council and EP will also be published and asked to confirm the order of procedure for acts voted in the PAFF: the launch of an inter service consultation before being sent to the EP and Council.

Chair explained that once the act is voted in the PAFF, it is transmitted to the EP and the Council and that the inter service consultation is carried out before the vote, in

order to allow COM to establish a cohesive position and to prepare a formal draft to put to the MS.

FRESHFEL requested more information on the IMSOC regulation, more specifically on the CHED. In relation to the calendar, FRESHFEL asked what would be the best moment to send comments, in particular on the format of the CHED and stressed that they would like their comments to be taken into consideration before the PAFF vote. FRESHFEL also expressed concern about the interaction between the CHED and the phytosanitary certificates, in particular in the case of fruit and vegetables where there can be different commodities in one consignment that require multiple phytosanitary certificates. FRESHFEL asked whether these certificates can be introduced under one single CHED. They also enquired whether COM will provide guidelines concerning fees or whether this falls under the remit of the MSs. FRESHFEL further asked COM to clarify whether the CHED is necessary solely for categories covered under article 47 of the OCR. Lastly, FRESHFEL enquired if the electronic signature will be ready by 14 December 2019.

In response to FVE's question on the meat inspection and relevant acts, COM confirms that they will be published in the second half of May 2019.

COM replied to FRESHFEL that comments or concerns are welcome and should be signalled as soon as possible. As regards different commodities on one CHED, COM said it will pass the question on to colleagues who are better placed to answer this question and to confirm whether the necessary technical arrangements have been made. In reply to the question if everything is ready for 14 December, colleagues in collaboration with IT specialists are doing the maximum to put everything in place. Regarding the fees, COM replied that according to the Regulation COM has no empowerments to lay down further detailed rules, but perhaps COM could prepare guidelines.

UECBV asked if COM is aware of a meeting with MSs in the second half of 2019 regarding the fees and transparency where MSs could express how they would put this transparency into place. UECBV further asked for the state of play on the delegated and implementing acts of the Directive 96/23/EC on residue.

EFFAB asked whether the feedback on the public consultation on import and the draft implementing regulation, which finished on 26 March 2019, and more specifically the provision in Chapter 2 Art. 5 paragraph 4 on rules for minimum requirements on border control posts, has already been integrated in the act and when stakeholders will receive an answer.

On fees and transparency, COM replied to UECBV that it is not aware of such a meeting planned in the second half of 2019, but referred to the Conference on OCR in December, where certain new issues with regard to the regulation will be addressed and which may offer the opportunity to also discuss transparency and fees. In relation to the question on residues, colleagues have advanced in the discussions. The legal service had reservations about transposing certain provisions from the existing Directive on residue control to the new legal framework, but this issue has been resolved and discussions have been concluded.

In response to EFFAB's question on feedback and the draft on minimum requirements for border controls posts for export of live animals, COM explained that the starting point was that certain facilities of border control posts should be dedicated exclusively to checks of live animals imported into the EU. MSs raised concern that this could potentially put a burden on them if they also have to certify animals for export and that in certain situations it would be logical to use the same

facilities for import and export checks. COM decided to allow for this option on the condition that MSs put in place certain risk mitigation measures, i.e. separation in time between import and export checks, cleaning/disinfection, etc. This option falls under MS responsibility. COM further added that SANTE will carry out audits in the course of 2020 to check the implementation in the MSs and that under the BTSF program a series of seminars will be organised for the MSs to provide a harmonised understanding of how the new rules should be applied in practice.

11. STATE OF PLAY OF NEW BREEDING TECHNIQUES AFTER CJEU RULING ON MUTAGENESIS

COM gave a short update on the next steps after the CJEU ruling on mutagenesis and informed the stakeholders of four points, starting with the report of the European Network of GMO laboratories (ENGL). Concerns have been raised by MSs and stakeholders about the detectability of products obtained with the mutagenesis techniques. MSs and food operators are responsible for the implementation of the GMO legislation, as the Court has interpreted it. In order to help MSs and operators, COM mandated EURL laboratories on GMOs, in collaboration with ENGL, to produce a series of reports on the detection of product using new techniques. The first report addressed the analytical challenges of genome edited food and feed of plant origin and was unanimously endorsed by ENGL. The report was published on 26 March 2019 and is available on the EURL website. In addition to this report, COM also asked the two bodies to work on detection methods for microorganisms as well as for animals and animal products obtained by mutagenesis techniques. Output will follow in the coming months.

COM further informed the stakeholders that it has sent several mandates to EFSA. In 2018, COM sent two mandates related to adequacy of the existing risk assessment guidance to synthetic biology products and gene drive engineered organisms. The adoption of EFSA's scientific opinions on these mandates is foreseen for the end of 2020 and will include public consultations. In addition, COM sent a third mandate on plants developed through SDN-1, SDN-2 and ODM. In view of EFSA's scientific opinion on SDN-3 in 2015, COM asked EFSA to assess whether the methodology and conclusions of the SDN-3 opinion could be applicable to the plants that are modified through the SDN-1, SDN-2 and ODM techniques. This scientific opinion is expected for April 2020.

As a third point, COM informed stakeholders about the work of the European Group on Ethics in Science and New Technologies (EGE), an independent advisory body that offers COM independent advice on ethical issues regarding science and new technologies in relation to EU legislation and policies. In 2018, COM asked EGE to work on a mandate on gene editing, including the use in animals and agricultural applications. This work is ongoing. COM further referred to DG RTD's webpage for more information on EGE.

Finally, COM informed the stakeholders about the joint Working Group of GMO competent authorities, which took place on 25 April, where MSs and the Commission discussed the implementation of the ruling.

Comments and questions raised

IFOAM-EU GROUP requested more information on how different MS implement the Court ruling.

In relation to feed additives for use in organic farming, the question was raised whether further to the Court of Justice ruling, EFSA would be required to review some past opinions and potentially adapt them.

In reply to IFOAM-EU GROUP, COM explained that MSs follow the Court ruling, e.g. if an operator applies for field trials in order to use or place on the market a product obtained with new techniques, these field trials have to be carried out under the GMO legislation. Another example is the registration of seed varieties where the applicant should indicate whether it is a GMO. COM stressed the importance of communication and clarity about the outcome of the Court Ruling. As products are not yet available on the market, MSs do not yet carry out systematic controls.

On the question on what EFSA has included as information on the genetic construct of GMMs, COM said not to have an answer, but that it will raise the question with SANTE colleagues.

12. ANY OTHER BUSINESS

The Chair expressed appreciation for the level of input and comments and informed participants about upcoming events, namely the Animal Health Advisory Committee on 20 May and the next Advisory Group meeting scheduled for 21 November. The Chair thanked all speakers and participants for their constructive contributions, and closed the meeting.