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

27 APRIL 2018

Summary Record

1. WELCOME AND OPENING BY MR MICHAEL SCANNELL, DIRECTOR, DIRECTORATE FOOD CHAIN: STAKEHOLDER AND INTERNATIONAL RELATIONS

SANTE Director of Directorate D (Food Chain: stakeholder and international relations) opened the meeting. The Chair stressed the importance of engagement with stakeholder representatives and the benefit of the Group as a consultative body and a sounding board for SANTE policies. Chair then presented the agenda, which reflects some of the key issues in SANTE's current work, namely the revision of the General Food Law impacting transparency and EFSA, involving huge amount of work and set of different consultations completed to a very tight schedule. European Council and Parliament are now progressing the proposal. He further mentioned the adoption of the future financial framework and stressed the importance of sufficient budget for agri-food sector in order to keep effectiveness of collective EU efforts, for example, in the area of animal health and food safety. Chair then previewed the other topics on the agenda including updates on trade agreements, plant health law, food contact materials and different aspects of official controls regulation as well as points suggested by stakeholders prior to the meeting. Chair further informed participants that Ms Celine Gauer has been appointed a new Deputy Director-General in DG SANTE and might join one of the plenary meetings of the Advisory Group in the future. He concluded by thanking Jeannie Vergnettes who is retiring for all her outstanding work and expertise, including into the drafting of the initial General Food Law and its recent revision.

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

COM presented the proposal stressing that it is a targeted exercise revising only some elements of the General Food Law (GFL) Regulation, since according to the findings of the Fitness Check of the GFL Regulation there is no need for overall revision. COM emphasised that the proposal tackles transparency of risk analysis, risk communication, the quality and reliability of scientific studies as well as the EFSA's need to maintain a high level of scientific expertise and to engage with stakeholders and MS. The proposal also delivers on the commitment given in the Commission's reply to the European Citizens' Initiative "Ban glyphosate" to come

forward with a legislative proposal covering transparency in scientific assessment, quality and independence of scientific studies and governance of EFSA.

COM reminded participants of the consultation carried out in preparation of the proposal, including an open public consultation, the consultation of MS as well as the ad hoc meeting of the Advisory group on the food chain and animal and plant health on 5 February 2018.

COM further explained that the proposal itself is built around four pillars.

Under the first pillar addressing "transparency of risk assessment", studies/data supporting applications for authorisation are to be made public proactively, early on in the risk assessment process (except for confidential information and taking into account protection of personal data). A final determination of confidentiality requests would be completed by EFSA (where its scientific opinion is requested) within 10 weeks from the date of receipt of the relevant information. The proposal further sets out a general list of items in the GFL that may be considered confidential upon verifiable justification. This list is further completed in some sectoral legislation with additional confidential items. Overall, the proposal amends eight sectoral legislations, in addition to the GFL, to ensure overall consistency. The confidentiality regime will apply without prejudice to intellectual property rights and data exclusivity rules.

The second pillar concerns the need for strengthening and improving risk communication (RC) as defined in the GFL, i.e. "a comprehensive interactive exchange of information on risk-related issues involving all interested parties in the context of risk analysis process". The proposal outlines the framework of RC by setting out precise objectives and general principles of RC. Based on these objectives and principles, it empowers the Commission to adopt a general plan on RC by a delegated act within two years after adoption of the proposal.

COM stated that many of these provisions reflect the concerns expressed in the public consultations.

The third pillar deals with the quality and reliability of studies submitted to EFSA. COM explained that EFSA would manage an EU Register of studies commissioned by applicants that intend to include these in a future authorisation dossier. Both applicants and laboratories would have to notify EFSA at the time of commissioning the studies. Further, at the request of the applicant, EFSA can give general advice in pre-submission meetings with minutes of such meetings to be made public. On planned studies (renewals) and submitted studies (renewals and new requests) there will be consultation of third parties regarding the studies supporting applications for authorisations. In exceptional cases, COM as risk manager could ask EFSA to commission scientific studies for verification studies.

The fourth pillar deals with the sustainability and governance of the EFSA system, where COM proposes the alignment of the Management Board structure with the common approach on decentralised agencies: MS representatives will be in the Management Board as well as representatives of the European Parliament and stakeholders. The other element would be that MS would nominate scientific experts to form a pool from which EFSA, in accordance with strict criteria on independence and scientific excellence, will select experts for the Scientific Panels.

COM finally mentioned additional elements of the proposal, such as the reinforcement of EFSA's own scientific capacity, strengthening cooperation with national scientific organisations and a very substantial budget increase for EFSA in line with the aim of meeting citizens' expectations on food safety.

Comments and questions raised

Chair emphasised the huge impact of this proposal on the whole food chain and invited participants to express their opinion.

EHPM asked whether industry could have an input in case it believes that expertise is not sufficient in Panels and a specific expertise in the working groups is needed.

SLOWFOOD asked for clarification on criteria for confidentiality of studies and what justification is accepted.

PFP expressed concerns about data which have to be published without delay and thinks it might lead to misinterpretation. Publishing of data e.g. on contaminants may create unnecessary concern on the part of consumers. PFP also asked what is meant in article 39(4) by "quantitative composition".

COCERAL asked whether this proposal would lead to lengthier authorisation process regarding in particular GMOs.

On possible need for a specific expertise, COM explained that EFSA looks for any required additional specific expertise when establishing the respective Panels' working group.

On contaminants, COM stated that rules on transparency and confidentiality are the same for all data supporting requests for a scientific opinion taking into account confidential information and the specific 'continuous call' under which these data are submitted by industry.

Regarding a SLOWFOOD question, COM explained that there are no criteria to assess confidentiality, but a positive list of what can be claimed as confidential based on verifiable justification.

COM underlined that the assessment of confidential data will not prolong the process of authorisation since various steps would run in parallel; so the process of assessment is not expected to be delayed.

On PFP's concern, COM emphasised that it is not the publishing of data but on the contrary the lack of transparency, that increases the concern. More transparency and better RC explaining the overall risk analysis process to the public should have a positive influence on public perception.

COM underlined that the whole study cannot be considered as confidential, only justified data. On quantitative composition, COM explained that the general description of a product is made public, but the full composition (for example each component with its percentage) is likely to be justified as confidential because its public disclosure may jeopardise the competitiveness and commercial interests of the applicant. COM pointed out that even information assessed as confidential by EFSA can be disclosed in exceptional circumstances, e.g. to protect public health or if it is a part of the conclusion of the scientific opinion.

FoEE expressed surprise that the role of MS will be more prominent in EFSA given that MS did not deal with BSE crises sufficiently. FoEE wondered how more involvement of MS would increase scientific scrutiny in EFSA. On publication of data FoEE asked whether an external expert can access data in a machine readable format.

FoodDrinkEurope expressed concerns that competitors may take advantage of the publication of data in studies e.g. in the area of novel foods. As a result it might be that potential applicants would in the end not submit an application. FoodDrinkEurope called for clear modalities to avoid jeopardising competitiveness. It also stressed the importance of collecting data from industry and MS e.g. in area of food additives. Regarding the RC FoodDrinkEurope acknowledged that many elements from the consultation were reflected in the proposal. It concluded by asking why in the case of the proposal the impact assessment was not considered necessary, since in particular the impact related to publication of studies, and confidentiality aspect has a huge impact on businesses.

EUROCOMMERCE welcomed the part on RC, which would help to build consumer trust. EUROCOMMERCE stressed the need for early and harmonised communication to consumers in time of crisis.

EU Speciality Food Ingredients expressed reservations regarding the timing of the public disclosure of the studies listed as non-confidential by applicants. It stated that if the information supporting applications for authorisation is published before the scientific opinion is adopted, their competitors gain an advantage, as they are able to connect the dots to capture the business strategy of the applicant, thus depriving this latter of its competitive advantage. It asked for clarification about the procedure for pre-notification of studies, which implies that the applicant has straightforward ideas about the way the ingredient is developed and tested, whilst this is generally an iterative process where the design of the testing scheme is adjusted depending on the results progressively obtained. It questioned the added value of the proposal given that the existing legislation lays down that information that is relevant to the assessment of the safety of food improvement agents and novel food ingredients shall not, in any circumstances, be regarded as confidential. It reminded that EFSA has already the possibility to obtain the views of third-parties via a public consultation on a draft opinion when this is considered necessary. It expressed concerns that the proposal might have a negative impact on innovation in the EU.

ECCA asked how the new proposal would relate to the decision of the European Court in the ongoing case on confidentiality. ECCA also asked whether the applicants in case they do not agree with EFSA's decision on confidential data would have a possibility to withdraw the data. Regarding the reliability of studies ECCA pointed out the fact that in the area of pesticides, pre-submission procedures take place with MSs and asked how EFSA would work with such a dossier in case of different views or data gaps.

IFOAM EU GROUP welcomed COM effort to increase transparency and asked whether the decisions of EFSA on confidentiality and reasoning behind it would be made public. IFOAM EU GROUP disagreed with the deletion of a positive list related

to GMO. It also disputed that DNA sequence information and breeding patents and strategy should not be confidential. According to IFOAM EU GROUP that is not improvement in transparency.

On the composition of the EFSA Management Board, the Chair underlined that the proposal is following the formula used for all EU agencies with MS as management board members but maintaining existing provisions and rules on independence. Chair explained that regarding the scientific experts, MS would nominate experts to form a pool from which EFSA, keeping to strict criteria on independence and scientific excellence, will select experts for the Scientific Panels. Chair stressed that we have to take account of sustainability of risk assessment system and ensure a sufficient pool of experts.

COM confirmed that the proposal provides that all studies should be available and easily accessible to be downloaded in machine-readable electronic format. COM further stated that there is a specific article setting out processes and standard data formats for different procedures that will facilitate the public scrutiny of studies.

On confidentiality and impact on competitiveness, COM confirmed that intellectual property rights are to be respected, as well as data exclusivity rules in sectoral legislation, so called data protection rules. In February 2018, the Court of Justice issued judgments in the area of medicines with respect to access to documents requests stating that increased transparency of scientific studies increases public trust, adds to credibility of agencies' work and does not harm competitiveness as the latter is protected through IPRs and data protection rules.

On IFOAM EU GROUP comments, COM clarified that in current GMO legislation DNA sequence is already considered as confidential. COM explained that only in legislation on plant protection products, a positive list of items considered as confidential currently exists. In all other food chain authorisation legislations there are currently only negative lists (what can never be considered as confidential). COM stated that the acts amended and items included in the positive lists ensure that competitiveness is not harmed.

Concerning the applicants' rights in the process of evaluating confidentiality by EFSA COM said that before EFSA takes a decision, applicants must be informed in writing on data to be disclosed. If applicants disagree, they can withdraw their application or exercise their legal rights for annulment after a decision by EFSA is issued and before the data are publicly disclosed.

The commissioned studies notified are made only available after an application dossier is submitted and an EFSA decision on confidentiality is known; EFSA needs to provide detailed rules on the management of the register.

On ECCA's comment, COM clarified that the Court case referred to concerns the existing framework; the proposal proposes a different approach.

On IFOAM EU GROUP question, COM confirmed that EFSA's decisions on confidentiality as such will not be made public but the outcome of that decision (namely a final determination of what has been considered to be justifiably confidential and what not) will be made public early on in the risk assessment

process. EFSA has to establish internal rules how this information will appear on the website.

3. UPDATE ON SPS IN TRADE AGREEMENTS

COM gave an update on free trade agreements (FTAs) discussions, in particular concerning sanitary and phytosanitary standards (SPS). COM stressed that EU is the biggest global player in agriculture trade and the EU robust food safety system is well known to trade partners. COM presented statistics on agri-food import and export for 2016/17 stating that the EU has a positive balance and that the main part of EU exports are value added products, processed food, cheeses and beverages. COM stressed that gradually CAP is becoming more market oriented and EU is getting more self-sufficient.

Regarding SPS measures, COM highlighted that they apply to high-risk products i.e. animal and plant products and relate to trade conditions in relation to safety. They are based on international standards in animal and plant health and food safety. If there is a deviation from these standards, a measure has to be based on a science-based risk analysis. COM however underlined that the use of SPS measures as trade barriers has increased considerably in recent years to defend the own markets.

COM further presented main objectives of the SPS Chapter of the agreements, namely to maintain and improve the level of health protection, non-negotiation of food safety standards, facilitate trade by establishing fair and balanced conditions (import conditions, regionalisation), build mutual understanding and trust and pursue the application of EU-wide export authorisation processes (concept of single entity). COM stressed the importance of cooperation with non-EU countries including technical assistance as well as to avoid using SPS standards to regulate trade as SPS barriers. Furthermore, COM underlined the significance of elements on animal welfare, and the fight against AMR.

COM gave a preview of different stages with various trading partners (implementation of existing agreements such as CETA with Canada, New Zealand veterinary agreement, negotiation of SPS Chapters within the ongoing Free Trade Agreement talks, and on-going bilateral relations with countries without agreements yet in place.

COM concluded by stressing that SPS related barriers showed the importance of having detailed and solid SPS chapters in FTAs and highlighted again the need to maintain and improve the level of health protection and non-negotiation of food safety standards.

<u>Comments and questions raised</u>

EFFAB asked about the role of DG SANTE and DG TRADE.

Regarding animal welfare in third countries, EFFAB asked what COM position is if these countries are not willing to discuss any issues of animal welfare.

EUROGROUP for ANIMALS welcomed chapters on animal welfare and AMR in agreement with Mexico. It agreed with importance of trust and mutual

understanding but called for caution on animal welfare and stressed the key role of auditing.

BEUC asked about the discussion with US, whether the request from US producers on allowing lactic acid for cleaning poultry carcases is back on a table or if there is any similar request being discussed. BEUC asked for more transparency in relation to trade discussion, asked whether the agendas and other relevant documents could be published, as it is important for stakeholders to know what is on a table (e.g. recent discussions in CETA committee).

FRESHFEL agreed with benefits of SPS chapter in FTA but asked how confident can we be and what would guarantee that what is in text will be also implemented. It also asked what could we do to facilitate access to the market where there is no FTA. Regarding the new focus on single market, FRESHFEL would like to know how this concept can be used to make joint efforts to succeed in new markets, whether a common EU framework protocol exists in order to avoid costs and discrimination of treatment among MS.

COM clarified that DG TRADE as chief negotiator, leads the overall FTAs but SANTE, as lead negotiator, leads the negotiations on SPS chapters.

COM stressed the importance of animal welfare in the FTA and COM's effort to push for it to be included either in SPS chapter or in a part on cooperation. Regarding audits, there are valid specific provisions agreed in the line with the approach that audit should look at the system not at the establishments. In the future within the Official Control Regulation the pre-listing of establishments (complying with the authority standards) will be included.

Regarding discussions with US, COM stated that although TTIP is lost, COM has contacts with US counterparts via FDA, and different working groups. During the discussion, COM explains the procedures to be followed as well as conditions on EU part.

On transparency issues, COM confirmed that CETA has now a dedicated website where agenda, minutes and other relevant documents of the meetings are publicly available.

On FRESHFEL's question, COM stressed that the commitment in the FTA is a first step forming a firm base for discussion in SPS committees and during bilateral contacts if the commitments made are not followed.

COM replied to FRESHFEL that the concept of single market is of high importance and COM supports the possibilities to lower the charges by harmonised provisions.

4. PLANT HEALTH LAW AND THE IMPLEMENTING AND DELEGATED ACTS

COM gave an update on implementing and delegated acts to be drafted under the new Plant Health Regulation that will be applicable from 14 December 2019 and outlined the timing of procedures stressing the importance of stakeholders' contribution to these acts, via stakeholder feedback.

Regarding formats of plant passports, implementing act on final users and traceability code exemptions is being discussed in working group and committees in the course of 2018, stakeholder feedback is expected in the 3rd quarter of 2018 and vote is foreseen for 4th quarter of 2018. Delegated act on final users-small quantities and criteria to be fulfilled by professional operators is expected to be adopted after discussion in expert group meeting in the 4th quarter of 2018.

In relation to high-risk plants and plants to be exempted from phytosanitary certification (PC) the stakeholder feedback is expected in June 2018, vote in December 2018.

On a delegated act on priority pests COM highlighted that it relies on support from JRC and EFSA to develop by July 2018 a methodology to identify the priority pests taking into account available data (e.g. input from MS). Expert Group meetings are scheduled to take place between the first half of 2018 and the first half of 2019, with stakeholder feedback in the second half of 2019. COM adoption is foreseen for the second half of 2019.

COM further outlined the main steps in the implementing act concerning the update of pests and measures where the stakeholder feedback is expected in the first half of 2019 and the adoption in the second half of 2019.

A delegated act on movement of scientific material is scheduled for adoption in December 2018 with stakeholder feedback expected in October-November 2018. The implementing act on release of material from quarantine stations is foreseen to be adopted in the 4th quarter of 2018 with stakeholder consultation in the 3rd quarter.

COM further gave an update on the legislation under the Official Controls Regulation (OCR), namely the implementing act on designation of EU Reference Laboratories where call for selection is scheduled for 2nd and 3rd quarter 2018 and the adoption of Commission Decision at the end of 3rd quarter 2018.

The draft text of the implementing act on internal movements is scheduled for discussion in the Standing Committee in May 2018, with stakeholder feedback expected in the 2nd quarter.

COM further listed the horizontal empowerments of the OCR where plant health aspects will be included.

As requested by stakeholders prior to the meeting COM gave a preview on interceptions of citrus in 2017 and 2018 (up to 24 April 2018) and informed participants on citrus black spot updated management system for 2018 export season from South Africa.

COM emphasised the importance of awareness raising on plant health risks and informed participants about the first meeting of the EU Plant Health Awareness Raising Expert Group held in January 2018 to which stakeholders were invited. The next meeting is planned for June 2018. COM is working on the creation of a platform for information sharing as well as on a template to collect examples.

Chair underlined the intense level of activities taking place in the plant health related area where vegetables and fruits figure very prominently in trading. From

the plant health perspective, it is challenging to ensure to trade safely and stated that trade must be properly controlled.

Comments and questions raised

COPA and COGECA asked about the list of high-risk material, whether it is short list and whether COM could share ideas from the meeting of the Standing Committee. Regarding citrus black spot (CBS) COPA and COGECA noticed that South Africa managed to lower its presence when under pressure from COM but later its presence increased again. COPA and COGECA expressed concern whether we can trust the trading partners, that they are taking the measures and improving as agreed. COPA and COGECA also asked for update on Xylella and the enforcement on its eradication.

ENA shared COPA and COGECA interest on the list of high-risk plants.

FRESHFEL welcomed scheduled public consultations on presented implementing and delegated acts, which should help to keep the debate technical, and not political. On evaluation of interceptions registered by EUROPHYT FRESHFEL stressed the important level of proportionality of the risk evaluation. According to FRESHFEL more analyses are needed to ensure smooth functioning of the new PH regime, and asked what role EFSA will play in it and how the work in pest risk analysis to be conducted will be divided between EFSA, COM, and MS?

Concerning the list of high-risk material COM explained that the proposals of MS on wood, plants for planting and fruits are being examined by COM following working group and Standing Committee on Plants, Animals, Food and Feed discussions. COM will establish a list with the plants for which a serious concern based on provisional assessment has been identified. Stakeholders will be consulted soon.

Regarding EFSA's role it provides pest risk assessments or commodity risk assessments. Whether an area or region is free of pests is not being assessed by EFSA but by COM together with MS.

COM underlined that problems with 2017 interceptions in South Africa should be remedied by the implementation of the new action plan but should also be seen in a broader context : climatic and weather conditions are influencing the presence of CBS. COM follows closely the evolution.

COM gave an update on situation related to Xylella fastidiosa. In Italy, the situation is difficult, particularly in Apulia. The disease is moving up to the north of Italy, which is the area of main production. A meeting with Italian authorities will take place shortly. In Germany, the case was only local, in a greenhouse and it has been eradicated. Situation is worrying in Spain, where on Canary Island different strains of the bacteria have been found and containment was finally given. The crucial point is now to prevent the spread of disease from the islands. Outbreaks were reported also in Alicante, with a lot of infected almond trees, an outbreak was notified on olive trees in Madrid. Another case occurred in the nursery with infested ornamental plants. COM stressed that the big problem is that there are no curative means and infected trees have to be cut down to eradicate the bacteria.

COM informed that the problem of Xylella was discussed at a high-level conference in Paris in December 2017 and that improved surveillance, immediate detection and quick action is needed to combat the disease.

COM supports MS in their efforts against the spread of the bacteria by co-financing surveillance but also by compensating the value of the destroyed materials.

ENA drew attention to unjust situation when a nursery with disease will be compensated but the well working neighbours not when their businesses might be closed.

5. STATE OF PLAY OF FOOD CONTACT MATERIALS RELATED ISSUES

COM presented the current EU legislative framework for all food contact materials (FCM) as well as specific measures on different materials and substances.

COM stressed that FCM must not endanger human health, must not bring about unacceptable change in composition of food or organoleptic characteristics. COM stressed the importance of safety.

COM explained that Framework Regulation sets out general procedures and rules and includes the requirements for Good Manufacturing Practices for all FCM.

COM gave an update on the evaluation of the FCM legislation which is 40 years old and there is a preliminary evidence of fundamental problems. The evaluation would aim at analysing provisional and actual effects of the Regulation and lessons learned, assessing whether the current EU legislative framework for FCM is fit for purpose and delivers as expected, and providing a basis for the COM to consider what, if any, possible steps need to be taken in the future concerning the regulation of FCM in the EU.

COM further outlined the evaluation process, its timing as well as current and next steps, namely conducting of the study to feed into the Staff working document and detailed the form of stakeholder consultations expected.

On Staff working document COM detailed that it would provide a description of the intervention (refined intervention logic) and the current situation, a description of the adopted methodology, assumptions, limitations and robustness of findings; analysis and answers to the evaluation questions addressing the five evaluation criteria of effectiveness, efficiency, relevance, coherence and EU-added value; main conclusions drawn from the evaluation identifying possible steps for the improvement of the current legal framework for FCM. It will also present stakeholder views and explain how these have been considered throughout the evaluation.

COM further previewed the main objectives of Circular Economy and Plastic Strategy, among others that in ten years plastic packaging must become 100% recyclable, uptake of recycled materials must be increased. COM stressed the significance of safety and mentioned issues of incidental contamination of recycled plastic by residues from previous use and difficulties to control the substances present in recycled plastic. COM further detailed the recycling process steps and role of EFSA in evaluating and authorising the processes. COM explained that

potential change considered - obligatory monitoring of incidental contamination. COM further presented the way the Recycling Regulation would be implemented and on what the focus will be in the future, e.g. the possibilities to recycle other plastics than non-PET, standardisation of waste stream, and safety of other materials (paper, board).

Regarding other activities in the area of FCM, COM stated that work is in progress on ceramics (on reduction of cadmium and lead limits) and printed FCM (complex file); on virgin plastic materials only authorisation is on-going.

Comments and questions raised

CEFIC asked about the timeline on printed FCM. COM stated that at present it cannot commit, it is being discussed internally.

BEUC asked about ceramics, whether stakeholders will be consulted, which COM confirmed.

6. OCR 625/2017 PROCESS ON IMPORTS AND DE-BRIEF FROM DISCUSSION WITH MEMBER STATES

COM gave an update on the state of play on OCR since the previous update to the Advisory group in November 2017. COM stressed that in 2018, the main focus is on derived legislation on entry into the EU (import, transit etc.) with considerable time pressure, especially as regards delegated acts due to the European Parliament's recess as from early 2019.

COM gave a preview of recent meetings taking place, namely presentation of DG SANTE work plan to the secretariat of the ENVI Committee in February 2018. There are meetings with MS experts and working groups on entry into the Union every two months as well as meetings on specific issues e.g. Computerised Information Management System for Official Controls (IMSOC), hygiene, food of animal origin, import conditions, rules on uniform official controls on plants and plant products, temporary increase of controls at Border Control Posts.

COM further detailed the first achievements in 2018, including adoption in February of a delegated act to establish EU Reference Laboratories for plant health (to be designated in 2018) and an implementing act adopted in March to designate an EU Reference Centre for animal welfare.

Regarding work in progress COM mentioned draft Regulations on import conditions as well as a draft Regulation on IMSOC.

COM then presented the entry into the Union empowerments documents at advance stage of discussion with MS, and detailed the recent developments on composite products and on manifest and prior notification.

Further COM gave an overview of the expected timeline of the delegated and implementing acts for border controls as well as for other projects.

COM reminded participants about the procedure of standard decision making process for implementing and delegating acts that also includes consultations of stakeholders.

COM concluded with outlining the legislative timeline for OCR in 2018 and 2019 and referred participants to a dedicated OCR webpages where all relevant information is regularly updated.

Comments and questions raised

FVE asked about the outcome of discussions with MS.

COM confirmed that once discussions with MS are concluded, stakeholders will have access to documents. More finalised versions of documents should be ready from June onwards. COM expressed readiness to clarify to stakeholders their specific questions in writing.

ATA asked whether there will be a completely new legislation on transit and trans-shipment.

COM replied that, as it is a very early stage, COM cannot give any details, more information on this matter should be available in June. COM however mentioned, as an example of an issue to be considered, the internal transit through a non-EU country in view of Brexit.

7. UPDATE ON OCR 625/2017 RELATED TO MEAT INSPECTIONS

COM gave an update on actions that took place after the Advisory Group dedicated working group meeting of 7 November 2017, namely further consultation of stakeholders on bilateral basis, two meetings with MS (January and April 2018), intra-SANTE consultation and an informal consultation of the Legal Service.

Concerning the Delegated Regulation in accordance with Article 18/ (7), COM detailed the main proposals with regard to ante-mortem inspections (AMI). COM stated that these inspections will be possible at the holding of provenance by official veterinary (OV) in all species, there should be focus on verification of the quality of the food chain information by OV. Inspections would be possible in the slaughterhouse by official auxiliary (OA) under the responsibility of the OV (absent) in case of AMI at the holding of provenance. COM also proposes that AMI in case of emergency slaughter would be mandatory by the OV, and twenty eight days instead of three days validity of AMI in farmed game farms supplying small quantities.

With regard to post-mortem inspections (PMI) COM explained that under the responsibility of the OV PMI can be carried out by the OA in low capacity slaughterhouses introducing a threshold of 5000 livestock units or 300 000 poultry/lagomorphs slaughtered per year.

Regarding other issues COM mentioned the possibility of official controls in cutting plants by competent authorities, derogations for AMI/PMI in reindeer and snared grouse, derogations for production and relaying areas for bivalve molluscs and minimum requirements for OV, OA and other staff designated by the competent authorities and slaughterhouses (e.g. training).

COM further presented the Implementing Regulation in accordance with Article 18(8) considering specific requirements for performance of official controls, practical arrangements for AMI/PMI, cases of non-compliance requiring measures, technical requirements for health marking, conditions for classification production

and relaying areas live bivalve molluscs, specific requirements for performance of official controls on milk, milk products and fishery products.

COM then detailed the main proposals with regard to practical arrangements, such as more risk-based approach in line with the 2011-2013 EFSA Opinions on the revision of meat inspection, a balance approach between public health and animal as regards the need for incisions and palpations taking into account also trade considerations, additional flexibility mainly in young ruminants and the need for additional inspections and palpations if abnormalities have been found. Regarding poultry discussions focus on whether each carcass must be checked. *Salmonella* control and *Campylobacter* official controls have been introduced as well.

COM concluded by giving an overview of next steps including meeting with MS on 2 May on Implementing Regulations (Article 18(8) on list of importing countries and import certificates. After inter-service consultation and the follow-up meeting with MS on 4 June 2018, the public consultation will be launched. The vote on Implementing Regulation and submission to the European Parliament of the Delegated Regulation is expected by end of 2018.

Comments and questions raised

FVE asked for clarification on availability of documents.

UECBV asked for clarification on the latest versions of implementing and delegated acts. UECBV sent a position paper regarding the implementing act where it explains its issue on wording regarding cleanness of animals, as well as the issue of slowing the speed of the slaughter line. Regarding threshold on small establishment, UECBV suggests continuing to use the risk-based approach rather than a threshold.

AVEC confirmed that it has already sent the comments on behalf of poultry sector. AVEC expressed concerns on non-compliance requiring measures, in particular the reduction of speed line. This issue was discussed within the sector and with poultry machine producers and the lowering a speed is according to AVEC not being a solution. On low capacity slaughterhouses, AVEC supported UECBV to continue to use the risk-based approach not a threshold.

Regarding the draft documents, COM confirmed that after distribution to MS a revised draft text of the implementing act will be available for stakeholders upon request. The delegated act was not yet distributed to MS, it might be available mid-May.

Regarding the threshold to identify low capacity slaughterhouses, COM was looking for certain harmonisation and to make it clear what a low capacity means. COM underlined that the whole meat inspection is risk based, and stated that hazards are the same in small as in big establishments but general policy for small capacity establishments is more flexible.

On AVEC non-compliance and reduce slaughter line speed COM explained that if lowering the speed of a slaughter line does not work there is a possibility to look at other corrective actions to improve the situation.

8. UPDATE ON OCR 2017/625 RELATED TO A PROPOSAL FOR AN IMPLEMENTING ACT ON TEMPORARY MEASURES GOVERNING THE IMPORT OF CERTAIN GOODS FROM CERTAIN THIRD COUNTRIES

COM presented the activity under official controls dedicated to import controls on certain goods, specifically food of non-animal origin (FNAO).

The discussion with MS is on-going on proposal on single implementing Regulation establishing temporary measures for the entry in the EU of certain goods.

The goods subject temporarily to control at border check posts would be organised around identified risk or evidence of widespread serious non-compliance, and around its origin: one third country, a region or a group of third countries.

The proposed implementing act will use three legal bases, two of OCR 2017/625, specifically, Art. 47 (2) (b) of OCR 2017/625 providing a legal basis for list of "goods" from certain third countries subject to a temporary increase of official controls at the entry into the Union due to known or emerging risk or evidence of widespread serious non-compliance. And Art. 54 (4) (a) of OCR 2017/625 providing the legal basis on rules on the frequency of identity and physical check. Further, there is Art. 53 (1) (b) of R. 178/2002 on GFL providing for emergency measures/special conditions for import of FNAO (referred to in Art. 47 (1) (e) OCR) due to a serious risk to human health, animal health or the environment, which cannot be contained satisfactorily by means of MS measures.

COM highlighted that the proposal aims at consolidation of measures on temporary increase of controls (currently provided by R. 669/2009) and existing emergency measures for feed and food of non-animal origin as well as a simplification of the system that will be supported by IMSOC - Integrated Management System for Official Controls. This simplification will be mainly related to a more reactive adaptation of the frequency of checks and the reporting obligations of control results.

COM further detailed the correlations and links of the proposal with OCR 2017/625 provisions and empowerments.

COM concluded by summarising the state-of-play and next steps, mainly the further discussion with MS experts in the Working Group on R. 669/2009. COM stressed the importance of stakeholders' involvement and informed participants that an ad hoc meeting of the Advisory group on the food chain and animal and plant health will be organised in the last quarter of 2018 to discuss a complete proposal.

Chair stressed the importance of appropriate official control measures on non-animal products, highlighting some recent issues in this sector, such as the contamination with melamine. He stressed the need to fill the gaps in regulatory framework, and have coherent and transparent measures to deal with emergencies related to this area.

<u>Comments and questions raised</u>

PAN EUROPE underlined that it is very relevant to facilitate the implementation and enforcement of the legislation that aims at reducing risk associated with imported goods. It is essential to focus on pesticide residues. PAN EUROPE mentioned the

need to be cautious also with bio products and to pay attention to risks of possible contamination during interim storage.

9. SHORT INFORMATION ON POINTS RAISED BY STAKEHOLDERS

- **UPDATE ON THE LOW-RISK ACTIVE SUBSTANCES INITIATIVES AT EU LEVEL**

COM gave an overview of the main provisions in Regulation (EC) No 1107/2009 on low risk active substances in plant health and gave a preview of naturally occurring low risk and basic substances already approved in recent years.

COM further highlighted the objectives of the sustainable plant protection working group which was established in 2016, namely to identify actions on increasing low-risk plant protection product availability and accelerating integrated pest management (IPM) implementation. The group laid down an implementation plan which was endorsed by Agri-Council in 2016 and included main actions to make progress in sustainable plant protection to be put in place by MS, EFSA, COM and also actions for applicants, such as submit high quality and complete dossiers, consider the use of the so-called "risk-envelope approach" and make use of pre-submission meetings provided by MS.

COM stressed that the progress report finalised in January 2018 is based on the replies to a survey questionnaire and gave information on main achievements with respect to planned actions.

With regard to IPM COM listed the main actions COM is undertaking as resulting from the follow up on implementation of the Sustainable Use of Pesticides Directive. Among other measures, move forward on harmonised risk indicators, develop methodology for assessment of IPM, and develop BTSF courses on IPM implications. COM stressed that IPM is considered an important area for EU research funding and under Horizon 2020 considerable funding was allocated to integrated health approaches and alternative pesticide use, new and emerging risks to plant health and stepping up IPM.

COM concluded by ensuring that it will continue working together with MS and EFSA in working groups on biopesticides, low risk and basic substances and underlined that the specific focus to address low risk and basic substances issues will be given within on-going REFIT evaluation.

Comments and questions raised

Chair stressed that it is of significant importance to progress in developing low risk plant protection products. Chair asked whether low risk would mean also low tech.

EU Specialty Food Ingredients asked whether there are minutes available from meetings between applicants and national competent authorities.

PAN EUROPE stressed that within IPM the chemicals should be the last resort. PAN EUROPE mentioned the issues with low risk substances, where in Italy the application to use a yeast was treated as an application for a normal pesticide which resulted in delayed process.

COM replied that low risk does not mean low tech, as the complex knowledge of the microorganisms and mode of action to control the pests is needed. Also big industry is moving more towards the research of new "biopesticides" such as derived metabolites that requires expertise and high tech.

Regarding the minutes of meetings between applicants and MS, in principle it depends on MS but would be logical if such minutes are drafted also for the purpose of traceability/further follow up on the way in which advice and recommendations given to applicant in preparation of dossier have been finally actualised.

COM stated that EFSA plays a key role in supporting and advising the MS and progress has been achieved in this area.

COM drew the attention of participants to the Platform on exchange of information among experts on assessment of microorganisms.

On PAN EUROPE's question, COM did not know the details of this specific case but most probably the substance was still under assessment and as provisional authorisation is not possible any more the national authorities cannot authorise a product for which an active substance is not yet approved.

- **UPDATE ON PLANT BIO STIMULANTS**

COM briefly reminded participants that proposal for a revised Fertilising Products Regulation was adopted by COM in March 2016 and currently is in a co-legislative process. This proposal aims at creating a level playing field between all fertilising products, protecting health and environment, facilitating nutrient recovery and reducing dependency on critical raw materials, and at reducing administrative burden and legal uncertainties.

On plant biostimulants that are covered under this Regulation, COM presented the definition of biostimulants, and explained that there is a clear distinction between fertilising products and plant protection products and the biostimulants are excluded from the scope of plant protection products Regulation. COM stressed that biostimulants improve nutrition efficiency and can help plants to tolerate abiotic stress.

COM further listed the requirements for plant biostimulants, namely safety requirements through contaminants limits, efficiency and additional safety requirements for microbials.

COM concluded that plant biostimulants is a new category of fertilising products associated with plant nutrition. COM stressed again that it is distinct from plant protection products with a different mode of action and functionalities.

<u>Comments and questions raised</u>

COCERAL welcomed the efforts to separate the regulatory framework on biostimulants from plant protection products regulation and asked whether there are still grey areas expected in which regulatory framework which product will fall. It also asked for clarification on the authorisation process.

COM said that the principle is that as long as the product has been authorised as a plant protection product, it will remain as such. If there is a claim to add the product as plant biostimulant, it can be added as such. Concerning grey area there are efforts

to solve these issues jointly by SANTE and GROW. COM underlined that each applicant can discuss this potential overlap with COM and seek clarification.

FOODDRINKEUROPE asked whether the area regarding plant biostimulants will be considered in the REFIT exercise on plant protection products and how the grey area will be addressed.

COM confirmed that the purpose of the proposed biostimulants Regulatory process currently in discussion is to clarify as far as possible these grey areas, so that the REFIT of plant protection products Regulation should not continue to address this issue.

- **STATE OF PLAY REGARDING NANOMATERIALS**

COM stated that EU is the only region having provisions for nanotechnology and nanomaterials in its legislation, in particular in the legislation on novel foods, food contact materials (FCM) and food information to consumers (FIC). Also in non-food legislation there are specific provisions in legislation on cosmetics, and biocidal products. Reference to nano appears also in REACH and legislation on medical devices.

COM further listed the principles applying to nanomaterials in the EU, among others the science based, workable definition, state of art risk assessment approaches, and proper enforcement and transparency.

On definition, COM stressed that nanomaterial definition in EU food legislation stem from the definition of Commission Recommendation 2011/696/EU which is currently under revision.

COM explained that the nanomaterial definition in foods makes the important distinction in referring to 'engineered' nanomaterials, i.e. nanomaterials intentionally designed and added to the foods. COM explained that it has an obligation to adjust/adapt the foods engineered nanomaterial definition to technical and scientific progress or to definitions agreed internationally and this is why any revision of the 'engineered nanomaterials' definition will be linked to the revision of the overall definition under Commission Recommendation 2011/696/EU.

COM explained that the revision/adaptation of Commission Recommendation is ongoing. COM indicated that while the novel foods, food information to consumers and the food additives regulations follow the novel food definition of engineered nanomaterials, there is no specific definition of nanomaterials in FCM legislation.

COM further stressed the importance of assessment of nanomaterials using the most up-to-date test methods to assess their safety.

COM underlined that although there is no reference to nanomaterials in regulation on FCM, in the regulation on plastics there is a specific reference saying *inter alia* that nano-substances shall only be used if explicitly authorised, that EFSA assesses them case-by-case before the authorisation and that the authorisation of conventional substance does not cover the same substance in nanoform.

Concerning FIC, nanomaterials are defined in this legislation in the same way as in novel foods legislation. COM stressed that there are labelling requirements using term nano to follow in brackets.

As regards the food additives legislation there is an indirect reference to nanotechnology. Article 12 says that if there is a significant change in the production methods or change in particle size, for example through nanotechnology the food additive prepared by those new methods shall be considered a different additive.

COM concluded by summarising the latest developments, including the revision of the 'general definition' of Commission Recommendation 2011/696/EU. DG ENV leads this process, public consultation will be launched in the second quarter of 2018, and adapted definition should be available by end of 2018. Once revised general definition work is completed, the work on revision of nanomaterials in food definition will start via delegated act.

COM underlined that concerning enforcement it relies on JRC technical support on methods and analyses. To this end the JRC organised and hosted a meeting of MS designated laboratories in April 2018. COM stated that European Committee for Standardisation might have some activities on nano in foods. Concerning risk assessment EFSA has revised the guidance on the risk assessment of nanomaterials to be adopted in the third quarter of 2018.

Comments and questions raised

BEUC expressed surprise that there is still discussion on methods to enforce labelling requirements since in France there were interesting developments in this respect, so it would be desirable to speed up the work at EU level. BEUC asked for more precise timing of consultations.

COM replied that it is aware of the results of the analyses in France on Titanium dioxide in foods but so far has not received any official reports and the results. COM confirmed that EFSA is conducting a supplementary assessment of recent evidence on Titanium and the result should be available before the summer.

On timing of the Public Consultation on the revision of the nanomaterial definition under Commission Recommendation 2011/696/EU, COM explained that it is dictated by other DGs but confirmed that it would be a 12-week consultation and should be launched shortly.

- **STATE OF PLAY REGARDING NITRITES/NITRATES**

COM shortly presented why nitrites/nitrates are used as food additives. On the one hand they are authorised under the food additives legislation as they are efficient preservatives contributing to microbiological safety of food especially as regards botulism. On the other hand, their use may give rise to the formation of potentially carcinogenic nitrosamines. COM stressed that it is important that the legislation strikes the right balance between the benefits of their use as preservatives and health risks regarding carcinogenic nitrosamines.

COM drew attention to the EFSA opinions re-evaluating safety of nitrites/nitrates as food additives adopted in 2017 within the on-going re-evaluation of all authorised food additives expected to be finalised by 2020.

Regarding the acceptable daily intake values, which are the reference values for risk managers for food additive authorisations; these have not actually been revised. As regards the exposure from food additives uses it is generally within the acceptable daily intake values. However, when the other exposure sources are taken into account (natural presence, contamination) then the acceptable daily intake values are exceeded. It was pointed out that it is not possible to avoid exposure to other sources whilst for food additive uses it can be controlled when and how much is added to foods.

COM further stated that EFSA in its scientific opinions is looking at the exposure to endogenous nitrosamines (i.e. formed in human body) as well as to exogenous nitrosamines (i.e. formed in foodstuffs).

EFSA concluded that the formation of nitrosamines in the body from nitrites added at approved levels was of low concern for human health. However, the exposure to exogenous nitrosamines was of some concern even if it was not possible to discern nitrosamines formed due to added nitrites from those produced already at the food matrix where nitrite has not been added.

EFSA further confirmed evidence to link preformed N-nitrosodimethylamine and colorectal cancers and some evidence to link dietary nitrite and gastric cancers and the combination of nitrite plus nitrate from processed meat and colorectal cancers.

COM pointed out that in the meeting with MS and EFSA in February 2018 the need to revise the food additive legislation was discussed, which was supported by several MS, but not all. The discussion with MS on a possible revision of the uses and use levels of nitrites/nitrates as food additives will be launched in coming months. Studies carried out previously showed that there should be certain scope to decrease the maximum use levels, in particular in non-sterilised meat products.

Comments and questions raised

CLITRAVI stated that the sector is committed to collaborate as regards the revision of the use of nitrites/nitrates in processed meat, and that it is working on some alternatives e.g. vegetable extracts. CLITRAVI asked whether also use of vegetable extracts will be taken into account.

BEUC expressed support for the revision in order to decrease the authorised maximum levels of nitrites/nitrates but stated that the use of the plant extracts (that may lead to formation of nitrosamines as well) in meat processing is not a solution.

COM replied that it is well aware of the trends on the market as regards plant extracts. COM pointed out that it is important to know the composition of such extracts and why they are used. COM drew the attention to two statements made by the Standing Committee on Plants, Animals, Food and Feed (2006 and 2010) as regards plant extracts containing high levels of nitrites/nitrates for which it was concluded that it is a food additive use which would need to comply with the

applicable legislation (on food additives, on their purity criteria and labelling). COM stressed it is open to further discuss with stakeholders.

Chair commented that a comprehensive overview report by SANTE Directorate F on food additives in meat processing industry is available. He pointed to traditional use of nitrites/nitrates for many years in products consumers like. However, he emphasised that measures have to be taken to find alternatives in order to minimise health concerns.

10. ANY OTHER BUSINESS

The Chair informed participants about upcoming events, namely the ad hoc meeting on issues related to the withdrawal of the United Kingdom from the Union scheduled for 1 June. The Chair thanked all speakers and participants for their constructive contributions, and closed the meeting.