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

26 NOVEMBER 2018

Summary Record

1. WELCOME AND OPENING BY MR MICHAEL SCANNELL, DIRECTOR, DIRECTORATE FOOD CHAIN: STAKEHOLDER AND INTERNATIONAL RELATIONS: OPENING SPEECH BY MS ANNE BUCHER, DIRECTOR-GENERAL, DIRECTORATE GENERAL FOR FOOD AND FOOD SAFETY

SANTE Director of Directorate D (Food Chain: stakeholder and international relations) opened the meeting and welcomed Ms Anne Bucher, the Director General of DG SANTE to her first appearance at the Advisory Group since her appointment. Chair then reviewed the agenda, which reflects some of the key issues in SANTE's current work, including the current state of the revision of the General Food Law (GFL) impacting transparency and EFSA. European Council and Parliament are now progressing the proposal. Chair also highlighted another topic for discussion on the agenda, at the specific request of a stakeholder, i.e. “mutagenesis” and in particular the ruling of the Court of Justice (CJEU) in July 2018 in this regard. Chair then handed the floor to the Director General.

She mentioned the vital role of the Group in the consultative process. Transparency and improved consultation of stakeholders are one of the main priorities of the Junker Commission and a fundamental part of Better Regulation. A strong partnership between SANTE and our stakeholders is essential to develop balanced and fit for purpose policies and legislation.
She then referenced the topics on the Agenda today as some of the most sensitive and important SANTE files. These range from the revision of the GFL , the new Plant Health Regulation, antimicrobial resistance (AMR), the Sustainable Use of Pesticides Directive , the “Strategic Approach to EU Agricultural Research and Innovation” , to be presented by DG AGRI and the closing point on “mutagenesis” .

In conclusion, she thanked the Members for all their contributions towards making the Group a success and stressed it is a collaborative effort not simply to promote specific interests, but to work together toward a better , more sustainable and even safer food chain in all out interests.

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 current state of play regarding the proposal insofar as it was permissible to do so. A common position by the Members States, (MS), on the general terms of the proposal has been achieved though the outcome is not fully, what COM put on the table. Now we await to see what will emerge from the discussions between the Council and the Parliament.

COM recalled the four pillars of the proposal, namely

(1) Risk Communication: there is a general understanding with the MS that better coordination and a strong framework is needed for this activity. However, concern was expressed by MS about how much delegated legislation in this regard would overrule their national activities. There is agreement that there *will* be either a delegated or implementing act, but which is yet to be seen. COM's position is that it would be nice to have a strong framework for this pillar.

(2) Sustainability of EFSA's activities and governance: there is a divergence between the COM and the MS regarding sourcing the pool of experts. COM wants a strong fingerprint from the MS, while the MS are in favour of a lighter involvement and say it will be an administrative burden otherwise. The outcome will arise from the discussions between the Council and the Parliament with the latter more on the side of COM. There has been fundamental change on the approach to transparency in the Council after much discussion, e.g. on when can raw data in studies be released and what shall be in the, so called, 'positive list", i.e. which elements can be claimed a confidential. Now the proposal is that everything shall be made public/transparent; nevertheless, to protect investment/research there may be elements that can be classified as confidential, i.e. the "positive list" approach. This is in contrast to the previous legislation, which had a "negative list" approach. Two big issues are when information shall be made public and what shall be made public. COM considers this decision shall be taken as early as possible and the Council came up with a compromise proposition after discussion reflecting the "positive list" approach. Com believes that, if this will be the outcome (after some discussion) it will be a big step towards transparency. Regarding when information relating to risk assessments shall be made public, we must await the vote in the ENVICOM tomorrow that will be an indication of the EP Plenary vote on, tentatively, 11/12 December. This, in turn, will set the scene for the trilogues between the EP/COM /MS and Coreper before Christmas. The trilogues and technical meetings are due to be over by mid-February 2019. This limited timetable shows the EP and Council are in line to adopt the proposal within the term of the current EP. An important element is the underpinning budget of €62, 5 million and an extra 106 staff for EFSA to implement the proposal, to which the EP and Council have agreed. The parallel discussion on the reform of the Financial Framework cannot be pre-empted by this agreement on the budget for GFL proposal

(3) Controls on laboratories: Do they comply with the standards to which they are accredited? MS came up with a light approach, not least on how to enforce laboratory standards in third countries. However, COM cannot regulate in third countries, so the rules need to depend on an international framework. COM is not very happy with MS approach but it will be necessary to see what emerges from the discussions with the EP.

(4) Access to Documents and the "Arhus Convention"; how do the provisions of the GFL proposal relate to this existing legislation? COM's position is that they do not pre-empt/prejudice rules on access to documents, nor the "Arhus Convention". There is a bigger divergence on access to documents than on the transparency issue.

Comments and questions raised

Chair emphasised the rapid progress made on this proposal since the Citizens' initiative under a year ago and the political determination of our inter-institutional colleagues to complete the process within the current inter-institutional cycle and invited participants to express their opinion.

FOODDRINKEUROPE, while supporting the proposal in general, raised the issue the lack of an impact assessment for this fundamental proposal.

FEFANA pointed out that the proposed proactive and automatic public (uncontrolled) disclosure of non-confidential business information at the time of application for authorisation of a new feed additive, i.e. as soon as a dossier is submitted to EFSA would reveal a company's business strategy to all competitors around the world. This may create risks of indiscriminate copying (plagiarism) of submissions, with dossier information copied by competitors seeking authorisation of a similar product in other parts of the world where there is no public disclosure but a potentially much faster authorisation procedure as we currently experience in the EU. This will put EU-based companies at a significant competitive disadvantage, potentially forcing many EU-based SMEs out of business and triggering others to relocate R&D and investments in innovative products outside the EU.

IFOAM EU GROUP (*ORGANIC FOOD+ FARMING MOVEMENT*) welcomed the proposal no least the transparency aspect but is concerned about the intention to maintain confidentiality for GMO sequences etc. as it is important this information is disclosed to organic breeders. Asked if this position would be maintained in the inter-institutional discussions.

Chair said this latter aspect would be covered either in this session or later on in relation to the "mutagenesis" ruling of the CJEU. Also in response to ECCA in the same connection, the Chair recalled that the COM had won the case so it would be highly unlikely it would change its view that its proposal, as updated, is legally compliant.

ECPA expressed support for the proposal including the transparency aspect, but is surprised COM has not looked to transparency precedents in other industries, e.g. PHARMA, where studies are disclosed six months after product approval. Is concerned at the ability of EFSA to act independently while studies are released and

on the control mechanism for disclosure, which could facilitate the growth of illegally produced pesticides.

"EU Specialty Food Ingredients" supported FOODDRINK EUROPE and FEFANA comments and considered this to be a bad proposal from the point of view of innovation in the specialty food ingredients sector. In its view, if an impact assessment had been conducted the current approach to early disclosure could have been prevented in the ingredient sector. Also asked COM to answer what would happen in case implementing finance is unavailable, (MFF), as EFSA has indicated there is no plan B in that event.

Chair summarised the three main aspects raised as, no impact assessment, data confidentiality/timing of disclosure and the MFF /budget and invited COM to respond to points raised.

COM (Ms Bucher) replied it was permissible to derogate from COM guidelines on the requirement to have an impact assessment where there had been a recent evaluation and extensive public consultation. Both conditions are fulfilled in this case.

On data confidentiality/timing of disclosure etc. COM pointed out that DNA sequencing etc. is considered as confidential based on current law. The CJEU ruling has no impact on the proposal. Our initiative relates to pro-active public disclosure, not disclosure upon request. The access to documents regulation will continue to apply, as well as the Arhus convention. Actually, COM did derive inspiration from the PHARMA sector where pro-active disclosure of document actually promoted innovation. Moreover, a positive list approach is not new; it already exists in the plant protection products legislation. Early timing of disclosure means that EFSA has the broadest information as the public will have the ability to provide information. Hence, it is important that public consultation take place before a decision. Control mechanisms of disclosure include a specific statement that disclosure is without prejudice to existing IP rights and data exclusivity rules, nor shall disclosure be considered as an explicit, or implicit, permission or licence for the data to be exploited. Practical arrangements for control mechanisms are a matter for EFSA to put in place. The main thing is to ensure that EFSA delivers robust findings within shorter timelines. Early disclosure of scientific information, with the exception of confidential information, will accelerate the process of having EFSA opinions more widely accepted.

On the concerns expressed regarding SMEs, COM mentioned the pre-submission phase to facilitate SMEs.

COM added that if we can get clear on what is to be disclosed than we will have solved the matter and timing will not be so important. Anyway, the first assessment of what is to be considered confidential is for the applicant to make and here the guidance is clearer than before, including due to elements brought forward by the MS.

On the budgetary aspect, COM indicated that while it cannot pre-empt a decision in this regard, there is a political will on the part of the co-legislators to find the money and this will be part of a bigger discussion.

3. PLANT HEALTH LAW AND THE IMPLEMENTING AND DELEGATED ACTS. PLANT HEALTH RELATED ACTS IN OFFICIAL CONTROL AND OTHER PLANT HEALTH RELATED ISSUES

COM gave an update on the new plant health Regulation (EU) 2016/2031 on protective measures against pests of plants is another important SANTE file. It was adopted in December 2016 and will become applicable on 14 December 2019.

It introduces a more proactive approach both for the imports and for the prevention of outbreaks of pests within the EU territory. We are now within the transitional period of three years and currently preparing the implementing and delegated acts that are the most essential for the completeness of the plant health regime.

In close co-operation with the Official Controls colleagues, the Plant Health unit is drafting plant health rules based on the new Official Controls Regulation 2017/625 for which stakeholder input will be important. The participation by those present today in the new Plant Health and Awareness Raising Expert Group is encouraged by COM.

Chair remarked that what is occurring in relation to EU plant health legislation and its implementation is revolutionary and this has not escaped the attention of our trading partners. Plants are an input to the food industry so there will be far reaching implications for that industry in general. Potential implications for MS are to be envisaged in relation to high-risk plants and priority pests.

Comments and questions raised

FEFAC asked if awareness raising would develop over time into an early warning/detection system on risks that could give rise to the safety status of crops, e.g. weather events. COM indicated the legislation would provide for early detection/surveillance and rapid action to avoid the consequences of late detection/late action. The implementation would be a joint exercise with stakeholders, citizens, MS, EFSA, and international organisations.

Chair added that COM is working hard to highlight its work in this area in WTO SPS Committee. Not clear if third countries, with less open regimes – but who are used to a permissive EU plant import regime, to our cost e.g. pinewood nematode, xyella – are aware of what is happening in the EU plant health field. They will be confronted by a new regime and some may be surprised. MS capacity is another aspect, with the Commissioner recently urging them to strengthen their plant health regimes. However, the low uptake of COM training offered to MS in the plant health field, unlike in relation to animal health has led the COM to initiate an "Awareness Raising", as mentioned before, directed at the MS. We have to prepare for the unexpected.

ECVC asked if measures adapted to small-scale farmers are envisaged. COM replied that in matters of eradication it make no sense from a phytosanitary point of view to make a distinction between big and small operators. Apart from existing measures applicable to small operators, COM has not identified any need for further measures. However, we will keep this under review in the implementation period, post December 2019. COM agreed with FRESHFEL that there should be more information on interceptions and this is planned. In addition, COM took note of FRESHFEL's repeated point that monthly updates are not sufficient and it will

contact stakeholders on certain interventions in between, when needed. For the annexes, there will be some elements for the notification of third countries and the normal SPS consultation. This will be preceded by consultation with EU stakeholders.

4. AMR: NEW EU ONE HEALTH PLAN

COM gave an update on operational/technical developments and initiatives relating to EU One Health Action Plan aimed at contributing to coherence and synergies between various EU policies and support for MS efforts. On the wider important political aspects of this issue which is causing many deaths worldwide and placing a heavy burden on healthcare systems COM highlighted the almost unanimous EP resolution on AMR, September 2017, combining plant, animal and environmental, i.e. the, so- called, "one health approach" with monitoring, as very crucial element. The MS are also attentive to AMR, including via the Presidencies. Internationally AMR is high on the international agenda, with WHO recently publishing a survey of members. The Plan, adopted in June 2017, is very ambitious. Moreover, it places AMR, a global issue requiring global answers in an international context, including in, WHO, G7+20, WHO , OECD, and via the Transatlantic Taskforce on Antimicrobials . COM has close monitoring mechanisms, (a priority for the EP), in place to ensure, we are delivering on the Plan with two reports in 2018 and two foreseen for subsequent years

Chair questioned if AMR was receiving the political attention it merited and asked COM if the possibility of fatalities was linear going forward or if it could increase and if the EU's leading efforts in this field are being undermined by non-EU partners which are not taking the risk as seriously? On the first point COM commented that it was difficult to say as many variables come into play e.g. longer life expectancy. In addition, prevention environmental/agricultural aspects must be considered e.g. potential release of antibiotics into the soil play a part. On the international dimension, COM will offer training and explanations of our approach in non-EU countries.

Comments and questions raised

FEFAC raised the prevention aspect and the role of feeding systems/animal nutritional solutions in AMR prevention and asked how stakeholders could be involved in COM Health Awareness events, a topic also raised by FVE. COM pointed out that while that that role of nutrition is important, environmental factors are as well. It is possible that stakeholders with something to contribute could be invited to participate, as appropriate. UECBV welcomed the work of COM on AMR.

Chair endorsed the contribution of BEUC on the importance of the EU side remaining ambitious in the CODEX AMR Task Force. We will press for a prohibition on the use of antimicrobials for growth promotion worldwide. Transparency is also crucial with documents available, including, via the COM website.

ECVC raised the model of big scale production and effect of the CAP overfunding same, as they see it,

5. ESTABLISHMENT OF HARMONISED RISK INDICATORS FOR PESTICIDES UNDER THE SUSTAINABLE USE DIRECTIVE 2009/128/EC

COM presented the draft amending Directive, which creates the first two of a number of possible indicators that will be used to measure whether MS are meeting the aim of the Directive. COM explained the indicator was based on existing data, valid since 2011, and used the existing categories for classifying pesticides under 1107/2009. As dependable data was not available for the volume of pesticides sold, or used, under Art 53 the second indicator used a measure of the number of derogations granted. The weightings given to each category encourage the use of lower risk pesticides or pesticide alternatives.

COM explained the stage the proposal was at and that the public consultation through the feedback mechanism would be launched this week. Comments on the text and on other possible indicators were welcome.

Chair remarked that the, undesirable, alternative to this proposal would be COM established targets and this should help focus minds. Therefore, it is important the exercise is a success from the point of view of COM credibility with stakeholders and citizens in general.

Comments and questions raised

Comments were received from a number of groups, ECPA were in support of the proposal, and IFOAM favoured additional mandatory targets, including crop specific targets, ECCA opposed the indicator and were critical of the categorisation provided for. BEUC indicated they would like further environmental indicators to be added.

6. STRATEGIC APPROACH TO EU AGRICULTURAL RESEARCH AND INNOVATION (R+I)

COM presented the "Strategic Approach to EU Agricultural Research and Innovation". This, together with FOOD 2030, will constitute the EU strategy for agri-food R+I activities in the last years of Horizon 2020 and in the future Horizon Europe.

R+I are fundamental for the sustainability and safety of agri-food systems, and to protect, and enhance, animal health and welfare and plant health. To that end, robust scientific evidence is crucial to supporting the development of policy making in those sectors. The Commission is proactively supporting MS and Stakeholders in identifying, and tackling, the key priorities for the Union. The future R + Programme, Horizon Europe, and I will be pivotal to efficient, safe EU agri-food systems.

Chair added that the foregoing shows how committed COM is to assisting R+I in the food area, which will, hopefully, feed through to your sectors, including under the future Horizon Europe.

Comments and questions raised

FEFAC welcomed the COM initiatives, asked how sectoral initiatives (databases) to monitor the effect of investment in the reduction of environmental impact might be supported by COM. In reply it was indicated that COM assistance with pilot data collection is possible but not with the routine collection.

7. SHORT INFORMATION ON POINTS RAISED BY STAKEHOLDERS: WHAT IS NEXT AFTER CJEU RULING ON MUTAGENESIS? INFORMATION ON COM NEXT STEPS TO IMPLEMENT THE RULING

DG Sante explained the outcome of the CJEU ruling and stressed that the EU legislation, as interpreted by the CJEU ruling, must be implemented by all actors across the MS, including importers from third countries and all food/feed chain operators. COM is currently discussing the implementation of the ruling with MS including the challenges on the issue of detection: DG SANTE requested DG JRC to address the issue, in collaboration with the EU Network of GMO laboratories with a view to issuing a joint EURL/ENGL report during the 1st quarter of 2019. Regarding the concerns of stakeholders related to the ruling, DG Sante encouraged all stakeholders to share their views with COM with as concrete data as possible, and importantly also to pursue discussions at national level and inform national authorities.

Comments and questions raised

IFOAM expressed concern on products produced with new breeding techniques (NBT) entering the EU and asked about the Commission's intentions on detection methods. FoEE raised concerns about additional administration due to delay for delivering testing methods for new GMO. Europa Bio asked if new legislation was possible. ESA commented on the negative impact already on research and innovation in the EU. ECVC suggested that applications/authorisations should state which techniques have been used. FEFAC commented on the distinction between agronomical (e.g. herbicide resistance) and functional (e.g. antinutritional factor reduction) traits as well as on potential benefits. EFFAB was working on the impact on their sector and suggested that research focuses also on potential NBT benefits.

In response, COM highlighted that MS were invited to share their experience and views on the implementation and impact of the ruling and thus encouraged all stakeholders to raise their points also with their national authorities. In parallel, COM is ready to meet with all stakeholders in order to understand their views on the topic and invited participants to provide concrete data and examples to support their views. For example on the impact of the ruling or on how NBTs could contribute to the current and future grand societal challenges of the agri-food sector, or on how products produced with NBT would differ from conventional GMOs, presently marketed in the EU or cultivated in third countries. COM confirmed that were no plans under the present College for a new legislative proposal.

8. ANY OTHER BUSINESS

Chair informed participants that the next AG meeting would be on 7th May 2019. He also expressed appreciation, echoed by participants, to Viera VOLOSINOVA who is moving to a new position in DG SANTE for her excellent work on behalf of the AG. He also announced his own imminent departure to DG AGRI. Chair thanked all speakers and participants for their constructive contributions, and closed the meeting.