



EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

SUMMARY REPORT

Ad hoc meeting of the Advisory Group on the Food Chain and Animal and Plant Health on Article 241 studies

Online meeting, 19 May 2021

Chair: DG SANTE E3 (morning), DG SANTE G1 (afternoon)

Stakeholders:

AMFEP, Arche Noah, BEUC, CEFS, CELCAA, CEPM, CEO, CIBE, COCERAL, Copa, COGECA, CropLife Europe, EASAC, ECO-PB, ECPGR, ECVV, EFFAB, EFFCA, EFI/EURFORGEN, EFM, EFNA, ELO, ENA, ENGA, ENSSER, EPSO, EU-SAGE, EuroCommerce, EuropaBio, EUSTAFOR, European Federation of Biotechnology, Euroseeds, EFNA, ENA, ENSSER, EPSO, Eurocommerce, Euro Coop, Europatat, European Federation of Biotechnology, FEDIOL, FEFAC, FEFANA, FESASS, FIAN International, FSE, FoEE, FoodDrinkEurope, Food Supplements Europe, Freshfel Europe, Greenpeace, IFOAM Organics Europe, IG Saatgut, NATRUE AISBL, OIV, Plant ETP, POLLINIS, Slow Food, Testbiotech, UECEBV, Union Fleurs, UNISTOCK, VBN.

Others: DG JRC, EFSA

Deputy Director General Claire Bury (SANTE) welcomed the participants of the ad hoc stakeholder meeting recalling the request of the Council to the Commission to submit two studies under Article 241: one on the status of new genomic techniques (NGTs) under Union law (Council Decision (EU) 2019/1904) and one on plant reproductive material (PRM) legislation (Council Decision (EU) 2019/1905).

In relation to PRM, she highlighted that many things have changed since the earlier attempt to revise the legislation. Certain concerns that existed at that time are still very relevant today such as food security and biodiversity loss. Some concerns, though, have clearly grown in importance: climate change, which requires adaptation to it, the need to enhance the sustainability of agri-food chain taking into account the new political priorities of the Green Deal and the Farm to Fork Strategy. The Commission considers that action needs to be taken to address the concerns that were at the basis of the Article 241 request of the Member States and further confirmed by the PRM Study. She stated that the PRM Study also covers forest reproductive material. It is the starting point for the creation of new forests and the

reforestation of existing forests. She concluded by saying that stakeholders will have the opportunity to comment on the upcoming Inception Impact Assessment and the subsequent full Impact Assessment.

Regarding NGTs she explained that, based on the findings of the study, the Commission has announced a policy action on plants derived from certain new genomic techniques, as the Commission believes that such action is necessary to address shortcomings of the current situation and steer innovation to benefit society. This policy action will aim at a proportionate regulatory oversight, which would maintain a high level of protection of human and animal health and the environment and allow reaping benefits from innovation, in particular regarding the capacity to contribute to the European Green Deal and the farm to fork and biodiversity strategies. An impact assessment, including a public consultation, will be carried out in accordance with Better Regulation rules, to examine potential policy options. The impact assessment will also examine the concerns expressed about NGTs during the consultation on the study, and how they can be addressed. She stressed that the Commission is interested in all views on the results of the study and on the next steps.

New genomic techniques

The Commission (SANTE E3) presented the main finding and the conclusions of the study on NGTs, as well as the announced follow-up action. The JRC and EFSA presented their scientific contributions to the study, namely the technological and market landscape reviews and the overview of EFSA and MS authorities' safety opinions.

29 stakeholders took the floor expressing their views and asking questions on the study and on the follow up action. Overall, views diverged both on the conclusions of the study and on the intended next steps.

Several stakeholders (Testbiotech, FoEE, IG Saatgut, ENGA, SlowFood, BEUC, Greenpeace, CEO, ECO-PB, IFOAM, ENSSER, FIAN International, Pollinis) took the floor to express their criticism to the study. They considered that the study outcome was biased, captured by the interests of the industry, and lacking scientific basis, criticizing also the supporting scientific contributions from JRC and EFSA. These stakeholders reiterated concerns, which had also been reported in the study, that benefits of NGTs are hypothetical, and that these techniques do not contribute to the Green Deal and Farm to Fork/Biodiversity strategies, but, on the contrary, would create a threat for the business model of organic and GM-free sectors. They noted that, in their view, the existing legislation provides the necessary flexibility and that there is no need for change. They disagreed with most conclusions of the study and considered the planned policy action as a deregulation attempt, contrary to the ruling of the EU's Court of Justice, the precautionary principle, and to consumers' right to information.

Several other stakeholders (EU-SAGE, EFFCA, EFFAB, EFB, EASAC, AMFEP, Euroseeds, Coceral, Unistock, Copa, CEPM, Europabio, Croplife Europe, CEFS, FESASS, EPSO) welcomed the study and its conclusions and expressed the view that NGTs have the potential to contribute to a more sustainable food system and to provide much-needed tools to overcome challenges in the agri-food system. They welcomed the proposed policy action and called for the Commission to move forward urgently, expressing their willingness to contribute with data and information where needed. Some underlined that the goal should not be deregulation or lowering of standards, but risk assessment should be proportionate to risk

posed and the regulation should move from a process-based approach to a product-based approach. Some stakeholders asked the Commission to consider also microorganisms in the scope of the policy action and stated their interest to contribute to fill in the information gap on microorganisms as well as on animals.

Stakeholders' questions related to the scope of the announced policy action, the work on detection methods, how to ensure consumer's right for information, coexistence with organic farming, how to promote dialogue, how to achieve a proportionate framework also for other NGTs and for animals and micro-organisms and how would traceability work.

In its replies and closing remarks, the Commission highlighted that the study was based on available information and supported by robust technical contributions by the JRC, which is the Commission's science service, and the European Food Safety Authority. The Commission noted that all concerns raised during the meeting were clearly reported in the study and confirmed that they will be further addressed in the course of the upcoming impact assessment. The Commission clarified that policy options have not been decided yet and underlined the importance to maintain high safety standards. The Commission will continue to inform and discuss on the outcome of the study and the follow up action in the coming months. The publication of the inception impact assessment, planned for Q3 2021, would be the first formal opportunity to provide feedback through the public consultations,

Plant reproductive material

The purpose of the meeting was to receive comments of the stakeholders on the Study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material ('PRM Study'), which had been requested by the Council pursuant to Article 241 of TFEU.

The Commission introduced the PRM Study. While recognising that the present legislation led to a competitive PRM sector delivering high quality material for its users, the main findings of the study nevertheless indicate that the legislation needs to be amended in order to address the issues/problems identified in the practical implementation, by the Council and confirmed by the PRM Study. Modifying the existing legislation is also necessary to contribute better to the priorities of the EU Green Deal, the Farm to Fork, EU Climate Adaptation, European Digital and new EU Forest Strategies. The Commission outlined the different policy options and presented potential upcoming policy actions.

Stakeholders welcomed the presentation and an exchange took place.. Several stakeholders agreed with the importance of updating the current legislation to align it with other EU strategies and noted that it should be aligned with the organic legislation as well.

The Commission concluded the meeting by highlighting that it was now time to think about how to improve the current system, while pursuing new additional objectives. The Commission mentioned that the comments presented would be taken into account and might lead to refining or clarifying the options, and that intention is to ensure transparent process. The Commission informed that the next step is the Inception Impact Assessment and for which a public consultation will be launched around 10 June 2021 for four weeks.