DAY 1 – Biodiversity and Environmental Safety

Questions for **Yann Devos:**

Gabriele Lombardi: What is the position of EFSA towards the distinction between GMOs and CRISPR-engineered crops? Are the risks comparable?

Yann Devos: Risk managers are responsible for the regulatory oversight of GMOs and regulatory decisions about their commercial use in the EU, while EFSA is responsible for the prospective/pre-market risk assessment of GMOs

Overall, it is considered that existing approaches for the risk assessment of "contemporary" GM crops are comprehensive and adequate for "genome edited" crops. However, depending on the "genome edited" crop, EFSA's GMO Panel reported that there are specific aspects of the risk assessment that may require adjustment on a case-by-case basis

References:

- Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis (https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6299)
- Overview of EFSA and European national authorities' scientific opinions on the risk assessment of plants developed through New Genomic Techniques (https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6314)
- Evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology (https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6301)
- Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function (https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2012.2943)

Piotr Ogrodowczyk: It seems to me that the key element of the risk assessment is the "acceptable risk". How do you define it?

Yann Devos: The definition of harm (e.g. levels of acceptable risk) is subjective and rooted in societal values. Consequently, risk managers must interpret objectives of policy and regulations, so that they can be translated into specific/operational protection goals for risk assessment purposes. This provides a context and boundaries to frame risk assessments, and guides risk managers in making regulatory decisions that align with societal goals

Actively engaging society through stakeholders about social and cultural acceptability of the risk analysis process for GMOs is essential, and would contribute to improving quality, legitimacy and sustainability of regulatory decision-making processes

Pradeep Kumar: what is the toxic standard?

Yann Devos: In laboratory bioassays designed to evaluate the potential adverse effects of insect-resistant GM crops on non-target organisms, it is recommended to include positive control treatments, where feasible, to demonstrate that the test system is able to detect treatment effects. A positive control consists of a substance known to have a – typically – toxic effect

Reference:

- Recommendations for the design of laboratory studies on non-target arthropods for risk assessment of genetically engineered plants (https://link.springer.com/article/10.1007%2Fs11248-010-9446-x)

Questions for **Domenica Auteri:**

Marco Hatem Vaquero: Paracelsus concept “dose makes the poison” (referring to individual substances) is one the classic toxicology maxim. However, I think taking into account the “cocktail effect” should be a critical point too. So my question is, how is this effect being addressing in the studies in order to determine the Ld50 or NOED?

> **Domenica Auteri**: Within the Regulation 1107/2009, data on formulated product should be provided when the toxicity cannot be predicted by the active substance. This could be the case of plant protection products including more than one substance. When they are tested the toxicity endpoints are related to the mixture. If specific tests are not available toxicity can be predicted by assuming in general additive effect and/or also synergistic effect.
>
> Effects due the occurrence of several residues in pollen and nectar from different sources are not cover by the 1107. Their assessment would require risk assessment methodology for the estimate the combined/synergist effects and measured residue data for exposure estimation.

Joana Prata: Domenica Auteri, what are the endpoints measured in each tier for assays in bees?

> **Domenica Auteri**: Based on the OECD guidelines, at the lower tier level the following endpoints from lab studies are used: LD50 for acute contact oral toxicity, LDD50 for oral chronic toxicity, NOED for larvae.
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> In the higher tier studies the biological observations may varies e.g.: forager mortality, colony strength, fly activity, behavior, and brood development.

Pradeep Kumar: there are other pollinator insects as well, why do we focus primarily on bees? is there any other programme or research for the other pollinators as well?

> **Domenica Auteri**: EFSA has initiated a project to consider insect pollinator other than bees. The plan is to investigate if other key driver species are more vulnerable and sensitive to pesticides and propose a risk assessment methodology that cover those species.

Elena Zioga: My name is Elena Zioga and I am a PhD student at Trinity College Dublin. I would like to address my question to Domenica Auteri and Agnes Rortais after thanking them for their very informative presentations. I know that the PPP industry is obligated to perform similar risk assessment studies for bees. I was wondering, is EFSA able to have access and see not only the results but the whole process of these studies? Also, why isn't the outcome of these studies available to the public/academia? Thank you.

> **Domenica Auteri**: The studies are reported and evaluated in the DAR/RAR which are made publicly available when the EFSA Conclusion on a specific substance is finalized.
>
> EFSA has access to the original study reports and the raw data.

Following the implementation of new provisions of Food Law Regulation (called Transparency Regulation) since March 2021, dossier studies that will be declared admissible and once the confidentiality assessment will be finalized are publicly available in the dedicated website 'Open EFSA https://open.efsa.europa.eu/'

Questions for **Agnes Rortais:**

Anas Shaikh: Given the increasing advent of wireless sensors for agricultural monitoring, is there a possibility that the interaction of bees with the electromagnetic waves in the atmosphere due to such digital devices affect the health of bees? Are there any scientific studies on these aspects? Are there any regulations to address such problems for a trade-off between digitalization and biodiversity conservation? Thank you in anticipation!!

Agnès Rortais: I am not aware of any study showing such effects and any regulation on this. You may find further information by contacting and asking directly the developers of such devices (e.g. https://io-bee.eu/)

Questions for **Mara Thiene:**

Dorin Mateut: how it is possible to move from an "ideal" contribution for ecosystem services to a real payment for their maintenance.

Mara Thiene: real payment is for the conservation and optimal use of natural resources can be implemented via PES mechanisms, that is payment for ecosystem services. PES schemes allow for real market transactions. Rather than suggesting a specific paper, I would point out to the journal Ecosystem Services, see the link below, where several applications can be found as well as the description of the mechanism.

See also: https://www.sciencedirect.com/journal/ecosystem-services

Questions for **Federico Casolari:**

Kalliopi Geronymaki: Which actions foresees the EU Green Deal to protect biodiversity without contradicting existing financial allocations and especially subsidies to the farmers for the use of conventional farming methods?

Federico Casolari: According to the European Commission, "The Commission is addressing societal concerns regarding sustainability under the European Green Deal, and in particular under its "Farm to Fork" and Biodiversity strategies. These initiatives will promote healthy ecosystems and biodiversity, more sustainable food production systems and healthier diets while ensuring sustainable livelihoods for farmers and access to high quality and nutritious food for consumers. It is recognised that innovative techniques will be required to achieve these ambitions"[1].

More precisely, the Farm to Fork Strategy maintains as follows: "The use of chemical pesticides in agriculture contributes to soil, water and air pollution, biodiversity loss and can

[1] European Commission, Report from the Commission to the European Parliament and the Council on the experience gained by Member States on the implementation of national targets in their National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides, doc. COM(2020) 204 final, 20 May 2020, p. 3.

harm non-target plants, insects, birds, mammals and amphibians. The Commission has already established a Harmonised Risk Indicator to quantify the progress in reducing the risks linked to pesticides. This demonstrates a 20% decrease in risk from pesticide use in the past five years. The Commission will take additional action to reduce the overall use and risk of chemical pesticides by 50% and the use of more hazardous pesticides by 50% by 2030. To pave the way to alternatives and maintain farmers' incomes, the Commission will take a number of steps. It will revise the Sustainable Use of Pesticides Directive, enhance provisions on integrated pest management (IPM) and promote greater use of safe alternative ways of protecting harvests from pests and diseases. IPM will encourage the use of alternative control techniques, such as crop rotation and mechanical weeding, and will be one of the main tools in reducing the use of, and dependency on, chemical pesticides in general, and the use of more hazardous pesticides in particular. Agricultural practices that reduce the use of pesticides through the CAP will be of paramount importance and the Strategic Plans should reflect this transition and promote access to advice. The Commission will also facilitate the placing on the market of pesticides containing biological active substances and reinforce the environmental risk assessment of pesticides. It will act to reduce the length of the pesticide authorisation process by Member States. The Commission will also propose changes to the 2009 Regulation concerning statistics on pesticides to overcome data gaps and promote evidence-based policymaking."[2]

Against this background, on 25 June 2021, the European Parliament and the Council of the EU agreed on a reform of a Common Agricultural Policy (CAP) which should incorporates the objectives of the European Green Deal and the Farm to Fork Strategy as well. In particular, the new CAP will be built around nine objectives. Among these objectives, one is specifically devoted to Biodiversity and farmed landscape. Further info may be found at https://ec.europa.eu/info/sites/default/files/food-farming-fisheries/key_policies/documents/cap-specific-objectives-brief-6-biodiversity_en.pdf

Rossana Roila: the community strategy on the green deal and the farm to fork approach is clear: what must be the response (commitment/actions) of the individual member states to ensure effective application?

Federico Casolari: First of all, it is important to stress that the Green Deal and the Farm to Fork strategy are not able to impose upon Member States binding obligations. They represent, indeed, soft law documents elaborated by the European Commission to pave the way for a new supranational strategy. This said, the Draft Action plan annexed to the Farm to Fork Strategy defines a roadmap and lists measures to be adopted at supranational level. Among these actions we may find legislative initiatives, recommendations to Member States.

In order to ensure an effective application of the Strategy, Member States should properly implement the supranational measures adopted by EU institutions to put flesh on the bones of the Strategy itself.

[2] European Commission, A Farm to Fork Strategy, doc. COM(2020) 381 final, 20 May 2020.