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cc : Ana Afonso (Head of NIF Unit, EFSA)

Brussels, 17 June 2024

Subject: CROPLIFE EUROPE, COCERAL, FEDIOL and UNISTOCK's views on the recent discussions on Post-Market Environmental Monitoring (PMEM) plans for genetically modified crops

Dear Ms. Sacristán Sánchez,

With this letter, CropLife Europe, Coceral, Fediol and Unistock would like to follow up to the meeting held on 18 April 2024 with the European Commission and EFSA to discuss post-market environmental monitoring (PMEM) for GM food and feed imported into the EU.

We wish to provide additional and more detailed information about the implementation of the PMEM plan (see Annex attached).

In addition, the above-mentioned associations are open to organising a workshop to explain the details of the current PMEM practices to relevant stakeholders.

We remain at your disposal for any questions.

Yours sincerely,

Iliana Axiotiades	Corrado Finardi	Nathalie Lecocq
Secretary General Coceral/Unistock	Director Regulatory Affairs CropLife Europe	Director General Fediol

Annex I: The framework and implementation of the post-market environmental monitoring plan of GM plants for food and feed use and processing in the EU

Under current EU regulations[1,2], all applications for the import of GM plants for food and feed use and processing (i.e. GMOs or food/feed containing or consisting of GMOs) must be accompanied by a food and feed safety assessment, an environmental risk assessment (ERA)[3] and a post-market environmental monitoring plan[4].

The food and feed safety assessments follow the data requirements laid down in Implementing Regulation 503/2013, which are based on the EFSA guidance from 2011.[5] These assessments aim at evaluating the risks that the genetically modified food or feed may present for human and animal health. The ERAs (of GMOs or food and feed containing or consisting of GMOs) are conducted following the principles outlined in Directive 2001/18 and follow the EFSA guidance on Environmental Risk Assessment (ERA)[6]. The level and routes of environmental exposure to the GM plants shall be taken into account (e.g. in relation to the scope of the application: cultivation in the EU versus import and processing). Since the scope of these applications does not include the cultivation of the GM plant in the EU, the ERA on persistence and invasiveness is concerned mainly with the environmental consequences of accidental release of viable GM seeds or propagating material during import, transportation, storage, handling and processing. Therefore, the ERA needs to consider the scale of environmental exposure.

The conclusions of ERA are used to determine whether the GM plant in question could pose a specific risk to the environment, if imported into the EU. Based on the outcome of the environmental risk assessment, a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC is outlined (PMEM plan). If specific safety issues are identified, a case-specific (CS) post-market monitoring plan should be implemented. CS monitoring is hypothesis driven, and it focuses on those species or processes identified as risk. They are designed in a way to provide the best test to the specific risk hypothesis. If no specific safety issues are identified, and there is no specific risk hypothesis, the post-market environmental monitoring is limited to general surveillance (GS) to facilitate the detection of unanticipated adverse effects related to the authorised uses of the GM plant. The principle of GS is to monitor such unanticipated adverse effects by using existing networks handling and processing GM plants and its products. It is worth noting that GS is not intended to introduce mitigation measures to reduce exposure to the GM plants or to monitor the potential spillages. Instead, it focuses on unanticipated and unintended effects of GM plants through existing surveillance networks.

The current approach, followed by developers regarding ERAs and PMEM plans for applications for import of GM plants, follows the EFSA guidance. To date, none of the ERAs

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

[2] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

[3] EFSA Panel on Genetically Modified Organisms (GMO); Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 2010;8(11):1879. [111 pp.]. doi:10.2903/j.efsa.2010.1879. Available online: www.efsa.europa.eu/efsajournal.htm

[4] Scientific opinion - Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Panel on Genetically Modified Organisms (GMO) https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2011.2316

[5] Scientific opinion - Guidance for risk assessment of food and feed from genetically modified plants. EFSA Panel on Genetically Modified Organisms (GMO) https://doi.org/10.2903/j.efsa.2011.2150

[6] EFSA Panel on Genetically Modified Organisms (GMO); Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 2010;8(11):1879. [111 pp.]. doi:10.2903/j.efsa.2010.1879. Available online: www.efsa.europa.eu/efsajournal.htm

conducted for GM plants approved for import for food and feed use in the EU has identified any specific risks that required performing a CS PMEM. Therefore, the PMEMs are based on a GS approach. For such GS, according to the EFSA guidance on PMEM of GM plants regarding the GS:

- Applications concerning import and processing for food/feed uses (excluding cultivation) do not require scientific information on possible environmental effects associated with the cultivation of the GM plants.
- The extent of GS for these GM plants will depend on the level of environmental exposure, the protection goals and indicators selected.
- The import and processing of GM material for food & feed uses or for other uses can lead to environmental exposure, *e.g.,* by accidental release into the environment of viable GM seeds, and through manure and faeces from animals fed GM feed.
- In the ERA of imported GM products containing viable propagating material, the applicant must show that environmental release and exposure will be at levels or in a form that does not present a risk to other living organisms or the environment, taking into consideration that the scope of the application does not include the full environmental exposure associated with cultivation of the GM plants.
- Appropriate management systems should be in place to restrict environmental exposure, if a risk is identified.
- Applicants should submit a PMEM plan addressing relevant exposure pathways and should report using the standard reporting format for applications for import and processing on a yearly basis.[7]
- GS plans should include questionnaires to those involved in the handling and processing of the GM materials for food and feed and be designed to monitor whether unanticipated levels of loss, spillage and establishment are occurring and/or if there are any adverse environmental consequences.

Three main existing networks that could provide the necessary information for the purposes of this GS were identified: COCERAL, as the importers and traders of crops; UNISTOCK, as the storekeepers of agribulk commodities; and FEDIOL, the EU vegetable oil and protein meal industry. These networks represent most of the European operators importing, handling and processing viable crop commodities. Other networks consisting of operators further down the food and feed chain focus on processed, non-viable material. Since the GS for import applications focusses on monitoring the occurrence and potential unanticipated adverse effects of imports and processing of **viable material**, it was considered that it was not necessary to engage these other networks in GS.

COCERAL, UNISTOCK and FEDIOL are associations of companies that work closely together with a continuous and efficient flow of communication between them, particularly, through the documentation that needs to accompany any shipment containing GMOs in accordance with the labelling and traceability requirements of Regulation (EC) No 1830/2003 and are therefore best placed to observe and report any unanticipated adverse effects. These companies deal routinely with the handling, transport and processing of crop commodities, **GM and non-GM**, and operate according to managing and safety standards such as ISO and HACCP (Hazard Analysis of Critical Control Point). Under these standards, applying to both GM and non-GM products, they have routine procedures in place to limit losses and spillage of **viable plant material** and to routinely eradicate adventitious populations on their premises.

[7] 2009/770/EC: Commission Decision of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council

Recommendations of the EFSA CompERA Working Group on the PMEM plan

The EFSA CompERA Working Group has recently published on its own initiative a set of recommendations on the PMEM plans[8] prepared by applicants, requiring further details on the methodology used. To date, no specific risks have been identified in the ERAs conducted for GM plants intended for import into the EU and no products have required CS PMEM plans. This implies that Member States' comments and these EFSA's recommendations apply to GS. Developers are committed to provide all necessary information regarding their PMEM activities in order to facilitate the review of submitted information. However, developers are not involved in the importing, handling and processing of viable crop commodities. These activities are conducted by parties that deal with all commodities imported into the EU, which is the reason why collaboration with the main parties involved in these activities was requested to assist in the GS programme.

Accidental spillage of viable material is not an adverse environmental effect *per se*. In fact, the ERAs conducted to support import applications make a worst-case assumption that accidental spillage will occur, and they analyse the potential consequences that these spillages could have on the environment. In the context of GS, given the standard practices followed by operators, adventitious plants in their premises and/or during transport to the processing facility are eradicated, being GM or non-GM. It is of the responsibility of food and feed business operators to organise and operate their own quality control, management and safety standards for GM and non GM plants. The idea of a PMEM plan based on GS using existing networks is to have a mechanism to monitor unanticipated adverse effects, not foreseen in the ERA. GS is not meant to change the existing networks.

The EFSA CompERA working group recommendations suggest that applicants *"provide detail on the methodology proposed for the GS of PMEM plans by clearly stating the specific monitoring activities proposed and their expected outcome"*. Some examples have been provided. We would like to share views on each of the recommendations, in order to facilitate further discussion and a common understanding.

1. ***Example: Accidental release of viable GM material during import, handling, storage and processing.***
   - *Affected area(s) of concern: Persistence and invasiveness; vertical gene transfer.*
   - *Operational strategy: Modern systems for handling seeds.*
   - *Description of actions: Monitoring the handling areas to identify spilled seeds/grains; cover with protective systems storage/transport containers by various means; cleaning equipment/handling areas in event of spillage.*
   - *Expected outcome: Prevent accidental release of GM seeds/grains.*

Comments: EU operators in the food and feed chain have the obligation to implement good practices to ensure the safety of the products that are handled and to achieve the objectives laid down in the EU food and feed safety legislation. The supporting role of operators in the GS falls under their routine operations.

The operator has in place measures to eliminate spillage. In the context of accidental spillage of any seed/grains, the operator has to undertake adequate cleaning up measures. In order to keep the working environment clean and orderly, regular eradication of weeds and oilseeds

[8] Annex I. to the minutes of the 258th Comparative Analysis and Environmental Risk Assessment (CompERA) Working Group of 23-24 January 2024 – published on 2 February 2024 https://www.efsa.europa.eu/sites/default/files/2024-02/Compiled%20minutes%20CompERA%20WG.pdf

volunteers must also be undertaken. These general measures are implemented by operators within the routine general surveillance of the commodities they deal with, irrespective of their status (GM and non-GM). These pre-requisite measures are verified through the operator's internal and external audits (including certification). The specific measures employed by each operator may vary, as this depends on the way the mechanical transfer is performed, on the machineries used and the type of transportation, but in general, the operator has to routinely eradicate adventitious populations of any plants on its premises. Therefore, measures for eliminating spillage and preventing accidental release are already in place.

- *Operational strategy: Inspection of ports, storage and processing facilities for target feral plants.*
- *Description of actions: Indicate operators in charge of the inspections; ensure personnel carrying out the inspections receive adequate training to identify target species and have basic knowledge on their biology and trait identification.*
- *Expected outcome: To identify potential feral GM plants.*

Comments: Operators' current practices include the routine eradication of adventitious populations of any plants on its premises, irrespective of their status (GM and non-GM). These measures are not targeted, they apply to all plants. Therefore, there is no need for training specific to GM plants. The purpose of the monitoring is to follow standard procedures, and if there is an issue with control of volunteers resisting eradication, operators inform CLE and/or authorisation holder(s), describing the plant species and characteristics. Therefore, sufficient measures are already in place.

- *Operational strategy: Monitoring of target feral plants (in ports, and storage and transformation facilities)*
- *Description of actions: To report monitoring strategy including inspected places, frequency and recording methodology of the observations. The strategy should clearly define threshold values that would indicate critical changes in the dynamics of the target feral populations and trigger control.*
- *Expected outcome: To observe changes in dynamics and behaviours of feral plants in import, storage and processing facilities.*

Comments: Operators do not conduct specific monitoring of feral GM plants and there is no specific methodology, their objective is to maintain a clean working environment, avoiding spillages through their standard practices and eradicating adventitious plants of any kind. Therefore, there is no necessity to devise strategies for monitoring feral populations, establish thresholds or study their behaviour.

- *Operational strategy: Control of feral plants.*
- *Description of actions: In case a feral plant is identified during the inspection, or a threshold value is reached during monitoring, adventitious plants are removed mechanically or chemically; in case of chemical control, the choice of the herbicides must be specified and communicated beforehand; the chemical control should not be specific for any event but general in its mode of action.*
- *Expected outcome: Prevent spread of potential GM plants. Operational strategy: Literature search*

Comments: Considering the operators' current eradication practice, there is no need to consider threshold values, the presence of a plant will *de facto* trigger its eradication. In addition, developers provide information to operators on the types of herbicides that can be

used to chemically remove a feral plant of a given species that could be a GM plant. This information is made available through the CropLife Europe website[9].

- *Description of actions: Annual literature search not limited to the specific event but relevant for this route.*
- *Expected outcome: Identify relevant publications that might change the ERA conclusions (no CSM needed). For example: information on overwintering capacity of GM crops.*

Comments: The annual literature searches conducted by developers as part of their PMEM obligation for approved GM plants for import in the EU already cover these aspects in their search terms. In addition, overwintering capacity of GM crops is assessed during risk assessment.

2. ***Example: Considered route of exposure: Accidental release of non-viable GM material during import, handling, storage and processing.***

- *Affected area(s) of concern: Horizontal gene transfer (HGT); interactions with NTOs; effect on biogeochemical processes.*
- *Operational strategy: Modern systems for handling seeds*
- *Description of actions: Cleaning the handling area to facilitate identification of spilled seeds/grains; cover with protective systems the containers transported by various means; others.*
- *Expected outcome: Prevent accidental release.*

Comments: This example refers to the accidental release of **non-viable** GM material, but the operational strategy refers to seed handling, which is **viable** material. In any case, current processes followed by operators aim at keeping their premises clean to avoid contamination and ensure transport methods that prevent spillage during transport, if any. In addition, non-viable material is not within the scope of PMEM nor is part of the objectives of the GS[10].

- *Operational strategy: Literature search*
- *Description of actions: Annual literature search not limited to the specific event but relevant for this route.*
- *Expected outcome: Identify relevant publications that might change the ERA conclusions (no CSM needed). For example: information on the degradation of the NEPs in the soil.*

Comments: The annual literature searches conducted by developers as part of their PMEM obligation for approved GM plants for import in the EU already cover these aspects in their search terms.

3. ***Example: Considered route of exposure: Exposure to GM plant matter imported or obtained after processing (see Section XX describing the processing of the GM plant) released in the soil as fertilizer or amendment.***

- *Affected area(s) of concern: Horizontal gene transfer (HGT); interactions with NTOs; effect on biogeochemical processes.*

[9] https://croplifeeurope.eu/product-information/

[10] 2001/18, EFSA PMEM guidance

- *Expected outcome: Identify relevant publications that might change the ERA conclusions (no CSM needed). For example: new information on toxicity on soil NTOs.*

Comments: The annual literature searches conducted by developers as part of their PMEM obligation for approved GM plants for import in the EU already cover these aspects in their search terms.

4. ***Example: Considered route of exposure: Exposure to GM plant matter imported or obtained after processing released in the environment as waste material.***

    - *Affected area(s) of concern: Horizontal gene transfer (HGT); interactions with NTOs and effect on biogeochemical processes.*
    - *Operational strategy: Containment of the GM waste material before release into the wider environment.*
    - *Description of actions: Storage of the waste material after processing to reduce exposure to NTOs and microorganisms until DNA and proteins have been substantially degraded.*
    - *Expected outcome: Reduced amounts of rDNA and NEPs are released to the environment.*

Comments: It is unclear whether this route of exposure refers to viable GM material. As previously indicated, non-viable material is not within the scope of PMEM. We would like to note that there is no "GM plant waste" *per se.* All processing waste is treated in the same way for conventional plants and GM plants that have been approved for food and feed use, as they have been assessed and considered as safe as their conventional counterparts. Environmental concerns regarding plant waste release are not unique to GM plants. There are recommendations under Good Agricultural Practices and the EU food law for the safe disposal of processing or plant material waste, including guidance on containment periods. For most of the newly expressed proteins (NEPs) in GM crops approved for import into the EU, the ERAs conducted show that the extremely low levels of expression of these proteins in GM plants will result in very low levels of exposure as a result of imports. This and the lack of hazard make a strong case to conclude that the risk to humans, animals and the environment will be negligible (risk is a function of hazard and exposure). If the processing involves any kind of heat or chemical treatment or digestion, there may be further degradation and even lower exposure. Therefore, these measures would be excessive in most cases and only appropriate if a risk was identified and they were considered important for risk management strategies. In addition, the processing of oilseeds has no waste, as every stream is used. If there is accidental spillage, the collected agricultural commodity volumes are sold to bio-gas companies or burnt.

- *Operational strategy: Literature search*
- *Description of actions: Annual literature search not limited to the specific event but relevant for this route.*
- *Expected outcome: Identify relevant publications that might change the ERA conclusions (no CSM needed). For example: new information on toxicity on soil NTOs.*

Comments: The annual literature searches conducted by developers as part of their PMEM obligation for approved GM plants for import in the EU already cover these aspects in their search terms.

5. ***Example 5: Considered route of exposure: Consumption of GM material as feed***

   a. ***Scenario 1***

- *Sub-route of exposure: Accidental release of GM material*
- *Affected area(s) of concern: Interactions with NTOs; effect on biogeochemical processes.*
- *Operational strategy: To provide the right amount of feed; to put in place containment systems to avoid consumption by NTOs.*
- *Description of actions: To provide training to farmers on the use of modern feeding systems to prevent release of uneaten feed, as well as the use of modern cages and storing facilities and the repair of broken ones.*
- *Expected outcome: reduction in the amount of uneaten GM feed that is released into the wider environment and becomes available to NTOs.*

Comments: It is unclear whether this route of exposure refers to viable GM material intended as animal feed that is not consumed and released into the environment. As previously indicated, non-viable material is not within the scope of PMEM.
Providing the right amount of feed, containment of and training farmers on feeding systems are activities over which developers have no authority. In the EU, there are guidelines and recommendations for farmers in terms of feed and management of farm waste. These apply to GM and non-GM material and aim at reducing the probability of releasing plant pathogens into the environment. Since there is no specific import channel for GM only imports, the guidance applies to all feed.
It is also unclear what NTOs would be considered at risk through this route of exposure. NTOs that feed on stored animal feed would be considered pests and therefore would not be part of the protection goals considered in ERAs.

   b. ***Scenario 2***

- *Sub-route of exposure: Exposure of microorganisms in the gastrointestinal tract of animals fed GM feed.*
- *Affected area(s) of concern: Horizontal gene transfer (HGT).*
- *Expected outcome: Identify relevant publications that might change relevant elements that were used to conclude that no CSM was needed. For example: evidence that DNA is not degraded in the GIT.*

Comments: The annual literature searches conducted by developers as part of their PMEM obligation for approved GM plants for import in the EU already cover most of these aspects in their search terms.

   c. ***Scenario 3***

- *Sub-route of exposure: Exposure of microorganisms in the environment to faeces of animals fed GM feed.*
- *Affected area(s) of concern: Horizontal gene transfer (HGT); effect on biogeochemical processes.*
- *Operational strategy: Literature search*
- *Description of actions: Annual literature search not limited to the specific event but relevant for this route.*
- *Expected outcome: Identify relevant publications that might change relevant elements that were used to conclude that no CSM was needed. For example: evidence that DNA is not degraded in the GIT.*

Comments: This route of exposure is considered in the ERAs conducted for applications for import approval. In addition, the literature searches conducted by developers as part of their PMEM obligation for GM plants for import in the EU already cover most of these aspects in their search terms.

To conclude, the outcome of PMEM activities has confirmed that the environmental risks assessments supporting applications for the import and food and feed uses of GM plants have adequately assessed potential environmental risks after more than two decades of experience with GM crops. To date, no adverse effect has been observed for any of the GM products approved for import and processing, in line with the published PMEM reports submitted by authorisation holders on an annual basis. The recommendations provided by the EFSA CompERA WG addressing viable material have already been put in place and only viable material is relevant for the scope of PMEM plans of GM plants. Based on the above, CropLife Europe, COCERAL, FEDIOL and UNISTOCK, consider the current framework for monitoring as fit for purpose.