Post-Market Environmental Monitoring (PMEM) for food/feed import authorisations

18 April 2023

EFSA *ad hoc* meeting with GM applicants

Introduction

- Authorisation holders shall ensure that a monitoring plan for environmental effects, as set out in the respective authorisation decisions, is put in place and implemented for all GM crops once they are authorised.
- The authorisation holders shall submit to the European Commission annual reports on the implementation and on the results of the activities set out in the monitoring plan.

PMEM plans

- All PMEM plans consider general surveillance (GS) activities. Only in case specific risks would be identified in the Environmental Risk Assessment (ERA), case-specific environmental monitoring is considered necessary.
- The monitoring plan includes GS and is in line with the intended uses of the authorised GM products.
- GS for unanticipated adverse effects is not based on specific hypothesis (not case specific monitoring).

General surveillance

- GS is a harmonised monitoring system set up by authorisation holders and operators handling and using viable GM products.
- The harmonised approach has been agreed by the European Commission.
- This approach facilitates the systematic reporting of potential unanticipated adverse effects of GMOs, if any.

Interplay between ERA and PMEM

- Accidental spillage and its potential consequences are events considered during the ERAs conducted to support import applications
  - More specifically, numerous ERAs conducted by EFSA on GM oilseed rape (OSR) products and have concluded that there are no indications of an increased likelihood of spread and establishment of feral OSR plants in the event of the accidental release into the environment of viable GM OSR seeds during transport and/or processing
- Accidental spillage **is not considered an adverse effect as such**

PMEM: Operators' role

- Operators implement GS in the framework of their management or safety standards.
- Operators have procedures in place to limit losses and spillage of viable seeds/grain and they routinely eradicate adventitious populations on their premises.
- By undertaking such eradication/containment measures, operators are able to report any effect that would be considered as unanticipated and potentially attributable to GMOs.

Conclusions

- The current harmonised PMEM plans for GM products are fit-for-purpose, adequate and comply with legislative requirements.
- The joint collaboration of the authorisation holders and the relevant operators is effective and fulfills the commitments in the PMEM plans.
- Accidental spillage has no impact on the validity and implementation of the PMEM plans and does not constitute in itself an adverse effect.
- To date, **no unanticipated or adverse effects have been observed** for any of the GM products approved for import and processing in the EU.