FER-PLAY EVENT

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Challenges of the application of FPR from Notified Bodies' point of view

Challanges in general - Awarness

- Awarness about the Regulation (FPR) is still relatively low among new applicants. Readiness for module D1 of first applicants is still challanging.
- FAQ is better known than the regulation itself which leads to misinterpretation sometimes.

Challanges in general - Manufacturer

The legal manufacturer, who is indicated on the label as manufacturer.

„‘manufacturer’ means any natural or legal person who manufactures an EU fertilising product or has an EU fertilising product designed or manufactured, and markets that EU fertilising product under his or her name or trademark”

Challanges in general – Technical documentaton

- Incomplete technical documentation is still a problem, but situation improved a lot and for returning customers and those who were helped by consultation companies, the technical documentations are better quality.
- Improved situation with the categorisation of PFCs and CMCs, but it still happens that manufacturers categorise their products into incorrect PFC or CMC.

Challanges in general - REACH

- We experience a lot of imrpovement and manufacturers now tend to apply for certification only when they already have REACH registrations
- Still a challange to comply with the FPR requirements in addition to REACH (e.g.: <1t, Chelates, Colorants, additives).

Challanges in general - Labelling

- Claims without proof
- Biostimulant claims for PFC 1
- Pesticide claims

Challanges - Biostimulants

- Apply for module B or D1, but no trial reports are available or not complete.
- Wait for the trials before applying.
- We carry out a quick pre-evaluation and process is not started before all trial reports are available.
- Improved awarness about non-listed micro organisms.

Module D1

Quality assurance of the production process whereby the manufacturer fulfils certain obligations and declares on his or her sole responsibility that the EU fertilising products concerned satisfy the requirements of the FPR.

When Module D1 is applicable?

It can be applied for any EU fertilising product, except ammonium nitrate fertiliser of high nitrogen content.

Mandatory or an opportunity?

Who should apply for Module D1?

The legal manufacturer, who is indicated on the label as manufacturer.

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Main parts of Module D1 procedure

Preparation time:

- technical documentation (reviewed by the nobo)
- set up a quality management system (if it was not used before)
- check if the FPR’s requirements are implemented in the qm system (education of the FPR, analytical criteria etc.)

Main parts of Module D1 procedure II.

The on-site audit:
- organising the audit
- on-site audit

Follow-up:
- Corrective actions (if there was any non-conformity) – reviewed by the nobo
- The certificate can be issued
- Audit / sampling / testing of CMC 3,5,12-15

The most common challenges since 2022

Several economic operators in the supply chain

- Manufacturer(s) by the law
- Physical manufacturer(s)
- Producer(s) of the supplied CMC 3,5,12,13,14,15 materials
- Importers / distributors

More locations

- More locations for the EU fertilising products

- locations of the suppliers of Module D1 obligated materials (CMC 3,5,12,13,14,15)
- Sometimes parts of the requirements are fulfilled by the manufacturer and not the supplier (e.g. internal audit / FPR related trainings / testing).
- Monitoring and organising the frequent sampling, testing and audit is a significant challange.

Contractual dificulties between suppliers and legal manufacturers

- Somtimes the suppliers of CMC 3,5,12-15 do not want to let the Notified Bodies in their facilities upon the manfuacturer’s request. In such case the module D1 audit cannot be fulfilled.
- Sometimes the flow of information is not totally open between the suppliers and the manufacturer due to business related issues.
- Sometimes the supplier and manufacturer cannot agree who shall obtain the certificate as manufacturer.

Technical documentation

- REACH registration
- analytical results (requirements from Annex I, II, III)
- sampling and testing criteria for CMC 3,5,12,13,14,15
-suitable laboratories

Thank you for your attention

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