Commission expert group on fertilising products
Meeting of 15-16 April 2024
Item 4.6 on the agenda

Note
of the Coordination group of Notified Bodies
Proposals for the conformity assessment according to module D1 for fertilising products containing CMC3 and CMC5

We propose to differentiate between the conformity Assessment on PFC and CMC level. According to FPR, the following activities are required:

a) At PFC-level (Annex IV):

- The PFC production site shall **be conformity assessed by a Notified Body**.
- **PFC-Audit** of the manufacturer: all aspects of Module D1, explained in the Document issued by the NB Coordination Group ("Guideline for the practical application of the conformity assessment procedures (modules A1, B, D1) according to Part II of Annex IV of the (EU) 2019/1009 Regulation)
- **Sampling** of PFC-production behalf of the manufacturer under its quality management system, Notified Bodies may take additional samples during the audit.
- **Analysis** of PFC-product on the applicable requirements of the EU FPR (by or on behalf of the manufacturer, Notified Bodies may take additional samples and have them tested)

b) At CMC-level (Annex II and Annex IV of FPR):

- The CMC production site (e. g. compost, digestate, STRUBIAS materials) shall be conformity assessed by a third-party organisation (e.g.: a **quality assurance organisation recognised under a European Quality Assurance Scheme** (e. g. ECN-QAS) or a Notified Body)
- **Sampling of compost/digestate** (frequency Table in Annex IV – paragraph 5.1.3.1. (f)) by acknowledged, third-party sample taker
- **Analysis** of CMC materials (e. g. compost, digestate) on the applicable requirements of the EU FPR by accredited third party laboratories
- The overall CMC-site audit shall take place once a year. According to Annex IV this **CMC-audit** shall include:
    - Elements from paragraph 5 that are related to the CMC (e.g. compost, digestate, STRUBIAS material) production (quality system, resources and personnel, input materials, procedure for non-conform batches, corrective actions management, calibration of thermometers for time/temperature control, internal audits, management review, …)

- The final CMC-documentation~~certificate~~ of conformity issued according to a European Quality Assurance Scheme (e. g. ECN-QAS) will be accepted as complete CMC control (including samples, analyses, control if input materials and time/temperature schemes and annual CMC-production site audit) as part of the PFC requirements audited by the NB.
    - Technical documentation ~~and assessment of the risks~~ is fully included in the documentation ~~Certificate~~ of conformity that is issued for the CMC production site (e. g. compost, digestate, STRUBIAS production sites).
- This proposal can also offer a solution in the cases
    - where the mixing of different quality assured component materials produced in different locations (CMC plants) leads to a PFC product (and for which a separate risk assessment is needed).
    - where a CMC producer delivers to several different PFC production sites (which might be conformity assessed by different NB) with the same CMC material.

Final integration of the CMC documentation ~~certification~~ in the certification procedure of the PFC

The NB can make use of this CMC documentation ~~certificate~~ of conformity based on a European Quality Assurance Scheme (e.g. ECN-QAS) for the specific CMC materials (e.g. compost, digestate, struvite, biochar) ~~or digestate materials~~ covered by documentation~~the certificate~~ of conformity. For the final conformity assessment of the PFC-product, the CMC documentation ~~Certificate~~ of conformity, together with the audit reports (sampling and analytical reports of the component material including the audit report of the CMC production site) can be forwarded to the NB who makes the final conformity assessment of the PFC.

Advantages

If the National Quality Assurance Organisations (NQAOs) recognised under an European Quality Assurance Scheme (e.g. ECN-QAS) would carry out the conformity assessment at CMC level, NB and manufactures will take advantage of many benefits:

- NQAOs are already managing compost and digestate sampling (acknowledged, third-party sample taker) and testing (accredited laboratories) with a frequency like that of FPR.
- NQAOs have been dealing with biowaste recycling and quality compost and digestate production for three decades, so they can guarantee a high level of technical experience in preforming CMC-audits and checking the analytical results.
- The European Quality Assurance Scheme 'ECN-QAS' is built to verify the process and the quality of the final product (compost and digestate), therefore NQAO already collect and check a lot of information about the whole process (e. g. process stages and monitored parameters) and the final products (e. g. heavy metals, salmonella) of the manufactures that have obtained a documentation ~~Certificate~~ of conformity.
- A lot of manufacturers are already involved in ECN-QAS, so NQAOs can have a key role in promoting the transition from a National Regulation towards the European FPR.

- This proposal involves NQAOs in the conformity assessment at CMC level for CMC3 and CMC5 and can be easily adapted and applied for other CMC's such as CMC12, CMC13, CMC14, and CMC15 as well.

In this case the manufacturer/producer/NQAO of CMC still has to prove that the required sampling and testing of the CMC is carried out. Sampling and analysis ~~-~~may be carried out in their inhouse laboratory (1st party), but the minimum required sampling and testing frequency according to 5.1.3.1. (f) must be carried out by or on behalf of a third-party. In this case the only change is that instead of a Notified Body, a third-party organisation is allowed to carry out the task still under the umbrella of a NB (this third-party may include a Notified Body as well, but opens the possibility for National Quality Assurance Organisations (NQAOs) recognised under a European Quality Assurance Scheme (e.g. ECN-QAS) and for laboratories for instance). The proof of this third-party conformity assessment can be delivered as a documentation ~~certificate~~ of conformity of the CMC-material.

Change proposal in the Regulation:

	Current rules	Changes proposed
1.	6.3.2. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, the notified body shall take and analyse output material samples during each audit, and those audits shall be carried out with the following frequency: (a) during the notified body's first year of surveillance of the plant in question: the same frequency as the sampling frequency indicated in the tables included in points 5.1.3.1(f)and, respectively, 5.1.3.1(fa); and (b) during the following years of surveillance: half the sampling frequency indicated in the table included in point 5.1.3.1(f) and, respectively, 5.1.3.1(fa).	6.3.2. For materials belonging to CMCs 3, 5, 12, 13, 14 and 15, as defined in Annex II, a third-party organisation (preferably accredited) shall take and analyse output material samples and inspects the requirements set out in 5.1.3.1 e) ~~and 5.1.4.1~~, with the following frequency: (a) during the ~~notified body's~~ first year of surveillance of the plant in question: the same frequency as the sampling frequency indicated in the tables included in points 5.1.3.1(f) and, respectively, 5.1.3.1(fa); and (b) during the following years of surveillance: half the sampling frequency indicated in the table included in point 5.1.3.1(f) and, respectively, 5.1.3.1(fa). An ~~general~~ audit on CMC according to the requirements set out in paragraph 5 shall be carried out annually by a third-party organisation (preferably accredited). A general audit on PFC according to the requirements set out in paragraph 6 shall be carried out annually by a notified body.