Industrieverband Agrar

EFCI
NANDO 2832

Presentation

Getting your biostimulant FPR 2019/1009 certified

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By Giel Tettelaar, Chairman EFCI Register
info@fertilizer-certification.eu
+31 (0) 6 28724490

FPR 2019/1009

- Harmonises market for EU Fertilising Products
- Optional
- Does not replace national rules
- PFC's & CMC's.
- 'Modules' for certification
  - Module B+C – Design assessment
  - Module D1 – Management system
- Module B is ideal for Biostimulant manufacturers.
- CMC 3, 5, 12,13,14 & 15 require Module D1
- First time a framework for Biostimulants is defined
- Notified Bodies are required for Biostimulants.
- CE Marking

Certification, registration, what?

- ‘Notified Bodies’ are the new registration authorities.
- Notified Bodies are private, you can choose your Notified Body.
- Pragmatic approach, Notified Bodies are approachable and answer your questions.
- You submit a dossier to the Notified Body, once approved you get an FPR certificate. Simple.
- 1 certificate is sufficient for the entire EU, valid for 3-5 years.
- Module chosen makes no difference for acceptance
- Market surveillance is part of FPR
- Changes to a product must be reported
- Large responsibility for manufacturer

What's the catch?

- **There is no catch, certification is straight to the point:**
- Lab analyses for nutrients, contaminants & pathogens
- Dossier per ingredient used (CMC)
- Label example
- Details on manufacturing process
- Claims:
  - Define them
  - Prove them (field trials, literature, other evidence)
- Timeline: few weeks (2-4) to process the paperwork
- Certification costs = EUR 2000 to EUR 3500 ex testing + field trials.
- 5 year expiry date
- EFCI = No renewal fees unless product changes or underlying standards change
- That's essentially it!

Certification process: An EFCI Register example

- Step 1:
  - Initial Teams call (optional)
  - Formal offer for a fixed price
  - Application and signing of a contract
- Step 2:
  - Submission of initial documents (email, free format)
  - Non-conformity list (if applicable)
  - Submission of resolution documents
- Step 3:
  - Review of documents
  - Administrative handling
  - Certificate
- **Notes:**
- You decide the timeline, can take as long as it takes
- Auditor will assess documents and issue a report.
- Non-conformities are not a problem.

FAQ's

- Do I have to do field trials?
- Is there a standard for field trials (CEN/TS 17700)?
- Can you review our field trial design before we start?
- What do I have to do for the risk assessment?
- What if I use a micro-organism not on the CMC 7 list?
- When can I start CMC 10 products?
- Do you do the analyses if I already have a test report?
- Can I use German national methods for analyes?
- Can I add a claim later based on new field trial reports?
- Can I change desired claims during or after the certification process?
- Do Notified Bodies face a backlog or delays?
- Fulfilling your FPR obligations as a dealer: who does receive technical documentation?

- Any others? Please ask!

Questions and next steps?

Get in touch later using info@fertilizer-certification.eu or call me directly at +31 (0) 6 28722490.

No obligations - if you just have questions please reach out!

Want to learn more? We always setup an introductory Teams call to discuss your specific situation and come up with a plan of action for certification.