EU – Registrant Perspective

MAY 27, 2020

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Topics

I. Process for a registrant going thru EU Renewal Process – Cindy
II. Options for a registrant when a product is not renewed in the EU –Michelle
III. Responding to questions from Foreign Ag Service (FAS) and growers- Heidi
IV. Open up for questions from the audience for the panel

I. Process for registrants facing renewal in the EU

- Commercial assessment – is it still a commercially viable product in the EU?
- Data requirement assessment – new data requirements, gaps in data
- Does the registrant own the active ingredient globally or is it owned by a commercial partner?
- Assessment of likelihood of success
  - Cut Off Criteria?
  - Other Human Health Concerns?
  - Environmental Concerns – Persistence? Leaching? Impact on non-targets?
- If can't justify submission for renewal process – can MRLs be converted to Import MRLs
- Internal and external communication

II. When a product is not renewed in the EU

- Reason for non-renewal
  - Environmental
  - Human Health
- Origin of existing MRLs
  - Codex / IT or EU use
- Other options
  - Codex Harmonization
  - Evaluation of export risk
    - Residue definition
    - Exporting region GAP
- Complex and very specific to active ingredient and crop

III. Providing Growers and USDA with Information

USDA –

- Requests for comments on WTO Notifications and Article 12 Reviews
  - What is Article 12?
- Are proposed MRLs going to impact trade?
  - How the US tolerance was established and why it may or may not be an issue exporting to EU
- Is there data to support higher MRL?
- Does registrant have insight into the status of the MRLs/ITs for the active ingredient?
- Any information that can be used to encourage harmonization?

III. Providing Growers and USDA with Information (continued)

Growers –

- Support –
  - who is the registrant? Who to contact that can provide insight?
  - Registrant and grower information
- Are proposed MRLs going to impact trade?
  - History of US tolerance compared to EU MRL
  - Residue information
- DFUs –
  - Used to establish MRLs versus labeled rates
- Timing – when can US growers expect lower MRLs to go into effect?

III. Providing Growers and USDA with Information (continued)

Process -

- Registrant responses are often a collaboration of many internal experts
  - US product experts here and abroad assessing data
  - Commercial insights
  - US usage and trade impact
- Everyone wants to avoid risk and speculation – so what can we say?
- Expectations:
  - Clarity – what we know right now
  - Data – what we have; GLP data, non-GLP data
  - Insight