Ad-hoc meeting with stakeholders' representatives

Concluding remarks

Brussels, 19 June 2019

efsa
European Food Safety Authority

Guidance on Renewals

Guidance on Renewal

‘Confirm whether the product complies with the conditions of the existing authorisation’

Why there is the need to update it?

- Administrative (reference to new guidances)
- Practical aspects learned by doing renewal assessments
- Consideration on the impact of the new guidances on some aspects of the renewal

Guidance on Renewal

Section II – applies in full, where possible indicate what has been modified and the likely impact on the characteristics and safety of the additive.

Practical aspects for applicants, for instance considerations on the requirements for batches to be analysed within the timelines specified.

Characterisation of microorganisms and fermentation products – Requirements of the new guidance apply in full.

Guidance on Renewal

Section II – microorganisms

Change in the taxonomic classification – From a QPS to a non QPS. This may require addressing safety aspects that were not previously addressed.

Species not considered in the QPS list – processed upon receipt of the dossier.

Guidance on Renewal

Section III – Safety for the target species

(Impact on the new guidances - data requirements)

Predictability for new requirements to be addressed by the applicants: when, how, what? Difficult to cover all possible cases in a guidance

When there is the need to address safety aspects for species that were not previously considered. The safety may not be addressed only with tests with animals. Make use of alterative ways, use of data available where possible, public literature…

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Section III – Consumer

Introduction of the FACE model – best consumption estimate for Europe, new categories of consumers.

EFSA's new developments in the requirements on how to address genotoxicity may have an impact on the renewals and should be considered in the renewal guidance.

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Section III - User Safety

User safety needs to be fully addressed in all cases. Make use of available data, however there is the need to consider the nature/composition of the additive that is in the market.

Section III – Environment

The new guidance introduced modifications on the calculations and factors – need to redo the calculations in the renewal application.

Guidance on Renewal

Other topics:

- Literature searches, better guidance on how to conduct them also considering the substance under assessment.

- Substances that were re-evaluated within a consortium dossiers may be received separated in the renewal exercise. This may deserve consideration on how to process them.

- Impact of the refit of Regulation (EC) No 178/2002 on EFSA's work – EFSA is currently evaluating how to tackle the changes.

Open Plenary meeting and Info-session

Next meetings with stakeholders

Open Plenary meeting November 14 (AM): Guidance on renewals

Ideas :

- Overview on status of the re-evaluation process,
- Experience with renewal assessments,
- Data protection and use of data from other applicants – practical aspects

Next meetings with stakeholders

Info-session on 14 (PM) – 15 (AM): Open discussion with stakeholders regarding some of guidance documents: microbial characterisation, environmental risk assessment and efficacy.

Ideas:

- Assessment of microorganisms
- FACE and the dataset that is expected
- Mixtures of chemicals
- Update on the user safety assessment

- Alignment between food and feed

Thank you!

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