Statement establishing a need to update FEEDAP Guidance Documents

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MANDATE

To identify those guidance documents that need to be updated, taking into consideration scientific developments and the experience gained in the assessment of feed additives.

Are the current Guidance documents fit-for-purpose?

Rules are for the guidance of wise men and the obedience of fools.

Substitute "Applicants" and "the Panel" as you think appropriate


The FEEDAP Panel has developed
20 Guidance documents
with one further document (GMM)
in preparation

GUIDANCE DOCUMENTS

At present guidance is organised as:

- **5 "vertical" documents each covering one category of additive**

- **14 "horizontal" documents each dealing with specific aspects relevant to one or more categories of additive**

FEEDAP PANEL'S GUIDANCE DOCUMENTS

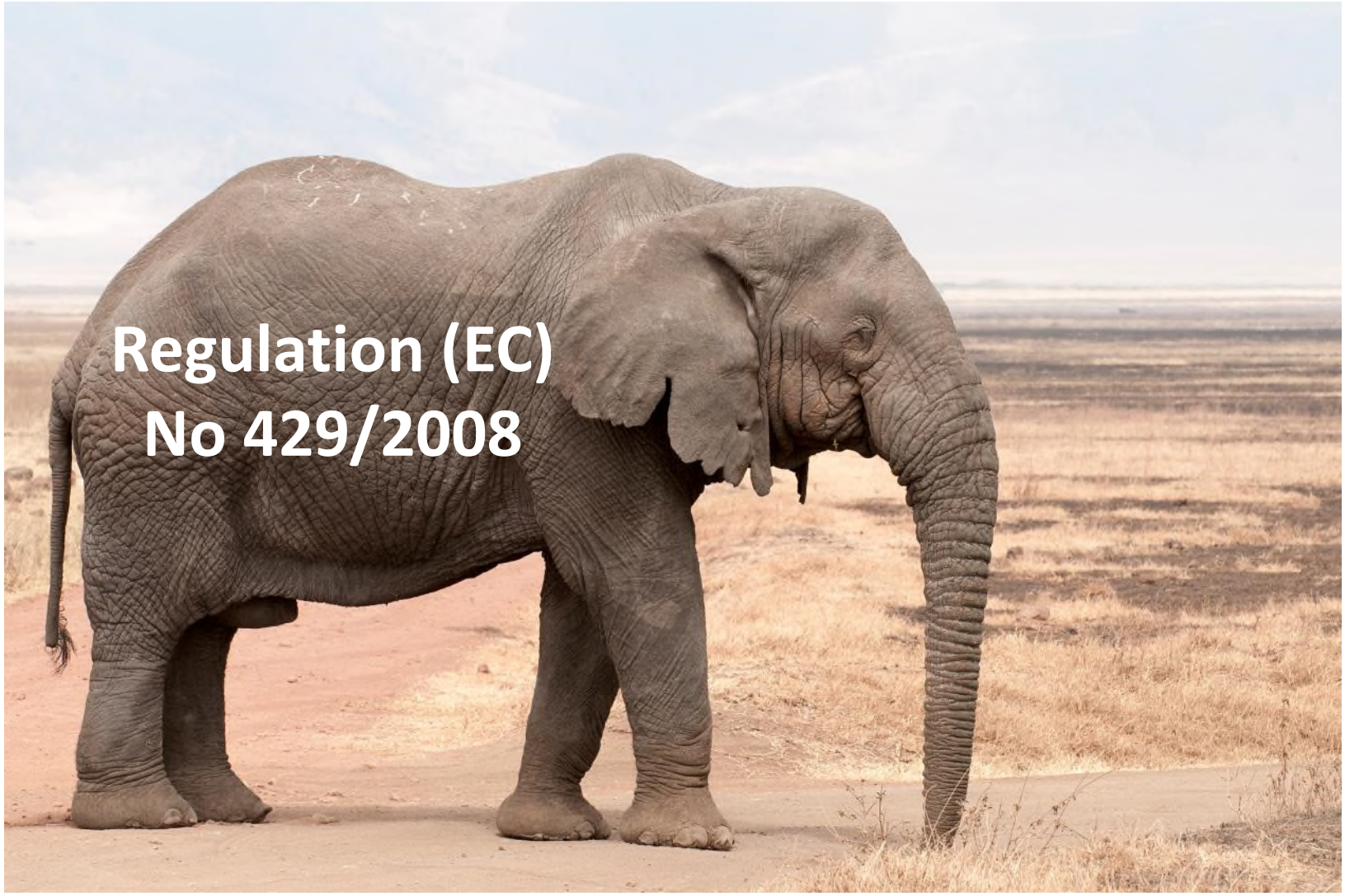
Vertical
Technological
Sensory
Nutritional
Zootechnical
Coccidiostats
Biomasses

Horizontal	
Tolerance & efficacy	Minor Species
Consumer	Pets & non food-producing animals
User	Food to feed
Environment	Re-evaluation
Microbial studies	Renewal
Compatibility	*Bacillus*
Antimicrobial resistance	*Enterococcus*

Is the present organisation user-friendly or could it be improved?

- **Several changes have been proposed:**
  - Remove the 5 vertical guidance documents and introduce a new guidance covering only Section II
  - Split current Technical Guidance on tolerance and efficacy in target animals
  - Consolidate 5 (6?) existing guidance documents relating to microbial products

WE NEED YOUR VIEWS


Regulation (EC)
No 429/2008

Three principle elements were found to drive a need to revise many of the existing documents:

1. Parts of the existing guidance documents were developed before the re-evaluation and/or before the submission of actual dossiers (e.g. most technological additives, sensory additives) with requirements set that proved not appropriate or useful
2. Novelty in additive design introducing products with properties not considered when developing guidance
3. Introduction of new or modified assessment methodologies from within EFSA or from other recognised bodies (e.g. OECD, ECHA, EMA).

Issues which could benefit from review and possible revision were identified in virtually all of the existing guidance documents. Some questions of general significance were:

- Is the present guidance on environmental risk assessment fit for purpose?
- What should be the data requirements for additives not linked to a holder of authorisation?
- Is the approach taken for assessing the safety microbial additives or products of microbial origin consistent and appropriate?
- Is the present approach to target animal safety appropriate or could the number and type of studies be reduced?

Guidance on Environmental Risk Assessment

ENVIRONMENTAL RISK ASSESSMENT

This Guidance document was given the first priority for a number of technical reasons and because it is not consistent with other approaches used within EFSA and by other bodies.
Among the issues identified were:

1. The need to harmonise approaches with other frameworks considering the environmental impact of chemicals (REACH, PPP, Biocides and VMPs).
2. The protection goals should be clearly defined: What ecosystems are we protecting? What communities?
3. Phase I should be revised. The decision tree should distinguish between high-risk (coccidiostats, heavy metals) and low-risk substances (substances of natural origin)

ENVIRONMENTAL RISK ASSESSMENT

4. RA for groundwater (GW) should be redefined. GW should be protected as an ecosystem and as a source of drinking water.
5. Metabolism of substances should be taken into consideration,
6. An exposure model of feed additives in aquaculture should be included in the guidance
7. The use of "in silico" methods should be reviewed. Additional guidance on deriving data by such methods should be provided.
8. Guidance on required ecotoxicological tests should be revised and additional information provided.

GENERICS!

In the absence of a specific formulation is there any point in collecting data on:

- Potential contaminants,
- Physical properties such as bulk density, particle size/dusting potential,
- Data on User Safety, other than any potential for systemic toxicity?

Who establishes how generic is a generic? – How do you base a safety assessment of additives with a natural variation using data from a single example?

MICROBIAL PRODUCTS

1. **Need for a consistency of approach (e.g. products from GMM v non-GMM)**
2. **What is the need/relevance of toxicological studies for fermentation products when considering micro-organisms of known lineage and the purification steps taken in production?**
3. **Is there a need to review the battery of antibiotics used to assess the resistome? Should the emphasis remain on phenotype or should more consideration be given to genomic data.**

TARGET ANIMAL SAFETY (1)

- **Target animal safety is increasingly being derived from laboratory animal studies. Should this continue and are the end points measured the most appropriate for this purpose?**
- **Should a comparison of human and animal exposure for additives used in food be used to derive target animal safety? Experience has shown that this is of little practical value.**

TARGET ANIMAL SAFETY (2)

- **Do the current default values reflect current European production practices and progress in breeding?**
- **What is the most appropriate set of studies which would allow extrapolation to all animal species?**
- **Should the statistical analysis of tolerance data be based, in part at least, on tests of equivalence rather than difference?**

With the exception of the guidance for environmental risk assessment, no work on the revision of guidance documents has started

We, the Panel and the Unit, have ideas for change but -

ultimately, our Guidance documents are intended to aid the preparation of your dossiers and we NEED your input on both organisation and content