Amendment of Regulation (EC) No 429/2008: some proposals

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Scope of the amendment

As a result of scientific and legal development or from previous experiences

***Confidentiality**: improvement of procedure*

- ***Annex I**: administrative revision*
- ***Annex II**: identity of the additive, analytical method.*
- ***Annex III**: alignment to the new functional groups; user safety, revision of rules of Article 14, Article 10, Article 13; extrapolation.*
- ***Anne IV**: revision of animal species*

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CONFIDENTIALITY

Modification of the procedure

Communication to the Commission of all requested Confidentiality related to

- *missing part (MIP)*
- *supplementary information (SIN)*
- *Supplementary information requested by COM following an inconclusive EFSA opinion*

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Annex I

- *Application form:* ***review of the model***
  - *to avoid repetition*
  - *simplifications*

- ***Form of monograph/Annex*** *(New)*

  (Identity of the additive, function, specifications of the active substance, physico-chemical properties of the additive, MRLs, other characteristics suitable for identification of the additive, conditions of use …..)

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ANNEX II

- *<u>Identity of the additive</u>:*
- *impact of the "preparations" (criteria)(tbc)*
- *holder/ non-holder of authorisation (tbc)*
- *analytical methods (e.g. GM, LMRs)(EURL)*
- *new nanoparticle section (MS)*
- *stability rules (vs criteria) (MS)*
- *updated to the related legislation/EFSA guidance (where necessary)*

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ANNEX II

- *safety of the additive:*
- *identification or the most sensitive species (tbc)*
- *extrapolation from species/categories (tbc)*
- *tolerance test for some species (animal welfare) (tbc)*
- *user safety*
- *updated to the related legislation/EFSA guidance (where necessary)*

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ANNEX II

- *efficacy of the additive:*
- *extrapolation from species/categories (tbc)*
- *use in liquid feed (MS)*
- *use in water (MS)*
- ***criteria** for efficacy test (tbc)*
- ***criteria**/new rules for new functional groups*
- *updated to the related legislation/EFSA guidance (where necessary)*

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ANNEX III

- *new functional groups*
- *revision of silage additives (alignment to other technological additives)*
- *development of general criteria for the efficacy studies (more transparency and predictability) (tbc)*
- *new approach forward the innovative additives (tbc)*
- *updated to the related legislation/EFSA guidance (where necessary)*

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ANNEX III

- *Amendment of Annex III.9 Modification*
  - criteria for non-holder of authorisation additives
- *Amendment of Annex III.10 Renewal*
  - better definition of the part of the dossier to considered essential for the procedure
- *Amendment of Annex III.11 Re-evaluation*
  - revision of this part in line to the new development of the re-evaluation procedure

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ANNEX IV

- *Better definition of some species/categories: minor species, pets and non-food producing animals*
- *Revision of the present species:*
  - *zootechnical parameters (criteria)*
  - *physiological parameters (criteria)*
  - *redefinition of the categories (FEFANA proposal)*

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Next steps

- *EFSA feedback on our mandate (Article 7)*
- *A draft proposal for a first discussion on September Standing Committee and following*
- *Consultations with Stakeholders*
- *Finalisation*

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Thank you for your attention

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