The FEEDAP Panel's Guidance on Renewal

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RENEWAL: THE THIRD STEP IN THE PROCESS

Pre-1831/2003

Notification (2004)

>10000 notifications - >2500 additives

Re-evaluation (as of 2010)

400 applications- ~1200 additives

Renewal (as of 2015)

??

GENERAL REMARK

Renewal is not a 2nd re-evaluation

- Ensure that the additive remains safe
- Level of complexity depends on the request
  - Pure renewal
  - Renewal with modifications

INDEX

- A bit of history
- Objectives of the guidance on renewal
- Renewal application: what is expected ?

A BIT OF HISTORY

- Self-task (December 2012)
- WG Guidance
- Endorsement public consultation (June 2013)
- Public consultation (June-August 2013)
- Adoption (8 October 2013)

www.efsa.europa.eu/en/efsajournal/doc/3431.pdf

Some concerns expressed

SOME CONCERNS

- "The need for such guidance is questioned"
- No need to comply with EFSA guidance not consolidated in legislation
- This is a second re-evaluation!
- "A complete extensive dossier should be submitted"
- No need to provide evidence of the same composition – "EFSA should not police purity data"
- Copy/paste from Regulation (EC) No 429/2008
- Efficacy should not be reviewed

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GENERAL OBJECTIVE OF THE RENEWAL GUIDANCE

To ensure that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, workers and the environment.

STRUCTURE

- Regulation (EC) No 1831/2003
- Regulation (EC) No 429/2008

  Section 10 of Annex III

General aspects

- Section I
- Section II
- Section III
- Section IV
- Section V

GENERAL ASPECTS

- Stand-alone dossiers
- Omission of requested information justified
- Headings and numbering
- Copies of publications, opinions and studies

Up-to-date scientific knowledge, scientific/methodological approaches and the most updated guidance documents

OBJECTIVE OF SECTION II - IDENTITY

Evidence shall be presented to show that the additive has not been significantly changed or altered in composition, purity or activity in respect of the additive that was authorised. Any change in the manufacturing process shall be reported.

OBJECTIVE OF SECTION III - SAFETY

Evidence shall be presented that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, workers and the environment. A safety update for the period since the original authorisation, or the last renewal of authorisation shall be presented

OBJECTIVES OF SECTIONS III AND IV

When the applicant includes a proposal for amending or supplementing the conditions of the original authorisation that may have an impact on the safety or efficacy of the additive additional safety/efficacy studies may be required.

Follow the relevant guidance

INDEX

- A bit of history
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DIFFERENT SCENARIOS

- Renewal without any changes or "pure renewal"
- Renewal with changes in manufacturing process, carriers, concentration of active substance, purity, physical properties...
- Renewal with changes in conditions of authorization

DIFFERENT SCENARIOS

Renewal with changes in conditions of authorisation

- Increase maximum recommended level
- Increased bioavailability active substance
- Change MRLs
- Reduction of minimum recommended level
- Compatibility with coccidiostats
- …

DIFFERENT SCENARIOS

Renewal with changes in conditions of authorisation

Not considered under renewal

- Extension to other species
- Use in water
- New category/functional group
- …

SECTION I

- Public summary
- Scientific summary
- List of documents
- Confidential information
- Previous authorisation
  - EU authorisation
  - Previous assessments
  - New uses

SECTION II - IDENTITY

Are we assessing the same additive?

- Authorisation (specifications)
- "Old" Section II
- New analytical data (3 batches)
  - Composition
  - Purity
- Additional data if changes

SECTION II - IDENTITY

Microorganisms

- Name and taxonomic classification confirmation
- Antibiotic susceptibility
- Virulence factors

SECTION II – IDENTITY "PURE RENEWAL"

2.1 Identity of the additive
- 2.1.1 Name of the additive
- 2.1.2 Proposal for classification
- 2.1.3 Qualitative and quantitative composition
- 2.1.4 Purity
- 2.1.5 Physical state of each form of the product

3 batches

2.2 Characterisation of the active substance(s)/agent(s)
- 2.2.1 Description
- 2.2.2 Relevant properties

Identity confirmation
Antibiotic susceptibility
Virulence factors

2.3 Manufacturing process

2.4 Physical-chemical and technological properties of the additive
- 2.4.1 Stability
- 2.4.2 Homogeneity
- 2.4.3 Other characteristics
- 2.4.4 Physico-chemical incompatibilities or interactions

2.5 Conditions of use of the additive
- 2.5.1 Proposed mode of use in animal nutrition
- 2.5.2 Information related to users/workers safety

2.6 Methods of analysis and reference samples

SECTION II – IDENTITY "RENEWAL WITH CHANGES OF THE ADDITIVE"

- 2.1 Identity of the additive
  - 2.1.1 Name of the additive
  - 2.1.2 Proposal for classification
  - **2.1.3 Qualitative and quantitative composition**
  - **2.1.4 Purity**
  - **2.1.5 Physical state of each form of the product**
- 2.2 Characterisation of the active substance(s)/agent(s)
  - **2.2.1 Description**
  - **2.2.2 Relevant properties**
- 2.3 Manufacturing process
- 2.4 Physical-chemical and technological properties of the additive
  - 2.4.1 Stability
  - 2.4.2 Homogeneity
  - 2.4.3 Other characteristics
  - **2.4.4 Physico-chemical incompatibilities or interactions**
- 2.5 Conditions of use of the additive
  - 2.5.1 Proposed mode of use in animal nutrition
  - 2.5.2 Information related to users/workers safety
- 2.6 Methods of analysis and reference samples

SECTION III - SAFETY

- Structured database search related to the additive and its components
  - agricultural/aquacultural, toxicological and medical/veterinary databases
  - since last assessment
  - reporting
- reports on adverse effects including accidents
- reports on new interactions and incompatibilities identified
- data from residue monitoring

SECTION III - SAFETY

- data from epidemiologic and/or toxicological studies
- any other information concerning the safety of the additive to animals, humans, and environment
- Post-market monitoring
- Use of the product (contextualise)
  - volume, geographical distribution and time

SECTION III - SAFETY

Microorganisms

- Antibiotic susceptibility
- Virulence factors

Most recent guidance

SAFETY

A few examples where additional studies would be expected

- Increase maximum recommended level
  - Target species/consumer/environment…
- Increased bioavailability active substance
  - Deposition studies…
- Change MRLs or withdrawal time
  - Residue studies…
- Change in physical properties: User safety studies…

EFFICACY

In general not required, a few exceptions:

- Reduction of minimum recommended level
  - Efficacy studies at the new level
- Compatibility with coccidiostats
  - *In vitro* or *in vivo* studies
- Change bioavailability
  - Bioequivalence studies
- Coccidiostats

EFFICACY

Coccidiostats: contemporary confirmation

- Safety issue for the target species
- Limited to maintained susceptibility
- Sensitivity tests
  - Three sources
  - Mixed infection
  - 1 year pre-submission
- No extrapolation

SECTION V – POST-MARKET MONITORING PLAN

- Results of PMM, if applicable
- Proposal for PMM, if relevant

Thank you for your attention

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