Renewal of authorisations: industry expectations

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1. Purpose of renewal

- Objective n°1
  - Confirm the intention of the industry to keep a given additive on the market
    - Keep list of authorised additives up-to-date

→ Application for renewal to Commission

- Objective n°2
  - Confirm that the additive is still in line with the conditions of the authorisation
    - + provide any new information on safety

→ Renewal dossier to EFSA

2. Applicants and access to information

- Two cases
  - Holder-specific authorisations
  - Non holder-specific authorisations

In the case of authorisations not issued to a specific holder, any person who first places the additive on the market or any other interested party may submit the application to the Commission and shall be considered as the applicant.

In the case of authorisations issued to a specific holder, the holder of the authorisation or his legal successor or successors may submit the application to the Commission and shall be deemed to be the applicant.

Access to former application/information

- Holder-specific authorisations
  - Applicant or its legal successor should, in principle, have access to the whole information, and to the former application (and technical dossier)
- Non holder-specific authorisations
  - Applications for renewal can be submitted by <u>any interested party</u>
  - No requirement for former applicant(s) to apply for renewal
  - The only legal basis for placing the product on the market is the existing authorisation

2. Renewal dossiers

- Renewal is not re-authorisation
- Important to focus only on the information relevant for renewal

→ What is the relevant information ?

What says the regulation ?

Article 14(2) of Regulation (EC) No 1831/2003

2. At the time of application, the applicant shall send the following particulars and documents directly to the Authority:

(a) a copy of the authorisation for placing the feed additive on the market;

(b) a report on the results of the post-market monitoring, if such monitoring requirements are included in the authorisation;

(c) any other new information which has become available with regard to the evaluation of the safety in use of the feed additive and the risks of the feed additive to animals, humans or the environment;

(d) where appropriate, a proposal for amending or supplementing the conditions of the original authorisation, *inter alia*, the conditions concerning future monitoring.

Starting point is the annex entry

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: preservatives								
1a297	Fumaric acid	*Additive composition* Fumaric acid 99,5 % Solid form *Characterisation of active substance* Fumaric acid $C_4H_4O_4$ CAS no 110-17-8 *Analytical method* (1) For the determination of fumaric acid in feed additive: infrared absorption spectrophotometry and titration with sodium hydroxide (Food Chemical Codex 7). For the determination of fumaric acid (as total fumaric acid) in feed premixture and feedingstuffs: ion exclusion High Performance Liquid Chromatography with UV detection (HPLC-UV).	Poultry and pigs	—	—	20 000	For safety: breathing protection, glasses and gloves shall be used during handling	21 November 2023
			Young animals fed with milk replacers	—	—	10 000 (2)		
			Other animal species	—				

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/crl-feed-additives
(2) mg of fumaric acid per kg of milk replacer.

Composition, chemical formula, description, analytical method

Dossiers for renewal

- Three main sections
  - Section 2 – identity
  - Section 3 – safety
  - Section 4 – efficacy

+ Section 5 – PMMP if applicable (Post Market Monitoring Plan)

→ What is the relevant information for each section ?

Section 2 - Identity of the additive

- Renewal is not re-authorisation

→ **Basis for renewal shall be the existing authorisation**

Fumaric acid	*Additive composition*
	Fumaric acid 99,5 %
	Solid form

- Information on identity shall be restricted to what is mentioned in the annex entry as characteristics of the active substance/additive
  - Any other identity related information is irrelevant since it is not linked to the renewal of the existing authorisation

Section 2 – which data ?

- (recent) Analytical data from 5 batches for composition
  - Section 2.1.3 Qualitative and quantitative composition
- (recent) Analytical data from 3 batches for purity
  - Section 2.1.4 Purity / impurities listed in the annex entry
- Confirmation on production process may be relevant when indicated in the annex entry
  - Section 2.3 Manufacturing process, including any specific processing procedures
- The above should be sufficient in most cases to prepare the Section 2
  - The other sub-sections are only relevant if information is part of the annex entry

Section 2 – Identity - examples

Propionic acid	*Additive composition*
	Propionic acid ≥ 99,5 %
	Characterisation of the active substance
	Propionic acid ≥ 99,5 %
	$C_3H_6O_2$ CAS No: 79-09-4
	Non-volatile residue ≤ 0,01 % when dried at 140 °C to constant weight
	Aldehydes ≤ 0,1 % expressed as formaldehyde

Calcium D-pantothenate	*Additive composition*
	Calcium D-pantothenate.
	Characterisation of the active substance
	Calcium D-pantothenate
	$Ca[C_9H_{16}NO_5]_2$
	CAS No: 137-08-6
	Calcium D-pantothenate, solid form, produced by chemical synthesis.
	Purity criteria:
	1. Min. 98 % (on dry basis)
	2. Max. 0,5 % 3-aminopropionic acid.

Section 2.1.3

Section 2.1.4

Section 2.3

Section 2 – Identity - examples

Cobalt(II) carbonate	*Additive composition*
	Cobalt(II) carbonate, as powder, with a minimum content of 46 % cobalt Cobalt carbonate: minimum 75 % Cobalt hydroxide: 3 % - 15 % Water: maximum 6 %
	Particles < 11 µm: below 90 %

Canthaxan-thin	*Additive composition*
	Preparation containing minimum: 10 % of canthaxanthin; ≤ 2,2 % ethoxyquin;
	dichloromethane: ≤ 10 mg/kg additive.
	Characterisation of the active substance canthaxanthin $C_{40}H_{52}O_2$ CAS No: 514-78-3 Assay: Minimum 96 %
	Produced by chemical synthesis

Section 2.1.3

Section 2.1.4

Section 2.1.5

Section 2.3

Section 2 - Identity

- If identity of the additive is different from what is specified in the authorisation, it would fall under other types of applications within Regulation (EC) No 1831/2003
  - Art. 4 (new application) or
  - Art. 13 (modification of application)

Section 2 - Method(s) of analysis

- Analytical methods (section 2.6) should not be revised unless:
  - Evidence/experience from EURL/NRLs shows that official method(s) is(are) no longer fit for purpose or
  - Method(s) higher in the cascade is(are) recently available (e.g. CEN method developed in the framework of a CEN mandate)

Analytical method (1)

For the determination of fumaric acid in feed additive: infrared absorption spectrophotometry and titration with sodium hydroxide (Food Chemical Codex 7).

For the determination of fumaric acid (as total fumaric acid) in feed premixture and feedingstuffs: ion exclusion High Performance Liquid Chromatography with UV detection (HPLC-UV).

In most cases, no specific action needed for EURL, but what about the fee ?

Section 3 - Safety of the additive

- Any new information which has become available with regard to safety
  - Target species, users (workers, farmers), consumers, and environment
- Target: demonstrate that the additive remains safe under the approved conditions of use
  - If the intention of applicant is to modify the conditions of use, this is not “renewal of the authorisation” but Art. 13 (modification of the authorisation)

Section 3 – Safety

- Assessment should be quite straightforward
  - Unless the newly available information raises additional questions and would require generation of additional data
  - Examples:
    - Consumer safety: change of UL or ADI
    - Worker safety: new classification of a product under REACH/ECHA

→ Detailed risk assessment relevant for very specific cases only. In most cases, no systematic safety assessment should be necessary.

Section 3 – Safety

Proposed EFSA tool: structured database searches

- Same approach as for re-authorisation
- Search should cover at least the period since the last assessment of the additive

  → From publication of the EFSA opinion

Section 3 – Safety

"*In order to place the results of database searches into context, where possible, information on use of the product (e.g., volume, geographical distribution and time) should be provided*"

- Non-holder specific additives
  - Information not possible to provide due to competition of law issue + free-riders
  - Applicant(s) never representing the whole market
- Holder-specific additives
  - Authorisation holders are not controlling 100% of the sales (sub-contractors): exhaustive information not possible
- Are '10' years data enough representative for new / low market products ?

→ Relevance of this information is questionable

Section 3 – Safety

- History of (safe) use was a possible approach under re-authorisation of feed additives
  - How was this used/handled ?
    - While the possibility to demonstrate safety of an additive through "long history of use" was envisaged by some applicants during re-authorisation, it is not clear what information was expected by EFSA experts and how they have used the information

"How this information will be used and assessed" ?
Clarifications needed on the relevance of this information in the frame of renewal of authorisations

Section 4 – Efficacy of the additive

- If new efficacy data would allow to include a proposal for amending or supplementing the conditions of use of the additive then this should not be considered as an application for renewal but if falls under other types of applications within Regulation (EC) No 1831/2003
  - Art. 4 (new application) or
  - Art. 13 (modification of application)

Section 4 – Efficacy

- If no modifications of the conditions of use are foreseen, no efficacy data are needed

→ Section 4 is not applicable for applications for renewal of authorisation

Section 5 – PMMP

- If relevant for the additive
  - In relation with Section 3

+ follow-up of bacterial resistance in case of some coccidiostats

5. Conclusions

- Renewal
  - Confirmation of the identity and safety of the additive
  - Not a systematic re-evaluation
- Identity
  - Demonstration that the additive is the same as in the annex entry
- Safety
  - Only newly available information
- No re-submission of information from the former technical dossier
- (future) orphan products
  - What if no application made on time ?
  - Any interactive monitoring tool foreseen ?

Thank you for your attention !

Renewal is not re-authorisation