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Preparatory work to support the re-evaluation of technological feed additives

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Abstract

Technological feed additives are intended to improve or favourably affect the characteristics of feed but have generally no direct biological effect on animal production. The authorisation procedure for feed additives including technological additives is established by Regulation (EC) No 1831/2003. Article 10 of the Regulation sets the principles of the re-evaluation of feed additives which are already on the market in the EU and/or which were authorised under the previous regulatory framework. The aim of the re-evaluation is to ensure that all feed additives in the EU market are evaluated under the same safety standards taking into consideration the most recent data. The scientific evaluation is carried out by the Scientific Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority with the support of the FEED Unit. The evaluation is based on the data contained in the dossiers submitted for the re-evaluation. In 2013 EFSA launched a procurement call for the provision of summary data sheets as part of the preparatory work with regard to the re-evaluation of technological feed additives. The analysis of the data contained in the dossiers focused on the identification of gaps between the available information and the data requirements set in the applicable legislation and guidance documents. Seventeen dossiers were then analysed with respect to the requirements for technological additives. For each dossier a summary data sheet and a list of missing information was elaborated. With regard to the completeness of the information, gaps have been identified in all three main sections (identity, safety and efficacy) in all of the dossiers reviewed. Such gaps might delay the evaluation process preventing risk assessors to conclude on all aspects of the safety and efficacy of the additives.

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Key words: animal feed additives, technological additives, dossier evaluation

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Summary

A technological additive is any substance added to feed for a technological purpose and which favourably affects the characteristics of feed. The category “technological additives” is further divided into 13 functional groups according to Annex I of Regulation (EC) No 1831/2003; preservatives, antioxidants, emulsifiers, stabilisers, thickeners, gelling agents, binders, anticaking agents, acidity regulators, substances for control of radionuclide contamination, silage additives, denaturants and substances for reduction of the contamination of feed by mycotoxins. Since livestock depends essentially on the availability of safe and good- quality feedingstuffs in order to ensure the safeguard of human health, animal health and the environment, feed additives are expected to undergo a safety assessment through a well defined standardised procedure before being allowed to be on the market, used or processed within the European Union (EU).

The authorisation procedure for feed additives including technological additives is established by Regulation (EC) No 1831/2003. Regulation (EC) No 429/2008 provides detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. Additionally, the Panel on Additives and Products or Substances used in Animal Feed (EFSA-FEEDAP Panel) has adopted a series of guidance documents which aim to complement the above mentioned Regulation to help the applicants in the preparation and submission of technical dossiers for the authorisation of additives.

According to the provisions of Article 10 of Regulation (EC) No 1831/2003, the 8th November 2010 was the deadline for the submission of dossiers for the re-evaluation of the feed additives that were on the market in the EU. The aim of the re-evaluation is to ensure that all feed additives in the EU market are evaluated under the same safety standards and take into consideration the most recent data. The scientific evaluation is carried out by EFSA-FEEDAP Panel with the support of the FEED Unit.

In 2013 EFSA launched a procurement call for the provision of summary data sheets as part of the preparatory work with regard to the re-evaluation of the technological feed additives with the following objectives:

- To collect data for each additive from the dossiers on identification, description, physico-chemical properties, purity, manufacturing processes, safety for target species, safety for consumer, safety for user/worker, safety for the environment and efficacy of the additive.
- To contrast all collected data according to the information contained in the dossier and the data requirements set in the applicable legislation and guidance documents.
- To integrate all this information in summary data sheets according to the EFSA's requirements within the specified timeframes.

Further to the call a framework contract has been signed to deliver around 60 summary datasheets over a four year period based on EFSA's needs. During the first year of the framework contract 17 dossiers have been analysed with respect to the requirements for technological additives. For each dossier, data was extracted and compared with the Regulation (EC) 429/2008 to generate summary data sheets of each technological additive. With regard to the completeness of the information, gaps have been identified in all three main sections (identity, safety and efficacy). Such gaps of information found in the dossiers might delay the evaluation process preventing risk assessors to conclude on all aspects of the safety and efficacy of the additives.

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1. Introduction

A technological additive is any substance added to feed for a technological purpose and which favourably affects the characteristics of feed. The category “technological additives” is further divided into 13 functional groups according to Annex I of Regulation (EC) No 1831/2003; preservatives, antioxidants, emulsifiers, stabilisers, thickeners, gelling agents, binders, anticaking agents, acidity regulators, substances for control of radionuclide contamination, silage additives, denaturants and substances for reduction of the contamination of feed by mycotoxins. Since livestock depends essentially on the availability of safe and good-quality feedingstuffs, in order to ensure the safeguard of human health, animal health and the environment, feed additives are expected to undergo a safety assessment through a well defined standardised procedure before being allowed to be on the market, used or processed within the European Union (EU).

In 2013 EFSA launched a procurement call for the provision of summary data sheets as part of the preparatory work with regard to the re-evaluation of the technological feed additives with the aim of:

- Collecting data for each additive from the dossiers (identification, description, physico-chemical properties, purity, manufacturing processes, safety for target species, safety for consumer, safety for user/worker, safety for the environment and efficacy of the additive).
- Contrasting all collected data according to the information contained in the dossier and the data requirements set in the applicable legislation and guidance documents.
- Integrating all this information in summary data sheets according to the EFSA’s requirements within the specified timeframes.

Further to the procurement call a framework contract has been signed to deliver around 60 summary datasheets over a four year period based on EFSA’s needs.

This report has the aim to present the work carried out during the first contract year.

1.1. Background and Terms of Reference as provided by the requestor

Background as provided by EFSA

The Scientific Panel on Additives and Products or Substances used in Animal Feed (EFSA-FEEDAP) of the European Food Safety Authority (EFSA) assesses the safety and efficacy of feed additives.

Regulation (EC) No 1831/2003 establishes the rules for the authorisation of feed additives in the European Union (EU). Applicants wishing to place a feed additive in the EU market shall send an application to the European Commission (EC) and a technical dossier to EFSA. It is the task of EFSA to provide the EC with a scientific opinion in which the assessment of the safety and the efficacy of the feed additive are reported. This task is entrusted to the FEEDAP Panel whereas the FEED Unit provides scientific/technical and administrative support to the Panel.

Regulation (EC) No 429/2008 provides detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. The FEEDAP Panel has adopted a series of guidance documents which aim at complementing the above mentioned Regulation to help the applicants in the preparation and submission of technical dossiers for the authorisation of additives.

Article 10.2 of Regulation (EC) No 1831/2003 provides for the procedure to re-evaluate all additives that were present in the market at the time of implementation of this Regulation. In the course of the re-evaluation process EFSA has received a total of 396 dossiers for the re-evaluation of feed additives. Among these, 40 dossiers on technological additives (functional groups: emulsifiers, gelling agents, stabilisers, thickeners, anticaking) were included.

The FEED Unit is requested to launch a procurement call for the provision of summary data sheets to support the re-evaluation of technological feed additives.

Terms of reference as provided by EFSA

The aim of the invitation to tender was to select one contractor with relevant experience to prepare summary data sheets, as a basis for the re-evaluation of certain groups of feed additives currently authorised in the EU. The contractor was requested to analyse data regarding the identity and characterisation of the additive, efficacy and/or safety data, including:

- qualitative and quantitative description of the additive, purity
- physico-chemical properties of the additive
- manufacturing process
- safety for the target species
- safety for consumer, including studies on metabolism and residues, toxicological studies (e.g., genotoxicity, subchronic toxicity, chronic toxicity), exposure assessment
- safety for user, including studies on irritation, sensitisation, respiratory toxicity
- safety for the environment
- efficacy studies

The data to be analysed and summarised could include experimental studies, peer reviewed data or other published or non-published data.

Summary Datasheets are used by the EFSA-FEEDAP Panel and its Working Group on Technological Additives as preparatory documents for the risk assessment of these substances.

This contract/grant was awarded by EFSA to:

Contractor/Beneficiary: Institut de Recerca i Teconologia Agroalimentàries (IRTA)

Contract/Grant title: Preparatory work to support the re-evaluation of technological feed additives

Contract/Grant number: OC/EFSA/FEED/2013/01

2. Data and Methodologies

The overall objective of the contract is to analyse the information provided by the applicants to EFSA in the technical dossiers in support of the re-evaluation of technological feed additives currently authorised in the EU. The analysis of the data in the dossiers has to focus on the identification of gaps between the information contained in the dossier and the data requirements set in the applicable legislation and guidance documents and to prepare summary datasheets.

The specific objectives have been defined as follows:.

OBJECTIVE 1. To Identify and to characterise the additive including a qualitative and quantitative description about their purity, physico-chemical and technological properties, manufacturing process, and other characteristics referred to the additive.

OBJECTIVE 2. To identify and to characterise the additive with regard to its safety:

- Safety for the consumer including information on metabolism and residues, toxicological studies and exposure assessment
- Safety for the user, including studies on irritation, sensitisation, respiratory toxicity
- Safety for the environment

OBJECTIVE 3. To identify and to characterise the additive according to its efficacy.

OBJECTIVE 4. To contrast all collected data according to the information contained in the dossier and the data requirements set in the applicable legislation.

OBJECTIVE 5. To integrate all the information in a summary datasheet (SDS) and a list of missing information according to the EFSA's requirements.

2.1. Data

During the first year of the framework six batches of dossiers were provided:

- Batch 1: 1 dossiers
- Batch 2: 3 dossiers
- Batch 3: 3 dossiers
- Batch 4: 3 dossiers
- Batch 5: 3 dossiers
- Batch 6: 4 dossiers

Each dossier was presented for one technological feed additive, so that there were 17 dossiers in total, containing 17 technological feed additives.

The data to be analysed and summarised ranged from experimental studies (composition of the additive, impurities, stability, homogeneity or efficacy) to peer reviewed data or other published and non-published data.

At the end of the first year, this annual report was prepared summarising all the activities carried out during this period.

2.2. Methodologies

In order to reach the objectives set in the procurement, the following methodology was proposed and implemented:

Training of scientific reviewer

The Scientific Committee (SC) is formed by the staff researchers of IRTA (four experts in animal nutrition, one of which serves as project coordinator, one in food biotechnology, one in marine biology, and one in environmental microbiology), two experts in food safety of ACSA (subcontracted) and one expert on microbiology of CRESA (subcontracted; as of the 1st of January 2015 CRESA is integrated in IRTA).

The first task of the SC was the training of the scientific reviewer (SR) in the different aspects of the SDS, so that the SR was able to revise the dossier and identify the missing parts. The training covered the chemical, environmental, toxicological, technological, and zootechnical aspects necessary for the analysis of the information presented in the dossier. The coordinator revised and ensured that all aspects were addressed.

Procedure for the analysis of the dossiers

A detailed communication plan was put in place in order to ensure that all the analysis, results and reports (SDS and list of missing information) were developed and delivered correctly on time. After the reception of the Dossier from EFSA by the Project Coordinator (PC), the PC communicates to the SC and SR the reception of the document and the analysis of the Dossier starts. The SR reads the dossier and completes the templates of check list, SDS and list of missing information provided by EFSA. The data provided in the dossier is compared with the data requirements set in the applicable legislation (Regulation (EC) No 1831/2003 and Regulation (EC) No 429/2008) and the EFSA-FEEDAP guidance documents (Guidance on technological additives, Guidance on the re-evaluation of certain

feed additives, Guidance on user safety, Technical guidance: Tolerance and efficacy studies in target animals, Technical guidance for Environmental Risk Assessment, Guidance on consumer safety, Guidance on additives already authorised in food, Guidance on the assessment of additives intended to be used in pets and other non-food producing animals, Technical Guidance: Microbial Studies). The requirements set in the legislation and guidance documents were previously revised together with EFSA staff and EFSA provided the templates during the kick-off meeting. During this process, if necessary, the SR consults the members of the SC in the different areas of their expertise. The initial review takes a maximum of 5 working days.

The first draft of the two documents is then submitted to the members of the SC. They then revise the SDS and the list of missing information and recommend the necessary changes in the document. This process takes a maximum of 5 working days.

During the process of elaboration of the final version of the two documents, the SR looks for more information on the additive (i.e. Web of Knowledge, EFSA, JECFA, FDA, FSA, ANSES and IUCLID) and then prepares a revised version of the SDS and list of missing information, which is submitted to the PC for approval. In case the PC identifies more changes, the SR revises again the document until the final approval is obtained. This process takes a maximum of 2 working days. Once the final approval by PC is obtained, the documents are sent to EFSA.

In some instances EFSA requested some amendments to the SDS or list of missing information. If necessary, a revision based on the evaluation conducted by EFSA was carried out. The SR prepares a new version (v2) of the SDS and list of missing information which are then submitted to the PC who validates them and sends to EFSA the second version of the documents.

Summary data sheet and list of missing information content

Characterization of the final product

This includes information on identity, characterisation and conditions of use of the additive; namely: identity, name of the additive, proposal for classification, qualitative and quantitative composition, purity, physical state of each form of the product, characterization of the active substance(s)/agent(s), relevant properties, manufacturing process, physico-chemical and technological properties of the additive, conditions of use of the additive.

Analysis of data regarding the safety target species

This part includes the description of the studies to assess the safety of use of the additive for the target species per se.

Analysis of data regarding the safety for consumer

This part provides information to establish the potential risks of the presence of the additive or its metabolites in food derived from animals consuming the additives.

Analysis of data regarding the safety for the user

This part includes information on the user safety including specific studies, the MSDS and a revision of the precautionary measures to be taken when handling the product.

Analysis of data regarding the safety for the environment

This section includes information on the environmental safety aspects.

Analysis of data regarding the efficacy of the additive

This part includes a description of the efficacy, compared with the corresponding end-points for each functional group.

3. Assessment/Results

In the first contract year 17 dossiers on technological additives have been analysed which resulted in the creation of 17 summary data sheets including 17 reports on missing information. Seven of the SDS and list of missing information were amended following comments received from EFSA.

The additives reviewed belong to the following functional groups: emulsifiers, gelling agents, stabilisers, thickeners, binders, substances for control of radionuclide contamination, anticaking agents, and acidity regulators. Some of the additives indicated claims for more than one functional group.

Sixteen out of 17 were already authorised as food additives. Some of the additives were intended to be used in more than one category of target animals. Five dossiers were for pets other than non food-producing animals, four were for a target group of animals and ten were intended for all animal species.

Based on Regulation (EC) No 429/2008 and the applicable guidance documents, the data requirements for technological additives further depend on the functional group, on the target species and whether the additive is authorised in food. Consequently, the content of the dossiers varied depending on their classification or their use as food additives.

4. Conclusions

With regard to the completeness of the information, gaps have been identified in all three main sections (identity, safety and efficacy) in all dossiers reviewed. Such gaps might delay the evaluation process preventing risk assessors to conclude on all aspects of the safety and efficacy of the additive.

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Abbreviations

ACSA	Agència Catalana de Seguretat Alimentària
ANSES	French Agency for Food, Environmental and Occupational Health & Safety
CRESA	Centre de Recerca en Sanitat Animal
EC	European Community
EFSA	European Food Safety Authority
EFSA-FEEDAP	EFSA's scientific panel on additives and products or substances used in animal feed
EU	European Union
FDA	Food and Drug Administration
FSA	Food Standards Agency
JECFA	the Joint FAO/WHO Expert Committee on Food Additives
IRTA	Institut de Recerca i Teconologia Agroalimentàries
IUCLID	International Uniform Chemical Information Database
MSDS	Material Safety Data Sheet
PC	Project Coordinator
SC	Scientific Committee
SDS	Summary Data Sheet
SR	Scientific Reviewer