EU legislation supports innovation with control

Feed additives have to be approved before being allowed to enter the European feed chain. A strain-specific selenium (Se) yeast is one of the first feed additives approved under the new EU legislation, illustrating the need for both resources and innovation.

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The EU market for food and food products is now the most valuable in the world. As a result, European legislation affecting the food chain has global implications, since operators wishing to supply this market must comply with all relevant laws. The total ban on antibiotic growth promoters (AGPs), effective since January 2006, is just one element in a wave of EU legislation ultimately affecting food animal production around the world.

The new feed additive regulation (EU FAR), published in 2003, will have further profound effects on this sector, requiring producers to pay close attention to the quality and legal status of feed additives used. Sel-Plex®, a yeast providing organic selenium, is one of the first feed additives to be approved under EU FAR. The dossier submitted illustrates that meeting current EU standards requires considerable expertise and resources, as well as a high-quality data package (*Figure 1*).

Increased control of feed additives

The EU FAR began to bite with an initial requirement to notify all feed additives currently in use. Notifications were checked for legality by the EU authorities prior to producing a new positive list, the Community Register of Feed Additives (CFAR). Products such as amino acids and silage agents were classified as feed additives for the first time and all vitamins, provitamins, and flavours/aromas required individual specification. Over 11,000 notifications were received, resulting in a CFAR of approximately 300 pages. *Table 1* shows the basic structure of the CFAR. The EU plans to review this list. In order to maintain a legal status for most products, feed additive manufacturers will have to submit dossiers to current regulatory standards by November 2010. Many additives have never been formally evaluated and most manufacturers

Figure1 - Data supporting EU authorisation of a feed additive

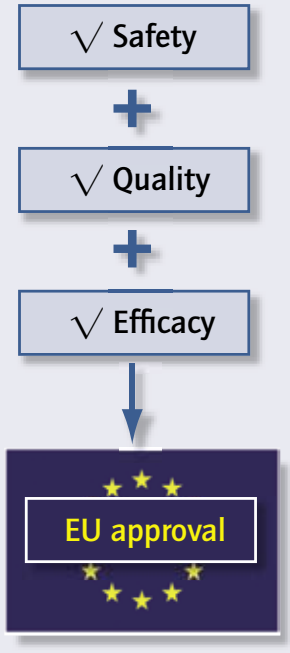


Table 1 - Basic structure of the Community Register of feed additives: categories and functional groups

Category	Main functional groups	Examples
1. Technological	Preservatives	Citric Acid
	Anti-oxidants	Ethoxyquin
	Emulsifiers	Lecithins
	Stabilisers	Glycerol
	Thickeners	Guar gum
	Gelling agents	Agar
	Binders	Sepiolite
	Anti-caking agents	Calcium silicate
	Acidity regulators	Benzoic acid
	Silage additives	*Lactobacillus acidophilus*
2. Sensory	Colourants	Astaxanthin
	Flavours, Appetents, Aromas	Thymol
3. Nutritional	Vitamins, Provitamins	Vitamin A
	Trace elements	Organic Se from *Saccharomyces cerevisiae* CNCM I-3060 (Sel-Plex®)
	Amino acids, salts, analogues	Methionine
	Urea, derivatives	Urea
4. Zootechnical	Digestibility enhancers	Non-starch polysaccharidases
	Gut flora stabilisers	*Bacillus subtilis* C-3102 [DSM 15544] (Calsporin®)
	Substances that favourably affect the environment	Phytases
	Other (eg: performance enhancers)	Potassium Diformate (Formi® LHS)
5. Coccidiostats/ histomonostats		Monensin (Elancoban®)

lack the skills and experience to produce the required data and documentation.

These changes in EU feed additive legislation are taking place in a new legislative environment where all operators in the food chain are held responsible for any food- or feed-related health or contamination problems and must finance product recalls if necessary. *Table 2* illustrates that the EU food chain is effectively and efficiently policed by RASFF (Rapid Alert System for Food and Feed), which detects illegal and unsafe products destined for the European market, resulting in withdrawal or prohibition. The expense of product recalls can cripple a business. Operators in food, feed and animal production have become extremely sensitive to the legal status of all products used.

"Grey-Zone" Additives

In parallel with the EU reduction in antibiotic usage and the completion of the AGP ban in 2006, there is a substantial "Grey-Zone", largely composed of natural or nature-identical additives marketed as alternatives to AGPs. Additives include herbs, spices, essential oils, nutraceuticals and phytogenics. Many of these achieved a positive listing on CFAR as flavours, aromas or appetents (flavours). In fact around 60% of CFAR additives are categorised as flavours, although, in the majority of cases, this classification is a temporary regulatory strategy to maintain an EU legal status, thus permitting continued sales and market access. By the November 2010 dossier submission deadline it is expected that many so-called 'flavours' will attempt reclassification by submitting zootechnical dossiers supporting improved animal performance.

Innovation in feed additives

Organic Se from yeast, an innovative concept in nutrition, was not approved as a feed additive in the EU prior to 2006; this was one reason for Alltech to submit the Sel-Plex® dossier. The other reason was the innovative nature of the product, which offers selenium in bioavailable and nature-identical organic forms, resulting in enhanced selenium status and associated performance and health benefits throughout the food chain. The submission of this pioneer dossier was in March 2005, with approval in November 2006, a time scale that indicates the complexity of the evaluation process (*Figure 2*). Other Se yeast dossiers submitted in 2005 have not yet completed assessment.

The cost and resources involved in achieving and maintaining EU approvals is such that only innovative feed additives backed by sound scientific data and supported with adequate resources will succeed.

Table 2 - Examples of RASFF alerts in animal nutrition, 2000-2006

Problem	Type of product	Additional comments
Dioxin contamination	Citrus pulp	EU actions against Brazil
Dioxin contamination	Zinc oxide	EU actions against China
Dioxin contamination	Zinc sulphate	EU actions against China
Dioxin contamination	Copper sulphate	EU actions against China
Dioxin contamination	Sepiolite	Product recall and/or exclusion from EU market
Dioxin contamination	Unauthorised industrial waste oils	Extensive food chain contamination (broilers) Expensive product recalls
Dioxin contamination	Pig and vegetable fats	Extensive food chain contamination (milk, pork) Expensive product recalls
Dioxin contamination	Choline chloride	Product recall and/or exclusion from EU market
Cadmium contamination	Zinc sulphate	EU actions against China
Cadmium contamination	Manganese oxide	EU actions against China
Arsenic contamination	Horse feed	Product recall and/or exclusion from EU market
Lead contamination	Animal feed	Product recall and/or exclusion from EU market
Salmonella contamination	Various feed ingredients	Health risk for animals and humans Product recalls and/or exclusion from EU market
Mycotoxin contamination	Various feeds and feed ingredients	Product recalls and/or exclusion from EU market
Unauthorised feed material	Meat and bone meals	Product recalls and/or exclusion from EU market
Unauthorised additive	Selenium yeast	Product recalls and/or exclusion from EU market
Unauthorised additive	Selenium yeast in pet foods	Product recalls and/or exclusion from EU market
Unauthorised additive	Chromium yeast in pet foods	Product recalls and/or exclusion from EU market
Unauthorised additive	Superoxide dismutase in horse feed	Product recall and/or exclusion from EU market
Unauthorised additives	Hormones in animal feeds	Product recall and/or exclusion from EU market
Unauthorised additives	Coccidiostats in layer feeds	Cross-contamination at feed mills Product recall and/or exclusion from EU market
Unauthorised additive	Salinomycin	Product recall and/or exclusion from EU market
Unauthorised additive	Flavophospholipol	Product recall and/or exclusion from EU market

Table 3 - Examples of safety, quality and efficacy considerations (Sel-Plex®)

Evaluation criteria	EFSA Opinion (2006)	EU Authorisation specifications
QUALITY	Producer Strain Identity, Characterisation, Genetic Stability, Deposit in International Culture Collection	Strain-Specific Authorisation
	Nature of Se	>97% organic Se 63% of Se is selenomethionine
	Content of Se	2000 to 2,400 ppm Se
EFFICACY	Improved bioavailability over inorganic Se Higher Se content of meat milk and eggs Animals: Acceptable safety margin (~10 fold)	Nutritional Category Approved for all species. Maximum total Se content: 0.5 ppm in final feeds
SAFETY	Consumers: Safe to consume products from animals fed Sel-Plex®	No withdrawal period required
	Workers: Safe with standard handling precautions	Breathing protection and wear safety glasses
	Environmental: Organic forms of Se exhibit better retention and lower excretion than inorganic Se	No environmental precautions necessary

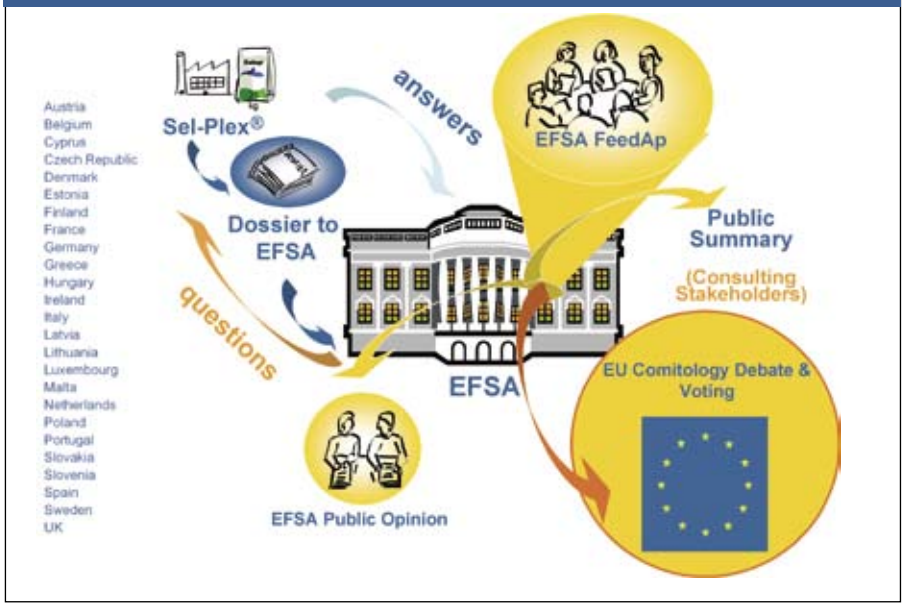
EU evaluation and authorisation

The dossier is first validated by EFSA (European Food Safety Authority) and then evaluated by the EFSA FeedAp Panel (20 independent scientists, often supported by external experts forming dossier- or subject-specific working groups). Experts from the 25 EU Member States conduct a parallel assessment and as a result their questions may be added to those generated within EFSA. Often, substantial additional data is requested during dossier assessment.

Meanwhile, three samples of the feed additive are sent to the Community Reference Laboratory (CRL), who audit the methods of analysis proposed in the dossier and maintain reference samples of the additive.

Scientific review of a dossier takes a minimum of six months, often longer when questions are asked and more data is required. EFSA then publishes an opinion on the safety, quality and efficacy of the additive, including the CRL report on analytical methods. The EFSA public opinion is subject to stakeholder consultation. Stakeholders include all interested parties, including EU citizens, who may express their own

Figure 2 - EU evaluation process



opinions on whether the additive should be approved or not.

Taking into account EFSA's scientific opinion (risk assessment) and relevant risk-management considerations highlighted by stakeholders, the EU Commission drafts a Regulation to approve or prohibit authorisation of the additive. The draft is subject to Comitology, a debate involving delegates from all EU Member States. Such debate may take two or more meetings of Comitology after which a vote is taken.

Three evaluation pillars

For the draft Regulation to be approved, a qualified majority vote (QMV) is required. This means that at least 50% of Member States and 70% of votes cast must be in favour. Finally, the Regulation approving (or not) the additive is published in the Official Journal of the European Union. An approval under EU FAR is valid for 10 years, after which an updated dossier is required to renew the authorisation. Examples of categories of feed additives under EU FAR are shown in *Table 1*.

As illustrated in *Figure 1*, the three pillars of feed additive evaluation by EFSA are Safety, Quality and Efficacy. EFSA and the EU's objectives are to ensure safety of animals, consumers, workers and the environment, as well as to prevent fraud (e.g. unsubstantiated claims). Due to feed hygiene and traceability obligations, premixes and feed manufacturers require a clear legal status for all additives used in their businesses. Finally the EU evaluation and authorisation process illustrated in *Figure 2* meets the needs of all key stakeholders. ■

References available on request (rmurphy@alltech.com)