

New regulations: chances or restrictions?

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Why new regulations?

- Crises
 - BSE
 - Dioxin
- New developments



Feed safety

- Feed safety is more than contaminants alone

Focus on:

- Feed additives
- Feed materials



Basis of new regulations

- Regulation (EC) No 178/2002
- Regulation (EC) No 1831/2003
- Regulation (EC) No 183/2005
- Regulation (EC) No 429/2008
- Regulation (EC) No 767/2009

Further to be considered:

- EFSA guidance documents
- CRL guidance documents
- Future: Catalogue of feed materials



Factors related to safety of feed additives

- Impurities related to the production of the active substance or formulation of the product
 - Chemical impurities
 - Microbial impurities



Hazards for different additives

- Micro-organism (fermentation products): microbial contamination, mycotoxins, heavy metals
- Plant derived substances: microbial and botanical contamination, mycotoxins, pesticide residues, solvents
- Animal derived substances: microbial contamination, heavy metals, solvents
- Mineral substances: heavy metals, dioxins, PCBs
- Chemical produced products: materials used and residues of intermediate products



Hazards related to aspects of the additive itself

- Potential dust formation
- Mixing properties: homogeneity
- Chemical characteristics
- Micro-organisms: potential toxins and virulence factors; antibiotic production and antibiotic resistance



Safety of new additives

- Tolerance for target species
- Antibiotic activity
- Metabolic and residue concerns
- Toxicological concerns
- Safety for user/workers
- Safety for the environment



Assessment

- All these hazards are assessed in the safety and risk assessment for a new additive by EFSA
- If necessary ADI (or UL) and MRL are set
- Assessment of consumer exposure



Regulations

Safety assessment and risk management of all points put in regulations, based upon:

- Regulation 1831/2003
- Regulation 429/2008

And

- Guidances going more in detail on requirements for different kind of additives. Set up by EFSA (FEEDAP)



Disadvantage of new regulations

- High demands → high costs to set up a good dossier
- Long period to get new additives approved

This leads to less new (innovative) products,
negative effect on competition from outside
EU



Chances through new regulations

- Rules are consistent and up to date, thereby optimally ensuring safety, minimising risks
- Rules are much more clear → demands are more clear
- Better estimation of costs possible
- Equal demands for similar products
- More fair competition within the EU



New feed law: 767/2009

(published 1st of September 2009)

- Aim to simplify and harmonise current laws: replacement also of local rules (unify)
- Focus on circulation and labelling of feed and feed materials



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New feed law

- Definitions of feed materials, compound feed, feed additives and medicated feed
- Complementary feed follows compound feed
- Dietetic feeds: feeds with “particular nutritional purpose”. Certain claims are possible
- No definition of feed supplements



New feed law

- EU suggests a “Catalogue” of feed materials, to be set up by stakeholders; to be used voluntary
- EU will decide on list of prohibited feed materials
- Complementary feeds: contain $< 100x$ max level of additive in feed



New feed law

- More rules on labels, to ensure tracking and tracing
- Claims: must be verifiable and scientific information must be ready and is to be provided by manufacturer on request
- Not possible to claim that the feed will prevent, treat or cure a disease
- Penalties for companies that don't follow the regulations



Conclusions

New feed legislations:

- Leaves less open
- Needs more dedicated work
- Creates possibilities

