Regulation (EC) 429/2008 "Worker safety "

EFSA Info section
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EU legal framework on the health worker protection

- Council Directive 98/24/EC of 7 April 1998 on the protection of the **health and safety of workers** from the risks related to **chemical agents** at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)
- Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the **protection of workers from risks related to exposure to biological agents** at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)
- Council Directive 2004/37/EC Of on **the protection of workers from the risks related to exposure to carcinogens or mutagens at work** (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)

EU legal framework of evaluation of the chemicals/feed additives 1/2

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency…….
  - Art.2. 5 (b) iii, vi and 6 (d) iii, vi)
  - Exclusion of the application of Title II, V, VI and VII

EU legal framework of evaluation of the chemicals/feed additives 2/2

- Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
  - Article 5 (a)

- Regulation (EC) No 429/2008 on the detailed rules for the implementation ….
  - Section III 3.3

- **The provisions cover also microbial evaluation**

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Section III 3.3
Regulation (EC) 429/2008

- Toxicological risk assessment …. *"**series of studies** using the additive in form ….."*
  - Effects on respiratory system
  - Effects eyes and skin
  - Systemic toxicity
  - Exposure assessment

- Measures to control exposure
  - specific measures
  - modification of the composition

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Section III 3.3 Regulation (EC) 429/2008 new approach?

- **Toxicological risk assessment**
  - literature research (studies, opinion from other authorities ….) for special and systemic aspects
  - exposure assessment
  - studies only when other elements are not available if required (preventive assessment from applicant? Criteria to be established?)
  - extension of a pre-established statement as micro-organisms or enzymes on the status of the substances (EFSA)

- **Measures to control exposure** (from EFSA)
  - specific measures
  - modification of the composition

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Section III 3.3
Regulation (EC) 429/2008

- Holder of authorisation additives
  - clear definition of the product characteristic
  - clear definition final formulation
- Not-holder of authorisation additives
  - well characterised active substance
  - **final formulation?**