

RENEWAL OF AUTHORISATIONS: LEGAL BACKGROUND

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LEGAL BASIS

ARTICLE 14 TO REGULATION (EC)1831/2003.

- **When:** 1 YEAR BEFORE THE EXPIRY DATE;
- **Who:** ANY PERSON WHO FIRST PLACE ON THE MARKET, INTERESTED PARTY/ HOLDER OF AUTHORISATION OR LEGAL SUCCESSOR;
- **What:**
 - COPY AUTHORISATION
 - RESULTS POST-MARKETING MONITORING
 - NEW INFORMATION ON SAFETY
 - PROPOSAL AMENDING SUPPLEMENTING THE CONDITIONS/FUTURE MONITORING.
- **How:** EFSA OPINION - DECISION



REGULATION 429/2008. Annex III, POINT 10



REASONS FOR CHANGE

- - *Updating to the new scientific and technical developments (e.g. EFSA guidance, MSs suggestion, stakeholders requests);*
- *updating to the new legislative approach;*
- *updating to the experience.*





Main modifications 1/5

Annex I= Application form

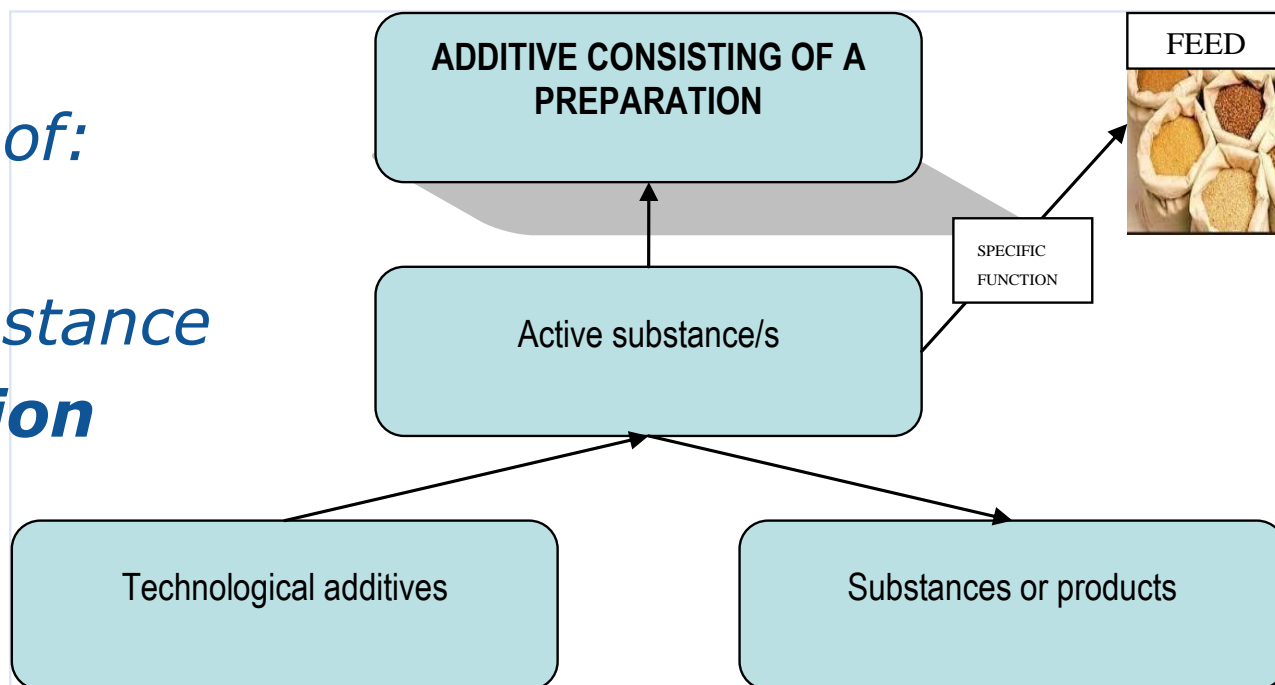
- *Simplification of some parts (e.g. use in complementary feed, re-organisation of animal species list)*
- *Improvement of the modification section*
- *Modification of the re-authorisation section*

Main modifications 2/5



- *description of:*
 - *additive*
 - *active substance*
 - ***preparation***

Section II





Main modifications 3/5

Section III

*This section, on safety for animals, human (consumer and workers) and environment, will be updated **if and where** it's necessary, in comparison with new guidance and new requirements from the MSs*



Main modifications 4/5

Section IV



- *Technological additives section (e.g. new end-points)*
- *New uses (e.g. water for drinking where not already defined)*
- *General part to be modified in relation to the new functional groups*

Main modifications 5/5



- Modification of the authorisations
 - More detail regarding same more common requests (e.g. strain number, concentrations, carriers)
- Renewal of authorisations
 - Point 10.2 on the Section II requirements will be revised to better comply with Regulation (EC) 1831/2003

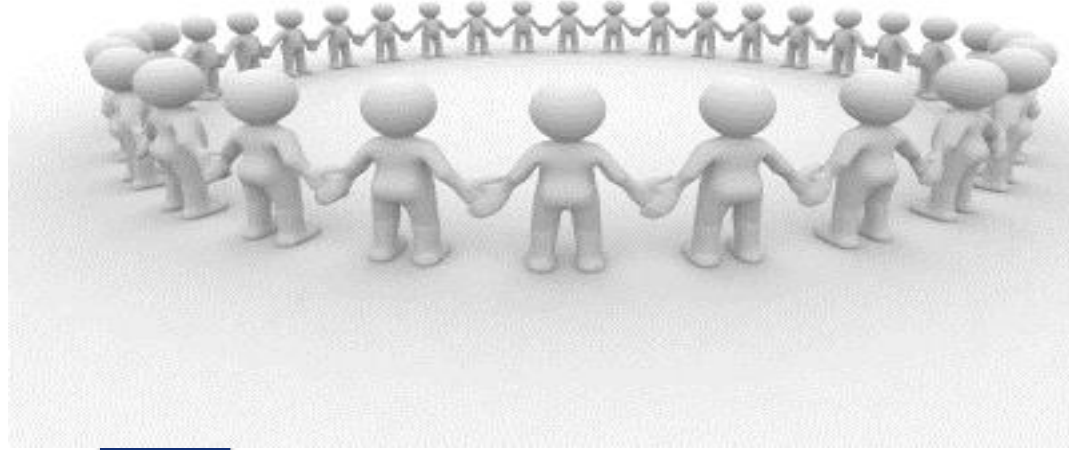
Annex IV

- Revision of animal categories (better definition and new animal species/categories)



CONCLUSIONS

- ***No dramatic modifications** of the present Regulation, **but***
- *Preliminary EFSA consultation*
- *Preliminary stakeholder consultation*



Thank you

**Muchas
gracias**

