# Assessment of safety and efficacy for the target species: zootechnical feed additives

REGULATION (EC) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 September 2003
on additives for use in animal nutrition
(Text with EEA relevance)

# Zootechnical Feed Additives

Used to affect favorably the performance of animals in good health or the environment

Functional groups

1. Digestibility enhancers (for enzymes)
2. Gut flora stabilisers (for micro-organisms)
3. Substances which affect the environment
4. Other zootechnical additives

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37 and 152(4)(b) thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Economic and Social Committee (2),

Following consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty (3),

Whereas:

(1) Livestock production occupies a very important place in the Community economy. Consumer confidence depend to a large extent on the use of safe and good-quality foodstuffs.

(2) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

thereto. It is therefore necessary to subject imports from third countries of additives for use in animal nutrition to requirements equivalent to those applying to additives produced in the Community.

(6) Action by the Community relating to human health, animal health and the environment should be based on the precautionary principle.

(7) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information.

(8) Experience with the application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (4) has shown that it is necessary to review all the rules on additives in order to take into account the fundamental principles governing the protection of animal and human health and of the environment. It is also necessary to take into account the fact that technological progress and scientific developments have made available new types of additives, such as those to be used on silage or in water.

This Regulation should also cover mixtures of additives

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Following consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty (3),

Whereas:

(1) Livestock production occupies a very important place in the agriculture of the Community. Satisfactory results depend to a large extent on the use of safe and good-quality feedingstuffs.

(2) The free movement of safe and wholesome food and feed is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

thereto. It is therefore necessary to subject imports from third countries of additives for use in animal nutrition to requirements equivalent to those applying to additives produced in the Community.

(6) Action by the Community relating to human health, animal health and the environment should be based on the precautionary principle.

(7) In accordance with Article 153 of the Treaty, the Community is to contribute to promoting the right of consumers to information.

(8) Experience with the application of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (4) has shown that it is necessary to review all the rules on additives in order to take into account the need to ensure a greater degree of protection of animal and human health and of the environment. It is also necessary to take into account the fact that technological progress and scientific developments have made available new types of additives, such as those to be used on silage or in water.

(9) This Regulation should also cover mixtures of additives

Primary legislation requires demonstration of:

Safety
- for target animals
- for consumers of animal products
- for users (including pet owners)
- for the environment

Efficacy

# Safety

- A majority (~70%) of zootechnical additives are based on micro-organisms or enzymes for which conventional toxicological testing may not be appropriate or necessary.

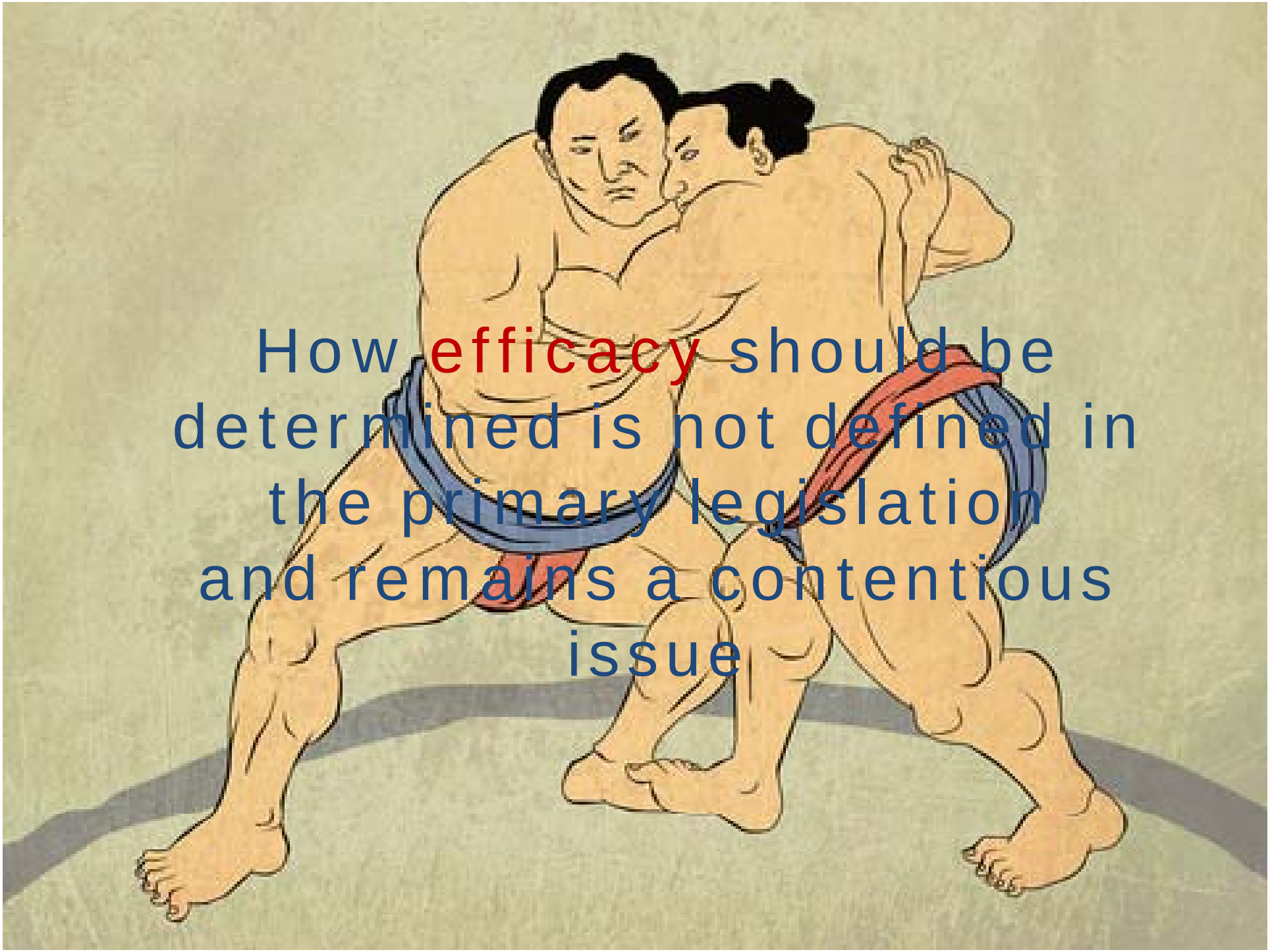
# Safety

- Enzymes may be highly purified by ultrafiltration with much reduced contamination with low-molecular weight compounds

- Full genome of micro-organisms with bioinformatic analysis readily available

# Safety

- QPS approach established for micro-organisms.
- Most micro-organisms commonly introduced into the food chain do not require routine testing other than for:
- 1. antibiotic resistance
- 2. known virulence factors


How efficacy should be determined is not defined in the primary legislation and remains a contentious issue

# What constitutes evidence of efficacy?

Credibility

Biomarker

Short-term *in vivo* study

Performance trials

# Performance trials

## How many (and how long)?

One trial equivalent to none

50+ trials might allow quantification of effect under most practical situations

*Present compromise*

Three trials with significant beneficial results

*This only allows the conclusion that the additive shows the potential to improve performance*

# Should efficacy be linked to a financial benefit?

For example - Can a significant effect of an additive in the early stages of the growth of an animal be considered efficacious if the difference is not retained at time of sale?

# Efficacy and health

"Used to affect favorably the performance of animals in good health"

*Most zootechnical additives*:

- Show greatest effects with very young vulnerable animals and with animals in less than good health
- Beneficial effects are more difficult to demonstrate when husbandry and facilities are of high standard

# In conclusion

Following the principles of the General Food Law the use of feed additives must be safe for the consumer and any claims made should not to mislead the user.

However, the primary consumer of a feed additive is the target animal

Most farmed animals do not have choice when it comes to food selection