

New EU - feed additive legislation

Impact for poultry production and feed additives

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Ankara, 10th February 2005

TOPICS FOR TODAY :

- New Feed additive Regulation
 - History
 - Novelties in the new Regulation
 - Future AGP (Antimicrobial Growth Promoters)
 - Long term future anticoccidials in the EU
- BSA - Brand Specific Approvals
 - What is BSA
 - Impact BSA
 - Approved BSA products
- Future outlook
 - poultry production/feed additives

History

- 1995 - 2000 : Multiple food scares !
 - Escalating BSE - crises
 - Salmonella eggs / poultry
 - Resistance debate
 - Dioxin crises,
 - GMO, clenbuturol, hormones
 - ...

History

- 1995 - 2000 : Multiple food scares !
- Uncoordinated reactions from Member States & food chain
 - unilateral bans
 - Import and trade restrictions
 - Media hypes
 - opportunistic behaviour retail chains

History

- 1995 - 2000 : Multiple food scares !

- Escalating BSE - crises
- Salmonella eggs / poultry
- Growth promoter bans
- Dioxin crises,
- GMO, clenbuturol, hormones,
- ...

- Uncoordinated reactions from Member States & food chain

- unilateral bans
- Import and trade restrictions
- Media hypes
- opportunistic behaviour retail chains

**Consumer
Confidence
crises in
food safety**

History

- Old legislation : (Dir 70/524/EEC)
 - 5 major amendments since 1970
 - Numerous modifications of annexes, never consolidated
 - no flexibility in categories of additives + mode of administration (drinking water, ...)
 - procedure for dossier evaluation : confusing, not “user friendly” and time consuming
 - different types of authorizations
 - certain derogations at national level were still possible
 - ...

History

EU COMMISSION : White paper on food safety (12.01.2000)

- Creation of EFSA
Parma, Italy
- New feed legislation
Feed additives Reg 1831/2003

History

EFSA

European Food Safety Authority

- Functioning since May 2003
New Location : Italy, Parma
- All scientific advisory EU panels
- Best possible scientific expertise & advise.

“European FDA”

18.10.2003

EN

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L 268/29

**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)**

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⁾,

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.

Novelties

BASIC (modified) PRINCIPLES in the new feed additive Directive 1831/2003:

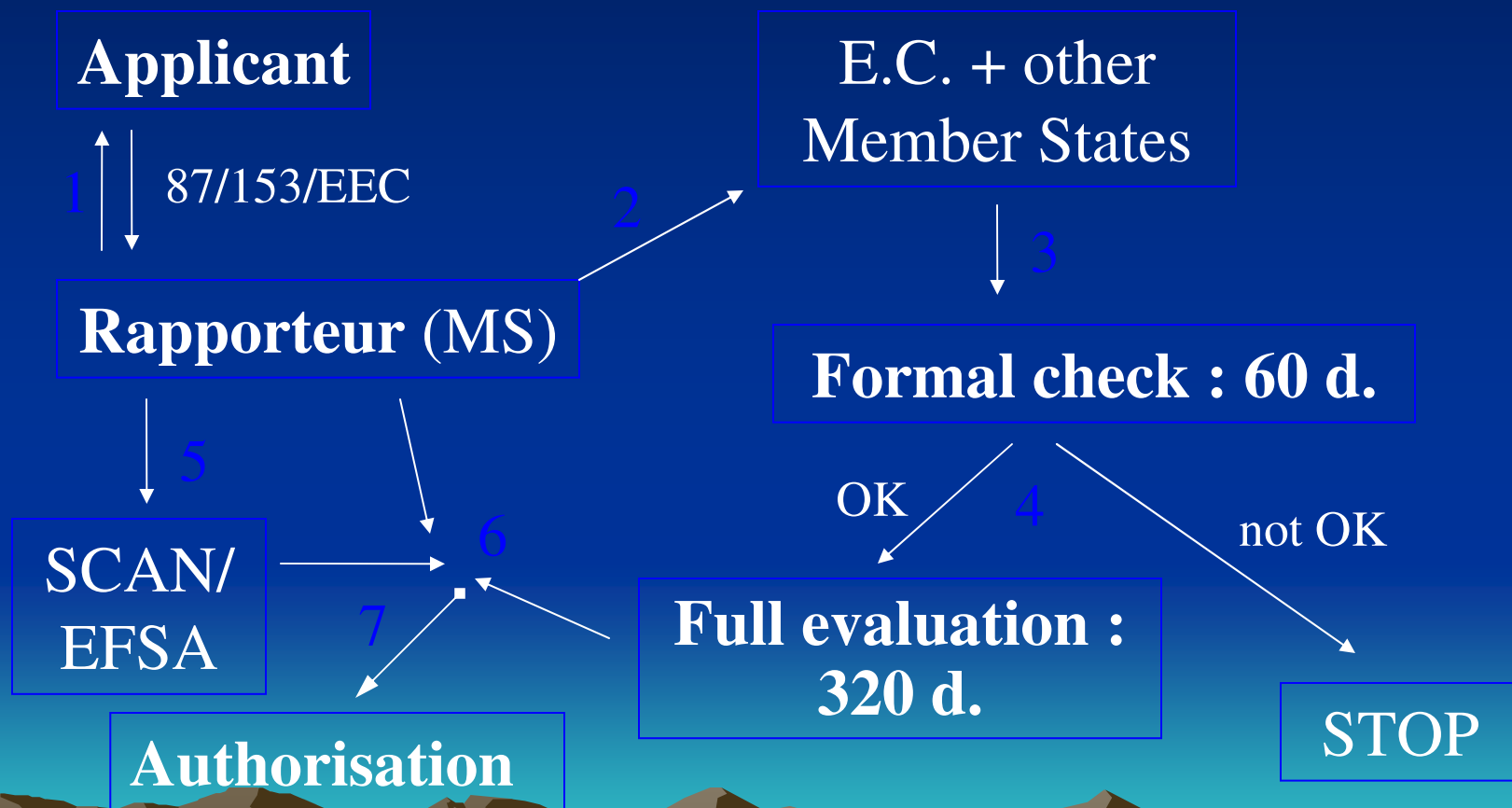
1. Definitions and categories of feed additives
2. Procedure for dossier evaluation - EFSA
3. Authorizations subject to renewals for all additives
4. Supervision and post-market monitoring
5. Introduction of precautionary principle in feed legislation
6. Phasing out growth promoters + Status anticoccidials

1. Definitions and categories of feed additives

- Drinking water included
- Possibility to create new categories
- 5 main categories of feed additives :
 - Technological additives
 - Sensory additives
 - Nutritional additives
 - Zootechnical additives
 - Coccidiostats and histomonostats

New EU feed additive Regulation
Novelties

2. Procedure for dossier evaluation - EFSA Old procedure (70/524/EEC)



New EU feed additive Regulation
Novelties

- new procedure **EFSA**

Applicant

via E.C. (inform MS)

EFSA (European Food Safety Authority)

confirm receipt <15d
submit info to MS/EC
summary: public

Scientific body's
in member states

Opinion within 6 + x months

E.C. (European Commission)

3 months (comitology = Voting by Member States)

Authorisation (or not)

3. Authorizations subject to renewals for all additives

- Duration of authorisation : 10 years
- Possibility to modify, suspend or revoke an authorisation at any time based on opinion from EFSA (on own initiative, or following request of E.C. or MS). Opinion shall be made public
- Existing products : re-evaluation or new dossier within 7 years

4. Supervision and post-market monitoring

→E.C. : conditions for supervision / post-market monitoring may be imposed by authorisation (art. 9(4)c)
(additive specific)

5. Introduction of precautionary principle in feed legislation

The Precautionary Principle – origin :

'... Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation '

(Principle 15 of the Rio Declaration, 1992)

Precautionary Principle introduced in legislation :

(17) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account, including societal, economic or environmental factors, feasibility of controls and the benefit for the animal or for the consumer of animal products. **Therefore, the authorisation of an additive should be granted by the Commission.**

Different approach to products approvals EU versus US :

US : FDA approval (science based)
market decides on use

EU : EU-commission approves based on :
scientific advice
other societal, environmental, economic
benefit for the animal or the consumer
(e.g. hormonal or antibiotic growth promoters)

New EU feed additive Regulation
Novelties

6. Phasing out growth promoters + Status anticoccidials (art 11)

Antibiotic growth promoters :

phase out by Dec 31, 2005

New EU feed additive Regulation
Novelties

Antibiotic growth promoters :

Art. 11 : “... antibiotics, other than coccidiostats and histomonostats, may be marketed and used as feed additives only until 31 December 2005; as of 1 January 2006, those substances shall be deleted from the Register”

= Ban on all antibiotic growth promoters as from Jan 2006

Maxus (avilamycin), (broiles – pigs)

Romensin (monensin-sodium), (cattle)

Salocin (salinomycin-sodium), (pigs)

Flavomycin (flavophospholipol), (broilers, pigs, cattle)

Long term future anticoccidials in the EU

art 11 : “... with a view on the phasing out of the use of coccidiostats and histomonostats as feed additives by 31 December 2012, the Commission shall submit to the European Parliament and the Council before 1 January 2008 a report on the use of these substances as feed additives and available alternatives, accompanied, where appropriate, by legislative proposals.”

Conclusions for anticoccidials :

- report by 2008 advising on the further use.
- New legislation on anticoccidials by 2012
 - possible by 2012 : transition of anticoccidials to a new veterinary product status or maintain feed additive status

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- **BSA - Brand Specific Approvals**
 - What is BSA
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BSA - Brand Specific Approvals

- What is BSA
- Business Impact BSA by product
- Approved BSA products

BSA - Brand Specific Approvals

- Directive 96/51 installed BSA regime for anticoccidials and growth promoters
 - Robenidine, maduramycin, lasalocid, salinomycin, monensin, ...
 - approvals per species
- BSA : approval at brand level for 10 years
 - CYCOSTAT, CYGRO, AVATEC, DECCOX, BIOCOCX
 - approval per species

BSA - Brand Specific Approvals

- - Requires complete registration file
 - Quality
 - Efficacy
 - Toxicity – human and animal safety
 - Ecotox – environmental safety
 - Additive is approved – not the molecule
 - Additive definition includes composition, brand, producer.
 - Producer linked to approval
 - Increased traceability
 - Increased product responsibility
 - Multiple BSA possible for one molecule :
 - e.g. : Sacox®: BSA approved salinomycin from Intervet
 - Salinomax® : salinomycin from Alpharma (BSA pending)
- Each approved based on a complete registration file.

BSA : Impact

- Removal of all generics from the market
 - increased market potential for branded products
 - stop to generic driven quality erosion
- BSA approvals :
 - Alpharma : Avatec[®], Cygro[®], Cycostat[®], Deccox[®],
Salinomax[®] (pending)
 - Elanco : Elancoban[®], Monteban[®], Maxiban[®]
 - Intervet : Sacox[®]
 - Janssen : Clinacox[®]
 - Phibro : Aviax[®]

BSA : Impact

- Remain approved as generic molecules
 - Until Dec 31, 2005 : monensin, salinomycin, avilamycin and flavomycin as antimicrobial growth promoter
 - Untill 2014 : halofuginone as anticoccidial

BSA Impact : banned in EU

- Generic copies :
 - salinomycin, monensin, robenidine, ... : banned as from 2005
- Banned during the BSA process :
 - dinitolamide (DOT) per 1.10.99 (Zoalene[®])
 - ipronidazole per 1.10.99
 - aprinocide per 1.10.99 (Arpocox[®])
 - ronidazol per 18.3.98, Dir 98/19/EC
- Banned May 2002 (Monographs not accepted)
 - amprolium,
 - amprolium/ethopabate (Amprolmix[®])
 - meticlorpindol (Clopidol[®] - Coyden[®])
 - meticlorpindol/methylbenzoquate (Lerbek[®])
 - dimetridazole (Emtryl[®])
 - nicarbazin (Carbigran[®], Cycarb[®], Nicrazin[®] ..)

BSA : Impact

Other feed additives banned in the EU :

- Olaquinox, carbadox
- Avoparcin (1997)
- Tylosin, virginiamycin, spiramycin, zincbacitracin (June 1999)
- Nifursol (May 2003)

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Future outlook

Importance for Non-EU produced meat

Rapid explosion of broiler meat imports from Brazil & Thailand

France = largest EU broiler producer

Brazil imports >> French production !!

BRAZIL = largest EU broiler producer

INCREASED VISIBILITY WITH : - AUTHORITIES
- PRODUCERS

Future outlook

Increased visibility with authorities – producers - consumers

AUTHORITIES :

Residue controls on borders

Increased concern on quality of imported meat

EU production : generic quality gap closed oct 2004

EU imports : need for increased quality criteria &
controls

Future outlook

Increased visibility with authorities – producers - consumers

RETAILERS – CONSUMERS :

- Competitive strength = be more consumer friendly
= be more strict than legislators
(e.g.: labels, brands)
- Consumers : Need for risk free products
(e.g.: BSA approved)
- Retailers ‘solutions’
 - = Growing influence on integrated food chain
 - = Choice of products :
 - EU approved
 - Consumer accepted
 - Restrictive lists of ingredients for production
(e.g.: no AGP)

Animal production in the EU

- Declining broiler numbers in EU
 - Regulatory constraints (precautionary principle)
 - Lower productivity in EU: ban on hormones, AGP, GMO, repartioning agents; medicines availability crisis, zero residue tolerance, environment legislation, ...)
 - Increased imports (WTO, Brazil, Thailand, ...)
 - Relocation of production to new member states or outside EU.
 - Pressure on meat consumption

Future outlook

Consumer confidence in meat :

Still low and damaged by to many real and/or perceived scandals :

BSE, Dioxin, AGP, hormones, MPA, B-agonistssalmonella, food poisoning, animal welfare, transport, manure, pollution, ..

Future outlook

Increased importance consumerism

=

Increased importance retailers in production chain

- * Retailers imposing production methods
- * Restricted list of feed additives by retailers
 - for EU production
 - increased awareness to impose this for on imported meat as well.

- - - > more animal health problems
(necrotic enteritis, coccidiosis, ...)
- - - > lower zootechnical performance

Future outlook

Development of new feed additives for the EU :
green image
replace antimicrobial growth promoters

New products : prebiotics (mannans, inuline, other FOS)
immunostimulants (B-glucans, ...)
probiotics
organic acids
herbs
aromatic substances

....

Future outlook

‘Green consumer’ ?

Who is he ?

Future outlook

Monday - Friday : Convenience food

Objective criteria :

- * Safe
- * Price
- * Tast
- * Healthy
- * Convenience : easy to prepare - consume

Future outlook

Monday - Friday : Convenience food

Saturday - Sunday ?

Future outlook

Saturday – Sunday = **BIO-TIME !!!**

Emotional criteria :

Environment

Animal welfare

Traditional production

Small scale

Premium priced luxury item

Consumers with higher income

Future outlook

Restore consumer confidence

=

Everyone's responsibility

* authorities : legislation, EFSA, controls, ...

* production : ISO, GMP, HACCP, ...

+ communication with consumers, retailers, press

Future outlook

Consumer confidence restoration

BE GOOD AND TELL IT !