

20.2.2003

FEFAC INITIAL COMMENTS ON THE DRAFT FEED HYGIENE REGULATION

1. GENERAL COMMENTS

FEFAC welcomes the establishment of hygiene rules embracing the overall feed chain from primary producers to livestock holdings.

We are glad to see that the EU Commission has recognised that the current EU feed legislation on approval of feed establishments excluded most feed business operators (suppliers of feed materials, transporters, home mixers, etc.). The recent feed safety incidents however resulted from shortcomings at the level of suppliers of feed materials. In setting hygiene requirements for all operators in the feed chain, i.e. primary production of feed, suppliers of feed materials (including the food industry), transporters, traders, retailers, compound feed manufacturers, home-mixers and livestock holdings, the EU Commission finally tackles the root cause of these incidents with the appropriate means. We hence believe that this text on feed hygiene provides a unique opportunity to the EU legislators and operators of the feed chain to complete a consistent, reliable framework on feed&food hygiene to rebuild consumer confidence in animal feed and livestock products.

However, and as already stated in our general position on the EU Commission White Paper on Food Safety, FEFAC regrets that no measure is proposed to address the crucial question regarding the sources of risk factors. Any contamination has a source, which may often be found outside the feed chain, i.e. in industrial pollution of the environment (municipal waste incinerator) or shortcomings in the implementation of the waste legislation (MPA contamination). We believe that strengthening the EU feed & food legislation can only be effective if accompanied by measures aiming at privileging source-directed measures reducing the exposure of the feed chain to external contamination risks.

1.1. Provisions which FEFAC fully supports

We welcome the willingness of the Commission services to ensure the **highest level of consistency between feed and food hygiene rules**, thus embodying the integrated approach from farm to table endorsed by the EU authorities in the General Food Law. We however regret that, in addressing the issue of feed and food hygiene in two separate texts, an important occasion has been missed to improve the transparency of the new integrated approach, like in the case of official feed and food controls.

We welcome the **all-inclusive scope of the text**, limiting exemptions to very specific circumstances. We indeed believe that **compulsory registration, as a minimum requirement, is an essential step** towards an efficient traceability system and to increase feed business operators awareness of their responsibility in the overall improvement of feed safety.

We also welcome the **mandatory introduction of HACCP** together with good hygiene practices. Such a requirement is already laid down as a cornerstone in FEFAC's guidelines for the development of national codes of good practice for compound feed production.

We finally support the proposal aiming at facilitating the development, the implementation and **the official recognition of professional codes of good practice**. We share the views that such codes are very instrumental in speeding up the implementation of good practice all along the feed chain. We also support the two-pronged approach, namely the development of national codes and the establishment of EU guidelines for such codes. However, we would like to insist on the essential role of the EU Commission in ensuring that existing or new national codes will maintain a **level playing field and preserve the internal market**.

1.2. Provisions which FEFAC cannot fully support in their present form

We believe that the **exemptions provided to primary producers concerning the implementation of HACCP** could seriously undermine the overall objective of improved feed safety. App. 98% of what food animals are fed with are primary crops, either in a natural or processed state. Many contamination cases can take place at primary production level. Setting rules on the control of hazards must be based on an a-priori analysis of such hazards. We believe that the origin of contaminations should be subject to a thorough risk analysis enabling to identify the critical control points and the adequate corrective actions that any primary producer can and should take. Such a hazard analysis should be carried out at least for each sub-sector of primary production of feedingstuffs.

We also hold the view that the present scope for the **approval of feed establishments should allow for a future extension to all feed business operators**, including primary production, food industry, transporters, traders, etc. Many recent feed safety incidents clearly took their origin in feed business not currently subject to official approval (Dioxin in milk coming from primary crops grown next to municipal waste incinerator, contamination of glucose syrup by MPA at the level of a waste disposal plant, contamination of cereals with Nitrofen in a warehouse). We therefore believe that the Commission could miss the lessons of the recent incidents if it would not foresee the possibility to enlarge the scope of the approval procedure to any feed business operator. Furthermore, experience proved that the implementation of HACCP may take a long time if no official control pressure is put on operators. An approval procedure would considerably accelerate the adoption of this risk control technique. We do realise that such an approach may be complex and time-consuming, warranting a step-wise approach to be considered.

1.3. Provisions which FEFAC believes should be dealt with outside this text

We are **surprised to see in the working document a specific obligation for feed business operators to contract financial guarantees, a provision currently not foreseen for food business operators**. We believe that three conditions are required for the implementation of such a provision in EU legislation:

- the responsibility of the operator should be clearly established by the authorities as well as the responsibility of the control authorities themselves in their function as risk managers in applying the precautionary principle as well as in case it should not be possible to determine the responsibility at operator's level.
- the risk should be known and demonstrable (it is difficult to evaluate the costs of unknown risks, in particular since they depend to a large extent on the risk management measure which public authorities would take in application of the precautionary principle);
- insurance companies should accept to cover the costs; taking into account that the reaction of public authorities to incidents is often unpredictable and driven by newspaper headlines rather than scientific risk evaluation, insurance companies are reluctant to provide their service to say the least.

We therefore believe that the Commission should further reflect on this issue which we think may be **better addressed in horizontal texts such as Directive 85/374/EEC** on liability of defective products or Directive 2001/95/EC on general product safety.

1.4. Provisions which FEAC misses in the present text

A key objective of the recast of the EU feed legislation as mentioned in the white paper for food safety was to identify and fill in the loopholes and withdraw the shortcomings of the present legislation. One key area of concerns for the feed industry has been for years the **issue of concentration of feed additives**, either delivered to animals as **nutritional supplements or complementary feed**. The recent control reports of the FVO however show that the current EU legislation can give rise to different interpretations by national control authorities on this issue leading to problems as regards the question what approval conditions should apply to feed business operators producing or using these products. The new draft regulation on feed additives does not address the issue of nutritional supplements and does no longer provide for concentration rules for complementary feed. We expected the feed hygiene regulation to take up the issue. However, there is no reference in the new draft proposal to the legal limits between premixes, complementary feed and nutritional supplements. We therefore ask the Commission to clarify its working intention in that respect.

We also believe that **there is a need to clarify whether the manufacturing of medicated premixes & feed should also fall inside the scope of a feed hygiene regulation**. We believe that this text offers a unique opportunity to the Commission to lay down harmonised rules for the implementation of Directive 90/167/EC. We have noted that there are significant differences in the legal interpretation of Directive 90/167/EC by the Member States. In some Member States medicated feed is legally classified as veterinary medicines. Such an interpretation at EU level would have as a consequence that most feed compounders have to stop the production of medicated feed as they can not fulfil the requirements for the production of veterinary drugs under normal feed manufacturing conditions (i.e. because of the request for a 0-tolerance as regards cross-contamination). Such a step may lead to serious control problems to the detriment of animal health and public health.

We also miss a **technical annex providing for minimum hygiene requirements for transport of feed or for feed production machineries**. We indeed believe that transport or the use of machines are critical points in the control of hazards along the feed chain and that a dedicated annex as foreseen in the proposal for a Regulation on food hygiene (COM (2003) 33) would contribute considerably to increase transporters' awareness of their role and obligations regarding the respect of feed hygiene requirements.

1.5. International dimension

We understand from the explanatory memorandum that third country operators who wish to export feed to the EU should comply with equivalent requirements as these laid down in this draft proposal for feed hygiene. This mirrors the approach taken in the food policy, i.e. that third country operators who wish to export food to the EU should implement equivalent requirements as provided for in the draft food hygiene regulation. However, the proposal on food hygiene does not include any requirement regarding feed safety except the proper use of feed additives (see COM (2003) 33, Annex 1). We believe that, in this respect, the EU Commission did not fully match the objective laid down in its White Paper on Food safety (par. 8), i.e. a "comprehensive integrated approach" (Farm to Table policy) "at the EU external frontier and within the EU". The credibility of the system depends to a large extent on the ability of EU authorities to **impose the implementation of equivalent measures in third country feed & food establishments** exporting to the EU. We believe that any livestock product imported in the EU may only be seen as meeting the EU standards if the same hygiene rules as provided for in the EU have been implemented in third countries for any operation of manufacturing, storing, processing and distribution of feed to animals to be exported to the EU.

2. DETAILED COMMENTS

Recital 28:

- Recital 28 refers to the ban on dilution provided for in Directive 2002/32/EC. We do not see the rationale for such a statement since, as far as we can read, no further reference is made to this ban on dilution in the rest of the text. Furthermore, we miss an equivalent reference to the ban on dilution in the Common Position on the food hygiene regulation, thus suggesting that dilution might be allowed in the food sector.

Art 2, par. 1:

- Does the scope also cover the water supply to food animals as suggested in Annex III? If yes, this should be clearly mentioned in Art. 2.
- In its Common Position on Food Hygiene, export of food is clearly included in the scope of the text. The EU Commission does not provide the same clarification in the scope of the draft feed hygiene regulation. Should we understand that the Commission considers that the current wording is clear enough and covers also feed for export purpose? Or would that mean that feed for export is excluded from the scope of the present proposal?
- Animals may receive feed in case of long distance transport. Does the scope of the regulation cover such a feeding practice?

Art 2, par. 2:

- The wording used in indent a) and b) may give raise to different interpretations. We would suggest to use the following alternative:
“a) any operation, carried out at private domestic level, for feeding of food-producing animals for private domestic consumption;
b) any operation, carried out at private domestic level, for feeding of animals not kept for food-production;”
- In indent c), what does “small quantities” mean? We are aware that the same concept has been introduced in the EU Council Common Position on the proposal for a food hygiene regulation but we believe that it is in practice an open invitation to national authorities to exempt thousands of farms from any obligations in terms of feed hygiene. We would therefore every much encourage the Commission to provide for a maximum figure, f. ex. 100 kg.

Art 3:

- Reference is made in Annex II par. 6 to water of potable quality for animals. Is there any definition of “potable quality for animals”?
- The border line between primary production and home-mixing is not clearly established: does primary production cover the blending in mixer wagons on the farm of feedstuffs produced on the farm?

Art 4:

- Its is not clear when reading this article whether livestock holdings are covered by the definition of feed business when their activity consists only in feeding animals: the feeding operation is indeed subject to a different paragraph than other operations. This is essential since most provisions laid down in this draft regulation (and in particular the mandatory registration) apply to feed business operators only.

Art 8, par. 3e:

- Is the extension of the scope of approval under the competence of the Commission or should it be subject to co-decision?

Art 10:

- Article 10 provides for the establishment of a list of approved feed business. There is no equivalent requirement for registered feed business. Since traceability is clearly identified as a key objective of this proposal, we think that any feed business operator should have the possibility to check if its supplier is registered, which may only be achieved through an updated EU list of registered feed business operators.

Annex 1:

- Record Keeping, par. 2: it does not seem to us essential that information regarding the use of fertilisers are to accompany consignments of primary products.

Annex 2:

- Facilities and equipment, par. 8: this clause should state 'proofed against pests', not '*pest-proof*'. It is virtually impossible to make an opening window or door '*pest-proof*'.
- Quality control, par. 2: 'Feed businesses... to guarantee and check, before release of the products with a view to putting them into circulation, that they comply with the specifications defined by the manufacturer'. Taking into account the rapid turnover in final products, in particular in case of emergency manufacturing and delivery, a requirement imposing a "positive release" is simply unworkable. Standards for Quality Management System have been developed internationally in particular with a view to provide at least part of the guarantee where checks before delivery are not feasible.
- Quality control, par.4: keeping of reference samples 4 months after expiry date is not realistic and of no practical value. Results from analyses performed after the expiry date may not be used since the principle of an expiry date is that beyond this date, the status of the product may no longer fit safety standards.
- Storage and transport, par. 6: in hot countries, over-cooling the product can also create condensation.
- Labelling, par.3: this provision would apply to any feed, either feed materials or compound feed. However, the supplier of feed materials does not know in which species feed its product will end up. If the purpose of this provision is primarily customer's information of any restriction of use, for example the ban on intra-species recycling of processed animal proteins, or for additives authorised for certain species only, we believe that this provision should read "the label should also contain information about restrictions of use".
- Documentation, par. 2 b): is there any explanation supporting the fact that no record-keeping of the details of the customers is required for additives, whereas it is foreseen for other feed?