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FEFAC comments on the proposal for a European Parliament and Council Regulation on additives for use in animal nutrition (2002/0073 (COD))

Key issues:

- **the re-evaluation process and the ten-years authorisation period could lead to the loss of a large number of essential feed additives;**
- **the case of minor species is not addressed;**
- **a link should be made with the EU food additives legislation; in particular a simplified authorisation procedure should be set for additives already authorised for food use;**

Other issues:

- **amino-acids are included within the scope of the proposal without any explanations;**
- **methods of analysis of additives in feed should be published;**
- **the withdrawal of authorisation of an additive should require the publication of a regulation with a time period for using up remaining stocks of products, even within the framework of a renewal of authorisation.**

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I. General comments

1. FEFAC welcomes the principle of a revision of the feed additives legislation. The complexity of the current legislation, the limitations which could be seen in the authorisation procedure, the new integrated approach towards more harmonised rules in the food and feed chains, the necessity to fill in loopholes in the Public Health legislation and to avoid grey zones: all these issues are clear arguments in favour of a recast of the legislation on feed additives that we fully support.

2. However, FEFAC would like to share its reservations as regards the result of this revision process carried out by the Commission, i.e. the proposal for a regulation on additives for use in animal nutrition (2002/0073 (COD)):

- the proposal may be seen as a step forward when it comes to clarification and transparency; however, most useful but complex provisions such as those concerning inclusion rates have simply been removed, thus creating new legal gaps;
- we do consider that the authorisation procedure is worded in a more understandable way; however, as it is proposed, the new authorisation procedure means that a large number of essential additives will be lost just because their re-evaluation every ten years will be too costly, although they have been used over long periods in animal nutrition; such a result would be detrimental to the welfare of farm animals and to the competitiveness of the EU livestock chain; the case of minor species is not solved at all and the brand specific approval system remains in place, which is in complete contradiction with the promotion of use of generic products favoured in the medical area;
- we expected from this new text to establish a link to the food additives legislation in application of the integrated approach on food safety demanded by the Council and the EP; this would have enabled the feed chain to benefit from a simplified procedure for the use of certain food additives and thus recognised as safe from a public health perspective; we therefore regret that no reference is made to food additives.

3. FEFAC would like to recall that, in contrast to the food sector, feed additives and in particular those belonging to the categories nutritional additives, zootechnical additives and coccidiostats play an essential role in contributing to animal welfare. FEFAC therefore urges the Council to take into consideration the cost in terms of animal welfare which would arise from the withdrawal of authorisation of orphan additives, e.g. sources of trace-elements.

4. FEFAC would like to stress that adequate measures should be taken to ensure that imported animal products do not stem from animals fed with feed additives which have been either withdrawn or not approved for feed use within the EU for safety reasons. European consumers interests should be protected whatever the origin of the products.

5. For these reasons, FEFAC considers that the proposal could prove to be a step backward from a public health, animal welfare and economic perspective in many areas compared to the current Directive 70/524/EEC, without providing additional guarantees in terms of Public Health nor in terms of fair trading practice.

II. Specific comments

- Scope

6. FEFAC welcomes the extension of the scope to cover all different routes of administration of feed additives. FEFAC has always argued that the safety of animal products was not just the question of commercialised compound feed but depended on a legislation which would take care of all feedstuffs (including drinking water) consumed by farm animals. In this sense, the EU Commission proposal is a step in the right direction.

7. We feel there is a case to maintain coccidiostats in the scope of the feed additive legislation. The consequence of removing these products from the scope of this legislation and to request authorisation as veterinary drugs would be an increase in cost in administering these products to farm animals while jeopardising their efficient control at farm level at the expense of the protection of animal and public health. We therefore fully welcome the proposal to include coccidiostats under the umbrella of the new regulation.

8. FEFAC does not see the reason why amino acids should be brought under the scope of the feed additives legislation. We hold the view that there is no case to consider such products separate from other feed materials, as is the case today although they have been subject to an authorisation procedure within the framework of Directive 82/471/EEC on certain constituents.

9. We can support also the exclusion of processing aids and unavoidable residues thereof from the scope of definition of additives. These issues should be best addressed in separate legislation such as the long awaited feed hygiene regulation.

- Categories of additives

10. FEFAC shares in principle the idea to reduce the number of feed additive categories for the sake of transparency. We believe that the objective to regroup additives under new categories characterising their main purpose could improve the comprehension for the need of these additives by our customers, the livestock farmers as well as the final consumer of animal products.

11. We also strongly support the introduction of a flexible subcategory system. A number of potential feed additives could not be registered in the past just because they did not fit in the classification system in operation under Directive 70/524/EEC.

12. We do not see the purpose of introducing a specific category for coccidiostats which perfectly fit in the definition of zootechnical additives.

- Authorisation procedure

13. FEFAC agrees that it should be the role of the EFSA to draft the guidelines for products application files. However, FEFAC believes that it would be worth mentioning that these guidelines may be different according to categories. FEFAC would also like to call for the establishment of a simplified procedure for all additives which have already been subject to an authorisation procedure under the food legislation. The one door / one key principle proposed by the EU Commission for GM food and feed (see COM (2001) 425)) should also apply in the context of additives.

14. While FEFAC remains supportive of a species-based approval system, FEFAC sees also the case for a simplified procedure enabling to extend an authorisation to minor animal species once a product has obtained approval for a major animal species. The alternative approach would be to seek authorisation for all animal species, including minor species, with the possible exception of certain zootechnicals.

15. We do not see any benefit in term of public health of having feed additives authorised on the basis of efficacy criteria. FEFAC does believe that the best judge of the efficacy of a feed additive is the customer himself.

16. FEFAC welcomes the obligation made to petitioners to present a method enabling to analyse the additive in feed. However, FEFAC holds the view that this method should be subject to evaluation by competent technical committees with a view to official publication.

17. FEFAC strongly supports the idea of seeking EMEA's product evaluation with the establishment of MRLs for certain feed additives under the condition that the additional expense for product dossiers would not lead to the loss of these products which continue to play an essential role in the livestock management. We believe that such MRLs should serve as a basis for the determination of an acceptable level of adventitious presence of these additives in feed for non-target animals in the framework of the feed hygiene regulation in application of the ALARA principle.

- Re-evaluation of additives authorised under Directive 70/524/EEC

18. Although we recognise the need for a thorough safety evaluation based on a risk assessment by the EFSA to exclude animal and public health risks, we find it hard to accept that all authorised feed additives shall be subject to a re-evaluation and a 10-years authorisation period. For a number of products, no potential petitioner can be identified, for example for sources of trace-elements. In other cases, the economic cost/benefit assessment of the re-evaluation procedure is clearly not in favour of the introduction of a petition.

19. We fear that the short delay for the renewal of authorisation for coccidiostats may lead to the loss of several molecules. We would like to remind that it is essential for the livestock chain to have the largest possible spectrum of molecules in order to fight coccidiosis efficiently and thus ensure animal welfare.

- Withdrawal of authorisation

20. FEFAC fully supports the principle that any withdrawal of authorisation requires the publication of a regulation. It should however be made it clear in art. 11 par. 5 that in the absence of decision before the expiry date for reasons beyond the control of the applicant, the period of authorisation of the product shall be extended (as foreseen in art. 15 par. 5 for renewal of authorisations). Along the same logic, it should be mentioned in art. 15 that the non renewal of an authorisation requires the publication of a regulation, which may provide for a period of time within which existing stocks may be used up.

21. FEFAC would like to insist that equivalent rules apply to animal products imported within the EU. This approach should apply in particular where a feed additive is withdrawn or not approved in the EU for safety reasons and on the basis of sound science. This principle should be taken into consideration when considering the proposal for a phasing out of the four remaining antibiotic growth promoters.

- Other issues

22. Since all provisions regarding the concentration of additives have been withdrawn, in particular art. 12 of Directive 70/524/EEC, FEFAC would like to seek clarification as regards the future legal framework within which the issue of additives concentration is to be addressed and which transitional measures would apply pending the adoption of this new legal framework.