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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT CARRIED OUT IN DENMARK FROM 27 JANUARY 2015 TO 04 FEBRUARY 2015 IN ORDER TO EVALUATE THE PRODUCTION AND USE OF CERTAIN PROTEINS OF ANIMAL ORIGIN IN FEED FOR AQUACULTURE ANIMALS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Denmark from 27 January to 04 February 2015.

The objective of the audit was to evaluate the ability of the system of official controls to ensure that the requirements regarding the derogation allowing the use of processed animal protein (PAP) of non-ruminant origin to be used in the production of feed for aquaculture animals are complied with. In terms of scope, the audit focused on the new legal and administrative measures introduced with the last amendment of Regulation (EC) No 999/2001 aimed at ensuring that only eligible PAP of non-ruminant origin is used for the production of feed for aquaculture animals. Particular attention was paid to the requirements for authorisation of establishments (slaughterhouses, processing plants and producers of compound feed) and cleaning procedures concerned with this derogation.

Overall, the report concludes that the system of official controls already in place in slaughterhouses, ABP plants, transporters of ABP and PAP and in feed manufacturers producing feed for aquaculture animals has not been extended yet to include the requirements related to the use of derogated PAP. Although the competent authority undertook some immediate actions to address some of the shortcomings identified during the audit, the ability of the competent authorities to ensure that only eligible PAP is used for the production of feed for aquaculture animals is still limited.

The report makes a recommendation addressed to the Danish competent authorities, aimed at rectifying the shortcomings identified and further enhancing the implementing and control measures in place.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ABP	Animal by-products
ABP/DP	Animal by-products and derived products
ABP Regulations	Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2001
DVFA	Danish Veterinary and Food Administration - Fødevarestyrelsen
EU	European Union
EURL-AP	European Union Reference Laboratory for Animal Proteins
FCO	Food Control Office
FVO	Food and Veterinary Office
HACCP	Hazard Analysis Critical Control Point
OF/SI	Organic fertilisers and soil improvers
PAP	Processed animal proteins
PCR method	Polymerase Chain Reaction method for DNA analysis
RASFF	Rapid Alert System for Food and Feed
VCO	Veterinary Control Office

1 INTRODUCTION

The audit took place in Denmark from 27 January to 04 February 2015.

The audit team, which comprised two auditors from the Food and Veterinary Office (FVO), was accompanied throughout the audit by two representatives of the central competent authority, the Danish Veterinary and Food Administration (*Fødevarestyrelsen* – DVFA).

An opening meeting was held on 27 January 2015 with the central competent authority, during which the audit objectives, itinerary, and the standard reporting and follow-up procedures were confirmed, and additional information required for the satisfactory completion of the audit was requested.

2 OBJECTIVES AND SCOPE

Article 7 of Regulation (EC) No 999/2001 of the European Parliament and of the Council establishes the prohibition of using certain proteins of animal origin for feeding farm animals (prohibition known as the "feed ban"). Commission Regulation (EU) No 56/2013 amends Regulation (EC) No 999/2001 and allows the feeding of aquaculture animals with processed animal protein (PAP) of non-ruminant origin provided some specific conditions are met. The objective of the audit was to evaluate the ability of the system of official controls to ensure that the requirements introduced by this Regulation are complied with. The above was assessed against the following audit criteria:

- Regulation (EC) No 999/2001 of the European Parliament and of the Council
- Regulation (EC) No 1069/2009 of the European Parliament and the Council
- Commission Regulation (EU) No 142/2011
- Regulation (EC) No 882/2004 of the European Parliament and the Council.

In terms of scope, the audit focused on the new legal and administrative measures introduced by Commission Regulation (EU) No 56/2013, which amends Regulation (EC) No 999/2001. Regulation (EU) No 56/2013 sets out conditions to ensure that only eligible PAP of non-ruminant origin is used for the feeding of aquaculture animals. These conditions are provided for in Section D, Chapter IV of Annex IV to Regulation (EC) No 999/2001. In this respect, particular attention was paid to the implementation of the requirements for authorisation of establishments (slaughterhouses, processing plants and producers of compound feed) wishing to handle both ruminant and non-ruminant proteins and the measures adopted to prevent cross-contamination of PAP and feed for aquaculture animals with these proteins. In this context, the testing for the detection of ruminant protein through the detection of ruminant Deoxyribonucleic acid (DNA) using the polymerase chain reaction (PCR) in PAP or feed for aquaculture animals was also examined.

The audit itinerary included the following:

Visits/meetings		No	Comments
Competent authority	Central	2	Opening and closing (de-briefing) meeting
	Regional	2	Meetings with a Veterinary Control Office (VCO) and a Food Control Office (FCO)
Slaughterhouse		1	Slaughtering ruminant and non-ruminant animals, delivering Animal by-products (ABP) for the production of feed for aquaculture animals
Processing plants (Cat 3)		2	Processing exclusively ABP from non-ruminant animals
Transporters		1	Transporting ABP to a processing plant and PAP to be used for the production of feed for aquaculture animals from the processing plant
Feed establishments		2	Producing feed for aquaculture animals, using PAP from non-ruminants other than fish meal
Laboratories		1	Discussions with the DVFA laboratory in Ringsted held after the opening meeting
Aquaculture farms using feed containing PAP from non-ruminant animals		1	A trout farm using feed containing PAP from non-ruminants

3 LEGAL BASIS

The audit was carried out under the general provisions of Community legislation and in particular, Article 21 of Regulation (EC) No 999/2001, Article 49 of Regulation (EC) No 1069/2009 and Article 45 of Regulation (EC) No 882/2004.

4 BACKGROUND

4.1 PREVIOUS FVO AUDITS

The last audit on ABP requirements performed in Denmark was DG(SANCO) 2010/8466. The report concluded that the control system for ABP, despite some minor shortcomings, largely ensured compliance with the requirements of the ABP legislation with a satisfactory system for the separation and disposal of ABP in place. The report can be found here:

http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=2512

4.2 INFORMATION ON THE CHAIN OF PAP TO BE USED IN AQUACULTURE FEED

There are two processing plants in Denmark producing PAP of non-ruminant origin to be used in aquaculture feeding. PAP produced for that purpose concerns feather meal, porcine blood meal and spray-dried blood products from porcine animals. Produced PAP is sent amongst others to fish feed producing establishments in other Member States, either directly

or through traders based in other Member States, or are sent to the two fish feed manufacturers in Denmark. Both processing plants produce together annually almost 7000 tonnes of PAP eligible for use in aquaculture feeding.

The two processing plants are mostly supplied by single species slaughterhouses, however, the competent authority does not avail yet of the complete picture as regards the destination of the ABP originating from mixed-species slaughterhouses.

There are two fish feed manufacturers in Denmark using derogated PAP from non-ruminants in their formulations. The total annual production of these is around 130,000 tonnes, which are sold mainly in the EU but are exported also to third countries.

There are no traders in Denmark for PAP for aquaculture feeding and no aquaculture farms with on-farm mixers. All aquaculture farms in Denmark obtain compound feed directly from the feed manufacturers.

5 FINDINGS AND CONCLUSIONS

5.1 OFFICIAL CONTROL SYSTEMS

Legal requirements

Article 4(3), 23, 24, 45 and 47 of Regulation (EC) No 1069/2009; Article 32 of Regulation (EU) No 142/2011; Article 3 of Regulation (EC) No 882/2004; Article 7 and section D, Chapter IV and section A and F Chapter V of Annex IV to Regulation (EC) No 999/2001; Annex VI to Regulation (EC) No 152/2009.

5.1.1 Competent authorities

1. The competent authority for the official controls along the chain, from the production of ABP, the transport of these ABP to the processing plant, the processing into PAP, and the use of the latter in compound feed for aquaculture animals is DVFA. Each one of its three disciplinary departments is responsible for performing official controls at different stages along the chain.

    a. The Meat Inspection Department with its meat inspection units in the slaughterhouses is responsible, aside from the meat inspections, for the official controls on ABP generated and dispatched from slaughterhouses.

    b. The Veterinary Department, with its three VCOs, carries out amongst other duties official controls on ABP/DP in ABP plants.

    c. The Feed and Food Department with its five FCOs carries out official controls in feed establishments.

5.1.2 Derogations, registration, specific authorisation and listing

2. Denmark makes use of the derogation allowing the use of non-ruminant PAP in the production of feed for aquaculture animals and, at the time of the audit, no authorisations had been given to any mixed-species slaughterhouses delivering ABP for the production of PAP to be used in feed for aquaculture animals. Nonetheless, the audit team noted that one slaughterhouse visited, occasionally slaughtering also bovine animals, was supplying porcine blood for the production of PAP to be used in feed for aquaculture animals without being subjected to prior authorisation by the competent authority (see point 11).

3. Lists of slaughterhouses, ABP processing plants producing derogated PAP to be used in feed for aquaculture animals and feed manufacturers using these derogated PAP, are publicly available on-line. However, the audit team noted that the lists of slaughterhouses did not include any indication or remark on whether ABP for the production of derogated PAP for aquaculture feed can be sourced, contrary to the requirement laid down by Chapter V, Section A of Annex IV to Regulation (EC) No 999/2001. Nonetheless, the competent authorities explained that an initiative aimed at obtaining information about the species slaughtered had been rolled out since December 2013 and it should be finalised by the end of 2015. Moreover, following the discussions during the audit, the audit team noted that the competent authority undertook immediate actions to include the establishments already known in the publicly available lists.

4. The competent authorities have authorised cleaning procedures for transporters carrying feed for non-ruminants containing PAP (including fishmeal), blood products, dicalcium and tricalcium phosphate of animal origin, milk replacers containing fishmeal and feed containing ruminant materials (i.e. pet food, feed for fur animals), if the subsequent load is feed for ruminants. The majority of cleaning procedures concerns transporters carrying fishmeal and blood products and subsequent feed for ruminants. Nevertheless, no authorisations of procedures for the cleaning of vehicles and containers used for transportation of ruminant and non-ruminant ABP were yet granted, if the latter is destined for the production of PAP for aquaculture feeding (see point 12).

5.1.3 Organisation and planning of official controls

5. In the slaughterhouse, in the processing plants and in the transporter visited, the audit team noted that, although checks on requirements of the ABP legislation were carried out during official controls, these had never included the specific requirements applicable to sourcing and transport of ABP to be used for the production of derogated PAP for aquaculture feeding. Moreover, it was noted that neither guidelines nor checklists were available to the inspectors to assist them in verifying compliance with these requirements. As a result, official controls overlooked a number of deficiencies (see points 11, 12 and 13). This is not in line with the requirements on official controls laid down in Section F, Chapter V of Annex IV to Regulation (EC) No 999/2001.

6. Official controls in manufacturers of feed for aquaculture cover aspects related to the feed ban in general. A specific checklist, which includes feed ban related issues, is available,

although it is officially no longer in use because it needs to be updated in order to include the specific requirements for the use of derogated PAP for aquaculture feeding. In this respect, the audit team noted that some requirements related to operators' own checks and their procedures for sourcing eligible PAP had been overlooked during official controls (see points 14 and 17). This is not fully in line with the requirements on official controls laid down in Section F, Chapter V of Annex IV to Regulation (EC) No 999/2001.

7. A sampling plan for detection of ruminant DNA in feed for aquaculture animals is in place but only in compound feed producers. A guidance document has been prepared by DVFA in the framework of the so-called PCR project for detection of ruminant DNA in feed for aquaculture. This guide includes instructions for inspectors about the raw materials to be prioritised during sampling. Samples of blood meal, blood products, hydrolysed protein, collagen and gelatine and feed containing fish meal to be taken in fish feed producing establishments and establishments producing feed for ruminants are considered as a priority, although it was noted that the vast majority of the samples taken so far derived from feed for aquaculture animals containing only fishmeal. This is not fully in line with the requirements on the risk-based approach for official controls laid down by Article 3 of Regulation (EC) No 882/2004. Nonetheless, the competent authorities undertook immediate actions in this regard and the audit team saw evidence of a new guideline for inspectors and laboratory staff to address this issue.

8. The DVFA laboratory in Ringsted is the only laboratory in Denmark carrying out analyses for detection of ruminant DNA in PAP or fish feed containing PAP. The audit team noted that, although the polymerase chain reaction method (PCR method) for detecting ruminant DNA is not yet in the scope of accreditation of the laboratory, the method has been validated and it will be included in the scope of the accreditation during the next assessment by the accreditation body, planned at the beginning of 2016. Moreover, the laboratory has successfully participated in two proficiency tests for detection of ruminant DNA in feed organised by the European Union Reference Laboratory for Animal Proteins (EURL-AP) and has proven its capability to deliver valid results for this type of analyses.

9. However, the audit team noted that the DVFA laboratory did not always use the Standard Operating Procedure describing the operational protocols for the combination of light microscopy and PCR, developed by the EURL-AP, although this procedure is a binding complement of the requirements laid down by Annex VI to Regulation (EC) No 152/2009. All samples were first submitted to screening by the light microscopy method irrespective of the nature of the concerned sample. It was noted that aquaculture feed samples containing blood meal were not submitted to PCR, contrary to the aforementioned Standard Operating Procedure, because the light-microscopy method did not detect any particles from terrestrial origin. Following the audit and during the drafting of the report, the competent authority informed the audit team that the laboratory would now follow the above-mentioned Standard Operating Procedure.

Conclusions on official control systems

10. A system of official controls on the requirements concerning the ABP legislation and the general feed ban is in place in slaughterhouses, ABP plants, transporters of ABP and PAP and in feed manufactures producing feed for aquaculture animals. This also includes a sampling plan to detect ruminant DNA in feed for aquaculture animals. However, no specific checks on the new requirements pertaining to the use of derogated PAP in aquaculture feed have been organised yet. As a consequence, although the competent authorities undertook some immediate actions to address some of the issues identified, they are not yet in position to ensure that only eligible PAP is used for the production of feed for aquaculture animals.

5.2 OFFICIAL CONTROLS ON THE IMPLEMENTATION OF FEED BAN REQUIREMENTS ALONG THE CHAIN

Legal requirements

Article 7 and Section F, Chapter V of Annex IV to Regulation (EC) No 999/2001, Article 21, 22, 45(1), 46, 53 of Regulation (EC) No 1069/2009, Article 17(1) of Regulation (EU) No 142/2011; Regulation (EC) No 882/2004 and Annex VI to Regulation (EC) No 152/2009.

5.2.1 Origin of ABP and their processing into PAP

11. The slaughterhouse visited, which was sending blood of non-ruminant origin for the production of PAP to be used in the production of feed for aquaculture animals, was recently identified by the competent authority as also occasionally slaughtering bovine animals (emergency slaughters). Although the business operator declared that bovine animals arrive at the slaughterhouse already bled out and are processed in a separate slaughter hall than the one used for slaughtering pigs, this could not be confirmed from the documentation available. More importantly, the audit team noted that the competent authority had not carried out any check to verify whether the requirements applicable in case of multi-species slaughterhouses supplying ABP for the production of derogated PAP were fulfilled by the operator, as required by Chapter IV, Section D, point (a) of Annex IV to Regulation (EC) No 999/2001. This is not in line with the requirements on official controls laid down in Section F, Chapter V of Annex IV to Regulation (EC) No 999/2001.

12. In one of the processing plants visited, the transport of ABP was outsourced to an external ABP transporter, who was also authorised to transport Category 2 and Category 3 ABP with no limitations in terms of animal species. This transporter was also providing the reusable containers. The audit team noted that the processing plant operator did not have any measures in place to ensure that the reusable containers were either dedicated exclusively for transport of eligible ABP or were cleaned by means of an authorised cleaning procedure prior to being used for the transport of ABP destined for production of

derogated PAP as required by Chapter IV, Section D, point (b) of Annex IV to Regulation (EC) No 999/2001. This was not identified during official controls.

13. The audit team noted that in one of the two processing plants visited consignments of PAP were dispatched without the required warning sentence in the commercial documents, as laid down by Chapter IV, Section D, point (e) of Annex IV to Regulation (EC) No 999/2001. This was not identified during official controls.

5.2.2 Use of PAP for producing compound feed

14. Both fish feed producers visited in Denmark were dedicated to the production of fish feed. According to the feed business operators, the only information required to their suppliers of PAP was an evidence of approval/registration in accordance with Regulation (EC) No 1069/2009 and a written declaration of the origin of PAP in terms of animal species. The audit team noted that no further information to confirm the origin and the eligibility of the PAP had ever been requested by the feed business operators. This issue was not checked during official controls.

15. The fish feed manufacturers visited, were sourcing eligible PAP both from Denmark and other Member States. The audit team noted that incoming PAP was correctly labelled in accordance with the requirements laid down by Chapter IV, Section D, point (e) of Annex IV to Regulation (EC) No 999/2001.

16. Both fish feed producers had a sampling plan for periodical testing of incoming PAP for the presence of ruminant DNA, although this is not strictly required by Regulation (EC) No 999/2001. Nonetheless, the audit team noted that one of the fish feed manufacturers was using for that purpose a laboratory located in another Member State which did not use the method described in Annex VI to Regulation (EC) No 152/2009 as required by Regulation (EC) No 999/2001.

17. The fish feed manufacturers visited used labels on the products containing information in several languages. In order to accommodate the information required in all languages, the operators made use of very small fonts difficult to read. Moreover, it was noted that in feed containing fish meal and other PAP, the operators used at the same time the warning sentence required for fish meal and the one required for PAP. As a result there was a risk of misinterpretation because fish meal can be fed to all farmed animals except ruminants, whereas PAP can only be fed to aquaculture farmed animals. This issue was not checked during official controls.

5.2.3 Actions in case of non-compliance

18. The audit team saw several actions taken following non-compliances found in ABP plants or feed producing establishments. These concerned written warnings but also injunctions. The audit team noted that there was always a follow-up control whenever cases of non-compliance detected.

Conclusions on official controls on the implementation of feed ban requirements along the chain

19. Official controls carried out in slaughterhouses, ABP plants, transporters of ABP and PAP and in feed manufactures producing feed for aquaculture animals, do not yet include regular checks on the new requirements pertaining to the use of derogated PAP in aquaculture feed. This limits the ability of the competent authorities to ensure that only eligible PAP is used for the production of feed for aquaculture animals.

6 OVERALL CONCLUSIONS

The system of official controls already in place in slaughterhouses, ABP plants, transporters of ABP and PAP and in feed manufacturers producing feed for aquaculture animals has not been extended yet to include the requirements related to the use of derogated PAP. Although the competent authority undertook some immediate actions to address some of the shortcomings identified during the audit, the ability of the competent authorities to ensure that only eligible PAP is used for the production of feed for aquaculture animals, is still limited.

7 CLOSING MEETING

A closing meeting was held on 04 February 2015 with representatives of the central competent authority and of the meat inspection team of the slaughterhouse visited. At this meeting, main findings and preliminary conclusions of the audit were presented by the audit team. The central competent authorities did not indicate any disagreement with these.

8 RECOMMENDATIONS

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendation set out below, within 25 working days of receipt of this audit report.

No.	Recommendation
1.	To organise and carry out official controls on the new requirements concerning the use of PAP of non-ruminant origin in feed for aquaculture animals, as laid down by Section F, Chapter V of Annex IV to Regulation (EC) No 999/2001. *Recommendation based on conclusions: 10 and 19.* *Associated findings: 5, 6, 9, 12, 13, 14 and 17.*

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 152/2009	OJ L 54, 26.2.2009, p. 1-130	Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed
Reg. 1069/2009	OJ L 300, 14.11.2009, p. 1-33	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Reg. 142/2011	OJ L 54, 26.2.2011, p. 1-254	Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive
Reg. 999/2001	OJ L 147, 31.5.2001, p. 1-40	Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies