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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
DENMARK
FROM 26 MAY 2015 TO 04 JUNE 2015
IN ORDER TO
EVALUATE THE CONTROL SYSTEMS FOR ORGANIC PRODUCTION AND
LABELLING OF ORGANIC PRODUCTS

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 a Food and Veterinary Office audit in Denmark, carried out from 26 May to 4 June 2015, under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.

The objective of the audit was to evaluate the controls on organic production and labelling of organic products.

The report concluded that Competent Authorities involved in official controls of organic operators have been designated and have a clear division of competences. Competent Authorities are internally audited and inspectors are trained and supervised regularly. Communication and exchange of information between Competent Authorities and the Customs Administration is overall good.

The Competent Authorities have procedures in place for the control of organic production which are overall in line with EU requirements. Controls of operators are carried out satisfactorily. Labelling checks were effectively carried out and the control systems allow for the traceability of each product at all stages of production, preparation and distribution. Controls of import are adequate and procedures for taking measures in cases of non-compliance/irregularities are in place.

The system in place for the control of organic production is largely in line with EU requirements. The control system is effectively implemented in the majority of its elements. Deficiencies were identified along the controls system implemented, in particular related to annual control of small operators, documentary evidence requirements, the risk assessment carried out for additional visits and sampling.

The report makes a number of recommendations to the Competent Authorities, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CA(s)	Competent Authority(ies)
CB(s)	Control Body(s)
DAFA	Danish AgriFish Agency
DVFA	Danish Veterinary and Food Administration
EU	European Union
FVO	Food and Veterinary Office
GMOs	Genetically Modified Organisms
MANCP	Multi Annual National Control Plan
MS(s)	Member State(s)
OFIS	Organic Farming Information System
SKAT	Danish Customs and Tax Administration
TC(s)	Third Country(ies)

1 INTRODUCTION

This audit took place in Denmark from 26 May to 4 June 2015. It formed part of the Food and Veterinary Office's (FVO) planned programme. The team comprised two auditors from the FVO and a national expert from a Member State (MS).

Representatives from the Competent Authorities (CAs) accompanied the FVO team for the duration of the audit. An opening meeting was held on 26 May with the CAs. At this meeting, the objectives of, and itinerary for, the audit were confirmed by the FVO team and the control systems were described by the authorities.

The report makes a number of recommendations to the CAs, aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

2 OBJECTIVES

The objective of the audit was to evaluate the control systems in place for organic production and labelling of organic products and in particular the implementation of the requirements set out under Regulation (EC) No 834/2007 concerning:

- All stages of production, preparation and distribution of organic products, including controls at import and
- The use of indications referring to organic production in labelling and advertising.

In pursuit of these objectives, the following sites were visited:

Table 1: Mission visits and meetings

Visits/meetings		Comments
Competent Authorities		
Central	3	Danish AgriFish Agency (DAFA) Danish Veterinary and Food Administration (DVFA) Danish Customs and Tax Administration (SKAT)
Regional	2	DAFA and DVFA regional offices
On-Site-Visits		
Farmers	2	
Feed producers	1	
Processing establishments	2	
Importers	1	

In terms of scope, the audit assessed the performance of the CAs, as well as the organisation of the controls carried out by CAs including import controls, controls of operators producing, preparing and distributing organic products, controls on the labelling and marketing of organic products. The audit also addressed verification procedures and audits.

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

EU legal acts quoted in this report refer, where applicable, to the last amended version. Full reference to documents quoted in this report is given in Annex 1.

4 BACKGROUND

Between 1999 and 2004 the FVO carried out a total of 16 audits on organic production and labelling of organic products in nine MSs and seven Third Countries (TCs). A new audit series in MSs was started in 2011, and 15 MSs have been audited since.

So far no audits on organic production were carried out by the FVO in Denmark.

5 FINDINGS AND CONCLUSIONS

5.1 RELEVANT NATIONAL LEGISLATION AND PROVISIONS

Legal Requirements

Article 291 of the Treaty on the functioning of the EU.

Findings

1. Denmark has adopted national legislation to further develop obligations contained in EU regulations with regard to the organisation of the control system for organic production. The Law on organic production No 416 of 03/05/2011 issued by the Ministry of Food, Agriculture and Fisheries contains the legal basis for the Danish organic control system in respect of EU regulations on organic production and labelling of organic products.
2. Based on this law DVFA has issued Order No 49 of 22 of January 2013 on organic food and aquaculture. This order lays down the DVFA control system including control in respect of processing, labelling, import and marketing of organic food and organic aquaculture.
3. DAFA also drafted national legislation to implement EU regulations as follows:
 - Order No 488 of 8 May 2014 on the production of organic poultry;
 - of 27 of June 2012 on organic agricultural production;
 - Order No 956 of 7 December 2013 amended Order No 716;
 - Order No 1053 of 6 September 2010 on the use of organic control label in agricultural products;
 - Order No 1112 of 21 November 2011 on the production and marketing of organic pullets.
4. DAFA and DVFA also issued several guidelines and manuals to help organic inspectors carry out official controls and to ensure a harmonised implementation of the legislation. Both CAs have detailed instructions for inspectors to carry out inspections in the different types of premises and have comprehensive checklists.

Conclusions on legislation

5. All measures of national law necessary to implement legally binding Union acts relevant to this audit have been adopted by the CA.

5.2 ORGANISATION AND IMPLEMENTATION OF CONTROLS

5.2.1 Competent Authorities, Control Authorities and Control Bodies

Legal Requirements

Articles 27(1), 27(4), 27(4)(a) and 27(14) of Regulation (EC) No 834/2007.

Article 92 of Commission Regulation (EC) No 889/2008.

Articles 4 and 6 of Regulation (EC) No 882/2004.

Findings

6. Organic production in Denmark is under the control of DAFA and DVFA under the *aegis* of the Danish Ministry of Food, Agriculture and Fisheries. Both DAFA and DVFA are designated as CAs to control organic production. These two CAs do not confer control tasks to any control authority. The control system for organic production in Denmark is based on CAs.
7. SKAT is the Customs authority in charge of control of imports including organic products.
8. The distribution of tasks between DVFA and DAFA in the area of organic production is clearly divided and is described in cooperation agreements between the two entities. DVFA deals with the rules on importing, marketing, processing, labelling and production in aquaculture farms and in organic food establishments, while DAFA deals with rules on organic production for organic agricultural farms and associated supply operators. In addition, DAFA deals with tasks concerning area-based subsidies for organic farming and project and market aid schemes, including the organic production promotion scheme.
9. DAFA and DVFA are well structured, documented procedures are in place, and internal supervision of inspectors takes place.
10. Cooperation between DAFA and DVFA has been formalised in a principal cooperation agreement and in three sub-agreements. Cooperation agreements have also been signed between DAFA and DVFA and SKAT for official control on imported products including organic products.
11. DAFA, DVFA and SKAT exchange information when necessary, and as prescribed in the agreements. Good communication and co-operation, in line with Article 31 of

Regulation (EC) No 834/2007 and Article 92 of Regulation (EC) No 889/2008 is in place. The FVO audit team was provided with examples of the exchange of information between the two CAs when non-compliances were found during inspections.

12. Regular meetings are held between the CAs. Two annual meetings are held between DAFA and DVFA in the “Dialogue Forum on Organic Production” to discuss specific issues relating to organic production. Other channels of communication are established, such as letters and the frequent exchange of e-mails.
13. The DVFA’s Chemistry and Food Quality Division is responsible for organic controls at central level. DVFA has six regional offices involved in organic production control. These offices carry out the organic controls and also the general food control.
14. Coordination and cooperation within DVFA is done through experience groups called ERFA. There is an ERFA group specifically dealing with organic. The group members are inspectors from DVFA's regional offices as well as specialists from the Chemistry and Food Quality Division. The ERFA group meets twice a year to discuss issues related to organic control and to ensure that there is continuous control coordination and mutual knowledge sharing across DVFA. Participants of these groups should later disseminate the information to the other colleagues in the relevant regional offices. Intranet is also a useful tool for coordination and cooperation between central level and regional offices. Agenda and minutes of the ERFA meetings were provided to the audit team.
15. The Organic Farming and Fertilizers Team within DAFA is responsible for organic controls. DAFA local offices carry out the on-the-spot visits at organic operators.
16. Cooperation between the central Organic Farming and Fertilizers Team and the local offices has been formalised in the 2015 monitoring agreements on controls in the organic sector. The agreement stipulated that the Organic Farming and Fertilizers Team must, among other things, hold four ERFA meetings per year with the local offices. The meeting must ensure the sharing of knowledge. Agenda and minutes of the ERFA meetings were provided to the audit team.
17. Regular supervision of inspectors is in place in DAFA and DVFA. Witness audits are carried out on inspectors.
18. DAFA carries out supervision of all inspectors in a five year period. Staff from the central office accompanies the inspector during an inspection visit to assess the inspector’s performance. A report is produced of this supervision. DAFA provided to the FVO audit team supervision reports carried out on inspectors.
19. Internal audits are carried out on DAFA by the internal audit service. The organic control system was audited in 2014. The FVO audit team reviewed the audit report where two recommendations were made. Corrective actions had been taken in response to these recommendations.

20. DVFA carries out supervision of all inspectors at least once every three years, and each new inspector during the first year. In total, at least half of the inspectors are supervised every year based on a needs assessment.
21. There is an internal audit programme where control of organic food is part of the audit universe. DVFA has not been audited yet for organic production.
22. Training and regular evaluation of inspectors is organised by the two designated CAs.
23. DVFA control offices must ensure that the inspectors have the necessary competences to carry out organic controls. Training is organised by DVFA to ensure inspectors have knowledge on organic production. There are three types of courses organised. Course level one for general matters (one day), course level two (two days) specifically focusing on control documents, input-output balances and course level three that is more specialised and intended for key persons that should later disseminate the knowledge to other colleges in the relevant regional offices. At least one inspector in each regional office should follow course level three. DVFA inspectors met during inspection visits had participated in the above-mentioned courses.
24. DAFA also organises training sessions for organic inspectors. Instruction courses are organised once a year. Two types of these courses are organised: one for inspection of farms and the other for inspection of suppliers (feed mills).
25. Records of training activities organised by DAFA and DVFA were provided to the FVO audit team.

Conclusions on competent authorities

26. A system of controls is in place in accordance with EU provisions. The CAs are designated and the tasks clearly distributed. Exchange of information between CAs, included SKAT, is carried out and good communication and cooperation is in place in line with Article 31 of Regulation (EC) No 834/2007 and Article 92 of Regulation (EC) No 889/2008.

5.2.2 Registration of Operators

Legal Requirements

Articles 28(1), 28(2) and 28(5) of Council Regulation (EC) No 834/2007.

Article 92b of Commission Regulation (EC) No 889/2008.

Findings

27. DVFA requires operators to apply for registration on-line in order to undertake organic activities. A set of documents have to be provided (description of premises, production plan, precautionary measures, etc). DVFA assesses the documentation submitted by the

operator and if the evaluation is satisfactory, an on-the-spot visit is normally carried out. If the visit is satisfactory the operator is approved to carry out new organic activities and market organic products and the documentary evidence (Article 68 of Regulation (EC) No 889/2008) is issued. It is valid for one calendar year. The list of approved operators is published containing updated documentary evidence related to each operator. The level of detail of the information provided on the activities and production of each operator allows for the public to be adequately informed.

28. DVFA does not use the model of the documentary evidence set up in Annex XII of Regulation (EC) No 889/2008 which is not in line with Article 68 of Regulation (EC) No 889/2008. The date of control is missing.
29. DAFA also have a detailed procedure for registration of organic operators. In case of organic farmers, applications have to be signed by a consultant approved by DAFA. If the assessment of the application and accompanying documents are satisfactory an inspection visit is organised within the next six months. If the result of the inspection is satisfactory the operator is approved for conversion. In case of agricultural operators, documentary evidence is issued during the summer period and is valid until next year. A procedure for registration of suppliers is also in place.
30. DAFA keeps and publishes on the Internet a list of organic operators under their control. The list is updated every month. However, documentary evidence related to each operator is not published with this list, which is not in line with Article 92b of Regulation (EC) No 889/2008.
31. Denmark has made use of the exemption provided for in Article 28(2) of Regulation (EC) No 834/2007. Retailers who only sell pre-packaged and labelled products directly to the final consumer or user are exempted from the requirement of registration. DVFA is the CA in charge of the control on general food hygiene in food establishments, included retailers. More than 200 retailers that do not meet the conditions to be exempted from the control system are under organic control. DVFA stated that those exempted are still under control for food hygiene requirements so DVFA is able to check that they fulfil the conditions to be exempted when those establishments are inspected for food hygiene. For example, in 2014, 22 exempted retailers were checked for organic labelling and no irregularities were found.

Conclusions on registration of operators

32. There is an adequate system in place for the registration of operators and overall it is effectively implemented. The CAs publish and keep an updated list of operators, in line with EU legislation. However, DAFA does not publish the documentary evidence and the documentary evidence issued by DVFA to the operators does not follow the model of Annex XII of Regulation (EC) No 899/2008.
33. Operators who only sell products directly to the final consumer or user and do not prepare or import these products are exempted from the organic farming control system in line with Article 28(2) of Regulation (EC) No 834/2007.

5.2.3 Planning and Prioritisation of Controls

Legal Requirements

Article 27(3) of Regulation (EC) No 834/2007.

Articles 65(4), 92c(2) and 92f of Commission Regulation (EC) No 889/2008.

Articles 3 and 41 of Regulation (EC) No 882/2004.

Findings

34. DVFA carries out inspections of organic operators as part of the general food control. The general food control is risk-based in accordance with Article 3 of Regulation (EC) No 882/2004. After a risk assessment is carried out, all food establishments are classified in five risk groups and the frequency of inspection visits is based on this risk categorisation. The ordinary inspection frequencies range from five inspections per year to as and when required. In addition, organic operators are visited for follow-up inspections and extra campaign visits.
35. Additional visits are also planned and are risk-based and unannounced. DVFA have a manual on inspection of organic food where criteria for additional visits are established as follows: follow-up of non-compliances, size of establishments, parallel production, and regular inspection campaigns. According with this manual additional visits are follow-up inspections ordinary inspections and extra inspections.
36. DVFA informed the FVO audit team that, in 2014, more than 2464 inspection visits were carried out at the organic operators registered (i.e. 1165 organic operators registered the full calendar year and the 458 new/discontinued organic operators). Around 800 of the total visits were considered additional visits in compliance with Article 65(4) of Regulation (EC) No 889/2008.
37. As a general rule, organic operators are visited by DAFA at least once a year. Additional risk based visits are carried out. However, there are 110 registered small farmers that are not visited annually. DAFA indicated that these operators do not sell organic products.

DAFA carries out an annual organic control only on 10% of these operators as long as they do not place any organic products on the market. This is not in compliance with Article 65(1) of Regulation (EC) No 889/2008.

38. In 2015 DAFA had planned to carry out around 250 additional unannounced visits. 75 of these additional visits are reserved to be selected by inspectors, for example in cases of suspicion. The organisation of additional visits to farmer operators is mainly based on previous non-compliances. This means that farmers without previous non-compliances are not selected for additional visits. This is not in line with organic regulations as the nature and frequency of the additional visits are not based on an assessment of the risk of occurrence of irregularities and infringements (Article 27 of Regulation (EC) No 834/2007), the size of the operator or the risk of exchange of products as established in Article 65(4) of Regulation (EC) No 889/2008.
39. Different types of farmers are selected for additional visits based on the evaluation of the totality of irregularities found the previous year to ensure that all types of potential non-compliances are covered. DAFA additional visits are only focused on one pre-selected aspect of the organic production (e.g. animal welfare, use of non- organic seeds, etc). In 2015 additional visits will be focused on: animal welfare in housing for cattle, pigs and poultry, access to grazing for cattle, use of fertilizers or plant protection products, production of fruits and vegetables and production records.
40. DAFA risk assessment for additional visits to suppliers of organic products takes into account previous non-compliances, size and parallel production which is in line with the organic regulation.
41. In the initial meeting DAFA informed the FVO audit team that the risk assessment process was being reviewed for 2016.

Conclusions on planning and prioritisation of controls

42. Controls on organic operators are in most cases annually carried out in line with Article 65(1) of Regulation (EC) No 889/2008. However, the frequency of control on a defined group of small farmers that do not place products on the market is not in line with the above-mentioned article.
43. Additional visits are primarily unannounced and based in most cases on risk assessment as established in Article 65(4) of Regulation (EC) No 889/2008. However, the risk assessment carried out to select additional visits to organic farms is not in line with Article 65(4) of Regulation (EC) No 889/2008.

5.2.4 Controls of Operators

Legal Requirements

Titles II and III of Regulation (EC) No 834/2007.

Titles II and IV and Article 65(1) and 65(3) of Regulation (EC) No 889/2008.

Articles 8 and 9 of Regulation (EC) No 882/2004.

Findings

44. DAFA has procedures in place to ensure that inspectors verify the precautionary measures when visiting operators. DAFA guidance on organic production for operators clearly specifies the type of precautionary measures operators should put in place to avoid potential contamination of crops, products or animals. Operators should ensure clear boundaries between organic fields and non- organic ones (buffer zones, fence, bare soil strip), separation of non-organic animals and organic ones (for grazing and housing), clear separation of organic products (crops, feed, seeds, etc) and non-organic products during transport, production and storage.
45. The FVO audit team noted that inspectors verified precautionary measures in place during the inspections to organic operators. Examples of cases with irregularities related to precautionary measures were shown to the FVO audit team.
46. The FVO audit team witnessed three inspections carried out by DAFA inspectors. It was noted that they have available plenty of information for the preparation of the visit. The inspectors check national databases related to registration and identification of animals, medical treatments, agricultural production, etc. All this information is a very useful tool for the inspector prior the inspection visit. It helps the inspector to focus the inspection in certain areas. Inspectors make a good preparatory work prior the inspections.
47. Overall, the three inspections witnessed by the FVO audit team were considered satisfactory. During the inspections the FVO audit team noted that:
 - Inspectors visited all the premises and visually checked the conditions and identification of animals;
 - Precautionary measures were verified;
 - Calculations to demonstrate the balance between the inputs and outputs were made;
 - Calculations of the feed consumption by animals were carried out in the farm visited. Calculation of manure produced by the animal was made;
 - Veterinary treatment records and the withdrawal period for treated animals were checked;
 - Animal welfare and husbandry were checked.
48. If there are no irregularities arising from the inspection an “OK report” is produced and sent to the organic operator. If irregularities are identified, the inspector gives 14 days to the operator to make comments. After this period, the inspector sends the report together with the organic operator’s comments to the central level where a decision is made.
49. DVFA carries out annual inspection visits to all operators under their control (retailers, wholesalers, processing establishments, importers, aquaculture farms). The guidance on organic production produced by the DVFA provides instructions to the inspectors on

how to carry out organic inspections. It establishes the control areas that inspectors should cover in an organic inspection. These areas shall be covered in a three year period.

50. These areas are: reception (transport, packaging, labelling accompanying documents), mass balance, documentation related to entries including documentary evidence, documentation related to Genetically Modified Organisms (GMOs), cross control, segregation/identification, cleaning of storage and preparation, imports, labelling including recipes and composition, transport from the company, organic plan to be updated. The annual inspection shall cover at least: mass balance, evidence of entries and documentary evidence, documentation related to GMOs and cross-checks. After the inspection, the inspector produces a report on the spot and informs the relevant operator on the outcome of the visit.
51. Besides the organic control described in the guidance, organic controls are also carried out under DVFA annual control campaigns, which are planned based on risk assessment. In the control campaigns conducted over the last three years there has been focus on the following areas; use of non-organic ingredients and additives, balance accounts and import of organic food from third countries.
52. The audit team witnessed three inspections carried out by DVFA inspectors. Overall the three inspections were considered satisfactory by the FVO audit team. The inspectors showed good knowledge of the organic production and were familiar with the activities carried out in the establishments visited (as they visit them for food safety controls). During the inspections the audit team noted that:
 - In all premises the inspectors focused on the storage and separation of organic and conventional products;
 - Calculations to demonstrate the balance between the input and output were made. The organic inspection procedure requires the operators to keep records of documentary accounts to demonstrate the balance between the input and the output. Inspectors verified the documentary accounts presented by the operators;
 - Traceability exercises were carried out by the inspectors;
 - Inspectors have adequate knowledge of how the activities are carried out.
53. DAFA and DVFA inspectors have available a significant number of manuals of inspection, guidelines and checklists to ensure harmonisation of inspections. The FVO audit team noted that inspectors followed these procedures and used checklists during inspections.
54. Overall, inspectors met during visits showed good knowledge of organic regulations.

Conclusions on control of operators

55. Controls carried out on organic operators follow the instruction and documented procedures issued by the DAFA and DVFA. Controls of operators are effective and carried out largely in line with organic regulations.

5.2.5 Controls on Labelling and Traceability

Legal Requirements

Articles 23, 24 and 27(13) of Regulation (EC) No 834/2007.

Title III of Commission Regulation (EC) No 889/2008.

Findings

56. Monitoring of the labelling of organic products is an integral part of the organic operator controls carried out by DAFA and DVFA.
57. In 2013, DAFA focused organic checks on labelling. Instructions were provided to organic operators on the labelling of organic products. Inspectors were also given guidance on the labelling rules. This was done after a number of infringements were noted in this area. As a result, in 2014 there was a reduction in the number of infringements concerning labelling.
58. Since the organic control is carried out as an integrated part of the DVFA's general control, a general control of the marketing and labelling of organic foods will always take place during DVFA's general inspections. This is especially the case where the irregularities are found for example in non-certified operators (i.e. 36 irregularities relating to the organic regulations were in fact found at non-certified operators in 2014).
59. Control on marketing and labelling of organic food can also be part of specific DVFA control campaigns. For instance, a campaign carried out in 2015 was focused on the requirements for labelling food as organic, the restricted use of non-organic ingredients and additives and processing aids. In another control campaign, carried out in 2014 one of the control areas was the verification of organic labelling at non-certified retailers (22 checks on organic labelling were carried out and no irregularities were found).
60. The audit team noted that checks on labelling were done in all registered operators visited by DAFA and DVFA.
61. Traceability checks were included in the inspections carried out by the inspectors in the establishments visited by the FVO audit team and were adequately carried out by the inspectors, in particular at processors. Inspectors check that lots were identified during all steps of processing, to avoid mixtures or exchanges with non-organic products. Full traceability exercises were performed to link final products to incoming raw materials, and records proving links between different processing steps were checked.

62. Cross-check is an important part of the CAs inspections which is a useful tool to ensure traceability of the products.
63. A traceability exercise was also carried out by DVFA during the FVO audit. Two processed products were collected from a supermarket. The outcome of the exercise was overall good, and all ingredients selected could be traced back to the producer.

Conclusions on controls on labelling and traceability

64. Labelling and traceability checks are regularly performed by DAFA and DVFA during inspections. There is an appropriate system in place to ensure traceability of products at all stages and to ensure that the labelling of the products complies with EU provisions.

5.2.6 Sampling and Laboratory Analysis

Legal Requirements

Article 65 (2) of Commission Regulation (EC) No 889/2008.

Article 12 of Regulation (EC) No 882/2004.

Findings

65. Sampling is carried out by DAFA to at least 5% of the number of operators under its control. Samples are only taken of feed and are focused on imported feed. 50% of imports shall be sampled, 100% in case Kazakhstan is the country of origin. A risk assessment is carried out based on origin, Organic Farming Information System (OFIS) notifications and history in order to set up frequency and analytical scope. Farmers and suppliers other than feed mills are not sampled. For example, soil or plant foliage are never sampled. This is not in line with Article 65(2) of Regulation (EC) No 889/2008 as sampling is not carried out at all stages of production, preparation and distribution.
66. Sampling witnessed by the FVO team was adequately carried out by DAFA inspector.
67. As a general rule samples are taken for pesticides and GMOs analysis. In the event that GMOs or pesticides are found, an investigation is launched to investigate the cause. For GMOs if detection is below 0.9% and the operators have taken measures to avoid contamination, the product can be marketed as organic. If the result is more than 0.9% or the operators have not taken measures the product is declassified.
68. In the case of pesticides, the DAFA policy is that in principle, organic products should be free of pesticides. When low level of pesticides (below maximum residue limit) is found in an organic product from an operator who complies with organic rules, an investigation is carried out. The analyses are sent to the Technical University of Denmark for further investigation and DAFA takes a decision based on this evaluation and the general circumstances of the cases, for example if the operators have taken measures to avoid contamination. If it is concluded that the presence of pesticides was

not intentional and if the contents of pesticides are insignificant the product might be marketed as organic. This procedure is followed in a case by case basis.

69. The only laboratory used for the analysis of pesticides and GMOs is designated by the CAs. It is the DVFA laboratory which is accredited under ISO 17025 for the pesticide methods. The analytical scope covers the pesticides relevant for organic farming.
70. Sampling is also carried out by DVFA to at least 5% of the number of operators under its control. DVFA takes risk based samples on the basis of notification in OFIS and from products where the consumption is large and also takes into consideration an EU regulated plan for pesticides sampling in risky organic products. DVFA has a specific sampling plan for pesticides in organic food that is drawn up every year. A proportion of the samples is taken from food where the consumption of organic products is large. A second proportion of the samples is taken on a risk-based approach, for instance based on the information in the notifications in OFIS. In 2014 and 2015, the plan includes extra samples of Danish apples, because of the discovery of prosulfocarb in apples from autumn 2013.
71. Nine positive results were reported in 2014. DVFA presented to the FVO audit team the measures taken following these results. The FVO audit team noted that measures taken were in line with the procedures above-mentioned. In case of pesticide residues found in low levels the result were sent to the Technical University of Denmark which concluded that the presence of pesticides was not intentional. At the same time DVFA carried out an investigation at the operator concerned. Based in these two evaluations the products could be marketed as organic.
72. The FVO audit team noted that samples are also taken by operators as part of their own-control system.

Conclusions on sampling and laboratories analysis

73. Both DVFA and DAFA had planned for 2014 an adequate number of samples to be taken. As a general rule, sampling is risk based. However, the selection of operators (which does not include farmers) by DAFA is not based on the general evaluation of risk of non-compliance with the organic production rules at all stages of production, preparation and distribution, which is not in line with Article 65(2) of Regulation (EC) No 889/2008.
74. The designated laboratory for analysis is accredited for the method used and analytical scope for pesticides is adequate.

5.2.7 Exceptional Production Rules and Other Derogations.

Legal Requirements

Article 22(2) of Regulation (EC) No 834/2007.

Article 29 and Sections 2 to 4 of Chapter 6 of Title II of Commission Regulation (EC) No 889/2008.

Findings

75. DAFA has procedures for granting derogations. Operators must submit an application for derogation which may be granted after DAFA assessment. Decisions are taken on a case by case basis after assessment of circumstances and documentation provided by the operator. If derogations are granted the conditions will be a key point for verification in the next inspection.
76. The FVO audit team noted that DAFA has criteria in place to justify decisions made for the grant of derogations. The conditions for granting derogations and the decision-making process are clearly established. The FVO audit team reviewed some examples of derogations which had been granted or refused.
77. DAFA granted derogations for organic production rules related to Article 9 of Regulation (EC) No 889/2008 on the origin of non-organic animals, Article 18 on the management of animals, Article 36 on recognising a previous period retroactively as being part of the conversion period, Article 39 on the tethering of animals, Article 40 on parallel production and Article 47 on catastrophic circumstances.
78. DAFA procedure to allow dehorning does not require prior authorisation. Farmers have to notify DAFA on dehorning through the annual reporting on livestock. The notification results in a retroactive grant of the derogation for that production year and has to be renewed each year. In the notification, the farmers declare that the reason for dehorning of calves is safety for personnel and to improve animal welfare/health. Farmers have to keep an updated list of calves that have been dehorned. Dehorning of calves is therefore allowed by DAFA if the farmers declare that they follow conditions under Article 18 of Regulation (EC) No 889/2008. This is not in line with Article 18 of Regulation (EC) No 889/2008 where it is established that dehorning shall not be carried out routinely and that it may be authorised by the CAs on a case by case basis.
79. Organic operators shall report to DAFA on the number of animals dehorned and provide the reason for doing so. The FVO team visited two farms where dehorning was carried out. It was carried out under veterinary control in line with the requirements of Article 18 of Regulation (EC) No 889/2008.
80. The FVO audit team noted that DVFA also had procedures for granting derogations. According to these procedures, organic operators have to apply for derogation. In case of derogations under Article 29 of Regulation (EC) No 889/2008, the operators shall demonstrate to DVFA that the organic product is not available on the market. DVFA also carries out investigations in order to ensure the unavailability of the product.
81. The FVO audit team reviewed some examples of derogations granted or refused by DVFA under Article 29 of Regulation (EC) No 889/2008.

Conclusions on exceptional production rules and other derogations

82. Generally, derogations granted comply with specific EU requirements. However, dehorning is carried out routinely and without prior authorisation by the CA which is not in line with Article 18 of Regulation (EC) No 899/2008.

5.2.8 Imports of Products from Organic Production

Legal Requirements

Articles 32 and 33 of Regulation (EC) No 834/2007.

Commission Regulation (EC) No 1235/2008. In particular, Article 7, Chapter 3 of Title III, Article 19 and Annexes II, III, V and VI.

Findings

83. DAFA is responsible for import controls on organic feed, seed grain, seed, plants and parts of plants. DVFA is responsible for import controls on organic food and organic aquaculture products.
84. The Danish National Order No 49 of 2013 obliges importers to inform the relevant CA and submit all relevant information of the imported product, including a copy of the certificate of inspection, at least one full working day in advance of the import.
85. DVFA is informed electronically via one of its two "entries points" (located at two of the regional offices). These two "entries" carry out a documentary check of the imported product, verify that the CB is included in the relevant Annex of Regulation (EC) No 1235/2008 and that it is approved to certify for the product being imported, and then uploads an electronic copy of the certificate of inspection (signed and stamped in box 16) in the electronic database (Data Administration Website) for information to SKAT. Copies of the submitted documents are also sent to the inspectors and regional offices that are responsible for the controlling the importer and the first consignee. A similar process occurs at DAFA.
86. The importer also has to present an import request to SKAT. The application form includes a field where the importer has to indicate that the product is organic. SKAT consults the database upon receipt of an import request indicating an organic product. Box 17 in the original certificate of inspection is signed by SKAT only after receipt of the scanned certificate of inspection in the electronic database and after the product is cleared. SKAT officials also complete Box 17 in the electronic database when signing the original certificate of inspection and the electronic database automatically informs DAFA and DVFA of the decision taken by SKAT. Box 18 is filled in by the importer after having received the products and inspected them.

87. Samples of certificates of inspections were seen at the importer visited by the FVO audit team. Boxes 17 and 18 had been correctly completed by SKAT and the importer respectively.
88. A physical check of the imported product may be carried out at the importer or first consignee by the DVFA or DAFA inspectors.
89. Danish import authorisations under Article 19 of Regulation (EC) No 1235/2008 have all expired, with the exception of one permit, issued by the DAFA, which was to expire on 30 June 2015 and another two permits, issued by DVFA, which were to expire on 1 July 2015. The FVO team reviewed DAFA procedures for authorisations. It was noted that DAFA adequately followed its procedures and make a full assessment of information provided by the control body prior granting the import authorisation.

Conclusions on imports of products from organic production

90. An adequate import system is in place for organic products, in line with Article 33 of Regulation (EC) No 834/2007 and Article 13 of Regulation (EC) No 1235/2008.

5.2.9 Measures in Cases of Irregularities and Infringements

Legal Requirements

Articles 54 and 55(1) of Regulation (EC) No 882/2004.

Articles 27(5)(d) and 30 of Regulation (EC) No 834/2007.

Articles 91, 92, 92a and 92d of Commission Regulation (EC) No 889/2008.

Findings

91. DAFA have catalogues of infringements describing the different situations and possible enforcement actions to take, from the lowest level to the highest level of enforcement for each type of non-compliance detected.
92. The catalogues of infringements are structured similarly to the Manuals of procedures and therefore contain the infringements and enforcement actions that are relevant for that particular sector only (e.g. farms, feed suppliers, etc.).
93. When an inspection report is issued, the operator has 14 days to reply to the non-compliances reported. The report is sent to DAFA after comments from the operator have been received. DAFA will consider non-compliance reported and operator's reply before deciding on enforcement measure to apply. DAFA have the possibility to take enforcement measures immediately in case of serious non-compliances.

94. When sanctioning operators, the policy is to apply the lowest level of intervention for the non-compliance detected. In cases when the non-compliance is repeated, the level of sanction escalates.
95. Enforcement actions are classified into warnings (given in case of minor non-compliances), administrative fines (given when a minor non-compliance has been repeated or in case of more serious non-compliance), reports to the police (for serious non-compliances). In addition to these enforcement actions others can be taken such as declassification of crops, reconversion of fields or animals, exclusion of animals, temporary ban on the sale of products under the organic label or withdrawal of the organic authorisation.
96. DVFA classify the controlled elements in four different categories/levels. One for compliances, two for minor non-compliances resulting in a warning, three for injunction order or prohibition and four for serious non-compliances which results in an administrative fine or report to the police.
97. When non-compliance is detected, the DVFA inspector is required to carry out a follow-up inspection within two months. A follow-up inspection costs in average approximately 250 Euros, depending on the time taken to carry out the inspection.
98. Guidelines on the categorisation of the non-compliances with organic regulations and the relevant enforcement actions are included in the documented procedures for official controls.
99. The FVO audit team saw examples of non-compliances and had evidence that both CAs take adequate actions when dealing with irregularities. The FVO audit team also noted that DAFA and DVFA exchange information in relation to irregularities found in the operators under their control:
 - In one case, a DVFA officer supervising activities at a slaughterhouse notified DAFA of his doubts about the origin of an organic animal. Following a documentary check on the farm, DAFA confirmed that the animal was not eligible for organic status and fined the operator. The carcass was sold without the organic labelling.
 - Another case concerning an organic pig farm was originally investigated by the police authorities and DVFA following a complaint on animal welfare. The pigs were confiscated by the police for animal welfare reasons. DAFA's investigation concluded that the pigs were not being bred under organic conditions and informed the police and the pigs were sold as conventional animals. The operator lost his organic authorisation.
 - A third case involved a dairy farm in which the conversion period had not been fully respected. The decision taken by DAFA was to prolong the conversion period of the operator. DVFA was informed of this decision in order to control the milk and meat.

Conclusions on measures in cases of irregularities and infringements

100. There is an adequate catalogue of sanctions for non-compliant operators and measures are in place to prevent that non-compliant products are marketed as organic. Information related to irregularities is shared between DAFA and DVFA in line Article 30(2) of Regulation (EC) No 834/2007.

5.3 SEED DATA BASE

Legal Requirements

Articles 48 and 49 to 56 of Commission Regulation (EC) No 889/2008.

Findings

101. DAFA keeps and updates a seed database with the species and varieties of organic seeds available on the Danish market. This database is available to the public and is kept up-to date. Data available includes the amount, the list of suppliers, the list of organic seed and organic vegetative propagating material available and the list of application submitted.

102. DAFA gave a demonstration of how the database is used to the FVO audit team. The FVO noted that the public can access the computerised database and that all information is available in line with Articles 48 to 56 of Regulation (EC) No 889/2008.

Conclusions on seed data base

103. A seed database has been established by the CA in accordance with Article 48 of Regulation (EC) No 889/2008.

6 OVERALL CONCLUSIONS

CAs involved in official controls of organic operators have been designated and have a clear division of competences. CAs are internally audited and inspectors are trained and supervised regularly. Communication and exchange of information between organic CAs the Customs Administration is overall good.

The CAs have procedures in place for the control of organic production which are overall in line with EU requirements. Controls of operators are carried out satisfactorily. Labelling checks were effectively carried out and the control systems allow for the traceability of each product at all stages of production, preparation and distribution. Controls of import are adequate and procedures for taking measures in cases of non-compliance/irregularities are in place.

The system in place for the control of organic production is largely in line with EU requirements. The control system is effectively implemented in the majority of its elements.

Deficiencies were identified along the controls system implemented, in particular related to the annual control of small operators, documentary evidence requirements, the risk assessment carried out for additional visits and sampling.

7 CLOSING MEETING

A closing meeting was held on 4 June 2015 with representatives from the CAs. At this meeting, the FVO team presented the main findings and preliminary conclusions of the audit.

8 RECOMMENDATIONS

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

No.	Recommendation
1.	<p>Ensure that the model for the documentary evidence in Annex XII of Regulation (EC) No 889/2008 is used and that the documentary evidence is published as is established in Article 92b of Regulation (EC) No 889/2008.</p> <p><i>Recommendation is based on conclusion No 32</i></p> <p><i>Associated findings: No 28 and No 30</i></p>
2.	<p>Ensure that all organic operators are inspected at least once a year as required in Article 65(1) of Regulation (EC) No 889/2008.</p> <p><i>Recommendation is based on conclusion No 42</i></p> <p><i>Associated findings: No 37</i></p>
3.	<p>Ensure that the risk assessment carried out for additional visits on organic farms take into account criteria in line with Article 65(4) of Regulation (EC) No 889/2008.</p> <p><i>Recommendation is based on conclusion No 43</i></p> <p><i>Associated findings: No 38</i></p>
4.	<p>Ensure that the selection of organic farmers to be sampled is based on the general evaluation of the risk of non-compliance with organic production rules and that samples are taken at all stages of production, processing and distribution as required in Article 65(2) of Regulation (EC) No 889/2008.</p> <p><i>Recommendation is based on conclusion No 73</i></p> <p><i>Associated findings: No 65</i></p>
5.	<p>Ensure that the conditions of Article 18 of Regulation (EC) No 889/2008 are met. In particular, that dehorning is carried out with prior authorisation by the CA on a case by case basis.</p> <p><i>Recommendation is based on conclusion No 82</i></p> <p><i>Associated findings: No 78</i></p>

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2015-7358

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. 834/2007	OJ L 189, 20.7.2007, p. 1-23	Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91
Reg. 889/2008	OJ L 250, 18.9.2008, p. 1-84	Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control
Reg. 1235/2008	OJ L 334, 12.12.2008, p. 25-52	Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries