

Special Report

The control system for organic products has improved, but some challenges remain

(pursuant to Article 287(4), second subparagraph, TFEU)



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GLOSSARY

Accreditation body: Public or private body that gives a formal recognition that a control body is competent to test and certify third parties according to organic standards.

Competent authority: Central authority of a Member State (or of a third country) competent for the organisation of official controls in the field of organic production, or any other authority to which that competence has been conferred.

Control body: Independent private third party or public administrative organisation of a Member State (also called 'control authority' in the legislation) carrying out inspection and certification in the field of organic production.

Equivalent: Capable of meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity.

Equivalent control body: Control body operating in a third country that is recognised by the Commission as applying equivalent organic rules and control measures as those applied in the EU.

Equivalent third country: Third country that is recognised by the Commission as applying equivalent organic rules and control measures as those applied in the EU.

OFIS: Organic Farming Information System – the Commission's IT system for the treatment of organic farming information. It allows (a) electronic data exchange between EU Member States, Norway, Iceland and the Commission; and (b) dissemination of public data to European citizens and operators.

Operator: Individual or business enterprise that is producing, storing, processing, transporting, exporting or importing organic products.

TRACES: TRAdE Control and Expert System – the Commission's online management tool for all sanitary requirements on intra-EU trade and importation of animals, semen and embryos, food. TRACES was established by Commission Decision 2004/292/EC pursuant to Council Directive 90/425/EEC.

EXECUTIVE SUMMARY

- I. The main objectives of an EU-wide framework for organic production are to better protect consumer interests, to ensure fair competition between the producers and to facilitate the free circulation of organic products in the EU. The control system for organic products is set out in the EU regulations. It aims to give consumers the confidence that when they buy organic products, EU – or equivalent – rules have been applied at every stage of the supply chain. This should be the case whether the products are produced in the EU or imported.

- II. In June 2012, we published Special Report No 9/2012 on the control system governing the production, processing, distribution and import of organic products. To assess whether the Commission had remedied the weaknesses identified in our report, we have carried out a follow-up audit. In addition, we have covered the import regimes for organic products more extensively. We found that the control system had improved and that our recommendations had generally been implemented since our previous audit, but that some challenges remained.

- III. For organic products produced in the EU – the major part of EU consumption – both the Commission and the Member States have addressed many of the weaknesses identified in our previous report. After our 2012 report, the Commission has resumed its audit visits to Member States, and has now visited most of them. The competent authorities of the Member States that we audited have taken action to improve their control systems. Some of them remedied the weaknesses observed last time through changes in the legal framework, others through improved coordination with the accreditation bodies, or better guidelines for the supervision of control bodies. We still found a number of weaknesses related to our previous findings. We also found that the use of enforcement measures had not yet been harmonised across the EU and that reporting in the Member States was sometimes slow and incomplete.

- IV. A smaller part of organic food consumed in the EU comes from imports. Equivalent control bodies operating in third countries certify more than 80 % of organic products imported into the EU. The remainder is imported from a limited number of third countries

considered as having equivalent standards. The Commission's audits since 2012 have covered most equivalent third countries. The Commission has also started visiting equivalent control bodies, and examined their activities on-the-spot in third countries. So far this has covered the systems applying to around a third of imports certified by the equivalent control bodies.

V. We saw that the Commission has only started to explore the possible synergies for supervising organic imports with the competent authorities of other significant import markets for these products, and with the work of the accreditation bodies. Regarding the control system for imports, when the Commission identifies problems it can be a difficult and lengthy process to remedy the situation, but new rules have been introduced to make enforcement faster and more effective. At Member State level, we found weaknesses in the checks on incoming consignments and found that the checks carried out by control bodies on importers were still incomplete.

VI. We again carried out a traceability exercise, following the paper trail back from retailer to producer. The results show an improvement with respect to the previous audit, particularly in the EU. Still, not all products could be traced back to the agricultural producer.

VII. We make recommendations to address the remaining weaknesses we identified in the Member States for EU products, to improve the supervision of imported organic products through better cooperation as well as to carry out more complete traceability checks.

INTRODUCTION

1. In June 2012, we published Special Report No 9/2012 on the control system governing the production, processing, distribution and import of organic products. To assess whether the Commission had remedied the weaknesses identified in that report, we have followed up our audit, giving more extensive coverage to the import regimes for organic products.
2. Organic production is “an overall system of farm management and food production that combines best environmental and climate action practices, a high level of biodiversity, the preservation of natural resources and the application of high animal welfare standards and high production standards in line with the demand of a growing number of consumers for products produced using natural substances and processes”¹. Organic products include processed or unprocessed food, beverages, as well as feed and seeds. The organic production sector encompasses producers in the agricultural and aquaculture sectors, as well as their suppliers, food manufacturers and distributors.
3. In 1991 a Council regulation introduced an EU-wide framework for organic production together with a control and certification system². Before that time, organic production in the EU had been defined through several standards issued by organic associations in the different Member States. The main objectives of the EU-wide framework were to better protect consumer interests, to ensure fair competition between the producers and to facilitate the free circulation of organic products in the EU.

¹ Recital 1 of Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1), which modified slightly recital 1 of Regulation (EU) 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1).

² Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ L 198, 22.7.1991, p. 1).

4. There is no scientific test for determining whether a product is organic. “Maintaining and justifying consumer confidence in products labelled as organic”³ depends on the capacity of the control and certification system to reduce the likelihood of operators not complying with the relevant standards.

The EU organic control systems

5. The EU logo (see **Figure 1**) shows that a product has been produced in accordance with the relevant EU standards, subject to a control and certification system. For processed products, it means that at least 95 % of the agricultural ingredients are organic. Next to the new EU organic logo, the control body code number is displayed as well as a statement regarding whether the agricultural raw materials composing the product have been farmed in the EU or outside the EU (or both).

Figure 1 – The EU Organic Logo



Source: Commission Regulation (EU) No 271/2010 of 24 March 2010.

6. Individual operators at various stages in the supply chain have their own procedures in place for organic products, ranging from simple checks to very complex processes. These are the building blocks to ensure that products eventually labelled with the EU logo as organic actually comply with the standards.

7. The EU has set up a control system involving bodies that carry out checks on the individual operators. These checks include physical inspections of the production or

³ Recital 3 of 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 (OJ L 189, 20.7.2007, p. 1).

processing premises, verifying the documentary accounts and sampling the final products, harvested products, leaves or soil to test for the use of unauthorised substances. These control bodies are a central element of all organic control and certification systems. Operators pay for the certificates issued by the control bodies.

8. Different control systems apply for products produced in the EU from those for imported products. The Commission plays a central role in all of these systems by supervising the Member States' control systems and by overseeing the actors involved in the different import regimes.

Control system for products produced in the EU

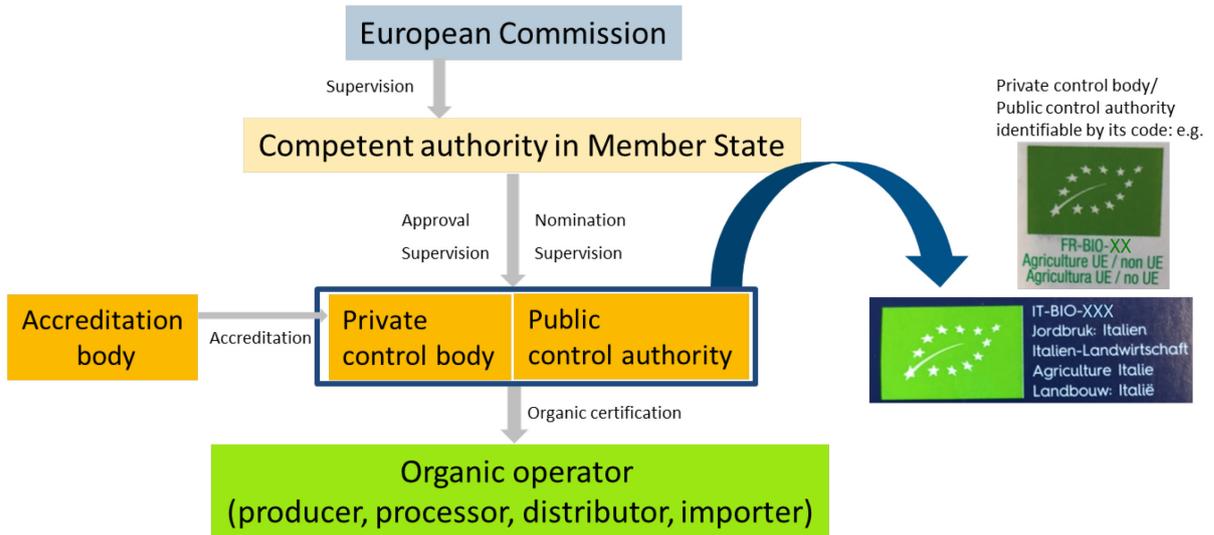
9. EU Member States may choose to set up a control and certification system which is private, public or a mixture of the two. The majority of Member States have approved private control bodies. Five Member States have nominated public control bodies, referred to as control authorities in the legislation, and two have chosen a mixed system. Around 250 control bodies and public control authorities have been approved across the EU⁴. These are referred to collectively as control bodies in this report.

10. Member States must designate one or more competent authorities responsible for approving and supervising the control bodies, and applying a range of enforcement measures (including sanctions) if necessary.

11. Private control bodies need to be accredited in accordance with the most recent version of ISO standard IEC 17065:2012. The checks performed by the accreditation bodies concern the technical competence, independence, impartiality and professional integrity of the control bodies. Public control authorities do not need to be accredited (see **Figure 2** for a schematic overview).

⁴ DG AGRI: List of Control Bodies and Control Authorities in the Organic Sector on 14.8.2018. see: http://ec.europa.eu/agriculture/ofis_public/r8/ctrl_r8.cfm?targetUrl=home&lang=en

Figure 2 - Control system for products produced in the EU



Source: ECA.

Control system for products imported into the EU

Equivalent third countries

12. The EU has recognised several third countries as having equivalent organic production rules and control systems. Competent authorities in equivalent third countries are responsible for guaranteeing that organic products are produced and operators are checked in accordance with their standards. The Commission has the right to carry out official controls in order to verify the equivalence of third country legislation and systems with EU rules

Equivalent control bodies

13. Imports from countries other than equivalent third countries and EFTA countries⁵ must be produced and checked according to standards that are equivalent to the EU rules. For this

⁵ Norway and Iceland are the only two EFTA countries that apply the EU organic legislation. Their relations with the EU are governed by the Agreement on the European Economic Area (EEA) and

purpose, the Commission approves private control bodies or public control authorities that certify organic operators outside of the EU; these are referred to as equivalent control bodies in this report.

14. In the case of equivalent control bodies, the Commission acts as competent authority, meaning that it is not only responsible for the approval of these control bodies, but also for their supervision and, if necessary, for the withdrawal of approval. The Commission supervises these control bodies by reviewing their annual reports and the assessment reports issued by their accreditation body. It may also carry out audit visits to examine the performance of the control bodies.

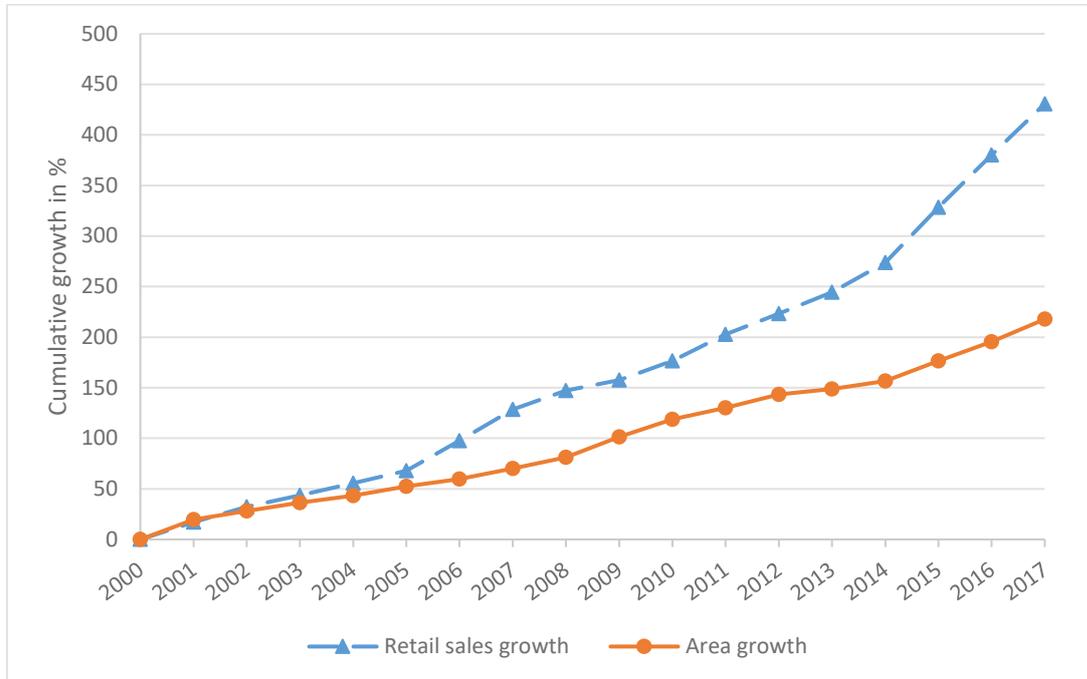
A rapidly growing market

15. The EU organic sector has developed rapidly over recent years, with regard to the agricultural area involved, the number of operators and its market share. The total farmland used for organic farming in the EU increased from 9.1 million ha in 2010 to 12 million ha in 2016, a 33 % increase. In 2016, the share of EU farmland devoted to organic production was 6.7 %. Over the same period, retail sales of organic products grew from 18.1 billion euro to 30.7 billion, a 69 % increase⁶ (see ***Figure 3***).

organic production falls within the scope of this agreement. As a consequence, organic products from Norway and Iceland can move freely in the EU.

⁶ <https://statistics.fibl.org/europe/key-indicators-europe.html>

Figure 3 - Europe: Cumulative growth of organic area and retail sales 2000-2017



Source: FiBL-AMI surveys (2006-2018): Research Institute of Organic Agriculture (FiBL), Frick, Switzerland.

16. There are no consolidated statistics on organic products imported from outside the EU. Some Member States provide data on the market share of organic imports. For example, in 2017, France, as the EU's second largest market, imported about 15 % of all organic products consumed in the country from outside the EU⁷.

17. The growing global trade in organic products involves long-distance transport of both internally and externally produced foodstuffs. "Organic" is not a synonym of "local", although the new organic regulation includes the objective of "encouraging short distribution channels and local production"⁸.

⁷ <http://www.agencebio.org/le-marche-de-la-bio-en-france>

⁸ Recital (17) of Regulation (EU) 2018/848.

18. The prices consumers pay for organic products are higher than those of conventional products, sometimes significantly so. The price differential is affected both by consumer demand and by differences in processing and distribution costs. The reported price premiums vary significantly across studies and food products, and only a part of the price premium benefits producers.

Financial support for organic production in the EU

19. Organic farmers in the EU can receive specific financial support under the EU rural development policy. This supplements support paid to all EU farmers (notably the Basic Payment Scheme/Single Area Payment Scheme, and Greening payments – for which organic farmers qualify automatically). The specific payment to organic farmers consists of combined EU and national support per hectare that varies depending on the Member State. Between 2015 and 2018, the EU subsidies amounted to €700 million on average per year.

The EU legal framework for organic production

20. The 2007 Council Regulation on organic production and labelling of organic products⁹, governs the current legal framework. It covers all stages of the organic supply chain, such as farming and aquaculture, food processing, distribution, and retailing activities¹⁰. More detailed rules are set out in two implementing regulations¹¹.

21. In March 2014 the Commission presented a new EU Organic Action Plan and a legislative proposal for a new set of organic rules. The new Regulation on organic production

⁹ Council Regulation (EC) No 834/2007.

¹⁰ OJ L 189, 20.7.2007, p. 1.

¹¹ 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 (OJ L 250, 18.9.2008, p. 1), and

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 (OJ L 334, 12.12.2008, p. 25).

and the labelling of organic products¹² was published in June 2018. The new rules will apply from 1 January 2021. Until then, the Commission will work in cooperation with the Member States and relevant stakeholders to finalise and publish Delegated Acts and Implementing Regulations.

22. Apart from the specific legislation on organic production, organic food must comply with the General Food Law¹³. Organic production falls within the scope of the Official Controls Regulation¹⁴, which has been amended recently¹⁵. Most of the articles in this new Regulation will apply from 14 December 2019.

23. The EU Member States, Iceland and Norway monitor pesticide residue levels in food samples and submit the monitoring results to EFSA (European Food Safety Authority). A recent report¹⁶ covering samples from 2013, 2014 and 2015 concludes that, overall, 44 % of the conventionally produced food samples contained one or more quantifiable residues, while in organic food the frequency of samples with measurable pesticide residues was

¹² Regulation (EU) 2018/848.

¹³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

¹⁴ 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 (OJ L 165, 30.4.2004, p. 1).

¹⁵ Regulation (EC) No 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

¹⁶ Monitoring data on pesticide residues in food: results on organic versus conventionally produced food – EFSA (<http://www.efsa.europa.eu/publications>).

seven times lower (6.5 % of the organic samples; see also **paragraphs 46 and 47**). The ECA has recently published a special report on the EU food safety policy¹⁷, focusing on chemical hazards.

AUDIT SCOPE AND APPROACH

24. Based on the results of our previous Special Report, published in 2012, the Commission increased its own evaluation of the risk linked to the control system for organic products. In particular, the Commission rated the reputational risk linked to the control system for imported products as 'critical'. In 2013 and 2014, it gradually lowered this risk level. In order to investigate whether the Commission had remedied the weaknesses identified and to provide recommendations before the new regulatory framework is fully defined (see **paragraph 21**), we decided to follow-up our audit, including more extensive coverage of the import regimes for organic products. In this context, our main audit question was "Can consumers now have greater confidence in the control systems for organic products?"

25. To answer the main question, we asked, firstly, whether the control system for organic products produced in the EU now provides greater assurance to consumers. We focused on the improvements introduced by the Commission and the Member States since 2012. In particular, we addressed the Commission's monitoring of the Member States' control systems, the Member States' supervision of control bodies and the exchange of information between the different bodies and authorities.

26. Secondly, we asked whether the control system for imported organic products into the EU now provides greater assurance to consumers. We examined the two import regimes currently in force for organic products, and the Commission's procedures and how it carried out its supervisory tasks.

27. Thirdly, we followed up on our 2012 report by carrying out a traceability exercise on organic food, the results of which are presented in the final section.

¹⁷ Special Report No 2/2019 "Chemical hazards in our food: EU food safety policy protects us but faces challenges".

28. We carried out the audit between December 2017 and July 2018, collecting audit evidence from the following sources:

- Documentary reviews and interviews with staff from two Directorates General of the European Commission: DG Agriculture and Rural Development (AGRI) and DG Health and Food Safety (SANTE).
- Documentary review and video conferences with representatives of the six Member States we visited for Special Report No 9/2012: Germany (North-Rhine-Westphalia), Ireland, Spain (Andalucía), France, Italy (Emilia Romagna), and the United Kingdom (England).
- Visits to two Member States: Bulgaria (where the number of organic farmers has increased quickly in recent years) and Czechia (where the organic area is large).
- Documentary review of the organic control system in Norway, in close cooperation with the EFTA¹⁸ Surveillance Authority.
- Participation in two audit visits by DG SANTE to third country control bodies operating in Mexico and Ukraine.
- Consultation meetings on the EU organic control system with relevant stakeholders, including the International Federation of Organic Agriculture Movement (IFOAM), the Research Institute of Organic Agriculture (FiBL) and the European Organic Certifiers Council (EOCC).
- Review of relevant studies related to the audit topic.

¹⁸ European Free Trade Association - intergovernmental organisation of Iceland, Liechtenstein, Norway and Switzerland.

OBSERVATIONS

The supervision of the control system for organic products produced in the EU has improved

29. Supervision of the control system for organic products in the EU is very important since the vast majority of organic products consumed in the EU are produced in the EU (see **paragraph 16** for example). Following our recommendations in Special Report No 9/2012, we expected the Commission to have strengthened its monitoring of Member States' control systems, and the competent authorities in Member States to have strengthened their supervisory role over control bodies. This included harmonising the definition of types of non-compliance and the corresponding enforcement measures. We present the result of our follow-up of these recommendations in the following sections.

Commission monitoring of the control systems in Member States has improved

30. In our Special Report No 9/2012, we recommended that the Commission should strengthen its monitoring of Member States' control systems by undertaking audit visits and gathering and making good use of the necessary data and information (see also **Annex**).

31. At the time of our 2012 report, the Commission had not carried out any audit related to organic farming in the Member States since 2004. Following our report, the Commission resumed its audit visits to Member States. Between 2012 and the end of 2018 DG SANTE carried out 63 audits related to organic farming of which 28 were in EU Member States (see **Table 1**)¹⁹. In 2015, the Commission (DG SANTE) published an overview report of the 14 audits in the Member States which it had completed by the end of 2014²⁰.

¹⁹ In addition, the Commission carried out five audits focusing on pesticide residue controls in organic production (in Germany, Poland and the United Kingdom in 2015 and in Finland and Spain in 2016).

²⁰ Overview report. Organic Production – Member States. DG(SANTE) 2015-8950 – MR.

Table 1 – Audits on organic farming carried out by DG SANTE in EU Member States between 2012 and 2018 (situation on 10/12/2018)

Type of audit	2012	2013	2014	2015	2016	2017	2018
Member States	Poland Portugal	Greece Spain France Germany United Kingdom Italy Romania	Netherlands Malta Czechia Finland Slovakia	Bulgaria Lithuania Sweden Denmark	Ireland Latvia Hungary	Austria Belgium Slovenia	Italy* Romania (2 audit visits)* Slovakia

* audit reports not yet available.

32. Overall, the Commission found that in most Member States the control systems were well organised despite some weaknesses in the supervision of control bodies and at the level of individual inspections.

33. We examined the Commission’s methodology, its reports and follow-up procedures. We confirmed that the audits covered the relevant topics, the audit process was adequately documented and audit findings were followed-up. In addition, we carried out two visits to Member States that the Commission had checked in 2014 and 2015 (Czechia and Bulgaria), and confirmed the relevance of the Commission’s findings. Commission’s audit reports are published on DG SANTE’s website²¹.

34. If the EU legislation on organic production has not been properly applied, the Commission can send pre-infringement letters (also called EU Pilots) to Member States or initiate an infringement procedure. EU Pilot inquiries are useful tools for engaging in a dialogue with Member States. Since 2012, the Commission has sent 41 pre-infringement letters to 22 different Member States²². These EU pilots lasted on average nine months, but the Commission could thereby avoid triggering more lengthy infringement proceedings.

35. The Commission makes good use of the meetings of the Committee on Organic Production (COP), which consists of representatives of the Member States and meets five to

²¹ http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

²² 21 letters related to the same topic (late notifications in OFIS) and were treated as a group exercise.

seven times per year. Norway, Switzerland and Iceland participate as observers. One of the recurring subjects of discussion during these meetings is the follow-up of irregularities and fraud allegations. Finally, the Commission has taken initiatives on coordination with, and training of, the competent authorities and control bodies, anti-fraud authorities and private sector organisations.

Many weaknesses addressed in Member States' supervision of control bodies

Procedures for approving and supervising control bodies

36. In our Special Report No 9/2012, we recommended that the competent authorities should apply appropriate documented procedures for approving and supervising control bodies (see also ***Annex***). During our follow-up audit, we found that the situation had improved since 2012, although some weaknesses remained.

37. In 2013, the European Commission amended Regulation (EC) No 889/2008²³, thus specifying the legal framework for the competent authorities of Member States and thereby helping them to fulfil this recommendation. For example, it details which type of supervisory activities competent authorities should carry out on control bodies and requires them to organise an annual inspection of control bodies²⁴.

38. The competent authorities of the six Member States that we followed up on have taken action to remedy most of the weaknesses observed last time. For example:

- changes in the legal framework (Germany, Spain and Italy),
- improved coordination with the accreditation bodies (Ireland, France, the United Kingdom and Germany),

²³ Commission Implementing Regulation (EU) No 392/2013 added a Chapter 9 on the supervision by competent authorities to Regulation No 889/2009.

²⁴ Articles 92(c) and 92(e).

- improved procedures and guidelines for supervising control bodies (Ireland, Spain, France and the United Kingdom),
- competent authorities are now checking that control bodies have risk analysis procedures in place for their inspections of operators and for rotating the appointment of inspectors.

39. Some of these changes were quite recent and will take some time to be fully implemented. We did not check the effectiveness of these actions on the ground during our audit.

40. Despite these improvements, we identified a number of weaknesses in these Member States related to our previous findings, including:

- In Italy, the two control bodies we checked carried out many inspection visits towards the end of the year, at a time where this is less effective, at least for plant growers;
- Member State authorities should publish the updated lists of operators and their organic certificates online ²⁵. In France, some control bodies do not make this information available online, reducing transparency and slowing down traceability checks;
- Checks by the competent authority in Spain (Andalucía) are insufficiently documented.

41. In 2014 and 2015, the European Commission audited Czechia and Bulgaria. We also visited these two Member States and found that they had taken action to improve their control systems. However, in Bulgaria we still found weaknesses in the supervision of control bodies:

- The competent authority did not identify some weaknesses during its annual inspection (see further in **paragraph 45** and **Box 1**);

²⁵ Article 92(b) of Regulation (EC) No 889/2008.

- There was no evidence, for the two control bodies visited, that the selection of operators where products had to be tested for non-authorised substances is risk-based as required by the Regulation.

Non-compliance by operators and corresponding enforcement measures

42. In our Special Report No 9/2012, we found that sanctions for non-compliance with the rules on organic production had been applied differently between Member States, within the same Member State and even within control bodies²⁶. We recommended promoting their harmonisation. During our follow-up audit, we found that harmonisation had significantly improved within control bodies and Member States, but not across the EU.

43. Since 2013²⁷, competent authorities are required to adopt a catalogue of types of non-compliance and send it to the control bodies so that it can be applied. There is no legal obligation to draw up an EU-wide harmonised catalogue of enforcement measures (including sanctions), but the Commission has recently started to work with the Member States in this direction. The Commission has identified the most frequently occurring, serious types of non-compliance in the organic control system and is collecting information on the corresponding enforcement measures.

44. All of the eight Member States that we visited or followed up on during this audit now have a catalogue of non-compliance types and corresponding enforcement measures²⁸, which is a useful step forward towards clarification and harmonisation.

45. However, in Bulgaria, further clarification and proper supervision are needed. We saw that one of the two control bodies we visited chose not to apply certain enforcement

²⁶ Paragraphs 35 to 37 of Special Report No 9/2012.

²⁷ Regulation (EU) No 392/2013 added Article 92(d) to Regulation (EC) No 889/2008.

²⁸ According to the regulation, the catalogue should contain at least those non-compliances which affect the organic status of products and the corresponding sanctions. In some Member States (Bulgaria, Ireland, France, Italy and the United Kingdom) the catalogue even includes minor non-compliances that do not affect the organic status of the product.

measures indicated in the catalogue and that neither applied the appropriate measure for the presence of unauthorised substances. The competent authority did not report on this in the context of its supervisory activities.

46. Restrictions on the use of chemicals and other substances²⁹ are a key requirement of organic production methods. Residue testing can be used by control bodies or competent authorities to detect the presence of unauthorised substances, in the final product, but also in the leaves or in the soil. In our Special Report No 9/2012, we observed that the EU regulations did not provide for a minimum number of laboratory tests to be performed by control bodies and that there was no harmonised approach as regards the measures to be taken if non-authorised substances were found to be present.

47. Since 2013, the EU rules have defined a minimum number of samples to be taken and analysed by the control bodies³⁰. For the future, the new organic regulation³¹ requires the competent authorities or control bodies to (i) carry out an investigation in order to determine the source and cause of the presence of these substances and (ii) provisionally block the products pending the results of the investigation. By the end of 2024, the Commission should present a report analysing whether further harmonisation is needed.

The exchange of information has improved, but it could be quicker and more comprehensive

48. In our Special Report No 9/2012, we concluded that the exchange of information within Member States, from Member States to the Commission and also between Member States was not yet adequate (see also ***Annex***). We recommended that the Member States should ensure a direct flow of all relevant information on infringements and irregularities from the control bodies to the paying agencies and vice versa. Furthermore, we expected

²⁹ Such as certain plant protection products, GMOs, fertilisers, feed additives, processing aids or products for cleaning and disinfection.

³⁰ Article 65(2) of Regulation (EC) No 889/2008 specifies the minimum number should correspond to 5 % of the number of operators under its control.

³¹ Article 29 of Regulation (EU) 2018/848.

the Commission to (i) specify the form and timing of communications on infringements and irregularities, (ii) introduce appropriate measures to ensure that Member States respect their reporting obligations and (iii) revise the information system provided for communicating infringements and irregularities.

49. The Commission and the Member States took a series of actions to implement our recommendation:

- The European Commission introduced a requirement³² for Member States to communicate the results of organic inspections to the paying agencies. This is important as it may affect a farmers' EU subsidy (see also ***paragraph 19***). The Member States/regions that we followed up and visited during this audit now have cross-notification systems in place, although in France this type of communication is only partially implemented.
- In 2013, the European Commission introduced³³ the requirement for control bodies to inform the competent authorities without delay about cases of non-compliance affecting the organic status of products. The Member States that we audited had developed procedures and, sometimes, technological solutions to improve communication between control bodies and the competent authorities regarding non-compliance. However, communication is not always prompt (see ***Box 1***).
- The European Commission also specified that if they find irregularities, Member States should notify the Commission and other Member States without delay via the Commission's online tool OFIS (Organic Farming Information System)³⁴. Communication

³² Article 92(6) of Regulation (EC) No 889/2008, as amended by Regulation No 392/2013.

³³ Article 92(4) of Regulation (EC) No 889/2008, as amended by Regulation No 392/2013.

³⁴ Irregularities involving products from other Member States (Article 92(a)(1) of Regulation (EC) No 889/2008, as amended by Regulation No 392/2013) and also involving products from the same Member State if the irregularity has implications for another Member State (Article 92(a) of Regulation (EC) No 889/2008, as amended by Regulation (EU) 2018/1584).

by Member States had become faster since our previous audit, but we still identified delays (see **Box 1**).

- Once a notification has been recorded in OFIS, the Commission expects the notified country to investigate the possible causes of the irregularity and to reply via OFIS within 30 days³⁵. Since our previous audit, the response times have improved. In 2017, 85 % of the replies were on time (60 % in 2016).
- Since 2013, Member States have had to include mandatory information on the organic sector and checks in the annual food safety reports they send to the Commission³⁶. In most of the reports we analysed, organic production is specifically mentioned. However, our current analysis confirms the continued presence of some of the weaknesses that we identified previously³⁷ (see **Box 1**).

Box 1 – Communication is sometimes slow and incomplete

Communication about non-compliances

In Bulgaria, we found that some control bodies notified the competent authority about certain types of non-compliances only through their annual reporting. The competent authority did not notice this during its supervisory activities. In Czechia, we found that on average control bodies took 33 days in 2016 and 55 days in 2017 to report a non-compliance affecting the organic status of a product to the competent authority.

Communication via OFIS

The time between the detection of a non-compliance and notification of it in OFIS by the Member State competent authority was on average 38 calendar days, whereas the Regulation requires that notifications should be without delay. In the meantime, products from the same batch can continue to circulate in the EU labelled as organic.

³⁵ Article 92(a)(4) of Regulation (EC) No 889/2008, as amended by Regulation No 392/2013.

³⁶ Article 92(f) and Annexes XIIIb and XIIIc of Regulation (EC) No 889/2008, as amended by Regulation (EU) No 392/2013.

³⁷ Paragraph 43 of Special Report No 9/2012.

In Bulgaria, control bodies did not include information about the origin of the product in their communications to the competent authority, so the competent authority did not have the relevant information to decide if the infringement/irregularity should be recorded in OFIS or not.

Annual reporting to the Commission

Member States still reported too late on their control activities. For 2014-16, the 12 Member States we checked were late by more than 4 months on average. By June 2018, three Member States had not provided their reports for 2016.

Information about the organic control system in the annual reports was still incomplete in a large number of cases. The Commission's own assessment of the 2016 annual reports showed that there were high and medium information gaps in 13 annual reports out of the 26 received.

The challenge of supervising the control system for imported organic products was partially met

50. A relatively small part of the EU's organic consumption comes from imported products (see [paragraph 16](#) for example). Organic products imported from outside the EU can be certified in two ways:

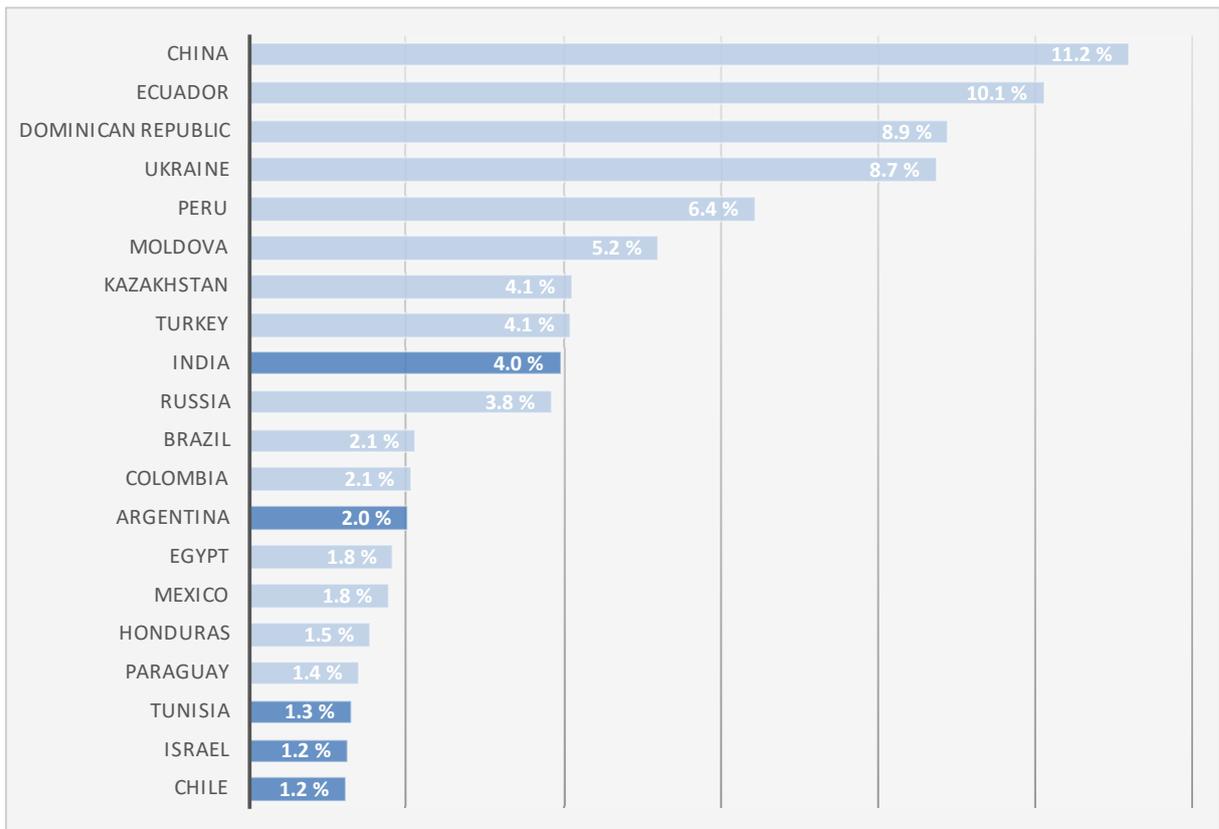
- Under the national rules of those countries that the Commission has recognised as having organic principles, production rules and control systems that are equivalent to those laid down in the EU regulations³⁸ (further referred to as **equivalent third countries**);
- For other countries, by control bodies that the Commission has recognised for organic production outside the EU according to equivalent production rules and control systems³⁹ (further referred to as **equivalent control bodies**).

³⁸ Articles 7 to 9 of Regulation (EC) No 1235/2008.

³⁹ Articles 10 to 12 of Regulation (EC) No 1235/2008.

51. In 2018, 114 countries sent organic products to the EU. **Figure 4** shows the top 20 countries, with equivalent third countries shown in dark blue. Around 87 % of the imported organic products are certified by equivalent control bodies.

Figure 4 – Breakdown of top 20 countries* from which organic products are imported into the EU in 2018 (based on weight)



Note: Equivalent third countries are shown in dark blue.

* Norway and Switzerland are not included in this graph since the Commission's TRAdE Control and Expert System (TRACES) does not contain any information about exports from these countries.

Source: ECA based on data extracted from TRACES (certificate status = 'first consignee declaration signed').

52. There are currently thirteen equivalent third countries⁴⁰ which represent approximately 13 % of organic imports. Each has signed an agreement or arrangement with the Commission on organic equivalence. Since 2014 a new recognition scheme based on international trade agreements applies to equivalent third countries⁴¹. The first such agreement was signed with Chile in 2017⁴² (see **Table 2**).

Table 2 – Overview of third countries which have signed an agreement with the Commission on organic equivalence

Third country name	Year of inclusion	Type of agreement
Australia	1996	Administrative arrangement
Argentina	1997	Administrative arrangement
Israel	1997	Administrative arrangement
Switzerland	1997	Chapter on organic products within full trade agreement
New Zealand	2002	Administrative arrangement
Costa Rica	2003	Administrative arrangement
India	2006	Administrative arrangement
Tunisia	2009	Administrative arrangement
Japan	2010	Administrative arrangement
Canada	2011	Administrative arrangement
United States	2012	Administrative arrangement
South Korea	2015	Administrative arrangement
Chile	2017	Trade agreement on organic products

53. In the following sections, we present our findings on the following topics, for each of the import regimes:

- the Commission's audits outside of the EU;
- the exchange of information;

⁴⁰ Annex III to Regulation (EC) No 1235/2008 latest amendment: Commission Implementing Regulation (EU) 2018/949, which added Chile to Annex III.

⁴¹ Article 47 of Regulation (EU) 2018/848.

⁴² Agreement between the European Union and the Republic of Chile on trade in organic products (OJ L 331, 14.12.2017, p. 4).

- the Commission's enforcement procedures.

We then address the role of the Member States in relation to imported products.

The Commission has started audits outside the EU, but most equivalent control bodies have not been audited so far

54. In our Special Report No 9/2012, we recommended that the Commission should ensure adequate supervision of the countries included in the list of equivalent third countries for organic production (see also **Annex**). The Commission should also ensure supervision of the equivalent control bodies⁴³.

55. Following up on the action the Commission had taken in response to our recommendation, we found that since 2012 it has been carrying out audits outside the EU (see **paragraph 31**) and that these now consume a large part of its audit resources for organic production (see **Table 3**).

Table 3 – Audits carried out by DG SANTE between 2012 and 2018 in third countries

Type of audit	2012	2013	2014	2015	2016	2017	2018
Equivalent third countries	Tunisia India	Switzerland Israel	Australia Argentina	Israel Canada India	Costa Rica		
Equivalent control bodies		China (3 different CBs)	Turkey Vietnam	Ukraine & Belarus South- Africa Peru Bolivia	Albania & Kosovo* Ukraine Thailand Peru	Brazil India Ecuador Bolivia Sri Lanka Turkey China	Paraguay Dominican Republic Mexico** Ukraine Kenya

* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

** audited through a desk review at the control bodies' headquarters in the EU.

Equivalent control bodies

56. Equivalent control bodies are frequently headquartered in the EU, but with activities extending all over the world. The supervision of equivalent control bodies is challenging for

⁴³ Article 33(3) of Regulation (EC) No 834/2007.

the Commission because it cannot rely on the work of a competent authority, as is the case for EU Member States or equivalent third countries (see **paragraph 14**).

57. At the end of June 2018, there were 57 approved equivalent control bodies. Control bodies may be recognised for one or more third countries, sometimes with one single body covering more than 50 countries. This results in a large number of control body/country combinations that the Commission has to approve and supervise⁴⁴.

58. The Commission started to audit recognised equivalent control bodies in 2013 and by the end of 2018 had carried out 25 such audits⁴⁵, usually at the control body's headquarters and in one third country for which the control body is recognised. We estimate that the control body/country combinations that the Commission has audited since 2013 cover approximately one third of the organic products imported through this regime. This means that several years may pass before the Commission visits a specific country or control body (see **Box 2**).

Box 2 – Low frequency of Commission audits

In 2018, the Commission audited an equivalent control body that has been active in the Dominican Republic since 2013. The audit revealed significant shortcomings in the certification activities of the control body⁴⁶. The Dominican Republic is the third largest exporter of organic products into Europe (see also **Figure 4**) and around one third of the organic products exported from the Dominican Republic to the EU are certified by the control body. It was the first time that this control body had been audited and the first time the Commission had visited the Dominican Republic for such an audit.

59. On the basis of security advice from the relevant Commission services and the European External Action Service (EEAS), planned visits to certain countries are sometimes cancelled or postponed (for example to Egypt and Mexico). This is understandable, but limits

⁴⁴ In some cases, the same control body applies different standards in different countries.

⁴⁵ These audits cover 17 of the 57 control bodies that were approved at the end of June 2018.

⁴⁶ DG(SANTE) 2018-6392 (http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3998).

the level of assurance the Commission can obtain based on its supervision in these countries.

60. The findings arising from the Commission's audits illustrate the need for thorough and regular supervision of equivalent control bodies. The Commission follows up on findings, but can take a long time to solve weaknesses across different control bodies operating in the same country. See **Box 3** for an example.

Box 3 – Difficulties in solving systemic weaknesses through control body audits

China is the largest exporter of organic products into the EU (see also **Figure 4**). In 2013 the Commission started to take action to tackle weaknesses in the control system for organic products coming from China. It wrote to all the control bodies active in China recommending that they take additional measures such as extra unannounced inspections and further samples and report on these actions in their annual reports. It also audited three control bodies, and de-listed one of them in 2014. The Commission audited another control body in 2017 and found continuing weaknesses in the organic production and control system in China. The Commission is aware of the problem and is working on developing a more systematic approach.

61. When the new organic Regulation comes into force (see **paragraph 21**), the equivalence regime will be gradually replaced, between 2021 and 2023, by a regime where the control bodies' organic standards and control systems need to comply with the EU rules. This compliance-based approach should reduce the time needed to prepare audit visits, and to examine new applications and annual reports, as the Commission will no longer have to assess the equivalence of the control body's organic production standards and control system.

Equivalent third countries

62. The Commission's supervision of equivalent third countries has improved with respect to our previous audit. Since 2012, the Commission has carried out ten audits on eight equivalent third countries (see **Table 3**) and took part in a peer review of the US control system in 2014. Equivalent third countries which have not been audited during this period are New Zealand, Japan and South Korea which together represent less than 1 % of organic imports into the EU, and Chile, which signed an agreement with the EU in 2017.

63. The audits carried out revealed significant shortcomings. In many cases, when the Commission followed up its audits, it found that the countries concerned had taken remedial action to address these (see **Box 4**).

Box 4 – The Commission’s audits revealed shortcomings and third countries have taken remedial action

The Commission audited India twice⁴⁷ and it found serious deficiencies in the effectiveness of the control bodies and the supervision by the competent authority. As a result, the Commission refused to further accept imports of processed agricultural products as equivalent because of changes in the Indian production rules and removed one control body from the list of accepted Indian control bodies. In February 2017, the Commission confirmed that India had implemented corrective action to rectify the shortcomings identified.

In its audit in Switzerland in September 2013⁴⁸ the Commission found shortcomings with regard to the supervision of control bodies and inadequate import controls. As a consequence, the Swiss authorities took action to resolve the issues raised, by amending their legal framework and enhancing their guidelines for control bodies.

64. The Commission did not carry out a risk analysis of the control system for organic products in the EFTA countries Norway⁴⁹ and Iceland. Moreover, it took more than eight years for the EU organic regulations⁵⁰ to be incorporated into the EEA Agreement⁵¹, in

⁴⁷ India (2012): http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3059; India (2015): http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3641.

⁴⁸ Switzerland (2013): http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3215.

⁴⁹ Based on Eurostat data, Norway is the third largest exporter of food to the EU. There are no specific data available on the share of organic food.

⁵⁰ Council Regulation (EC) No 834/2007 and the related Implementing Regulations.

⁵¹ The Agreement on the European Economic Area, since January 1994, brings together the EU Member States and the three EEA EFTA States - Iceland, Liechtenstein and Norway - in a single market, referred to as the "Internal Market".

March 2017. In October 2018, for the first time, the Commission accompanied the EFTA Surveillance Authority on an audit of the control system for organic products in Norway⁵².

The exchange of information has improved, but the Commission could use it better and more quickly

The exchange of information on irregularities

65. In 2013 the Commission extended the OFIS tool⁵³ to allow information to be exchanged between the Commission, Member States, equivalent third countries and equivalent control bodies on irregularities for imported products. The Commission has adopted procedures to follow up on these irregularities.

66. For notified irregularities concerning products imported via the regime of equivalent control bodies, competent authorities in the Member States are the main actors in the follow-up. These contact the relevant control body via OFIS and request further information until they are fully satisfied with the answer provided. When irregularities remain unanswered, the Commission then contacts the control body directly.

67. For products imported via the regime of equivalent third countries, the Commission monitors OFIS notifications. However, for some of these we found little evidence of effective follow-up.

Annual reports

68. In addition to notifications exchanged through the OFIS tool, the Commission should receive annual reports from each recognised equivalent control body⁵⁴ and third country⁵⁵

⁵² <http://www.eftasurv.int/press--publications/press-releases/internal-market/norway-needs-to-adjust-control-system-of-organic-production>

⁵³ Regulation (EC) No 125/2013 introduced amendments to Article 15 of Regulation (EC) No 1235/2008.

⁵⁴ Article 12(1)(b) of Regulation (EC) No 1235/2008.

⁵⁵ Article 33(2) of Regulation (EC) No 834/2007.

describing how they have implemented the control system. The annual reports of the control bodies should include the latest assessment reports from the accreditation body.

69. According to its internal rules, the Commission should review the annual reports within three months of receipt. We checked ten annual reports from control bodies. In one case, no assessment had been carried out. In only three cases had the Commission reviewed the reports within the three-month deadline, while the review of three other reports took nine months or more. We observed similar delays in the analysis of annual reports received from equivalent third countries⁵⁶.

Cooperation with other bodies and authorities

70. For its supervisory work over equivalent control bodies, the Commission also relies on the assessment reports from the accreditation bodies. In 2017 and 2018, the Commission organised an annual meeting with accreditation bodies. There are, however, no cooperation agreements in place which set terms for a regular exchange of information, or allow the Commission to access the evidence underlying annual assessment reports or to accompany accreditation bodies during their assessments, in cases where the Commission may consider a coordinated approach to be more efficient for supervising equivalent control bodies.

71. Exporters to the EU often also sell their products on other markets. Therefore, they also have to comply with rules on organic production set by these other importing countries and are subject to the supervision of their competent authorities. As the Commission has limited resources to analyse the information received (see ***paragraphs 67 and 69***) or to carry out its own audits (see ***paragraphs 57 and 58***), it could develop its cooperation with the authorities of other major importing countries to enhance its supervision of imports. The Commission has taken some initial steps in this direction by holding ‘plurilateral’ (round table) discussions with a number of third countries (United States, Canada, Chile, Switzerland, Japan and South Korea) since 2016. However more systematic cooperative channels are not yet in place. For example, the Commission further aims to promote an exchange of information on

⁵⁶ In three cases (out of six analysed) the review took place more than nine months after receipt of the documents.

infringements, on-the-spot mission reports and a discussion on the common understanding of problems in certain countries.

Enforcement by the Commission was difficult and lengthy, but upcoming changes to the rules are intended to make it faster and more effective

Equivalent control bodies

72. If a control body does not provide the Commission with the required information in due time, if it fails to take corrective measures or if it does not agree to an on-site examination, the Commission can suspend or withdraw it from the list of recognised control bodies⁵⁷, or amend its specifications. In practice, the Commission withdrew recognition from seven control bodies. However, the time which passed between the decision to withdraw recognition from the control body and the entry into force of this decision was four months on average. In the meantime, the control bodies continued to certify organic products and issue certificates of inspection for their export. Under the new Regulation⁵⁸, the Commission will be able to adopt immediately applicable implementing acts, on duly justified imperative grounds of urgency, in order to withdraw recognition from control bodies more quickly.

Equivalent third countries

73. If a competent authority of a third country refuses to implement recommendations or lets a deadline for implementing a recommendation slip, the Commission may withdraw the third country from the list of recognised third countries or change the scope of its recognition⁵⁹. The Commission has used this possibility once (see **Box 4**).

⁵⁷ Articles 12(1)(c) and 12(2) of Regulation 1235/2008.

⁵⁸ Article 46(9) of the new organic Regulation 2018/848.

⁵⁹ For example: remove a category of products from the recognition.

74. The 2017 trade agreement with Chile (see **paragraph 52**) includes mechanisms for communication, verification and solving disputes⁶⁰, which help to enforce the rules.

Weaknesses in the Member States' checks on organic imports

75. EU Member States also have an important role to play in the control system for imported products. They carry out checks on imported products and check importers.

Member States' checks on imported organic products

76. The Member States must verify consignments of products being imported into the EU before the products can circulate freely in the EU⁶¹. They must carry out documentary checks and can also carry out further physical checks (such as checks on the packaging, labelling or sampling for analysis and laboratory testing) as appropriate according to their risk assessment. Based on the outcome of the checks, the Member State authority may then endorse the related Certificate of Inspection (COI) (see further **paragraph 84**).

77. The Commission can work together with the Member States to develop a common approach towards the checks to be made on imported products. For example, in December 2015 the Commission published guidelines on additional official controls in reaction to a series of irregularities detected earlier on shipments from Ukraine and certain neighbouring countries. These guidelines have been agreed by the EU Member States, and revised every year. They currently apply to Ukraine, Kazakhstan and the Russian Federation.

78. We found weaknesses in the checks carried out by three Member States on imported organic products (see **Box 5**).

⁶⁰ Mutual exchange of relevant information (Article 6), the possibility of peer reviews (Article 7), the introduction of a Joint Committee on Organic Products (Article 8) and provisions concerning the settlement of disputes (Article 9).

⁶¹ Articles 13(2) and 13(4) and Annex V of Regulation No 1235/2008 – Box 20.

Box 5 – Weaknesses in checks on incoming consignments

In Czechia, we found several cases where, according to the information on the Certificate of Inspection (COI), a laboratory analysis had been carried out, where in fact it had not (or vice versa). This was due to the customs administration endorsing the certificate without waiting for a final decision to carry out the analyses.

In Bulgaria, the import of organic products was subject to 100 % documentary checks by the Food Safety Authority. However, there was no risk analysis and no physical checks or laboratory tests were carried out on imported organic products at the time of the audit.

We found that a consignment of wheat imported from Kazakhstan via Turkey had not been tested for non-authorised substances as required by the guidelines for imports from this country. The control body incorrectly marked the country of origin on the COI as being Turkey, so the United Kingdom authorities did not test the consignment.

79. In addition, Member States should carry out regular checks on all imported products (both organic and non-organic) at different points in the food chain, using a risk-based approach⁶². They report annually on these checks to the Commission. We analysed a sample of annual reports for 12 Member States. None of them provided specific information about official controls carried out on imported organic products. In the absence of this information, the Commission cannot know which checks have been performed on imported organic products and what the results were.

Member States' checks on importers

80. Through their supervision of control bodies, Member States can verify if the procedures and checks carried out by importers are adequate. In our 2012 Special Report we observed that checks carried out by control bodies on importers are often incomplete. In the current audit we followed up on this finding, and found that this is still the case in certain Member States (see also **Box 6**).

⁶² Articles 15(1) and 15(2) of Regulation (EC) No 882/2004.

Box 6 – Weaknesses in checks on importers

In Bulgaria, the two control bodies we visited did not have dedicated checklists for importers and used the ‘traders’ checklists instead, which did not contain some specific checks related to imports.

In Spain (Andalusia), the competent authority’s reports on the annual supervisory inspections of the control bodies do not mention the import checks or the review of the specific import checklists.

The competent authority in the United Kingdom does not require importers to notify their control bodies about each incoming consignment. However, this notification is mandatory under the Regulation and is an important tool for better targeting of physical checks on incoming consignments.

Traceability has improved, though some weaknesses remain

81. In accordance with the General Food Law, food and feed businesses should ensure traceability through all stages of production, processing and distribution. They must be able to identify the businesses to which their products have been supplied and trace food chain inputs back to the immediate supplier⁶³. This applies to all types of foodstuffs.

82. For organic products, traceability needs go beyond the requirements of the General Food Law. As there is no analytical method to determine whether a product is organic or not, traceability should allow the verification of the organic status of a product along the supply chain. The purpose of a traceability check is (i) to identify all the operators involved, (ii) to verify their organic certification and, (iii) when there has been a failure to comply with the rules, to trace the product back to its source and isolate the problem, preventing the products concerned from reaching consumers.

83. In our Special Report No 9/2012 we reported on our audit of the traceability of a sample of organic products. We concluded that the competent authorities in Member States had difficulty in ensuring that organic products could be traced within the territory under their authority and that it was even more difficult to trace products crossing borders.

We recommended that controls should be strengthened to ensure that operators fulfil the

⁶³ Also referred to as the ‘one step forward, one step back’ approach.

regulatory requirements regarding traceability and that the Commission should clarify the roles and responsibilities of the different actors (see also [Annex](#)).

Traceability has improved inside the EU, but not all producers could be traced

84. The Commission took action to implement our recommendation. It has added a module for organic imports to the online tool to monitor imports of food and feed called TRACES (TRAdE Control and Expert System)⁶⁴. Since October 2017, control bodies have to issue electronic Certificates of Inspection (COIs) to accompany each consignment of imported organic products. The TRACES-COI module was introduced to improve the traceability of organic products and provide much more comprehensive statistical data on organic imports.

85. In the framework of its audits in Member States, the Commission (DG SANTE) requires competent authorities to carry out a traceability exercise on two organic products (selected by the Commission's audit team). In case of ingredients coming from outside the EU, the exercise only covers the movements after entering the EU.

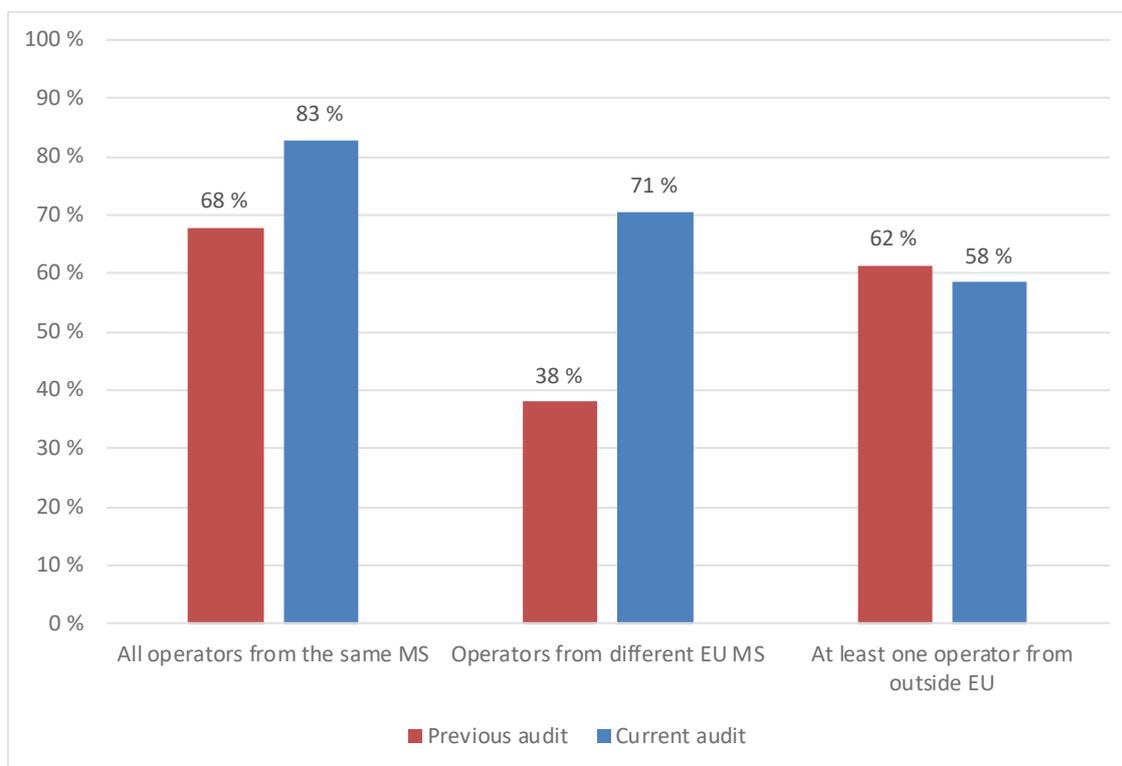
86. As part of our audit, we selected 105 products and asked competent authorities in 18 Member States and the Commission to:

- (i) trace those products back to the producer (also going beyond the EU border, if applicable); and
- (ii) provide, for all the operators involved, the organic certificate that was valid at the moment of handling/producing/processing the product.

87. The results of the traceability exercise were better than the one we carried out for our 2012 report for products from inside the EU (see [Figure 5](#)), and stable for imported products. Many products still could not be traced back to the agricultural producer.

⁶⁴ TRACES was established by Commission Decision 2004/292/EC pursuant to Council Directive 90/425/EEC.

Figure 5 – Percentage of products for which the traceability information requested was complete



Source: ECA.

88. Traceability checks are sometimes difficult and lengthy for various reasons, such as:

- (i) the complexity of the supply chain;
- (ii) problems in assessing the veracity of organic certificates using different databases across the EU, which are not harmonised in terms of content and are not practical if the control body of the operator is not known;
- (iii) a lack of coordination amongst certain competent authorities in the Member States.

It took more than three months to trace some of the products in our sample. Slow traceability has a negative impact on the capacity to act in case of non-compliances and to prevent the products concerned from reaching the consumers.

Our traceability exercise revealed problems with labelling and certificates

89. The traceability exercise resulted in a number of additional findings that are detrimental to the reliability of the control system, such as:

- Wrong origin of the product in the organic label (see **Box 7**);
- Incomplete inspection report of the control body, providing little assurance on a large number of production and processing units in different third countries (see **Box 8**).

Box 7 – Examples of wrong origin in the organic labels

The organic label of two products presented incorrect information on the origin of the product:

- pita bread was wrongly labelled as 'EU Agriculture', although the main product ingredient (wheat) came from Moldova, Ukraine and Kazakhstan.
- strawberry jam was wrongly labelled as 'EU/non-EU agriculture' although its agricultural ingredients were all imported from outside the EU (strawberries from Morocco and sugar from Brazil).

Box 8 – Example of an incomplete inspection report providing little assurance on a large number of operators in different countries

For one of the products of the traceability exercise, the certificate of the main operator in Turkey covered 10 production units and 15 processing units in Turkey, Ethiopia, Kirghizstan, Kazakhstan and Ukraine.

We requested the latest inspection report, which was the basis for the control body to certify the main operator and all its units. Our analysis revealed that basic information was missing from this 8-page report, such as the dates of the visits to the different units, the nature of the actual checks carried out in each of the different units. We therefore have little assurance that all the production and processing units had been adequately checked.

CONCLUSIONS AND RECOMMENDATIONS

90. The control system for organic products is set out in the EU regulations. It aims to give consumers the confidence that when they buy organic products, EU – or equivalent – rules have been applied at every stage of the supply chain. This should be the case whether the product is produced in the EU or imported. We found that the control system had improved since our previous audit and that our recommendations had generally been implemented (see **Annex**), but that some challenges remained.

91. For organic products produced in the EU – the major part of EU consumption – both the Commission and the Member States have addressed many of the weaknesses identified in our previous report.

92. After our 2012 report, the Commission has resumed its visits to Member States, and has now visited most of them. We found this work to be properly performed and followed up. The Commission's audits identified a number of weaknesses and prompted remedial action from the Member States. In addition to its audits, the Commission has taken initiatives on coordination and training, and frequently meets with Member States to discuss follow-up of irregularities and fraud allegations (**paragraphs 31 to 35**).

93. The competent authorities of the Member States that we audited have taken action to improve their control systems. The six Member States that we followed up on have remedied most of the weaknesses observed last time, through changes in the legal framework, improved coordination with the accreditation bodies, and better guidelines for the supervision of control bodies (**paragraph 38**). The eight Member States we examined now have a catalogue of non-compliances and corresponding enforcement measures (including sanctions) for control bodies to apply (**paragraph 44**). We still found a number of weaknesses related to our previous findings (**paragraphs 40 and 41**). We also found that the use of enforcement measures had not yet been harmonised across the EU and that reporting in the Member States was sometimes slow and incomplete (**paragraphs 43, 45 and 49**).

Recommendation 1 – Address remaining weaknesses in Member State control systems and reporting

The Commission should:

- (a) follow-up on the remaining weaknesses we identified in Member State control systems;
- (b) work towards better harmonisation of the definition of irregularities and infringements and their corresponding enforcement measures through discussion with the Member States and adoption of implementing acts;
- (c) provide guidance to the competent authorities to improve their reporting, for example by addressing information gaps in their annual reports.

Target implementation date: 2020.

94. A smaller part of organic food consumed in the EU comes from imports. Equivalent control bodies certify more than 80 % of organic products imported into the EU. The remainder is imported from equivalent third countries. The Commission's audits since 2012 have covered most equivalent third countries (***paragraph 62***). The Commission has also started visiting equivalent control bodies, and examined their activities on-the-spot in third countries. So far this has covered the systems applying to around a third of imports certified by the equivalent control bodies (***paragraphs 57 and 58***). The supervision of equivalent control bodies is challenging for the Commission because it is the competent authority and it cannot rely on the work of another competent authority, as in the case of Member States or equivalent third countries. When the Commission identifies weaknesses, it can take a considerable time to solve them across different control bodies operating in the same country (***paragraph 60***).

95. In addition to following-up on its audits, the Commission systematically analyses the annual reports received from equivalent control bodies and equivalent third countries. However, the Commission is often late in carrying out this assessment (***paragraph 69***). We found that the Commission relies on the reports of the accreditation bodies, but there are no formal cooperation agreements in place which set terms for a regular exchange of information or allow the Commission to coordinate supervision with accreditation bodies

(paragraph 70). We saw that the Commission had only started to explore the possible synergies for supervising organic imports with the competent authorities of other significant import markets (United States, Canada, Chile, Switzerland, Japan and South Korea)

(paragraph 71).

96. Regarding the control system for imports, enforcement by the Commission can be a difficult and lengthy process, but new rules have been introduced to make enforcement faster and more effective. The Commission will be able to adopt immediately applicable implementing acts, in order to withdraw recognition from an equivalent control body more quickly **(paragraph 72)**. Regarding equivalent third countries, by analogy with the trade agreement with Chile, future trade agreements could include mechanisms for communication and verification and for solving disputes **(paragraph 74)**.

97. Member States also have responsibility for carrying out checks on imported organic products and, through their supervision of control bodies, they verify if procedures and checks carried out by importers are adequate. We found weaknesses in the checks on incoming consignments and found that the checks carried out by control bodies on importers were still incomplete in some Member States **(paragraphs 75 to 80)**.

Recommendation 2 – Improve supervision over imports through better cooperation

The Commission should:

- (a) improve its supervision over equivalent control bodies, including by reinforcing cooperation with accreditation bodies and with the competent authorities of other significant importing markets;
- (b) promptly assess the annual reports of equivalent control bodies and of equivalent third countries;
- (c) issue guidance to Member States on how to carry out specific checks on the control bodies' supervision of importers and on imported organic products.

Target implementation date: 2020.

98. We again carried out a traceability exercise to verify if organic products can be traced back to the agricultural producer and if the organic status of the product can be demonstrated with a certificate at every stage of the supply chain. The results show an improvement with respect to the previous audit, particularly in the EU. Still, not all products could be traced back to the agricultural producer (**paragraphs 86 and 87**). We noted that most control bodies in the EU now have an online database of organic certificates for all their operators. However, these databases are not harmonised in terms of content and not practical if the control body of the operator is not known (**paragraph 88**). Traceability for imported products could benefit from the availability of online databases for operators outside the EU.

Recommendation 3 – Carry out more complete traceability checks

The Commission should:

- (a) carry out traceability exercises going beyond the EU borders in its supervisory activities of imported products and use the results to better target audits or ad hoc checks on control bodies and in third countries;
- (b) analyse, together with the competent authorities, the results of their traceability tests to identify weaknesses and possible corrective action;
- (c) improve cross-border accessibility to data on organic certificates, and require control bodies in third countries to list their certificates online.

Target implementation dates: (a) and (b) 2020, (c) 2024.

This Report was adopted by Chamber I, headed by Mr Nikolaos MILIONIS, Member of the Court of Auditors, in Luxembourg at its meeting of 13 February 2019.

For the Court of Auditors

Klaus-Heiner LEHNE
President

**Assessment of the level of implementation of the recommendations included in
SR No 9/2012**

Recommendation of SR No 9/2012	Current assessment	Comments
1 Competent authorities should strengthen their supervisory role over control bodies by applying appropriate documented procedures for approving and supervising control bodies, by promoting harmonisation in the definition of infringements, irregularities and corresponding sanctions, and by promoting identified good practices.	Implemented in most respects	Clear improvement but remaining weaknesses in Member States
2 Member States should ensure a direct flow of all relevant information on infringements and irregularities from the control bodies to the paying agencies and vice versa; and the Commission should specify the form and timing of communications of infringements and irregularities, introduce appropriate measures to ensure that Member States respect their reporting obligations and revise the information system provided for the communication of infringements and irregularities and consider including communications affecting third countries.	Implemented in most respects Implemented in most respects	Clear improvement but remaining weaknesses in Member States Clear improvement but remaining weaknesses concerning reporting obligations
3 Controls should be strengthened to ensure that operators fulfil the regulatory requirements regarding traceability; in this regard, the Commission should clarify the roles and responsibilities of the different actors.	Implemented in some respects Implemented in some respects	Improvement, but too many products still cannot be traced back Partly fulfilled (for products imported from third countries) through TRACES
4 The Commission should strengthen its monitoring of Member States' control systems by undertaking audit visits and gathering and exploiting the necessary data and information.	Implemented in most respects	The gathering and exploitation of information in the annual reports needs to be improved.
5 The Commission should ensure adequate supervision of the countries included in the list of those recognised as being equivalent for organic production and carry out a timely assessment of the applications from third countries applying to be included in that list.	Implemented in most respects	Late assessment of annual reports and very few annual meetings
6 As long as the import authorisations regime is in operation Member States should ensure its correct application. Competent authorities in Member States should reinforce the checks carried out on control bodies authorised to issue certificates of inspection.	No longer relevant	

REPLIES OF THE COMMISSION TO THE SPECIAL REPORT OF THE EUROPEAN COURT OF AUDITORS

“THE CONTROL SYSTEM FOR ORGANIC PRODUCTS HAS IMPROVED, BUT SOME CHALLENGES REMAIN”

EXECUTIVE SUMMARY

II. With reference to the recommendations issued by the ECA in Special Report No 9/2012, the Commission considers that the recommendations have been implemented. In particular, action was taken by improving the legal framework and by recalling Member States to their legal obligations. Moreover, the Commission put in place the Electronic Certificate of Inspection in the frame of the TRACES system that substantially improved the traceability of the products imported from Third Countries.

VII. The Commission accepts the recommendations.

INTRODUCTION

14. The Commission uses different means to supervise the activities of the equivalent Control Bodies in Third Countries. Additionally, the Commission makes ad-hoc requests for information, for instance to prove the traceability of a shipment or product.

OBSERVATIONS

41.

Second bullet: Regarding the evidence on the risk based approach, the Control Bodies should apply risk-based sampling but, in cases where the use of non-authorized product is suspected, sampling and laboratory analysis must be carried out in addition to such a risk based sampling.

43. The Commission launched the harmonisation exercise on the national catalogue of measures at the Committee of Organic Production meeting of 6th June 2018.

The framework consists of the following steps:

- (i) select a number of the most frequently occurring/serious non-compliances,
- (ii) draw a template with five columns (i.e. legal reference, classification of non-compliance, type of measure, administrative process and follow-up),
- (iii) ask the Member States to fill in the template based on their current national catalogue of measures,
- (iv) analysis of the completed templates-draw conclusions on the variations,
- (v) draft guidelines to how to set up the national catalogue of measures.

Box 1 – Communication is sometimes slow and incomplete

With regard to the communication via OFIS: The Commission has identified the problem on the timeliness of OFIS notifications and has invited Member States to take action on this matter. Moreover, during the audits in the Member States the Commission checks on a random sample of files of non-compliances:

- (i) whether the Control Body reports the non-compliances to the Competent Authority in a timely manner and,
- (ii) whether the Competent Authority makes the notification in OFIS.

In case of shortcomings, it issues recommendations to the Member States which have to take action.

Regarding the "Annual reporting to the Commission": The Commission undertook a number of initiatives to achieve improvements both in the timely submission of Annual Reports, and in their content. The Commission has discussed this matter in the Committee for Organic Production with Member States and sent reminder letters on the late submission of the Annual Reports. It has revised the "Annual Report assessment checklist" to clarify and improve the reporting of the Member States, in order to help Member States in the preparation of their Annual Reports, and ensure that the reports contain the required and relevant organic data.

The Commission expects to resolve this issue with the adoption of an Implementing Act under Article 25 (a) of the Official Control Regulation (EU) 2017/625.

Box 2 – Low frequency of Commission audits

In 2019, the Commission will audit another Control Body operating in the Dominican Republic precisely taking into account that this country is one of the largest exporters of organics to the EU.

59. Based on security advice, the Commission's planned visits to certain countries had to be cancelled or postponed. In such cases, the Commission has other means of supervision to obtain assurance about the Control Bodies' performance level as for instance: file checks at the Control Body office, verification of controls by Control Bodies inspectors in another country, direct follow up of irregularities with the Control Bodies, and through annual reporting.

Box 3 – Difficulties in solving systemic weaknesses through Control Body audits

The Commission together with the Member States have agreed to put in place new "Guidelines on additional official controls on organic products originating from China". This document is operational since 1st January 2019 and requires Member States to carry out, for a set of defined products, controls and verifications in all consignments from China.

Member States and the Commission considered these guidelines as indispensable considering the increasing number of irregularities notified in OFIS for certain type of products imported from China.

61. Under the new Organic Regulation, the Control Bodies' organic standards and control systems will need to comply with the EU rules. As pointed out by the ECA, this will result in some time saving as there will be no need any more to assess the standards. However, all the other parts of the assessment, monitoring and supervision remain unchanged.

67. The Commission continuously monitors OFIS notifications and contacts the Control Authorities of equivalent Third Countries in case of recurrent delays in the replies or in relation to specific issues.

In addition, in the context of the Committee for Organic Production, the Commission regularly presents and discusses notification cases with Member States.

70. The Commission considers the supervision of Accreditation bodies a corner stone of the control system.

It has to be noted that there is no legal provision in the Organic Regulation setting the frame of the relations between the Commission and the Accreditation bodies, which operate under a private contract with the Control Bodies.

However, there is an active cooperation between the Commission and the Accreditation bodies (specific workshops and ad-hoc meetings for instance), moreover Accreditation bodies are in copy of exchanges between the Commission and the relevant Control Bodies.

The main purpose of the meetings is to share with Accreditation bodies the challenges the Commission is facing as regards the supervision of Control Bodies recognised for the equivalence

and certifying organic products from Third Countries, and to get their views on the operational difficulties with the implementation of the Organic Regulation.

72. The Commission aims and will continue to aim at minimising the delay from the decision of a suspension or withdrawal from the relevant annex IV in Regulation (EC) 1235/2008 and its effective entry into force.

77. The Commission has incorporated in the revised checklist for the assessment of Annual Reports a field for the additional import controls and will follow-up on the quality and accuracy of data received on this topic.

CONCLUSIONS AND RECOMMENDATIONS

Recommendation 1 – Address remaining weaknesses in Member State control systems and reporting

(a) The Commission accepts the recommendation.

The Commission has systematic procedures in place for follow up of audit recommendations resulting from audits carried out by its Directorate-General for Health and Food Safety. In response to audit recommendations, Member States are requested to provide action plans addressing the shortcomings in the relevant national control system and provide evidence that they are implemented. The remaining weaknesses identified by the European Court of Auditors will be taken on board in the frame of this exercise or treated in targeted actions (bilateral discussion, and trainings).

(b) The Commission accepts the recommendation.

The Commission will continue the discussion already undertaken with Member States on the further harmonisation of measures, and will issue guidance on the drafting of national catalogues of measures for their discussion and approval.

The new Organic Regulation, which will enter into application in 2021, foresees the adoption of an Implementing Act to specify uniform arrangements for the cases where Competent Authorities are to take measures in relation to suspected or established non-compliances. The Implementing Regulation will not enter into application before 2021.

(c) The Commission accepts the recommendation.

The Commission will prepare the specific content of the organic chapter of the Annual Reports under the discussion for Article 25 (a) of the Official Control Regulation (EU) 2017/625.

A substantial improvement, through a clear and common template, can be done and sharing good practice can be a tool to achieve the improvement.

95. The Commission considers the supervision of Accreditation bodies a corner stone of the control system.

It has to be noted that there is no legal provision in the Organic Regulation setting the frame of the relations between the Commission and the Accreditation bodies, which operate under a private contract with the Control Bodies.

However, there is an established and active cooperation between the Commission and the Accreditation bodies (specific workshop, Accreditation bodies are in copy of exchanges between the Commission and the relevant Control Bodies, and ad hoc meetings for instance).

Recommendation 2 – Improve supervision over imports through better cooperation

(a) The Commission accepts the recommendation.

In addition to its annual meetings with the Accreditation bodies, the Commission intends to:

- Assess legal ways to reinforce cooperation with the Accreditation bodies.
- Foster cooperation in the context of the plurilateral discussions in view to explore synergies to deal with common risk and challenges.

(b) The Commission accepts the recommendation.

(c) The Commission accepts the recommendation.

The Commission intends to clarify legal provisions for control of imported products, in particular in the context of the new Organic Regulation and continue to draft guidance documents on imports of organic products in the EU from selected Third Countries. This will harmonise the approach among Member States. The Implementing Regulation will not enter into application before 2021.

Recommendation 3 – Carry out more complete traceability checks

(a) The Commission accepts the recommendation.

In addition to the ongoing ad hoc traceability exercises for suspicious consignments, the Commission intends to carry out every year a number of traceability exercises.

(b) The Commission accepts the recommendation.

The Commission intends to invite Member States to present to the Committee for Organic Production delegates the results of their traceability checks together with the analysis of the problems encountered and the enforcement actions.

(c) The Commission accepts the recommendation.

The Commission intends to develop an approach for an electronic certification for the internal market to be integrated into the future Information Management System for Official Control to first improve the cross-border accessibility to data on organic certificates.

Then, the Commission will take the necessary steps to extend such a system to Third Countries in particular with a view to compliance with EU rules that will be compulsory by 2024.

ECA TEAM

The ECA's special reports set out the results of its audits of EU policies and programmes, or of management-related topics from specific budgetary areas. The ECA selects and designs these audit tasks to be of maximum impact by considering the risks to performance or compliance, the level of income or spending involved, forthcoming developments and political and public interest.

This report was adopted by Audit Chamber I — headed by ECA Member Nikolaos Milionis — which specialises in sustainable use of natural resources. The audit was led by ECA Member Nikolaos Milionis, supported by Ioulia Papatheodorou, former Head of Private Office, Kristian Sniter, current Head of Private Office, and Matteo Tartaggia, Private Office Attaché, his Private Office; Michael Bain, Principal Manager; Els Brems, Head of Task; Blanka Happach, Greta Kapustaite and Radostina Simeonova, Auditors. Linguistic support was provided by Miroslava Chakalova-Siddy, Marek Riha and Fiona Urquhart.



From left to right: Michael Bain, Blanka Happach, Nikolaos Milionis, Matteo Tartaggia, Greta Kapustaite, Kristian Sniter.

Event	Date
Adoption of Audit Planning Memorandum (APM) / Start of audit	29.11.2017
Official sending of draft report to Commission (or other auditee)	3.1.2019
Adoption of the final report after the adversarial procedure	13.2.2019
Commission's (or other auditee's) official replies received in all languages	8.3.2019

PDF ISBN 978-92-847-1764-4 doi:10.2865/217286 QJ-AB-19-002-EN-N

HTML ISBN 978-92-847-1723-1 doi:10.2865/7119 QJ-AB-19-002-EN-Q

Since 1991, the EU has had a control system governing the production, processing, distribution and import of organic products. It aims to give consumers the confidence that organic rules are applied at every stage of the supply chain. The EU organic sector has developed rapidly over recent years. Following up on our Special Report No 9/2012 published in June 2012, we found that the control system had improved. Our recommendations had generally been implemented, but some challenges remained. We make recommendations to address the remaining weaknesses we identified in the Member States for EU products, to improve the supervision of imported organic products through better cooperation as well as to carry out more complete traceability checks.



EUROPEAN
COURT
OF AUDITORS



Publications Office

EUROPEAN COURT OF AUDITORS
12, rue Alcide De Gasperi
1615 Luxembourg
LUXEMBOURG

Tel. +352 4398-1

Enquiries: eca.europa.eu/en/Pages/ContactForm.aspx

Website: eca.europa.eu

Twitter: @EUAuditors

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