EUROPEAN COURT OF AUDITORS

Special Report No 14

THE COMMISSION'S MANAGEMENT OF THE SYSTEM OF VETERINARY CHECKS FOR MEAT IMPORTS FOLLOWING THE 2004 HYGIENE LEGISLATION REFORMS



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

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REPLY OF THE COMMISSION

ABBREVIATIONS

ALOP: appropriate level of sanitary protection

BIP: border inspection post, within the meaning of Council Directives 91/496/EEC and 97/78/EC

BSE: bovine spongiform encephalopathy

CIRCA: Communication and Information Resource Centre Administrator, a collaborative workspace with partners of the European Institutions

Comext: Eurostat's reference database for external trade

CVED: Common Veterinary Entry Document for products of animal origin, within the meaning of Annex III to Commission Regulation (EC) No 136/2004, and live animals, within the meaning of Annex I to Commission Regulation (EC) No 282/2004

cwe: Carcass weight equivalent

DG: Directorate-General

DG AGRI: Directorate-General for Agriculture and Rural Development

DG RTD: Directorate-General for Research

DG SANCO: Directorate-General for Health and Consumers

DG TAXUD: Directorate-General for Taxation and Customs Union

ABBREVIATIONS

EEA: European Economic Area

EFSA: European Food Safety Authority

EUR-Lex: online portal for European Union law

Eurostat: statistical office of the European Union

FAO: Food and Agriculture Organisation of the United Nations

FVO: Food and Veterinary Office

Hygiene package: the set of new legislation adopted since 2004 which mainly entered into force in 2006, establishing a new legislation framework for food safety in the European Union

ISO: International Organisation for Standardisation

NCTS: New Computerised Transit System

MANCP: multiannual national control plan

Potsdam Group: working party of veterinary experts

RASFF: Rapid Alert System for Feed and Food, a network of national authorities, managed by the Commission

SCoFCAH: Standing Committee on the Food Chain and Animal Health

ABBREVIATIONS

SPS: sanitary and phytosanitary measures

TARIC: online customs tariff database

TRACES: TRAde Control and Expert System

White Paper: White Paper on food safety

WTO: World Trade Organisation



The Food and Veterinary Office, based in Ireland, is a body of experts, mainly composed of veterinary professionals.

EXECUTIVE SUMMARY

١.

Veterinary checks on meat and meat product imports are an important component of the European Union's food safety policy. There is the risk that imported meat may be a vector for the transmission of diseases not only to consumers but also to livestock, affecting European Union (EU) production.

П.

While imports represent less than 4 % of EU meat consumption — and there is no evidence that the major health crises suffered in the past 15 years have been due to shortcomings in the import veterinary checks — public awareness and concern with regard to animal health and food safety have increased greatly. Moreover, while the EU budget normally allocates 300 million euro for veterinary disease prevention and eradication, and 100 million euro for feed and food safety related measures, the late 1990s crisis (mainly bovine spongiform encephalopathy (BSE)) imposed very substantial additional expenditure on the EU budget as well as on the budgets of the Member States.

EXECUTIVE SUMMARY

III.

The audit examined the Commission's supervision of the EU system of veterinary checks carried out at the border inspection posts (BIPs) on meat imports under the new framework introduced by the 2004 regulations forming part of the so-called 'hygiene package', which came into force in 2006. The authorities and BIPs of four Member States were visited (France, the Netherlands, Spain, Romania) and Court auditors participated in inspection visits of the Commission's Food and Veterinary Office (FVO) carried out in three Member States (Lithuania, the United Kingdom, Greece). Some relevant associations of stakeholders were interviewed (producers, importers, industries and consumers). The FVO's planning and reporting procedures were the subject of close scrutiny, in view of the particularly relevant role it plays in the Commission's supervision and control of the EU veterinary checks.

IV.

The audit concluded that the implementation of the 2004 'hygiene package' has been delayed and has still to be completed in important regulatory aspects. Moreover, substantial reductions in the levels of import controls were accepted in some 'equivalence agreements' established with third countries which are not supported by reasonable justifying evidence.

٧.

The information systems (TRAde Control and Expert System (TRACES) and Rapid Alert System for Feed and Food (RASFF)) on which veterinary checks on meat imports rely are widely and usefully employed across the EU. However, certain BIPs in three Member States still do not enter all the relevant data. This in particular affects the completeness and reliability of the data captured and the information systems as a whole.

VI.

Mainly through its FVO, the Commission continuously supervises the veterinary checks on meat imports. However, further initiatives are to be taken by the Commission in order to overcome the detected shortcomings:

- complete the 'hygiene package' regulatory framework and consolidate it in a codified, user-friendly manner;
- further develop TRACES and RASFF and their utilities;
- provide further guidelines and the performance indicators necessary for implementing an EU strategy for veterinary checks and for determining whether the 'hygiene package' objectives have been achieved;
- further improve the risk assessment models used by the FVO for its audit work planning;
- succeed in ensuring that Member States overcome any weaknesses detected in meat import veterinary checks in the shortest reasonable period of time.

INTRODUCTION

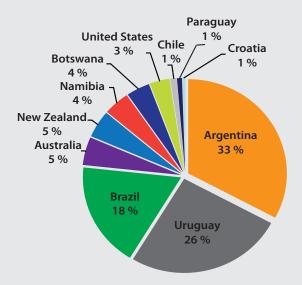
- 1. In modern societies food safety has become a major political concern since it is indispensable to public health in countries with industrialised agriculture and highly developed agri-food sectors. Ensuring the highest standards of food safety is thus clearly a political priority in the European Union.
- White Paper on food safety, COM(1999) 719 final, 12.1.2000.
- 2. In the wake of the serious health crises of the 1990s (BSE and dioxin-contaminated chicken), the regulations on food safety were thoroughly overhauled. On the basis of a White Paper¹ published by the Commission in 2000, a new legislative framework, otherwise known as the 'hygiene package', has replaced or expanded upon earlier regulations. Most of the new regulatory provisions came into force on 1 January 2006.
- 3. Imported meat products, by their very nature, have a potential role as a source of and vector for the transmission of disease not only to consumers but also to livestock, i.e. to EU production. Throughout the world there are many epizootic outbreaks of diseases and production conditions elsewhere do not necessarily meet EU standards.
- 4. The veterinary checks on imports into the EU and in the corresponding exporting third countries (see *Graph 1*) are carried out by the national authorities, with their cost being borne mostly by the operators and ultimately by the consumer. Community expenditure in this area essentially consists of the administrative expenditure of DG SANCO and, in particular, of its FVO, plus expenditure on training courses for national inspectors. The EU budget has also financed the setting-up and running of the information systems known as TRACES, responsible for monitoring imports of products of animal origin, and RASFF.

- 5. The cost to the EU budget of health crises — which can, in principle, result from poor implementation of the veterinary checks can be particularly high, involving emergency measures which by their nature need to be extensively applied. In some periods of crisis it may work out at well over 500 million euro of EU budgetary expenditure if the cost of veterinary measures to eradicate the disease is added to the expenditure on programmes to compensate farmers. However, in practice there is no evidence that any of the major health crises suffered by the EU in the past 15 years has been due to shortcomings in the performance of import veterinary checks. The origin of the diseases has been either internal to the EU or connected with illegal movements (fraud) or else failure to apply the appropriate measures for disposing of kitchen waste in international transport.
- **6.** Meat consumption and imports have been increasing and this trend is expected to continue at least until 2015 (see *Graphs 2* and *3*).

GRAPH 1

MAIN IMPORTS OF MEAT AND MEAT PRODUCTS IN 2009

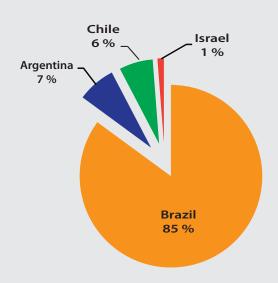






Argentina 3 % Australia 8 % New Zealand 84 %

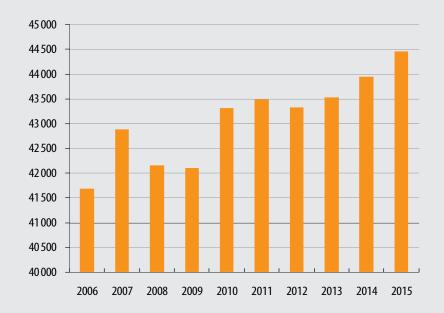
Poultry meat (196 801 tonnes)



Source: Comext — Trade statistics (Imports), EU-27.

GRAPH 2

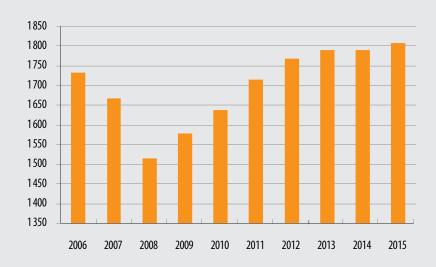
EU MEAT CONSUMPTION PROJECTIONS 2006-15 (1 000 TONNES CWE)



Source: Data from 'Prospects for agricultural markets and income, 2008–15', DG AGRI.

GRAPH 3

EU MEAT IMPORT PROJECTIONS 2006-15 (1 000 TONNES CWE)



Source: Data from 'Prospects for agricultural markets and income, 2008–15', DG AGRI.

- 7. Overall, for the four main categories of animals, meat imports account for 3,6 % of Community consumption. The share of imports is high for sheep/goat meat, significant for beef and poultry meat and insignificant for pork (see *Table 1*). The total value of the imports for these different categories was 3 375 million euro in 2009.
- 8. The basic principle underlying the EU system of veterinary checks on meat imports is that products entering the EU must satisfy sanitary requirements that are at least equivalent to those laid down by the EU for its internal production. In order to ensure that this principle is upheld there are two levels of control.

TABLE 1

PROJECTION REGARDING IMPORT AND CONSUMPTION IN EU IN 2010 (1 000 TONNES CWE¹)

| Species | Imports forecast | % of total imports | Consumption forecast | % Imports/Consumption |
|---------------------|---------------------|-----------------------|-------------------------|--------------------------|
| Beef meat | 391 | 26,4 | 8 126 | 4,8 |
| Sheep and goat meat | 264 | 17,8 | 1 100 | 24,0 |
| Pork meat | 32 | 2,2 | 20 428 | 0,2 |
| Poultry meat | 795 | 53,6 | 11 601 | 6,9 |
| TOTAL | 1 482 | | 41 255 | 3,6 |

¹ '1000 tonnes cwe' = 1000 tonnes carcass weight equivalent as calculated based upon agreed standards.

Source: DG AGRI, 'Short-term outlook for the arable crop, meat and dairy markets', October 2010.

- 9. Firstly, to be authorised for importation into the EU, products of animal origin must originate from an establishment that has been approved by the Commission and is located in a third country that is also authorised and must have been certified by the exporting country's veterinary authorities to the effect that the Community requirements have been met. Otherwise, a trade facilitating arrangement is that there is an 'equivalence' agreement with that third country, i.e. the control system of the third country has been accepted by the EU as being equivalent to its own system.
- See COM(1997) 183 final
 (30.4.1997) and COM(1998)
 32 final (28.1.1998) on the FVO organisation.
- 3 http://ec.europa.eu/food/fvo/ ir_search_en.cfm
- 10. The second level of checks takes place in the Member States. Every consignment of goods must be presented at a Commission-approved BIP, where it is subject to inspection procedures and granted a certificate by the national veterinary authorities. Once accepted by a BIP, the consignments can be moved freely from one Member State to another.
- 11. Verifying that Member States ensure that the requirements of EU legislation on the safety of food and veterinary products are being satisfied is the responsibility of the Food and Veterinary Office (FVO)², one of the directorates of the Commission's DG SANCO. It has a body of experts, mainly composed of veterinary professionals, and its inspections follow an annual work programme that has to be drawn up on the basis of risk analysis (228 inspections in 2008, of which 160 were in the Member States, 60 in third countries and eight in candidate countries). The FVO's reports, which are published and available on the Internet³, provide a central source of evidence for the Commission's supervision of EU food safety throughout EU territory.

AUDIT SCOPE AND APPROACH

- **12.** The objective of the audit was to assess the Commission's management of the EU system of veterinary checks for meat and meat products imports following the reforms of the hygiene legislation decided in 2004 and in force since 2006.
- **13.** The following questions were examined:
 - o Has the revision of the Community regulations initiated by the White Paper of 2000 been completed?
 - Does the Commission ensure that the information systems relating to veterinary checks on meat imports are performing effectively?
 - O Does the Commission (FVO) make sure that the national systems for managing veterinary checks are working properly?
 - Does the Commission carry out its role of coordination between the Member States and make general evaluations of the sanitary check system for meat imports?
- **14.** In addition, when carrying out its work, the Court collected information on how the Commission takes into account the interests of the various stakeholders (producers, processors, importers, consumers) when considering the stipulations specific to the Community regulations.

15. The following audit work was carried out in 2009:

- examination of relevant DG SANCO activities, in particular those carried out by the FVO;
- visits to the responsible authorities and BIPs in four Member States (France, the Netherlands, Spain and Romania);
- participation in FVO audits which took place in Lithuania, the United Kingdom and Greece;
- interviews with associations representing relevant stakeholders (producers, importers, industries and consumers)⁴.

⁴ UECBV (European Livestock and Meat Trading Union), COPA (Committee of Professional Agricultural Organisations)-COGECA (General Confederation of Agricultural Cooperatives in the European Union), CIAA (Confederation of the Food and Drink Industries of the European Union)-CLITRAVI (Liaison Centre for the Meat Processing Industry in the European Union), BEUC (European Consumers' Organisation).



Every consignment of goods must transit a Commission-approved BIP.

OBSERVATIONS

REVISION OF THE COMMUNITY HYGIENE REGULATIONS RELATING TO MEAT IMPORTS

16. The White Paper on food safety foresaw the revision of the regulations on food safety, most of which have been replaced by the new legislative framework known as the 'hygiene package'. The following paragraphs examine whether the relevant changes introduced in the 'hygiene package' were implemented and reflected in the veterinary agreements with third countries.

AVAILABILITY OF CONSOLIDATED VERSIONS OF THE RELEVANT LEGISLATION WOULD FACILITATE A CORRECT AND UNIFORM APPLICATION OF THE RULES

17. The rules governing imports of meat and meat products are contained in more than 50 legislative texts, to which must be added veterinary agreements (see *Table 2*). In paragraph 67, the White Paper underlines that individual legislation needs to be clear, simple and understandable for all operators to put into effect. However, in the absence of consolidated versions — or even a wholesale reformulation of the import rules — the sheer number of rules and their current complexity create difficulties and give rise to a variety of interpretations that prevent them from being applied in a single correct manner. This is the case, for example, for the practical rules for making reinforced checks, which DG SANCO and the Member States have returned to repeatedly since 1997 (see *Box 1*).

TIMING OF THE AMENDMENT OF DECISIONS AFFECTS THE VETERINARY CERTIFICATES SUBMITTED WITH MEAT IMPORTS

- 18. As the purpose of the hygiene regulations is to guarantee a high level of protection in matters of food safety, it is important, and required by Article 1(g) of Regulation (EC) No 852/2004, that third countries should certify that the foods they export are of the same or equivalent hygiene standard as food produced in the EU. If the conditions for the certification of imports are not updated at the correct time, it is possible that the products concerned will not be subject to the same rigorous production and control requirements.
- 19. The obligation for veterinarians in the country of origin to confirm that meat satisfies the hygiene regulations (which entered into force on 1 January 2006) did not take effect until August 2006 in the case of poultry, November 2006 in the case of meat products and July 2008 in the case of fresh and processed meat other than poultry.

BOX 1

LEGISLATION ON REINFORCED CHECKS UNCLEAR

Article 24 of Council Directive 97/78/EC sets out the rules for reinforced checks, which can be launched by a RASFF message after an infringement has been detected at a BIP. It requires that 'Member States shall carry out more stringent checks on all consignments of products from the same origin. In particular, the next 10 consignments from the same origin must be impounded, and a deposit lodged against inspection costs, at the border inspection post for a physical check, including the taking of samples and the laboratory tests provided for in Annex III.'

However, it was found that the procedure related to the reinforced checks is implemented differently by Member States. Some Member States take only the next 10 consignments from the same type of product at the same BIP where the error occurred, others take the next 10 at any BIP in their territory from the same type of product and origin or even establishment up to a maximum period of six months and others take only the next three consignments as they consider it to be not just a national but rather a European issue. As the legislation is not precise enough and is interpreted differently, there is neither a single, harmonised approach within the EU nor is it possible to monitor the process or assess the controls by DG SANCO or the FVO. Indeed, the FVO may well not be in a position to check that there is no systematic problem with goods from the same origin coming into the EU, especially if they enter the EU through various BIPs in several Member States.

REVIEW OF AUTHORISATIONS FOR EXPORT TO THE EU

- **20.** In 2004 the Parliament and the Council adopted a directive validating the lists of approved establishments and authorised third countries then in existence until such time as the hygiene regulations came into force on 1 January 2006, stating the following reservation: 'Pending the adoption of the necessary provisions on the basis of Regulations (EC) No 852/2004/EC⁶, No 853/2004/EC⁷ and No 854/2004/EC⁸, or Directive 2002/99/EC⁹'.
- 21. The established procedure for expanding the list of establishments approved for export to the EU was that the third country authorities must certify that each new establishment satisfied the requirements of the hygiene regulations. However, at the time of the audit the Commission had not yet reviewed the authorisations that had been granted to third countries and establishments before 2006 i.e. before the 'hygiene package' entered into force. The purpose of this review was to allow the Commission to verify the equivalence of the third countries' legislation and control systems with the new Community requirements. Nor had the Commission yet completed its reworking of the guideline concerning the information, which third countries were to provide on the general organisation and performance of checks.
- **22.** The 'hygiene package' was adopted at the end of 2004 and came into force on 1 January 2006. At the time of the audit (end of 2009) the Commission managed to renegotiate three of the 11 agreements previously existing in this sector with the EU's major trading partners¹⁰.
- **23.** The audit examined four of the most important such agreements (with Canada, New Zealand, the USA and Switzerland), which are shown in *Table 2*. The text of the agreements was scrutinised, the heads of the departments which had taken part in negotiations were interviewed and information was obtained from the competent authorities in the Member States visited.

- ⁵ Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC (OJ L 157, 30.4.2004, p. 33, (Corrigendum OJ L 195, 2.6.2004, p. 12).
- ⁶ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1, (Corrigendum OJ L 226, 25.6.2004, p. 3).
- ⁷ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55, (Corrigendum OJ L 226, 25.6.2004, p. 22).
- ⁸ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206, (Corrigendum OJ L 226, 25.6.2004, p. 83).
- ⁹ Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).
- ¹⁰ Andorra, Canada, Chile, EEA states, Faeroe Islands, Liechtenstein, Mexico, New Zealand, San Marino, Switzerland and the USA.

VETERINARY AGREEMENTS EXAMINED

| Third Country | Date of entry into force | Date of first amendment taking account of the 'hygiene package' regulations | Imports (2009) in tonnes (COMEXT data) |
|----------------|--------------------------|--|--|
| 1. Canada | 17.12.1998 | | 11 073 |
| 2. New Zealand | 26.2.1997 | 1.9.2006 (Agreement) Commission Decision 2006/854/EC of 26 July 2006 approving on behalf of the European Community amendments to Annexes V and VIII to the Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products. 25.12.2006 (Certificates) Commission Decision 2006/855/EC of 24 August 2006 amending Decision 2003/56/EC on health certificates for the importation of live animals and animal products from New Zealand. | 222 698 |
| 3. Switzerland | 1.6.2001 | 1.12.2006 (Entry into force) Decision No 1/2006 of the Joint Veterinary Committee created by an agree- ment between the European Community and the Swiss Confederation on trade in agricultural products of 1 December 2006 amending Appendices 1, 2, 3, 4, 5, 6 and 10 to Annex 11 to the Agreement . | 19 475 |
| 4. USA | 1.8.1999 | | 14 780 |

 ${\it Sources:} \quad http://ec.europa.eu/food/international/trade/agreements_en.htm$

http://eur-lex.europa.eu/en/index.htm

http://www.wto.org/english/tratop_e/sps_e/decisions06_e.htm

- 24. Naturally, the success of negotiations also depends on the other party. Nonetheless, owing to the length of the negotiations which thus postponed the application to imports of the same 'hygiene package' rules that were compulsory for EU producers the audit found that the reviewed agreement with New Zealand did not take effect until eight months after the package entered into force, despite the fact that the EU accepted to maintain a relatively limited level of checks (for which no acceptable reason was given in the Commission's records).
- 11 Article 46(1) of Regulation (EC)
 No 882/2004: 'Such official controls
 shall have particular regard to:
 ... (g) the extent and operation
 of official controls on imports of
 animals, plants and their products'.
- **25.** DG SANCO has no data on the physical pre-export checks (laboratory analyses) that were made in Canada and New Zealand on products bound for the EU. Moreover, the reports available from the Food and Veterinary Office (FVO) do not usually include an evaluation of the extent and operation of official controls by third countries on their own imports of animal products¹¹.
- 26. However, the Eurostat figures for 2008 show that the United Kingdom imported 111 930 tonnes of sheep meat, including 82 898 tonnes from New Zealand (around 77 %) which were redistributed to the other Member States. Despite the scale of these imports to the EU, the competent authorities in the United Kingdom informed the Court's auditors that, in contravention of the general rule that identity checks are to be made in all cases, some BIPs checked only 2 % of consignments the same rate as for physical checks. This practice was justified by the fact that the agreement with New Zealand includes no definition of identity checks.

NEED FOR COMMON INDICATORS TO EVALUATE VETERINARY AGREEMENTS

27. Where evaluations were in favour of maintaining equivalence, they were performed without first defining qualitative or quantitative indicators. No objective comparison was made between the level of sanitary protection (ALOP) conferred by the new hygiene regulations, the level that existed before the package adoption and the level of protection achieved by means of the control systems implemented by the third countries that were party to an agreement.

- 28. For example, New Zealand's legislation was reviewed against the hygiene regulations by a technical working group comprising representatives from DG SANCO, experts from New Zealand and the Potsdam Group¹² (members from the Commission, Greece, Finland and the United Kingdom). The evaluation concluded that New Zealand's legislation was such that the 'hygiene package' objectives could be met. The annexes to the agreement were then amended accordingly, and equivalence was maintained. However, there was no detailed documentation demonstrating that the conclusions of the working group and the Potsdam Group were based on evidence that allowed 'Yes-1' equivalence¹³ to be maintained.
- **29.** Lastly, the audit found that there was no common procedure for revision based on quantitative and qualitative indicators, and that there was no record that the observations made by the FVO in the course of its controls had been taken into account during negotiations.
- 12 The group was set up to assess the degree of equivalence of third country legislation. It is composed as decided by the Council (note 10225/08 AGRILEG 91) and comprises representatives from the Council and the Commission and experts from a limited number of Member States chosen with regard to the third country concerned.
- 13 'Yes-1' means that equivalence has been recognised and a simplified certificate may be used; 'Yes-2' means that equivalence is recognised subject to a number of production and/or control conditions; 'Yes-3' means that equivalence is recognised in principle and subject to certain specific conditions, with certification similar to that required from other third countries with which there is no agreement.

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MAIN DIFFICULTIES FOR REVIEWING THE SPS AGREEMENTS

USA: legal difficulties for the application of the 'hygiene package', for the harmonisation of audit frequency and for agreeing on the methodology for the verification of the equivalence.

Switzerland: most of the EU hygiene provisions have been transposed into the Swiss legislation. However, since it is not yet a member of the RASFF (Rapid Alert System for Food and Feed), Switzerland has to use other communication procedures (through DG SANCO or via the CIRCA system). Forthcoming negotiations should overcome this situation.

New Zealand: the updated agreement did not come into force until eight months after the 'hygiene package'. Moreover, the agreement provides for a very low level of controls which has not, however, been based on a documented risk analysis.

Canada: the delay in updating the agreement annexes in line with the 'hygiene package' was caused by difficulties in establishing equivalence, the need to make amendments to the Canadian legal texts and publication delays.

REDUCED CONTROL RATES SHOULD BE MORE FULLY JUSTIFIED

- **30.** The key Community rules, which include the provisions of Regulation (EC) No 136/2004¹⁴ and Directive 97/78/EC¹⁵, require veterinary officials to carry out systematic documentary and identity checks. These shall be supplemented by physical checks of animal products at entry into the territory of the EU. In the case of meat imports from Canada and New Zealand, the frequency of physical checks has been reduced to 10 % and 2 % respectively. However, where no specific decision or equivalence agreement exists the rate is 20 % (fresh pork, beef and yeal, sheep and horse meat) or 50 % (poultry).
- ¹⁴ Commission Regulation (EC) No 136/2004 of 22 January 2004 laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries (OJ L 21, 28.1.2004, p. 11).
- ¹⁵ Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

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APPLICATION OF REDUCED PHYSICAL INSPECTION RATES

Where reduced physical inspection rates are applied, the consignment selection method varies from one Member State to another. Generally speaking, checks should take due account of the results of statistical sampling and relevant risk factors¹⁶; often planning is left to the discretion of inspectors at BIPs. In France, the central veterinary authority has drawn up a selection grid which shows how consignments should normally be prioritised for verification. The advantage of this procedure is that it guarantees that selection will be random and unpredictable. According to the French authorities this procedure was not followed by the Roissy BIP, which is the busiest in terms of number of consignments. In the Netherlands, by contrast, sampling is done randomly and electronically at the moment a pre-notification is entered. To improve the effectiveness of checks, the Dutch electronic selection system factors in a range of subpopulations, such as 'product type' and 'third country of origin'.

In Spain, the frequency of physical checks exceeded the statutory reduced rates by 20 % to 30 %, yet the percentage of consignments found to be non-compliant was not necessarily higher¹⁷. Similarly, in Romania around 36 % (compared with the standard rate of 20 % in third countries, 10 % in Canada and 2 % in New Zealand) of red meat consignments were checked physically in 2008. There was also no central verification procedure to ensure that thresholds were reached, and the selection procedure offered no guarantees that the consignments to be inspected were selected at random.

¹⁶ Relevant risk factors include the risk to human health from the product or its packaging, the probability of non-compliance with the stated requirements, the target consumer group, the extent and nature of any further processing of the product, the exporting country's inspection and certification arrangements, and the compliance record of the third country producers and importers.

¹⁷ In 2008, for example, three consignments (meat and milk) out of a total of 4 694, or 0,06 %, were refused following a physical check. The overall figure for consignments refused was 0,63 % (EU average: 0,88 % in 2006).

The audit found that the results of the laboratory analyses carried out as a component of physical checks — initiated by a BIP in the Member States and/or by the third countries themselves prior to export — were not subjected to statistical analysis (e.g. contaminants detected, origin of the meat, point of entry). Such an analysis could form the basis of a more objective risk assessment and would undeniably be of use in negotiations with third countries — either to justify the frequency of physical checks by BIPs or to provide greater support when determining what type of analyte to look for in imported foodstuffs. To give an idea of the importance of exploiting this kind of statistical data, one report submitted in New Zealand 18 showed that 101 out of 103 samples of sheep tested positive for hormones despite being under the maximum residue limit. These data lend good support to the notion that the BIPs that are most concerned should act more selectively when taking samples for checking.

Residues and Contaminant Report (EU) of December 2008.

¹⁸ New Zealand National Chemical

VETERINARY AGREEMENTS DO NOT PRECLUDE DIFFERENCE OF TREATMENT BETWEEN MEMBER STATES

32. The agreement with Canada did not guarantee that there would be no discrimination among Member States, as at the time of the audit the Canadian authorities had not yet authorised imports from four Member States. Similarly, the authorities in the USA, where export controls are a matter for national departments, treat each Member State as a separate entity, although all Member States are obliged, under the terms of the current agreement, to accept meat imports from the USA. In one Member State just one slaughterhouse had been approved for export to the USA. Furthermore, 11 Member States' applications for equivalence, the earliest of which was lodged back in 2000, had not yet been approved by the US authorities.

INFORMATION SYSTEMS RELATING TO VETERINARY CHECKS

33. The EU finances the setting up and maintaining of the information systems known as TRACES (TRAde Control and Expert System), used for monitoring imports of animal origin, and RASFF (Rapid Alert System for Feed and Food). The following paragraphs examine whether these systems fully meet the objectives of the 'hygiene package' and, in the case of TRACES, whether the system contributes to decision-making.

OPTIMISING THE USE OF TRACES DATABASE

34. Despite TRACES' contribution to the harmonisation of control procedures in the EU, some Member States still prefer to use the non-TRACES-compatible software they developed due to the lack of some functionalities deemed important for their controls. Although compulsory, some BIPs in Germany, the Netherlands and Spain do not yet enter all the relevant meat import data into TRACES. This affects TRACES' completeness and, inter alia, the reliability of its statistical output. Moreover, in most Member States no link has been established with the customs databases allowing for the reconciliation of the data on meat imports registered in both systems. The Commission manages TRACES at EU level and contributes to its financing and development (2,25 million euro in 2009). The audit revealed that further developments are still needed to overcome the existing technical shortcomings concerning, for instance, the access security required for using TRACES, the electronic issuing of certified CVEDs (Common Veterinary Entry Documents) and the production of statistics useful for carrying out risk analyses so as to focus veterinary inspections better.

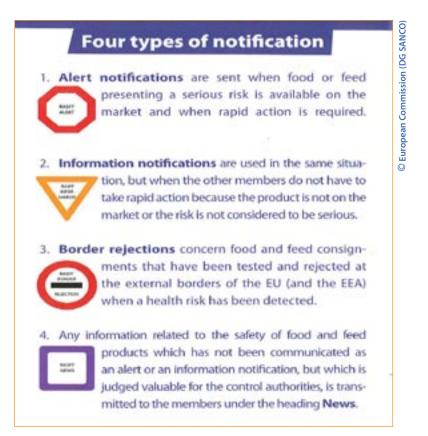
- **35.** The development of TRACES should have further explored the ways and means to link and/or ensure the necessary reconciliation between the relevant data processed for customs purposes and the data captured by TRACES¹⁹. The main reasons given to explain the ongoing difficulties related to the customs' specific requirements in respect of the codes used for identifying products. Nevertheless, it became clear from a pilot project run in collaboration with French customs that the existing interface problems could be overcome.
- **36.** The visits to Member States revealed that the use of TRACES is limited especially as regards the following possible range of useful functions:
 - (a) the selection of consignments for random or non-random physical checks, with and/or without laboratory analysis;
 - (b) the obligation to perform reinforced checks and monitoring of such checks;
 - (c) automatic compliance and authentication checks of veterinary certificates by, for example, cross-checking the data entered by the issuing third country (certificate number, identification — certifying officer's e-mail address and model signature²⁰, model stamp of the certifying department);
 - (d) the possibility of scanning irregular certificates;
 - (e) the possibility of entering a 10-digit TARIC (customs nomenclature) code;
 - (f) automatic cross-checks with customs data;
 - (g) simplification of the procedure for entering products imported by private individuals in excess of the duty-free limit²¹:
 - (h) the possibility of stating the place of first origin of reimported shipments;
 - (i) the possibility of entering in detail the reasons why a BIP has refused to allow an import;
 - (j) the uniform automatic calculation of fees and penalties;
 - (k) the compulsory entering of intra-Community shipments of imported foodstuffs, which would enable them to be more swiftly recalled in an emergency.

- ¹⁹ The importance of that link is identified namely by Articles 5 and 6 of Commission Regulation (EC) No 282/2004 of 18 February 2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community (OJ L 49, 19.2.2004, p. 11) and Articles 6 and 7 of Regulation (EC) No 136/2004.
- ²⁰ Certifying officers are persons who are accredited or approved by the CA in the exporting country to draw up and issue official certificates.
- ²¹ With the exception of a limited number of third countries and small quantities that are intended for personal consumption, the Community rules do not authorise imports of meat or meat products by private individuals unless they have submitted a prior declaration and a veterinary certificate.

- **37.** Generally speaking, users can only access those sections of TRACES which concern them. However, in 2007 an external study²² highlighted the need for periodic audits of the system's security. Where meat imports are concerned, TRACES is used by New Caledonia, Mexico and New Zealand. However, the European Food and Safety Authority (EFSA) did not have direct access to TRACES when it needed to gather data in all areas with a direct or indirect impact on food safety.
- ²² Gartner France, 'Hosting Traces project', 2007, DG SANCO.
- ²³ The Commission was waiting for the judgment of 29 October 2009 by the Court of First Instance of the European Communities in *Commission v. Bowland Dairy Products Ltd.*

MAKING THE BEST USE OF THE RAPID ALERT SYSTEM

38. The RASFF compiles all admissible alerts that are issued by a Member State and/or third countries. However, the conditions in which Member States can issue an alert may not be formally established until 2011²³.



RASFF compiles all admissible alerts that are issued by a Member State or third country.

- **39.** The auditors found that there was widespread satisfaction within the Union concerning the utility and operation of the RASFF system. However, the intensity of Member States' reactions to alerts issued by other Member States varied according to their interpretation of the application of reinforced checks and the 'quality' of the alert. For example, France does not launch reinforced checks unless the issuing country shares its criteria for analysis.
- 40. Overall, there is no clearly understood set of rules relating to the RASFF, either for launching an alert of a risk to human health at national level or for consequently launching it in all Member States. There is a similar lack of consistency as regards implementing more stringent checks following an alert or launching an enquiry under the supervision of the Commission's responsible services. The audit revealed that, in one case of meat exported to the EU that was reported by the national authorities in the third country of origin, the system was not capable of responding sufficiently early to trigger reinforced checks and ensure that all the meat in question was withheld from the market and returned to the country of origin. The Member States were not actually informed until one week later, the Commission's special prevention arrangements (e.g. the safeguard cell) were not activated, and there was therefore a delay in the launch of reinforced checks.

NEED FOR INTERFACE BETWEEN TRACES AND RELEVANT NATIONAL DATABASES

- **41.** It is still difficult, for a number of reasons linked to the rules and requirements of international trade, to cross-check the data in TRACES against customs information:
 - o company databases are not universally accessible;
 - the international rules do not require shipments (maritime or otherwise) to be described in detail;
 - there is no obligation to enter the 10-digit TARIC code for imported goods on the summary declaration (manifest);
 - o national customs data are not automatically transferred in real time to DG TAXUD. Moreover, the customs service of the final destination which releases the imported meat may not be that of the Member State through which the meat entered the EU.
- **42.** It is generally the case that the Member States have not established national procedures for reconciling the data in TRACES (e.g. volume of meat imports) with those logged in local systems or customs records, in Comext²⁴ and/or by the third country inspection bodies. For example, the visit to the Le Havre BIP revealed that, whereas the national database recorded some 14 560 consignments of meat imported for human consumption in 2008, the corresponding figure in the local system was 14 750.

NCTS — RISK OF EVADING VETERINARY CHECKS

43. The NCTS²⁵ is a computerised system that was introduced in 2003 to enable businesses to enter data on the movement of goods 'in transit'²⁶, for which final clearance may take place at any internal customs office of destination rather than at the point of entry into the EU.

- ²⁴ Comext is Eurostat's reference database for external trade.
- ²⁵ NCTS (New Computerised Transit System) Decision
 No 105/2000/EC of the European
 Parliament and of the Council of
 17 December 1999 amending
 Decision No 210/97/EC adopting
 an action programme for customs
 in the Community (Customs 2000)
 and repealing Council Decision
 91/341/EEC (OJ L 13, 19.1.2000,
 p. 1).
- 26 'Transit' is defined in the veterinary rules as relating to shipments between two third countries via the territory of the EU.

- 44. The relevant Community legislation does not require a TARIC code to be given when an entry is made in the NCTS. In the absence of filters which would allow declarations of goods concerned by the sanitary legislation to be identified, it is entirely possible for clearance to take place although no veterinary checks were made when the goods entered the EU. It is at the discretion of each customs administration to examine its operations and internal structure and decide whether such filters should be set up. Following a recent incident in which goods imported by air were forwarded elsewhere by road before being inspected, the Spanish customs authorities modified their national NCTS so that shipments of this sort can be detected and subjected to veterinary checks as soon as they enter the country.
- ²⁷ DG(SANCO)/ 2009-8203 MR –
 FINAL (Slovenia); DG(SANCO)/
 2009-8085 MR FINAL (Sweden);
 DG(SANCO)/ 2009-8081 MR –
 FINAL (Lithuania).

45. Several FVO reports²⁷ draw attention to the absence of appropriate filters in national NCTSs. Despite this, there has still been no amendment to remedy this omission in EU law.

SURVEILLANCE BY THE COMMISSION OF THE NATIONAL SYSTEMS FOR MANAGING VETERINARY CHECKS

46. Each Member State is required to prepare a multiannual national control plan in order to promote a consistent, comprehensive and integrated approach for its official controls on the feed and food chain, as well as on the implementation of legislation on animal health and animal welfare, and on imports.

NEED FOR AN EU STRATEGY FOR THE PREPARATION AND EVALUATION OF SURVEILLANCE PLANS

47. To date, the Commission has not taken the initiative to provide guidelines (e.g. for harmonised sampling and laboratory testing) for the drafting of the national monitoring plans defined in Regulation (EC) No 136/2004, which is left entirely to the discretion of the Member States. Although the FVO verifies through its audits that such plans exist and are being applied in practice, it does not examine their relevance in detail.

- 48. It was found that the national monitoring plans are prepared on the basis of a risk analysis and the results of the analyses which national laboratories are accredited to perform. However, it depends on the Member State whether the risk analysis takes account of the elements of Directive 96/23/EC²⁸ (findings of national residue monitoring plans) and of Regulations (EC) No 2073/2005²⁹, No 466/2001³⁰ and No 1881/2006³¹ (existence of EU or international rapid alerts and EFSA scientific opinions, and the characteristics and findings of and risks revealed by third country residue plans³²). Moreover, the plans were often found to suffer from budgetary constraints.
- ²⁸ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).
- ²⁹ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

TABLE 3

DIFFERENT LEVELS OF LABORATORY ANALYSIS

| | Number of consignments subjected to laboratory analysis / number of loads × 100 (approximate percentage) | | Remarks | |
|-------------------|--|-----------------|---|--|
| Country | Red meat | White meat | 2008 | |
| Lithuania | ≤ 10 % | | Every 10th consignment sampled | |
| France | 3% | | Two analyses made systematically | |
| Spain | 0,4 % | 1,8 % | Plan provided for 5 % analysis rate | |
| Greece | 0,02 % to 0,2 % | 0,02 % to 0,5 % | 1% of physical checks | |
| Netherlands | \leq 1,0 % residue $+ \leq$ 0,5 % microbiology | | % calculated on number of analyses not number of consignments sampled | |
| Romania | 1 % to 3 % planned depending on category of goods | | Data on testing unavailable | |
| United Kingdom | 0,02 % to 0,2 % | 0,02 % to 0,5 % | 1 % of physical checks (e.g. 0,02 % of meat from New Zealand) | |

Source: Data collected during on-the-spot audits in the Member States.

- 49. For instance, it was found that the United Kingdom and Spanish plans do not specify particular types of analyte to be looked for by third country of origin. In Spain, Lithuania and Romania, meanwhile, where the choice of tests is limited by the capacity of laboratories to perform certain analyses, and/or whether they have the accreditation to do so, the monitoring plans for 2008 did not cover the detection in meat of certain categories of hormonal residue (anabolics) and/or environmental contaminants (dioxins, heavy metals). Lastly, Greece had not yet drawn up a national monitoring plan, and as a result the veterinarians at Greek BIPs themselves determined which analytes they would be seeking.
- 50. According to the French authorities, increases in the workload of certain BIPs might cause them to exhaust their budgets before the end of the year and thus be unable to implement their monitoring plans in full, meaning that the choice of analysis could be dictated by financial rather than scientific considerations. It was found at one Romanian BIP that just 20 of the 63 laboratory analyses provided for in the 2008 plan had been carried out. Owing to budgetary constraints, the 2009 plan now contained just 44.
- **51.** EU legislation does not set minimum percentages either for overall numbers or for each type of laboratory test to be performed by volume, type of product or place of origin. However it foresees that implementing decisions will be adopted setting harmonised sampling and laboratory testing. As a result, the percentage of laboratory analyses that are to be made is specified in the national monitoring plan. Values for the various levels of laboratory tests that were planned and/or carried out in 2008 in the Member States visited during the on-thespot audit are given in **Table 3**.
- **52.** Different Member States operate different surveillance strategies. Some use a sampling frequency calculated on the number of import consignments and/or the nature/origin of the product concerned, while perhaps also allowing some discretion to BIP veterinarians. Others tie the sampling frequency to the physical checking rate specified in EU law, in which case laboratory tests may be particularly rare on foodstuffs from a third country with which the EU has signed an SPS (sanitary and phytosanitary measures) agreement (e.g. 0,02 % in the case of meat from New Zealand).

- ³⁰ Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs (OJ L 77, 16.3.2001, p. 1).
- ³¹ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).
- 32 http://ec.europa.eu/food/ food/chemicalsafety/residues/ third countries en.htm#3

- 53. The audit also revealed that the import controls in Member States did not always cover the entire distribution chain from the point of entry (BIP) to the final consumer, via the bodies responsible for loading (which are required to complete certain formalities with customs/BIPs), shippers, importers and distributors. It was also found that no reference is made to the objectives of the multiannual national control plan (MANCP) defined in Article 42 of Regulation (EC) No 882/2004 when assessing the results given in the annual reports which the Member States submit under Article 44 of the same regulation.
- **54.** Although the main responsibility for a consignment's entry into the EU lies with the importer, that responsibility is often shared with shipping and/or customs agents, which take on tasks such as the giving of prior notification and the presentation of shipments to the BIP.



Customs take on tasks such as the presentation of shipments to the BIP.

- **55.** DG SANCO has no data on the results of checks made at these 'stakeholders' in the shipping process, despite the fact that they must be able to provide evidence of the traceability of goods and store them in appropriate conditions.
- **56.** The results that were obtained and included in the annual reports were not sufficiently assessed in terms of the objectives set out in the MANCPs. The first Commission annual report referred to in Article 44(6) of Regulation (EC) No 882/2004 on the implementation of integrated multiannual national control plans was published on 25 August 2010³³.

FEES AND PENALTIES NOT HARMONISED

- Agriculture Organisation of the United Nations (FAO) guidelines, the Commission had stated in its White Paper³⁴ that the fees applied to import controls should be limited to the cost of those controls and that they should be applied in a uniform manner so as to avoid distorting trade. In practice, however, Article 27 of Regulation (EC) No 882/2004 requires the Member States either to charge fees on imports at the minimum established rates or to cover the costs occasioned by official controls.
- 58. The audit revealed that the Commission does not have precise information on whether the costs of controls correspond closely to the fees collected, especially where a Member State applies rates lower than the established minima. In two of the four Member States visited, the audit also found that the competent national authorities were unable to demonstrate by means of financial supporting documents that the statutory EU target of a balance between control expenditure and revenue had been achieved. A recent study³⁵ made for the Commission has also shown that the calculation methods used by the Member States are wanting in transparency.
- 59. In the same way as with fees, it is important to avoid trade distortions by harmonising the penalties that can be imposed when controls reveal shortcomings. The audit found that, in the course of its on-the-spot checks, the FVO determines whether penalties are available and are actively applied against businesses that are at fault. However, no general guidelines or good practices have been defined in this area, and the Commission's services were unable to give an opinion as to whether the various schemes that are implemented in the Member States are proportional and have dissuasive force.

- ³³ COM(2010) 441 final, 25.8.2010.
- ³⁴ Annex C, Article 1(f), of the WTO agreement on the application of sanitary and phytosanitary measures provides that 'any fees imposed for the procedures on imported products should be no higher than the actual cost of the service'. Paragraph 18 of FAO standard CAC/GL 20-1995 provides that '... any fees imposed by importing countries should be limited to what is reasonable and necessary'. Chapter 6, paragraph 87, of the WPFS states: 'quarantees should be introduced to ensure that fees are used only for the financing of controls'
- ³⁵ Food Chain Evaluation Consortium (FCEC) from April to November 2008, Agra CEAS Consulting.

CERTAIN BIPS HAVE A VERY LOW LEVEL OF ACTIVITY

- As regards the setting-up of the BIPs, cases were detected in Spain, Greece and Romania where the transactions were so insignificant that the need for such BIPs which require the permanent availability of experienced and updated experts is called into question. In fact, some BIPs exist for internal reasons not related to management efficiency or control effectiveness, and no cost/benefit analysis is available to justify their remaining in activity.
- **61.** Moreover, the audit on the spot has also shown that frequently BIPs have no access to the databases or relevant parts thereof available to the customs services. This hinders their ability to easily cross-check if all relevant consignments have been prenotified to the BIP for veterinary checks.

LIMITED ROLE OF THE INTERNAL AUDIT IN NATIONAL CONTROL SYSTEMS

62. In three out of the four Member States visited without the FVO inspectors, the internal control function was not appropriately organised and did not operate in accordance with either the applicable EU regulations (e.g. Regulation (EC) No 882/2004) or the relevant ISO standards³⁶ (e.g. existence of an audit plan, a description of tasks, quality control arrangements, an organised follow-up, a supervision audit committee). Moreover, the Commission has issued guidelines³⁷ for national internal audits in line with the abovementioned standards but they are not binding and they are not appropriately applied. The principle of the internal auditors' independence was not respected in two of the four abovementioned Member States since the internal auditors were not placed under the direct dependence of the highest level of the hierarchy of the competent national authority.

- ³⁶ ISO 19011: 2002 'Guidelines for quality and/or environmental management systems auditing', International Organisation for Standardisation, 1 October 2002; ISO 9000: 2000, 'Quality management systems Fundamentals and vocabulary', International Organisation for Standardisation, December 2000.
- ³⁷ Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules (OJ L 278, 10.10.2006, p. 15).

- **63.** The deficiencies detected in the Member States' internal audit procedures include:
 - (a) planning on the basis of informal risk analyses (Spain, Romania), without allowance for the workload of BIPs (Romania) or slavishly following a five-year cycle (Lithuania);
 - (b) audits not focused on the objectives in the MANCPs, or focusing on the compliance of installations rather than on that of the control procedures actually in place;
 - (c) controls carried out by just one inspector who may be insufficiently trained in performing veterinary checks on meat imports;
 - (d) control reports which do not conform, in structure and content, to generally accepted practice, especially as regards the description of shortcomings and the identification and prioritisation of the necessary corrective measures.
- 64. If the audit methods and techniques currently in use at the FVO were brought into line with the internal audits of the Member State authorities carrying out import checks, the FVO would be able to take account of the results of those audits and adjust the frequency of its visits and/or target the weak links in the control chain with a view to improving the control procedure.

NEED FOR PERFORMANCE INDICATORS TO MONITOR PROGRESS ON THE 'HYGIENE PACKAGE' OBJECTIVES

65. Contrary to what was affirmed in the White Paper³⁸, the Commission has not yet defined performance indicators for national control systems. Where third country exporters to the EU are concerned, there has also been no formal adoption of performance indicators in relation to the controls made at every stage in the production chain prior to export.

38 One of the objectives referred to in Chapter 6 (paragraph 91) of the White Paper reads as follows: 'There is therefore a clear need for a Community framework of national control systems ... This Community framework would have ... Community control guidelines. These would ... [set] Community indicators of performance.'

NEED FOR BETTER TARGETING OF BIPS AND CONSIGNMENTS ON THE BASIS OF RISK ANALYSIS

- Commission Decision 2001/881/EC as amended by Commission Decision 2005/13/EC of 3 January 2005 states in paragraph 3³⁹ that 'Inspections by the Commission veterinary experts will be based upon assessment of all relevant factors as detailed in paragraph 4 and the potential risks and impact of those factors for animal health and public health in the Community' and in paragraph 4: 'The Commission establishes destination and frequency priorities when planning missions of the Food and Veterinary Office, taking into account the history of previous inspections made in any Member State, the data collected under the TRACES system, information reported by Member States under Commission Regulation (EC) No 745/2004 and the following parameters:
 - the quantitative and qualitative patterns of trade concerning any Member State, including the type and species of animals or of products concerned, and their country of origin,
 - o relevant information concerning possible illegal imports and the potential risk of introduction of disease,
 - o information available under the Rapid Alert System,
 - o any other relevant information.'
- body of experts and plays an important role, together with national responsible entities, in maintaining the necessary control pressure on the quality of the control checks performed in the BIPs all across the EU. Overall, appropriate standards and detailed guidelines and procedures were adopted for the FVO's work planning, execution, reporting and follow-up. FVO inspections are performed in an organised manner and carried out in accordance with the rules adopted. However, there is room for further improvement, mainly as regards the formal risk analysis performed for establishing the annual audit work plan and regarding the targeting of missions on the follow-up of previous observations.

39 Commission Decision
2001/881/EC (OJ L 326,
11.12.2001, p. 44) was repealed by
Commission Decision 2009/821/EC
(OJ L 296, 12.11.2009, p. 1),
but the principles set out in
paragraph 3 remain relevant for
risk analysis.

- 68. In order to comply with the legal requirements, each year the inspection work of the FVO has to be planned with the support of a transparent risk model. The FVO has developed a model in Excel, the output of which is the allocation of a level of risk (green/orange/red) to each Member State.
- 40 Standard Operating Procedure
 PL-SOP01: Planning of the SANCO
 Mission Programme. Paragraph 4.4
 Identification of Priorities.
- **69.** There is some consistency between the risk criteria used and the FVO template for mission reports. As regards the weighting of the different criteria the FVO emphasised that the number of sub-criteria used for each main criterion gives more weight to some criteria than to others.
- **70.** However, it is not clear why the criteria adopted by the FVO⁴⁰ have been chosen while trade volume and relevant information obtained from TRACES or from RASFF have not been included even though their consideration is required by the relevant FVO standard operating procedure. Furthermore, neither is the weighting given to each criterion clear nor is there a clear rule for allocating a weighting to a Member State with a red, orange or green light in respect of a specific criterion in the planning table.
- **71.** The FVO inspection planning is presented to the Member States and they are asked to comment on it. However, very few comments have been received so far.
- 72. This being so, the risk model adopted for the annual prioritisation of the FVO inspections in Member States does not integrate important and legally required information facilitating a quantified analysis to sustain the prioritisation result. The relative importance of the criteria and of the sub-criteria used is neither sufficiently clear nor fully justified. As a consequence, the model adopted has limited value for explaining or for communicating the results of the analysis performed by the FVO in a transparent manner.

The audit has also highlighted the need for further formalisation of the choices made when planning inspections in the Member State (e.g. BIPs selected, cold stores, type of consignments, weakness of internal control) and of the role played by risk analyses in this process (factors such as findings in the last visit, type of consignments received and anomalies detected/registered in TRACES). On the basis of their personal experience the FVO inspectors tend to take these factors into account. However, there is a need for a more structured planning process, formally justifying the planning decisions taken, so as to allow effective external quality control of the inspections and to help to minimise the difficulties resulting from staff turnover.

REPEATED RECOMMENDATIONS OVER SEVERAL MISSIONS

74. The audit examined the successive inspection reports of the FVO issued for three of the seven Member States visited: Greece (2007–09), Spain (2002–08) and the United Kingdom (2001–09). The shortcomings reported recur very frequently and mainly relate to facilities, equipment and implemented procedures. Indeed the FVO reports repeated the same remarks frequently for four to five years for situations that had not yet been redressed.



FVO inspections are performed in an organised manner and carried out in accordance with the rules adopted.

75. As the FVO generally follows up its findings, there is evidence that Member States frequently do not effectively remedy the shortcomings detected within a reasonable time period. This shows that, at this stage, DG SANCO does not succeed in ensuring that the required corrections are made, despite the almost annual frequency of its inspection visits (e.g. monitoring plan introduced late, non-compliant infrastructure at certain BIPs, delayed application of fee rates, shortcomings in the system for identifying shipments, incomplete records in TRACES).

COORDINATION AND EVALUATION OF THE VETERINARY CHECKS SYSTEM

76. The Commission is entitled to coordinate the actions undertaken by Member States when it becomes aware of activities that could be contrary to feed and food law.

COORDINATION OF THE MEMBER STATE VETERINARY CHECKS SYSTEMS NEEDS IMPROVEMENT

77. In accordance with Title IV of Regulation (EC) No 882/2004, the Commission has taken several initiatives with a view to speeding up the harmonisation of BIP controls. Examples include the 'Better training for safer food' training programme for BIP officers from a range of Member States, the participation of national experts in the FVO's teams of on-the-spot auditors, the issue of guidelines for the application of certain provisions of the hygiene regulations and other guidelines on imports.

- 78. However, at the time of the audit around 49 Community BIPs (out of around 300) had still not been inspected by the FVO since before Decision 2001/812/EC laying down the requirements for the approval of border inspection posts responsible for veterinary checks on products introduced into the Community from third countries was adopted⁴¹. This is in spite of the fact that FVO inspections are a tool favoured by the Commission to verify the implementation of the EU legislation ensuring that good practices are implemented in all EU BIPs and that national authorities take whatever corrective measures are necessary at the appropriate time.
- ⁴¹ OJ L 306, 23.11.2001, p. 28.

- **79.** The audit also found that several key 'guidelines' are still in preparation or being updated. These include guidelines relating to the rules implementing Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.
- **80.** The audit has shown that the reinforced checks are implemented differently in the various Member States (see **Box 1**).
- 81. The audit has also highlighted the fact that the updating of the food and veterinary legislation in force is a heavy burden for all the administrative actors concerned. Legislation is frequently updated, amended and supplemented (e.g. SPS agreements, approved establishments or list of approved BIPs). In order to be informed in an up-to-date manner and have a comprehensive set of applicable legislation the FVO organises an internal updating itself. Therefore one member of the FVO's BIP inspection team is tasked with checking the Official Journal and informing the other colleagues of changes introduced. According to the FVO this procedure is necessary as there is no other source available where the consolidated and comprehensive set of legislation can be consulted. For the time being, legislative documents are accessible through the DG SANCO website and EUR-Lex. However, none of these sources provides a user-friendly way of easily obtaining exhaustive and complete information as no systematically consolidated versions are available (e.g. SPS agreements).

- **82.** Although the FVO's import team already designates one member of a team of six to this task and Member States have mostly established their own system or use an existing commercial system, which is subject to a charge, it would be beneficial if this information were to be provided centrally by the Commission in a consolidated and comprehensive manner. If the Commission were to supply such a tool, this would avoid the 27 Member States and the FVO and other Commission services having to develop and maintain their own system and would mitigate the risks of gaps and delays in updating.
- When the Commission has not facilitated the preparation and/or updating of the Member States' national plans (MANCPs) in relation to imports. At the time of the audit, all the Member States had a MANCP and had sent a first annual report to the FVO, which is supposed to produce an analysis of the documents received (plans and annual reports). The three-year programme of 'general' audits provides for audited Member States to be sent an initial set of findings. However, no Member States visited during the Court's audit had received views on either their MANCPs or their first annual reports; nor had they been sent any written recommendations concerning the establishment of an action plan.

IMPACT OF MORE STRINGENT EU STANDARDS ON THE COMPETITIVENESS OF EU PRODUCERS

84. The audit highlighted that certain standards (mainly on animal welfare) imposed on EU farmers and operators involved in meat production which are complementary to the international sanitary standards accepted by the WTO cannot be imposed on producers of imported meat. Any limitation on imports for sanitary reasons must be backed up by scientific evidence.

- 85. As regards the costs and benefits of such standards, the information available is incomplete. Some analyses and partial information on costs (e.g. regarding traceability) were provided in a 2005/06 DG RTD study on cross-compliance. A certain amount of information — relating in particular to agricultural marketing standards (labelling) — was also provided in the 2008 Green Paper on agricultural product quality⁴². In addition, sanitary measures were discussed in the DG SANCO Standing Committee on the Food Chain and Animal Health (SCoFCAH), and representatives of the parties which bear the brunt of the additional costs that are incurred when legislation is adopted (e.g. producers and processors) have the opportunity to raise their concerns through consultative committees, including the Advisory Group on the Food Chain and Animal and Plant Health⁴³. Lastly, consultation of professional stakeholders has improved in recent years, a view shared by the organisations interviewed representing the main chain of food and feed — producers, importers, industries and consumers even if feedback from the Commission services is still seen as weak.
- at present draw on a sufficiently comprehensive and reliable study comparing the costs and benefits of the controls imposed on EU farmers and operators with those applicable to meat imports, especially where other public grants to EU farmers have to be taken into consideration. The Council invited the Commission⁴⁴ to present a report to it and the Parliament, before the end of 2010, on the effectiveness and coherence of sanitary and phytosanitary import controls on foodstuffs. The Parliament has also commissioned a study of 'the cost of complying with EU legislation in the field of environmental, animal welfare and food safety', the results of which may help to remedy the weaknesses of the information available in the Commission's services in this respect.

- ⁴² COM(2008) 641 final,
- ⁴³ A committee composed of representatives of a range of associations, set up by Commission Decision 2004/613/EC of 6 August 2004 (OJ L 275, 25.8.2004, p. 17).
- ⁴⁴ Council Conclusions (Section 4.2), 16.12.2008, 17169/08 ADD 1.

CONCLUSIONS AND RECOMMENDATIONS

- Work governing the veterinary checks on imported meat initiated in 2000 by the White Paper and finally decided in 2004 with the adoption of the 'hygiene package' have been delayed and still have to be completed in several important aspects. Indicators on pre-export checks and for evaluating the veterinary agreements are missing (paragraphs 17 to 29). Reductions in the levels of checks imposed on imports were accepted under equivalence agreements with third countries which are not sufficiently documented, and discrimination against the exports of some Member States was not avoided (paragraphs 30 to 32).
- 88. The two information systems (TRACES and RASFF) on which the veterinary checks on EU meat imports rely are widely used but they need improving. Certain BIPs of some Member States still do not enter meat import data in TRACES, and interfaces with customs or other national databases have not yet been established. The RASFF does not ensure that the relevant alerts are launched and that preventive action is always taken as quickly as required throughout the EU (paragraphs 34 to 45).
- **89.** Mainly through its FVO, the Commission continuously carries out inspections in the Member States. However, according to the FVO whose reports can be consulted on the corresponding website together with the responses from the national authorities the shortcomings detected have often still not been remedied by Member States more than two years later (paragraphs 47 to 83). The audit concluded that there is still room for further improvements.

- **90.** In the framework of its supervisory and coordination competences it is recommended that the Commission take appropriate action on the following:
 - endeavour to ensure that all Member States have the same rights to export to the third countries with which veterinary agreements have been concluded by the EU;
 - further development of the regulatory framework necessary for the implementation of the 'hygiene package' and its presentation in a consolidated, user-friendly manner;
 - o further development of the TRACES and RASFF information systems so that all the necessary data are available in a timely manner and alerts are quickly communicated and acted upon, in similar ways, in all the participating countries;
 - development of guidelines for the national monitoring and control plans implementing a common EU veterinary checks strategy, with harmonised fees and effective BIPs checked by appropriate internal controls;
 - development of a common set of indicators for assessing the implementation of the 'hygiene package' and its achievement of the corresponding EU objectives;
 - o further improvement of the type and transparency of the risk assessment models used by the FVO for risk analysis in the framework of its audit work planning;
 - o need to take the appropriate initiatives, including legislative or judicial action if necessary, to overcome the present situation under which recurrent findings and recommendations to the Member States' authorities frequently remain waiting for corrective action for several years;
 - harmonisation among Member States of the rules for launching a sanitary alert and for implementing the consequent reinforced checks.

91. The competitiveness of EU meat production may be affected by the abovementioned animal welfare standards which go beyond the internationally accepted standards agreed by the WTO. The Commission should carry out an assessment of the effect of these specific rules on the competitiveness of EU producers. In this regard, the Commission has been invited by the Council to present a report on the veterinary checks on imports by the end of 2010. Moreover, the results of a study commissioned by the European Parliament should also be available by the end of 2010 and may shed light on the impact of the abovementioned measures (paragraphs 84 to 86).

This report was adopted by Chamber I, headed by Mr Michel CRETIN, Member of the Court of Auditors, in Luxembourg at its meeting of 17 November 2010.

For the Court of Auditors

vica.

Vítor Manuel da SILVA CALDEIRA President

EXECUTIVE SUMMARY

IV.

The general food law and the 'hygiene package', including Regulation (EC) No 882/2004, came into being in 2002 and 2004 respectively. Appropriate measures were taken to ensure that any delay in the implementation of measures under the hygiene package did not lead to a lower level of hygiene protection.

The frequency of physical checks has been reduced for third countries under veterinary agreements (VAs), because of the reliability of the central authorities' performance on controls for specific commodities exported to the EU.

٧.

The RASFF and TRACES are designed to ensure dissemination of information when non-compliances are found during controls on food and feed on the EU market. They also provide the capability to track imports of goods into the EU and intra-EU trade in live animals. TRACES is a relatively recent system which is still under development.

TRACES is a very ambitious initiative and there have been inevitable delays in Member States (MSs) adapting to its requirements in a uniform manner. The Commission has already taken action to encourage the Member States to use TRACES properly.

VI.

These recommendations will be taken into account in the Commission's ongoing work to ensure that import controls remain fit for purpose.

Second indent

The Commission agrees to further develop TRACES and RASFF and their utilities. In fact, the work is already in progress.

Third indent

The current legislation does not provide the Commission with legal powers to do so. The feasibility of such a proposal could be investigated.

Fourth indent

Staff within the FVO and DG SANCO's policy directorates are required to agree the criteria that are considered for setting potential mission priorities and, in the prioritisation process itself, to demonstrate and document that these criteria have been consistently applied. This in turn leads to more transparent choices in the event that changes have to be made to the programme. The exercise will, however, continue to be qualitative rather than quantitative. When a 'quantitative model' has been developed in the past, it has been found to be very cumbersome and has not provided any better result than the qualitative approach currently used (even when quantitative data, such as trade data, are considered).

INTRODUCTION

2.

Neither of the crises referred to originated from imported meat or meat products.

The general food law and the 'hygiene package', including Regulation (EC) No 882/2004, came into being in 2002 and 2004 respectively. Appropriate measures were taken to ensure that any delay in the implementation of measures under the 'hygiene package' did not lead to a lower level of hygiene protection.

5.

Legal imports of meat and meat products (or even of food of animal origin) are not a significant source of outbreaks of these diseases.

9.

The equivalence determination in veterinary agreements addresses legislation and standards and does not include performance of the control system unless specified otherwise.

AUDIT SCOPE AND APPROACH

12.

The legal basis for veterinary checks on meat imports remains Council Directive 97/78/EC, which is still in force (as are the decisions implementing it).

OBSERVATIONS

17.

The Commission has already started the exercise of simplifying the import legislation and also plans a review of such legislation, which will include the possibility of more user-friendly and uniform regulatory requirements. In the meantime, all relevant information, i.e. import guarantees, certificates and lists of authorised third countries and approved establishments, is available in the TRACES system so that Member State controllers at BIPs know which checks have to be carried out. Economic operators also have access to the system, i.e. to certificates, the list of approved establishments and the legislation on the specific requirements. Consolidated versions of EU legislation are available from the CELEX database, which is accessible to the general public.

A guide on reinforced checks is being drafted, including use of TRACES to ensure general application and harmonisation of the reinforced checks throughout the Member States.

Box 1 — Legislation on reinforced checks unclear

See response to the observation above.

18.

The Commission has always been careful to ensure that any delays in making changes to import requirements to reflect corresponding changes to requirements in the EU itself are kept to the minimum. Pending such changes, the existing requirements, which may be stricter, remain in place. Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 was adopted, inter alia, for this purpose.

19

These delays had no implications in terms of risks to health in connection with imported meat and meat products.

20.

The Commission acted on this reservation by making sure that there was no legal vacuum between the entry into force of the hygiene package and of certain provisions implementing it.

21.

Based on the priorities set for its mission programme, the FVO carries out regular inspections in third countries exporting significant quantities of meat and meat products to the EU.

Regulation (EC) No 882/2004 only requires third countries to provide the Commission with information on their control system for each type of product intended to be exported to the EU. Consequently, such guidelines on the general organisation and performance of checks carried out by third country CAs are not necessary or required under EU legislation.

24.

The delays were kept to the minimum and had no implications in terms of risks to human health in connection with imported meat and meat products and there was no legal vacuum between the entry into force of the 'hygiene package' and of certain provisions implementing it.

The measures which took effect after eight months were the result of the ongoing implementation of the agreement and the update of the references to legislation. The reduced checks were the result of the original negotiations on the agreement in 1996/97 and are not related to the 'hygiene package'.

25.

Pre-export checks are not compulsory in the EU legislation on meat and meat product imports, as there are four levels of control. These are: the approval of the country, listing of the country for the residue monitoring plan, listing of establishments and a harmonised health certificate setting animal and public health conditions. These levels rely on the third country CAs' control system for the commodities exported to the EU.

FVO inspections always include verification of the capacity of the third country's control system to use only EU-authorised sources of meat and meat products. This includes their import requirements.

26.

There is a general consensus that the animal health and hygiene status in New Zealand is among the very best in the world. Nonetheless, the next amendment to the veterinary agreement with New Zealand will clarify (in Annex VIII) that 100 % identity checks are required for imports from New Zealand.

27.

The process for determining equivalence in international organisations (WTO and Codex Alimentarius) is not based on use of indicators.

The ALOP for the EU did not change before or after the 'hygiene package'. First, it is set at political level, then the resultant measures are established in order to achieve the ALOP and not the other way around, which would mean that the ALOP is the result of the measures. Determination of equivalence is based on assessment of the measures and the standards without taking into account control system performance.

28.

This exercise was solely for information for both sides. It concluded that equivalence was not affected by the new EU legislation. Consequently, all that needed to be done was to amend the annexes with references to the new regulation.

29.

As stated in the reply to observation 27, no revision as such was necessary for the veterinary agreements and the various levels of equivalence achieved. Therefore, 'no common procedure for revision based on established quantitative and qualitative indicators' was necessary.

Originally, for the veterinary agreements the method for establishing equivalence recommended by the Codex Alimentarius based on comparison of legislation was used.

The FVO is not responsible for evaluating equivalence but for verifying that the standards laid down in the agreements are properly applied.

Box 2 — Main difficulties for reviewing the SPS agreements

As explained in the reply to observation 24, the reduced checks were the result of the original negotiations on the agreement in 1996/97 and are not related to the 'hygiene package'. Today, experience has proved that New Zealand is the best performer at meeting EU import conditions.

Box 3 — The physical check rates are minima. Member States may do more.

Import checks are conformity controls and not in themselves sufficient to establish applicable import conditions. Further proposals for harmonising some procedures and increasing use of TRACES by Member States are currently under way. Furthermore, the legislation on import controls is already under review and revision is very possible. Footnote 16 refers to risk factors which are not necessarily known at the BIP, for example, the target consumer group, the extent and nature of any further processing, the exporting country's inspection arrangements or the compliance record of the third country producers.

In line with the principle of subsidiarity, responsibility for the consignment selection method lies primarily with the Member States, which are best placed to exercise this role. The Commission nonetheless, both through FVO inspection reports and in its coordination work with Member States, promotes best practices and cooperation in identifying risks.

31.

The results of laboratory analysis are one of a wide range of factors taken into account in risk assessment. DG SANCO is considering a more targeted risk-based system of physical controls and will be using such data to inform Member States of the frequency of physical checks needed, which third countries/establishments need to be more closely monitored and which analytes to target in imported foodstuffs.

Hormones are naturally produced at low levels in animals and these results give no reason to suspect abuse or misuse of hormones as growth factors.

32.

Progress continues to be made on increasing the number of Member States recognised as fully equivalent.

Regarding the USA, no full equivalence status exists in either direction (except for fishery products imported into the EU). Consequently, US federal legislation and EU legislation apply to trade. For all Member States the import legislation is harmonised, so they should accept what is stated in the VA. In practice, for meat and meat products the general import guarantees and relevant certificates apply, as for all other third countries.

See above.

34.

Member States' acceptance of TRACES is continuing to increase and improve. The legal obligation to use TRACES (Decision 2004/92/EC) does not preclude use of national software.

There was a problem with convincing the three Member State named to use TRACES. However, implementation of TRACES in every Member States is now nearly complete.

Improvement of the TRACES system is indeed an ongoing process.

The Commission is seeking to address the issue raised by the Court in order to consider how to use such data for development of a risk-based approach to veterinary checks in BIPs' relevant model certificates.

35.

Comparing statistical data serving different aims is currently neither relevant nor practicable. Reconciliation of such data is therefore not yet operational. Discussions are ongoing between the relevant departments.

TRACES contains data on all consignments checked and released or refused or for transit to third countries at the border, whereas the customs authorities use two different systems, one for consignments released for free use in the EU at the border and one for consignments released for free use in the EU at their destination in a Member State.

36.

The relevant DG SANCO staff are aware of several of these points and are working on them. The Court's views will be helpful in this work.

37.

EFSA was provided with the data when it requested information for its assessment.

38.

Article 50 of Regulation (EC) No 178/2002 laid down the general conditions for notifying information to the RASFF. More detailed application measures drawn from experience (see footnote 23 of this report) as stipulated in Article 51 should be adopted in 2011.

39.

The Commission welcomes the widespread satisfaction expressed by the Member States.

In line with the principle of subsidiarity, Member States have discretion on how to react, but the Commission is actively working to promote a common approach.

40.

See response to observation 38.

The risk posed to public health from exposure to this meat in this case was considered negligible.

The Commission considers that the system reacted proportionately and in timely fashion — see above.

41.

As the aims of this data differ, their reconciliation is therefore not yet operational. Continuous cooperation exists between DG SANCO and DG TAXUD and a specific project group has been set up to define the links between the customs databases and TRACES.

The obligation to include the 10-digit TARIC code on the summary declaration was raised several times. However, stakeholders in the DG TAXUD working groups refused to include the code.

42.

TRACES contains data on all consignments checked and released or refused or for transit to third countries at the border, whereas the customs authorities use two different systems, one for consignments released for free use in the EU at the border and one for consignments released for free use in the EU at their destination in a Member State.

44.

Inclusion of the list of products in the Annex to Decision 2007/275/EC in the TARIC list and in the NCTS has been discussed several times. However, this requires the agreement of customs authorities, which has not been forthcoming. Discussions will continue in the context of the review of import control legislation.

45.

This is the responsibility of the Member States, but the Commission actively promotes a common approach.

47.

Regulation (EC) No 136/2004 imposes no legal requirement for the Commission to draft such guidelines.

In addition to verifying the existence and application of the monitoring plans required by Regulation (EC) No 136/2004, the FVO assesses the appropriateness of the plans (see the reply to observation 49).

48.

The relevance of these findings is very limited in terms of exposure of consumers to risks to human health and, especially, to chemical contaminants. Moreover, for food of animal origin, including aquaculture products, authorised third countries are listed on the basis of a residue and environmental contaminants monitoring plan.

The Commission has no powers over the budget allocated by Member States governments to CAs' control plans.

49.

The legislation in relation to such monitoring plans is not prescriptive and it is to be expected that the monitoring plan for each Member States is tailored to national needs. Where there are shortcomings in the design of the plan, the FVO highlights this.

Any remedial action would need to take account of the subsidiarity principle.

51.

This was intended by the legislative authorities to ensure flexibility and subsidiarity to work. Since there is no detailed legal requirement, such variations are to be expected and thus are not an infringement against EU legislation.

52.

The surveillance strategies are the responsibility of the Member States.

53.

The EU legislation stipulates that all consignments of imported food of animal origin must be controlled at BIPs. These consignments and possible further controls on them are tracked on the basis of Regulation (EC) No 882/2004.

55.

The person responsible for the load signs the CVED, committing himself to pay any fees due and stating the origin and delivery address of the goods. This guarantees full traceability.

Regarding conditions of storage, these consignments are subject to the normal rules on post-BIP release of intra-Community goods.

57.

The harmonisation of control fees is a complex and controversial issue where progress has proved difficult despite the Commission's best efforts. Once legislation has been formulated in coordination with the European Parliament and the Council, it is fully applicable in the Member States. The Commission, as guardian of the Treaties, is duty bound to ensure that it is implemented as it stands.

58

The Commission is required only to examine whether the fees comply with the requirements of Article 27 of Regulation (EC) No 882/2004.

The Commission has already announced that it intends to revise the current control fee structure. The related impact assessment is currently being conducted. If appropriate, a Commission proposal to amend the rules on the financing of official controls will be presented in 2012 (together with the other planned reviews involving Regulation (EC) No 882/2004).

59.

The aim of harmonisation is not included in the legal basis (Article 55 of Regulation (EC) No 882/2004). In addition, in terms of sanctions, the subsidiarity principle is particularly relevant.

During its audits, the FVO verifies correct implementation of Article 55.

As harmonisation of penalties is not included in the legal basis (Article 55 of Regulation (EC) No 882/2004), formulation of guidelines or good practices is not an issue.

60.

This is a power reserved for Member States under EU law. If a Member State requests approval of a BIP, all the Commission can do is to ascertain whether the facilities, equipment and staff in place comply with EU legislation. It has no powers to decide on its utility or otherwise.

62.

Similar findings have been reported by the FVO. Regulation (EC) No 882/2004 introduced the requirement for an internal audit (or to have external audits carried out). Given the complexity of such audit systems and the need to address issues of a higher priority, it is understandable that they have not yet been fully developed and that Member States are at different stages of development. However, the FVO has been evaluating Member States' audit systems in the series of general audits of Member States' control systems. The first round of this series will be completed in 2010. The FVO has already produced numerous findings, conclusions and recommendations regarding audit systems. Structured follow-up of these recommendations is already in place.

These are the legal provisions adopted by the European Parliament and the Council, which decided that such measures should not be binding. However they are taken into account by the FVO in its inspection activities.

63.

See the reply to observation 62. Internal control functions are in place in some Member States and the number should increase over time.

(c)

Due to the various commodities and animals/animal products imported via BIPs, inspectors cannot be specialists in every product. This is why the TRACES system is a very valuable tool to provide BIP inspectors with updated documentation.

64.

In view of the Court's assessment of Member States' internal controls in observation 62, it is too early to suggest aligning the Commission's controls with those of the Member States. However, once Regulation (EC) No 882/2004 has been fully implemented in the Member States, the Commission's objective would be to put in place such a coordinated approach.

65.

The White Paper is a policy document and is not in itself a sufficient legal basis for any action.

See above. Furthermore, Regulation (EC) No 882/2004 applies only partly to third countries.

67.

The FVO is constantly assessing the efficacy of its work to ensure that resources are put to the best use.

68.

This model takes into account most of the relevant parameters specified in paragraph 3 of Article 2 of the repealed Decision 2001/881/EC.

70.

Trade volumes are closely monitored by the FVO. They are part of the corporate knowledge of the inspection teams and are taken into account when planning missions. The RASFF messages are of limited value for selecting the Member States but may be used for selecting consignments to be evaluated at the individual BIPs or for selecting certain third countries or establishments there for an inspection.

The weighting given to each criterion is reflected in the number of associated subcriteria. The assessment gives a snapshot of the situation as good, average or poor.

71

The absence of comments is not indicative of a problem. Member States take the mission programme very seriously, as it is both important to health protection and a serious demand on their resources.

72.

A 'quantitative model' was developed in the past. It has been found to be very cumbersome and has not proved to provide any better result than the qualitative approach currently used (even if quantitative data, such as trade data, are considered). Moreover, the mission prioritisation is discussed and agreed with Member States whose input in deciding priorities is invaluable.

See the reply to observation 73.

Efforts to make better use of data in deciding priorities continue.

73.

The Commission is fully implementing the recommendations made in the independent evaluation of mission priority-setting in this respect. DG SANCO establishes criteria for setting potential mission priorities. In the prioritisation process itself, they must demonstrate and document that these criteria have been consistently applied. This in turn leads to more transparent choices in the event that changes have to be made to the programme.

Staff turnover, for the past several years, has not been very high.

75.

Member States are requested to present action plans to the FVO indicating how they intend to address any shortcomings identified in inspections. Verification of corrective action is an integral part of the FVO's activity and the FVO revisits Member States regularly to monitor progress.

Implementation of recommendations is continuously monitored by the Commission. Indicators are used for this purpose and demonstrate the effectiveness of the FVO's activities. Overall, by the end of 2009, Member States had taken action on 86 % of the recommendations made to them by the FVO since 2004. Action was in progress on a further 10 %. In 4 % of cases, Member States had yet to commit themselves to corrective measures. These cases are followed up continuously by DG SANCO.

78.

The FVO carries out on-the-spot checks in order to verify Member States' control/audit systems. EU legislation does not stipulate when BIPs are to be revisited. Scrutiny of TRACES data shows that the 49 BIPs referred to have low throughput and, thus, limited control activities. This indicates that priority is given to the most important ones.

The FVO's task is not to report on best practices but to verify proper and effective implementation of official controls and enforcement of the EU legislation by evaluating the performance of Member State CAs' control system. The action plans submitted by Member States to the FVO are followed up by internal procedures and supervised by a specific DG SANCO management committee.

79.

As already stated in the reply to observation 19, these delays had no implications in terms of risks posed to human health by imported meat and meat products.

81.

Regarding import controls, all current health certificates are available to BIP officials and the FVO via TRACES and also 'EU authorised' third countries and their establishments. A link is also provided to EU legislation for specific requirements.

Changes in legislative requirements are obviously closely monitored but this is not a resource demanding exercise and certainly does not require a full staff member.

82.

There are extensive information systems available to ensure that FVO staff are informed of relevant changes to legislation, including their formal consultation in the legislative process itself. DG SANCO also has a dedicated section of its website focused on import requirements and controls.

83.

Guidelines for drafting MANCPs, and action described by the Court in point 77, are sufficient to allow Member States to carry out import controls effectively.

Regulation (EC) No 882/2004 imposes no obligation on the Commission to assess MANCPs. However, each Member State receives feedback from the FVO on its MANCP in the general audit on the country. On completion of each general audit, a report is addressed to the Member State. It contains recommendations.

This regulation imposes no obligation on the Commission to provide any assessment of or advice on Member States' annual reports. However, the first Commission report required by Article 44 of Regulation (EC) No 882/2004 was adopted in August 2010.

84.

The rules on imports of meat into the EU include a requirement that animals must be humanely slaughtered in accordance with EU legislation. The question of competitiveness with third countries has been assessed in a Commission report to the Council and Parliament (COM(2002) 626 final), concerning animal welfare legislation for farmed animals in third countries and the implications for the EU. The Commission is now reassessing the issue in the context of its evaluation of EU policy on animal welfare, that was due to be published in December 2010.

85

The costs referred to are clearly important to the competitiveness of European producers. Any comparison of costs of controls would have to take into account a wide variety of economic factors, including direct subsidies, indirect support (e.g. in the form of preferential interest rates), the costs of land, building, feed and labour and many other factors. It should also be noted that the EU producers benefit from this situation in terms of complete access to the EU market including for live animals, while third countries' producers may be able to access such market only for certain products and therefore in a much more limited manner. The Commission remains committed to continue to consult stakeholders.

86.

This report will be presented to the Council and Parliament before the end of 2010, as requested, and will focus on the effectiveness and consistency of the measures in place to control imports of food, feed, animals and plants.

Concerning the European Parliament, the Commission launched the call for tenders of the pilot project assessing the end-user costs of compliance with EU legislation in 2009, but discontinued the procedure because it had received only one offer. A literature study on this subject is currently being prepared.

The results of the European Parliament study will be scrutinised, where relevant, by the relevant Commission departments.

CONCLUSIONS AND RECOMMENDATIONS

87.

Veterinary rules for import checks are governed by Directive 97/78/EC and were largely unaffected by the White Paper and the 'hygiene package'. Rules on approval of third countries and establishments were redrafted in the 'hygiene package' but remain similar to the previous rules.

Indicators on pre-export checks are not required either by the EU legislation on pre-export checks (which are not even required) or by international recommendations or standards regarding determination of equivalence.

VAs have been signed with highly developed countries, in which trust has been established with their CAs. Reductions in physical checks on imports were agreed only in cases of highly positive FVO reports on the CAs' control systems for the relevant commodities.

88.

The obligation to conduct veterinary checks on meat imports is enshrined in EU legislation. The RASFF, TRACES and FVO inspection mission reports and other information from third countries merely serve as tools to help the Commission establish the risk involved and thus determine the levels of physical checks applicable.

TRACES is a relatively new tool and every effort is being made to ensure that it is used uniformly by every Member State.

Users of the RASFF alert system depend on the timeliness and accuracy of the information found in it, much of which they themselves are responsible for supplying. The Commission is constantly looking for ways to ensure that this system provides up-to-date and accurate information on alerts in order to facilitate the risk management decisions needed to ensure that preventive and/or corrective action is taken as and when required. The system operates in a timely and proportionate manner.

89.

The reply to observation 75 explained how Member States commit themselves to corrective action and how the Commission monitors implementation thereof. It also explains the state of implementation at the end of 2009.

90.

First indent

Under the VAs, total equivalence is rarely achieved, meaning that the national legislation of the importing third country applies to exports from Member States. Differences could therefore exist between Member States in achieving third countries' sanitary requirements or level of official control of these requirements. In addition, regarding animal health status, TCs are often slow to accept Member States' guarantees. Lastly, third countries do not always consider the EU as a single entity when considering Member States' exports.

Second indent

The general food law and the 'hygiene package', including Regulation (EC) No 882/2004, came into being in 2002 and 2004 respectively. The Commission has already simplified its regulatory framework in order to consolidate it and make it more user-friendly. The Commission is committed to continue this process as part of its overall efforts to promote better regulation. Most of the consolidated versions of EU legislation are available in the CELEX database, which is accessible to the general public, and in the TRACES database, which is accessible to BIPs and operators.

Third indent

The new RASFF system is a web-based application that allows Member States and the Commission to enter information on alerts and notifications directly in the application. TRACES does not need to be further developed to display any data, but the legal base (Commission Decision 2004/292/EC) imposing the obligation on the Member States to use TRACES must be changed to ensure that Member States enter relevant information before the movement of commodities. This is essential to obtain all relevant data and to provide accurate information in the event of a sanitary alert. The manner in which TRACES operates will be further strengthened in the animal health law.

Fourth indent

Current legislation does not provide the Commission with legal powers to develop such guidelines. This notwithstanding, the Commission engages in many different activities which ensure a harmonised approach to the veterinary checks carried out in BIPs. These include regular meetings with competent authorities from the Member States in different working groups, for example the Veterinary Checks Working Group that meets three to four times a year, training provided to BIP staff under the 'Better training for safer food' programme (BTSF) and, of course, through EU legislation which is very prescriptive and clear as to the exact roles of BIPs.

Fifth indent

Current legislation does not provide the Commission with legal powers to develop such indicators. FVO audit mission reports, follow-up action and various reports are, however, tools that are in place which allow an assessment to be made of the implementation of EU legislation, including control and enforcement, especially with respect to the 'hygiene package'.

Sixth indent

An external evaluation made recommendations on the risk assessment models used by the FVO which have been followed by the FVO. However, quantitative models have very important limitations due to the complexity of the risk factors impacting on imports and could indeed lead to seriously misleading signals on priorities. Accordingly, the mission prioritisation process continues to rely extensively on experience, judgement and consultation of relevant stakeholders and especially the Member States' control authorities. In addition, quantitative factors such as import quantities and types of products imported are data integrated in the analyses made prior to mission planning. The scope of the recommendation goes beyond the sector audited. Only one risk assessment model has been looked at by the Court. A process to formalise further selection of the BIPs to be visited has commenced.

Seventh indent

In addition to carrying out specific followup inspections in specific sectors, the FVO introduced 'general follow-up missions' in 2005 in order to review progress on implementation of the recommendations made across all sectors. This process highlights issues where Member States have failed to take corrective measures. These cases are followed up continuously and, depending on the gravity of each specific case, the need for specific enforcement action is routinely assessed. An internal follow-up procedure already exists in order to produce further improvements following negative FVO findings and is used in the same way and with the same degree of severity with regard to import control issues as Member States' production controls.

Eighth indent

Agreed and in progress.

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WTO Member States are permitted to apply SPS measures that go beyond internationally accepted standards if these are demonstrated to be science-based, non-discriminatory and proportionate. Import rules must remain focused on safety whilst simultaneously respecting international obligations. The Commission is fully committed to carrying out impact assessments on proposals with implications for competitiveness, in keeping with the policy objectives of the 'Better regulation' and 'Europe 2020' initiatives.

This report will be presented to the Council and Parliament before the end of 2010, as requested, and will focus on the effectiveness and consistency of the measures in place to control imports of food, feed, animals and plants.

The results of the European Parliament study will be scrutinised, where relevant, by the relevant Commission departments.

European Court of Auditors

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IN THE WAKE OF THE SERIOUS HEALTH CRISES OF THE 1990S AND ON THE BASIS OF THE WHITE PAPER ON FOOD SAFETY, A NEW LEGISLATIVE FRAMEWORK KNOWN AS THE 'HYGIENE PACKAGE' WAS DECIDED ON IN 2004. THE AUDIT OF THE COURT ASSESSED THE COMMISSION'S MANAGEMENT OF THE EU SYSTEM OF VETERINARY CHECKS FOR MEAT AND MEAT PRODUCTS IMPORTS. IT CONCLUDED THAT THE IMPLEMENTATION OF THE 'HYGIENE PACKAGE' HAS YET TO BE COMPLETED AND THAT THERE IS STILL ROOM FOR IMPROVEMENT WITH REGARD TO THE INFORMATION SYSTEMS AVAILABLE TO BORDER INSPECTION POSTS AND THE CONTROLS THEY ASSURE.





