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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND TO THE COUNCIL

on the overall operation of official controls in the Member States on food safety, animal health and animal welfare, and plant health

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1. Background

Article 44 (1) of Regulation (EC) No 882/2004¹ ("the Feed and Food Controls Regulation") requires Member States to submit to the Commission each year a report on the implementation of their multi-annual national control plans established in compliance with Article 41 of the Regulation. The Regulation requires that the reports contain:

- (a) details of amendments to their multi-annual national control plans, to take into account among other factors, changes in legislation, new risk patterns, new science, the result of past controls;
- (b) the results of controls and audits carried out in the previous year under the national control plan;
- (c) the type and number of cases of non-compliance identified through the controls;
- (d) actions to ensure effective implementation of the national control plan including enforcement actions and their results.

In this context, mention should also be made of the complementary provisions contained in Article 7 of Regulation (EC) No 882/2004 on the need for Member States to ensure a high level of transparency in their control activities.

Article 44 (4) and (6) of the Regulation requires the Commission to establish and submit to the European Parliament and Council an annual report on the overall operation of controls in the Member States in the light of:

- (a) the annual reports submitted by the Member States,
- (b) EU audits and inspections carried out in the Member States, and
- (c) any other relevant information.

This Report may, where appropriate, include recommendations on possible improvements to official control and audit systems in Member States, specific control actions concerning sectors or activities, or coordinated plans aiming at addressing issues of particular interest.

The main purpose of the Commission's annual report is to provide an overview of the way competent authorities in the Member States carry out official controls to verify compliance with food law legislation (in the broadest sense, including not only food and feed safety but also animal health and welfare and - to some extent – plant

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p1).

health). The Commission considers that such a report should therefore also provide some basic indicators of the control activities carried out by Member States along the food chain in the different areas concerned, and of their outcome and results.

In this first report attention is being given to the following objectives:

- to provide a first screening of the data and information on official controls which is currently available to the Commission, including an analysis of such data and information resulting from the first set of annual reports transmitted by the Member States to the Commission in accordance with Article 44 (1);
- to present some initial conclusions on how to improve the current system of reporting by Member States.

The Commission intends to initiate discussions with the Member States on the issues raised in this report, and specifically on how the collection and handling of data on official controls can be rationalised and streamlined. The Commission also intends to review with the Member States the state of implementation of Article 7 of Regulation (EC) No 882/2004 on the need to achieve a high level of transparency in their control activities. Such discussion should give consideration to how the exercise of rationalising and streaming annual reports could help Member States ensure a high level of transparency of their official control activities, as required in Article 7.

2. Annual reports of the Member States

The Feed and Food Controls Regulation took effect from 1 January 2006. Member States were required to submit their first annual report on their control activities for 2007. The deadline for submission was 1 July 2008. Reports were received from all but one Member State.

The reports were received by the Commission in the second half of 2008 and early 2009. Each report was assessed under six main headings, which broadly follow the recommended structure of reports in the Commission's (non-binding) guidelines set out in Commission Decision 2008/654/EC²:

- Results of controls
- Analysis of non-compliance
- Actions taken in cases of non-compliance
- National system of audits
- Actions to improve performance of control authorities
- Actions to improve performance of food business operators

The Commission acknowledges the considerable efforts the Member States made in compiling their first annual reports under the Regulation. Overall, the annual reports gave the information as required by the Regulation. However, the information provided varied greatly in nature, detail and quality. Moreover, these were the very first reports submitted by the Member States under the provisions of Art. 44. Accordingly, the contribution which this information could make to this first

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² Commission Decision 2008/654/ECof 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council (OJ L 214, 9.8.2008, p. 56).

Commission report on the overall operation of official controls is limited. This situation has to be viewed also in the light of the information which had already been obtained either in the course of EU controls carried out under Article 45 of Regulation (EC) No 882/2004, or from other relevant information available to the Commission, for example the sectoral reports submitted by Member States under other provisions of EU legislation.

A summary of the main results of the Commission's analysis of the reports received is set out below. For most Member States, their annual reports were compilations of and/or references to reports prepared by different national authorities responsible respectively for food of plant origin, food of animal origin, animal feed, animal health, animal welfare and plant health though not always following the overall approach set out in the Commission guidelines. The quality of the information provided varied considerably according to which control authority was responsible. The summary also highlights where improvements could be made to take account of the Commission's guidelines, and should therefore be considered in this context.

Results of controls

In most reports, data were given for the number and type of inspections, samples and analyses carried out although the level of detail, of aggregation and the overall quality varied greatly. Information on controls according to sector, stage of production or hazard/disease was usually given, but with variable levels of detail and differences in how data were structured and presented.

Analysis of non-compliance

Information was generally missing or incomplete on the type and number of non-compliances identified.

Actions taken in cases of non-compliance

The effectiveness of enforcement action over time depends on the range and consistency of remedial actions and of enforcement tools deployed to address non-compliances - what warnings/recommendations are issued, what fines imposed, what closures/movement restrictions/destructions ordered and legal proceedings taken. On the whole, information under this heading was limited and where it was provided the range and level of detail varied between Member States.

National systems of audits

Article 4.6 of the Regulation places an important requirement on the authorities in the Member States to carry out their own audits to ensure they are meeting the requirements of the Regulation. The Commission issued guidelines in September 2006 advising how the national systems of audit should be organised (Commission Decision 2006/677/EC³). The Regulation specifies that annual reports from the Member States should report on the results of such audits conducted in the previous year. With a few exceptions the details provided for this purpose were incomplete. It should be acknowledged, however, that many Member States were still only in the early stages of establishing audit systems at the time of preparing their 2007 reports.

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 and OJ L 142M, 5.6.2007, p. 259).

Actions to improve performance of control authorities

Under this heading, Member States were invited to report on actions taken in 2007 to improve the performance of the control authorities themselves. Apart from information on training and on routine procedures, Member States generally reported little of significance under this heading, again with some exceptions.

Actions to improve performance of food business operators

Under this heading, Member States were asked to give information on what actions were taken to improve the performance of the different actors in the food chain, through publicity, advice, training, etc. In practice very little information was provided under this heading, and when it was provided it varied across Member States in its detail and content.

3. Commission audits and inspections in the Member States and subsequent actions of the Commission

The Food and Veterinary Office (FVO) of the Directorate General for Health and Consumers undertakes audits and inspections to verify compliance with feed and food law, animal health and animal welfare and plant health legislation, and to verify that national official controls in these areas are carried out in line with EU legislation.

Each year a programme of FVO inspections is developed, identifying priority areas and countries for inspection. These programmes are published on the website of the Health and Consumers Directorate-General⁴. In order to ensure that the programme remains up to date and relevant, it is reviewed mid-year. New inspections may need to be programmed, for example, in response to emerging risks such as disease outbreaks. These new inspections are reflected in modifications to the inspections programme.

The findings of each audit and inspection are set out in a report, together with conclusions and recommendations to address identified shortcomings. The competent authorities of the country visited are given the opportunity to comment on the reports at draft stage. The FVO makes recommendations to those authorities to deal with any shortcomings revealed during the inspections. Authorities are then requested to present an "action plan" describing how they have addressed or intend to address the recommendations. In turn, the Commission evaluates the action plan and systematically monitors the implementation of the actions through a number of follow-up activities: general follow-up missions during which the FVO and Member State authorities meet to review progress made on recommendations to that Member State; on-the-spot follow-up inspections or audits in the areas concerned; requests for written reports; and high-level bilateral meetings in the event of over-arching or persistent problems.

http://ec.europa.eu/food/fvo/inspectprog/index_en.htm

Where the circumstances require it, legal action may be taken by the Commission. This can take two forms: emergency, or safeguard, measures under an appropriate legal basis⁵, or infringement proceedings. Where an inspection identifies an immediate threat to human, animal or plant health, the Commission may take emergency or safeguard measures. These may include legal action to prevent trade in, or imports of, feed, food, animals, and plants or any of their products. In addition, where a competent authority fails to take satisfactory corrective action, the Commission may commence infringement proceedings against that Member State.

In this way, the Commission monitors and verifies on the spot in the Member States their compliance with feed and food law, animal health and welfare and plant health legislation, and where appropriate takes action to protect human, animal and plant health from risks, and/or to ensure compliance with that legislation. In addition through the publication of the inspection reports and the Member State action plans, as well as regularly updated country profiles, it provides stakeholders and citizens with a factual account of how control authorities in each Member State deliver on their duty to ensure and where necessary enforce, the correct implementation of the law in this area.

An annual report of such activities is produced, as required under art. 45(4) of the Feed and Food Controls Regulation, and published. It describes in some detail the overall results of such audits and inspections for the year in question. Reports covering 2007 and 2008 were submitted to the Parliament and Council and have already been published. These can be consulted on the Europa website⁶. The main problems identified in the audits and inspections carried out during the course of the year in question, and the actions taken in response thereto, are set out in those reports. In addition, the FVO produces other reports, such as general overview reports that summarise the results of a series of inspections to a number of Member States on the same subject.

Specifically as regards 2007 (the year to which the Member States' reports' referred to in paragraph 2 above relate), 260 inspections were planned by the FVO. Of those, 209 were completed, 63 were removed from the programme, for different reasons, and 43 new ones. The total number of completed inspections was therefore 252, of which 159 took place in Member States, 12 in candidate countries⁷ and 81 in third countries⁸. An FVO inspection can cover a number of different or overlapping objectives. Each objective is categorised into one of the four broad areas: food safety; animal health; animal welfare; or plant health. On this basis, 70% of the inspection objectives in 2007 concerned food safety. However, following the "farm to fork" approach, many food safety inspections also cover some animal health and

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For example, decisions taken in accordance with Article 53 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1–24)

http://ec.europa.eu/food/fvo/annualreports/index_en.htm

Candidate countries are those countries which are candidates for future membership of the EU but which have not yet started the formal process for accession.

Of the 81 inspections carried out in third countries in 2007, Brazil received the most inspections (7), followed by Argentina, Australia, Canada, Iceland, Switzerland (3 each). In contrast, in 2006 the most frequently inspected third countries were China (5 inspections) followed by Brazil (4), Norway (3), Thailand (3).

welfare elements. A full list of all the countries inspected in 2007 and the subjects of those inspections is presented in Annex 2 of the 2007 report.

For the most part, the findings and recommendations following on from the inspections and audits carried out in 2007 were of such a nature that they were dealt with through the follow up process described above. No such audit or inspection in the Member States identified any immediate threat to consumer, animal or plant health, such that the Commission had to take emergency, or safeguard, measures. However, as day-to-day implementation of relevant legislation is in the hands of the Competent Authorities of Member States corrective measures are overwhelmingly taken at their level. Four inspections focused on following up on more serious deficiencies in controls related to ongoing infringement proceedings against Member States.

The details of the findings and actions for 2007 can be found in the report itself, which can be downloaded from the Europa website⁹

Finally in 2007, the FVO initiated a series of "general audits" as foreseen in Art. 45 of the Official Feed and Food Controls Regulation. This series, which covers all Member States, will be completed in 2011. The purpose of the general audits is to verify that, overall, official controls take place in accordance with EU legislation, and with the multi-annual national control plans (MANCP)¹⁰. With the completion of this series, the Commission will have obtained a broad overview of the overall application of official controls in the Member States.

4. Other sources of information on controls in the Member States

Other means are also used to provide the Commission with information and data on the functioning of national control systems in the Member States.

Sector-specific reporting

Over the years as the body of EU legislation on food safety, animal health and welfare and plant health has expanded, the requirements on Member States to submit regular reports on the implementation of this legislation has increased accordingly. These reports provide extensive, sometimes detailed information on how different control systems operate in the Member States and on the results of these controls. They also provide information that is useful to the Commission when evaluating the impact of existing legislation or when considering whether and how it should be updated or modified.

The generation of the underlying data and preparation of the reports, with diverse formats and reporting frequencies across sectors, places an important burden on national authorities in the Member States. The Commission is also required to commit substantial resources to their translation and analysis.

On the basis of these national reports, the Commission in turn produces and makes available a number of sectoral reports, which provide an account of the state of implementation of certain aspects of EU legislation applicable to the food chain,

http://ec.europa.eu/food/fvo/annualreports/ann_rep_2007_en.pdf

The scope broadly covers other food law related aspects such as food labelling, organic food, food protected by geographic indications etc..

including in some cases specific data on official controls and of results thereof in the areas concerned.

Among the most relevant such reports, are the reports on: the monitoring and testing of ruminants for the presence of Transmissible Spongiform Encephalopathy (TSEs), the summary report on trends and sources of zoonoses, zoonotic agents and foodborne outbreaks in the European Union (mandated to the European Food Safety Authority (EFSA)), and the annual EU-wide pesticide residues monitoring report.

A list of published reports is included in the Annex to this Report.

Reporting at the Standing Committee of the Food Chain and Animal Healthmeetings

Reports on the operation of controls are also presented by Member States regularly at meetings of the Standing Committee of the Food Chain and Animal Health (SCFCAH). These can be either routine reports on the incidence and control of food borne illness, animal diseases or plant diseases; or they can be related to recent outbreaks and emergency actions taken in response. They represent another important source of information for the Commission to assess how controls are operating in the Member States. In recent years, the Commission has adopted the practice of publishing these presentations on the Commission's website along with the minutes of the respective meetings.

Also, in some areas the Commission prepares a compilation of such reports as received from the Member States and makes them available through the proceedings of the Standing Committee¹¹

Rapid alert systems and other reporting tools

The existing rapid alert systems for food and feed safety (RASFF), animal disease outbreaks (ADNS) and plant disease outbreaks (Europhyt) represent important tools for managing the rapid response to emergencies and emerging risks and a source of information on the pattern of hazards and diseases as they develop along the food chain. The data they provide can be an important indicator of compliance shortcomings in relation to established safety standards. Detailed results from these food safety and animal disease alert systems are summarised each year in annual reports on RASFF¹² and ADNS¹³ which are published on the Commission's web site. The Commission intends to produce from 2010 a similar annual report on the operation of Europhyt, the notification tool for plant disease outbreaks. TRACES, the system which allows the exchange of information between the Commission and the Member States on controls carried out on animals and animal products (on domestic produce and imports from third countries) is another important source of data, not only on volume of movements of the commodities covered, but also on official veterinary controls carried out.

5. Conclusion

The Commission forms its assessment of the effectiveness of control systems in the Member States based on information and data it receives from the Member States

http://ec.europa.eu/food/committees/regulatory/index en.htm

http://ec.europa.eu/food/food/rapidalert/rasff publications en.htm

http://ec.europa.eu/food/animal/diseases/adns/index_en.htm

through all the channels outlined above. The Commission considers that, on the whole, the weaknesses in controls identified, through FVO inspections or individual complaints in particular, are adequately addressed by the Member States. Where this is not the case, the Commission has taken all the measures at its disposal to enforce the requirements of EU legislation, up to and including the taking of infringement actions when necessary. A summary of the complaints received and investigated by the Commission in the areas of food chain law is summarised in the Commission's annual report on the application of EU legislation¹⁴.

However, this review of the various sources of information the Commission receives on the operation of controls in Member States indicates that there are a number of potential areas for improvement in the compilation, transmission and analysis of information on the implementation of food chain law, and on official controls in particular, where data production and handling can be simplified, and data presentation streamlined and made more relevant. The availability of more easily accessible and comparable data will in turn allow both national authorities and the Commission to operate more efficiently while at the same time giving full assurance to EU citizens that control systems are comprehensive, robust and effective.

The Commission therefore intends to examine, in close cooperation with the Member States, a number of actions to make more efficient and comprehensive the way in which information on controls is collected, analysed and presented at EU level, and in particular:

- 1. how reporting requirements currently imposed on Member States by existing EU legislation can be simplified and streamlined, including by the elimination of duplications and superfluous information, and by the use of standardised templates for quantitative data which could reduce substantially the requirements for translation from different official languages;
- 2. how the considerable potential for the electronic transmission and analysis of data through the use of the Internet can be fully exploited to achieve simplification and standardisation and to reduce the burden of generating, collecting and transmitting controls related data, with appropriate input and assistance from Eurostat;
- 3. how the simplification and standardisation of reporting requirements can assist the Member States to deliver on the obligation laid down in Article 7 of the Food and Feed Controls Regulation, which, requires them to ensure that their activities are carried out with "a high level of transparency", and more specifically that the public is given access to information on the control activities of the competent authorities and their effectiveness.

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http://ec.europa.eu/community_law/infringements/infringements_annual_report_en.htm

ANNEX

LIST OF PUBLISHED COMMISSION SECTORIAL REPORTS ON THE IMPLEMENTATION OF EU LEGISLATION ON FOOD SAFETY, ANIMAL HEALTH, ANIMAL WELFARE AND PLANT HEALTH

Report	Legal basis	Publication
Annual Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in the EU	Article 6 (4) of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies	http://ec.europa.eu/food/food/biosafety/tse_bse/ monitoring_annual_reports_en.htm
The EU Summary Report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in the European Union	Article 9 (2) of Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC	http://www.efsa.europa.eu/en/press/news/zoonos es100128.htm
	(Mandated to EFSA, elaborated by EFSA in cooperation with ECDC)	
The Rapid Alert System for Food and Feed (RASFF) annual report	Article 50 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety	http://ec.europa.eu/food/food/rapidalert/rasff_publications_en.htm

Report	Legal basis	Publication
Annual EU-wide Pesticide Residues Monitoring Report	Article 32 of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (Mandated to EFSA)	http://ec.europa.eu/food/fvo/specialreports/pestic ides index en.htm http://www.efsa.europa.eu/en/scdocs/doc/EFSA2007_Annual_Report_Pesticide%20Residue_e n.pdf
Annual report on food irradiation	Article 7(3) of Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation	http://ec.europa.eu/food/food/biosafety/irradiatio n/index_en.htm//
Commission Staff Working Paper on the Implementation of National Residue Monitoring Plans in the Member States	Article 8 of 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	http://ec.europa.eu/food/food/chemicalsafety/res idues/control_en.htm

Report	Legal basis	Publication
Report from the Commission to the European Parliament and The Council on the implementation of article 9 of Council Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses	Article 9 of Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses	http://ec.europa.eu/food/food/labellingnutrition/nutritional/foodstuff_particular_nutri_uses_en.htm
Commission summary of quarterly reports submitted by Member States on the implementation of the avian influenza programme in poultry and wild birds, including all positive and negative results of both serological and virological laboratory investigations obtained during surveillance	Article 19.1 (d) of Commission Decision 2006/875/EC and article 9.1 (d) of Commission Decision 2006/876/EC approving programmes for the eradication and monitoring of animal diseases of certain TSEs and for the prevention of zoonoses presented by the Member States and by Bulgaria and Romania for the year 2007.	For poultry: http://ec.europa.eu/food/animal/diseases/control measures/avian/res_surv_wb_annual_07_en.pdf For wild birds: http://ec.europa.eu/food/animal/diseases/control measures/avian/res_ai_surv_wildbirds_2007_en. pdf

Report	Legal basis	Publication
Annual report on the results of the implementation of the avian influenza surveillance programme in poultry and wild birds. (Summary of Member States annual reporting of surveillance results for avian influenza in poultry and wild bird, prepared by the Commission and the EU reference Laboratory for Avian influenza.)	Article 19.1 (f) of Commission Decision 2006/875/EC and article 9.1 (f) of Commission Decision 2006/876/EC approving programmes for the eradication and monitoring of animal diseases of certain TSEs and for the prevention of zoonoses presented by the Member States and by Bulgaria and Romania for the year 2007.	For poultry: http://ec.europa.eu/food/animal/diseases/control measures/avian/res_surv_wb_annual_07_en.pdf For wild birds: http://ec.europa.eu/food/animal/diseases/control_measures/avian/res_ai_surv_wildbirds_2007_en.pdf pdf
Reports of the meetings of the experts sub-groups (Bovine brucellosis, sheep& goats brucellosis and rabies) of the Task Force (TF) for monitoring disease eradication in the Member States.	The Task Force was created in 2000 as an action foreseen in the Commission White Paper on Food Safety.	http://ec.europa.eu/food/animal/diseases/eradicat ion/taskforce_en.htm

Report	Legal basis	Publication
Annual summary of submissions from Member States concerning imports of products of animal origin for personal consumption, summarising the relevant information on the measures taken to advertise and enforce the rules laid down in the Regulation, and on the results thereof	(repealing Art. 5 (1) of Commission Regulation (EC) No.	http://ec.europa.eu/food/animal/animalproducts/personal_imports/sum_personal_imports_2005_2007_final.pdf
Animal welfare: transport Regulation	Article 27(2) of Council Regulation (EC) No 1/2005	http://ec.europa.eu/food/animal/welfare/transport/inspections_reports_reg_1_2005_en.htm