

# **SELECTED ASPECTS OF IMPLEMENTATION OF REGULATION (EC) NO 882/2004 ON OFFICIAL CONTROLS IN THE CZECH REPUBLIC**

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## **Abstrakt v rodném jazyce**

Zajištění vysoké úrovně ochrany zdraví nejen lidí si vyžádala nový komunitární právní rámec oblasti bezpečnosti potravin a krmiv, tzv. od vidlí po vidličku. Primární odpovědnost za bezpečnost potravin a krmiv sice nesou provozovatelé potravinářských a krmivářských podniků, nicméně pravomoc a povinnost členských států kontrolovat dodržování povinností provozovateli musí zůstat zachována. Národní kontrolní systémy, včetně českého, musí pružně reagovat na nové požadavky. Předmětem příspěvku jsou tak vybrané otázky implementace úředních kontrol v oblasti bezpečnosti krmiv v České republice.

## **Klíčová slova v rodném jazyce**

Bezpečnost potravin a krmiv, úřední kontrola, příslušný orgán, Ústřední kontrolní a zkušební ústav zemědělský.

## **Abstract**

A high level of protection of human health has required a new Community legal framework in food and feed safety area. Even if food and feed business operators are primary responsible for food and feed safety, the power and the obligation of Member states to carry out controls on compliance with operators obligations have to be preserved. National control systems including the Czech one shall be flexibly adapted to new requirements. Consequently, the selected aspects of official control implementation in feedingstuffs area within the Czech Republic are topic of this contribution.

## **Key words**

Food and feed safety, official control, competent authority, Central Institute for Supervising and Testing in Agriculture.

## **1. ABOUT FOOD AND FEED SAFETY IN GENERAL**

High level of consumer protection together with smooth operation of the single market has required extensive harmonisation of food and feed law within European Union. Food safety has started to be viewed in a broader concept as a safety of the whole food chain which begins on farms and ends on tables.

It is laid down that food and feed must not be placed on the market if it is unsafe. There is primary responsibility of food and feed business operators that activities under their control are carried out in compliance with law. That is why business operators have the best position for source quality determination. That responsibility cannot be assumed by another person. On the other hand only state has power to enforce the law. There is established a general obligation for member states to organise official controls for the purpose. In compliance with

article 17 (2) of General Food Law<sup>1</sup> *member states shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.* Therefore there was established a harmonised Community framework to design and integrate national control systems at all stages of production and in all relevant sectors. The Regulation on Official Controls<sup>2</sup> has made new demands on member states and national competent authorities in this way. Of course, the Czech Republic through their competent authorities in this area has had to implement Community regulations in an appropriate way.

## **2. OFFICIAL CONTROLS IN GENERAL**

The control is a part and parcel of every managing activity and it is materialized through relevant managing relationships as well as it shares reaching of aims, which are achieved by pointed activity in a specific way. Primary control is carried out by food and feed business operators. They have obligations to apply internal control systems within their business activities. The competent authorities carry out the second level of the control whether food and feed business operators respect Community and national legislation. Finally, whether the member state controls are carried out in an appropriate way and whether these national control system is functional there are organised Community controls (inspections and audits) performed by the Commission's Food and Veterinary Office (FVO) for this purpose.

If we want to focus just on official controls it is necessary to define this term and its scope. Official control is defined in article 2 point 1 of Regulation on Official Controls as any form of control that the competent authority or the Community performs for the verification of compliance with food and feed law, animal health and animal welfare rules. There are two levels of official controls (national and Community) which scope covers food and feed safety together with other important factors affecting food chain, animal health and animal welfare. Performance of official controls should help in achieving of prevention, elimination or reduction to acceptable level risks to human and animal health and in ensuring of guarantee fair practices in feed and food trade and in protecting consumer interests. Regulation on Official Controls shall be without prejudice to specific Community provisions concerning official controls (special attention is paid for example to products of animal origin intended for human consumption<sup>3</sup> or to products of organic farming<sup>4</sup>). On the other hand, the area of common organisation of the markets of selected products which is ensured with a well established and specific control system is excluded from the scope of official controls.

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<sup>1</sup> 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, as amended.

<sup>2</sup> 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, as amended.

<sup>3</sup> Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for organisation of official controls on products of animal origin intended for human consumption, as amended.

<sup>4</sup> Council Regulation (EEC) No 2092/1991 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, as amended, which is repealed from 1 January 2009 by Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/1991.

Problematic aspect in definition scope of official controls could be found in phytosanitary area. It seems that plant health<sup>5</sup> is not explicitly involved in the definition of official controls. However, plant health in general is one of the aspects which should be taken into account when objectives of food and feed law are being achieved. Moreover, the food chain is really interconnected itself. Therefore, plant health control shall be the part of MANCPs and it is under Community control.

Member states organise official controls through their designate competent authorities. With respect to wide scope of official controls there has been created a complete control system in each member state for these purposes. Effective implementation of member state obligation on official control organisation is assisted by single integrated multi-annual national control plan (MANCP) which shall be prepared by each member state in accordance with guidelines<sup>6</sup> drawn up by the Commission. Competent authorities carry out official controls in compliance with MANCP. Minimal content requirements of MANCP are laid down by article 42 (2) Regulation on Official Controls.

There could be noted some general principles related to official control performance.

1. The performance of official controls shall be without prejudice to food and feed business operators' primary legal responsibility and any civil or criminal liability arising from the breach of their obligations. (Art. 1 (4) Regulation on Official Controls);
2. Official controls shall be carried out regularly, on a risk basis and with appropriate frequency, as a rule without prior warning. (Art. 3 (1) and (2) Regulation on Official Controls);
3. Official controls shall cover the whole food chain (from farm to fork). (Art. 3 (3) Regulation on Official Controls);
4. Official controls shall be carried out in compliance with both transparency and confidentiality principles. (Art. 7 Regulation on Official Controls) ;
5. The performance of official controls shall be applied, with the same care, to products within Community, to products imported from the third countries or to products exported outside Community. (Art. 3 (4) Regulation on Official Controls);
6. In case of non-compliance or breach law identification a timely and appropriate measures shall be adopted at national level throughout the Community to ensure remedy.

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<sup>5</sup> Official controls with regard to harmful organisms to plants and plant products are already adequately ensured by Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community, as amended (see point 8 Regulation of Official Control Recital).

<sup>6</sup> Technical guidelines are not binding but they are useful for better implementation of Community regulations and they shall be taken into account according to article 43 (1) of Regulation on Official Controls. The importance of the guidelines lies in promotion consistent, comprehensive and integrated approach to the operation of controls.

### 3. OFFICIAL CONTROLS IN THE CZECH REPUBLIC

The Czech national control system within food and feed safety area has been developed during more than last ten years. Regulation on Official Controls brings other new requirements which shall be implemented into national control system. Ministry of Agriculture in cooperation with other relevant subjects prepared MANCP for time period 2007 – 2009 in compliance with articles 41 – 43 Regulation on Official Controls and with respect to Commission Decision on Guidelines<sup>7</sup>. The MANCP summaries control systems in relevant areas in the Czech Republic and it is groundwork for planning, development and coordination of control activities.

In the Czech Republic official controls are carried out by competent state administrative authorities in the way of administrative supervision including monitoring. There are two central state administrative authorities, **Ministry of Agriculture** and **Ministry of Health**, which have powers to manage, control and coordinate administrative supervision performance, which is carry out by specialized administrative bodies. Ministries ensure instance control in relation to competent administrative body decision making. They are also responsible for making legal basis<sup>8</sup> for the official control performance.

It was already said above that performance of official controls is ensured by specialized administrative bodies within their law set competence. The structure of the Czech national control system is represented in Picture 1.

There is specification of competence scope of competent administrative authorities subordinated to the Ministry of Agriculture below:

- **State Agriculture and Food Inspection Authority**<sup>9</sup>, which is responsible for controls on agricultural products, foodstuffs including raw materials if there has no power another administrative authority;
- **State Veterinary Administration**<sup>10</sup>, which is responsible for controls on products of animal origin including raw materials, animal health and animal welfare. There is also the **Institute for State Control of Veterinary Biologicals and Medicines**<sup>11</sup> with a specific position (administrative body established by Ministry of Agriculture but subordinated to State Veterinary Administration), which is responsible for controls on veterinary medicines;

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<sup>7</sup> Commission Decision of 21 may 2007 on guidelines to assist Member States in preparing the single integrated multiannual national control plan provided for a Regulation (EC) No 882/2004 of the European Parliament and of the Council

<sup>8</sup> With the exception of general binding Community regulations legal basis for official controls comprise several laws.

<sup>9</sup> Its competence arises particularly from the Act No 146/2002 Coll., as amended, the Act No 110/1997 Coll., as amended, and the Act No 321/2004 Coll., as amended.

<sup>10</sup> Its competence arises particularly from the Act No 166/1999 Coll., as amended, the Act No 110/1997 Coll., as amended, and the Act No 154/2000 Coll., as amended, the Act No 246/1992 Coll., as amended.

<sup>11</sup> Its competence arises from the Act No 166/1999 Coll., as amended, and the Act No 378/2007 Coll., as amended.

- **Czech Institute for Supervising and Testing in Agriculture**<sup>12</sup>, which is responsible for controls on feedingstuffs;
- **Czech Breeding Inspection**<sup>13</sup>, which is responsible for controls on identification and registration of animals;
- **State Phytosanitary Administration**<sup>14</sup>, which is responsible for controls on plant health including plant protection products;

The Ministry of Health together with **Regional Public Health Offices** as public health protection authorities<sup>15</sup> are responsible for controls on food hygiene on catering.

Partial aspects of official controls come under competences of other central state administrative authorities. Ministry of Finance by force of Custom Administration participates on import controls. Radioactive contamination monitoring is carried out by State Office for Nuclear Safety. However state authorities mentioned in this paragraph have no competent authority status in accordance with Regulation on Official Controls. Their findings within their legal powers are impulse for above mentioned competent authorities.

In my opinion there should not be neglected an organic farming issue in the Czech national control system. There are rather specific requirements on controls on this area<sup>16</sup> but these don't exclude application of Regulation on Official Controls even the fact that controls on this area are carried out by private bodies<sup>17</sup> control approved by Ministry of Agriculture. These private bodies are commissioned for control performance except of imposing enforcement measures.

With respect to number of competent authorities it is necessary in compliance with article 4 (3) of Regulation on Official Controls to ensure efficient and effective coordination among all competent authorities. Food Safety Coordination Unit has worked since 2002 inter-ministerial body for coordination activities of Ministries and administrative supervisory bodies and non-governmental organisations with exception of control activities. Ministry of Agriculture made reorganisation three years ago and Food Authority was established as one of ministerial section which coordinates control activities of subordinated administrative bodies and communicates with Ministry of Health.

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<sup>12</sup> Its competence arises from the Act No 147/2002 Coll., as amended, and the Act No 91/1996 Coll., as amended.

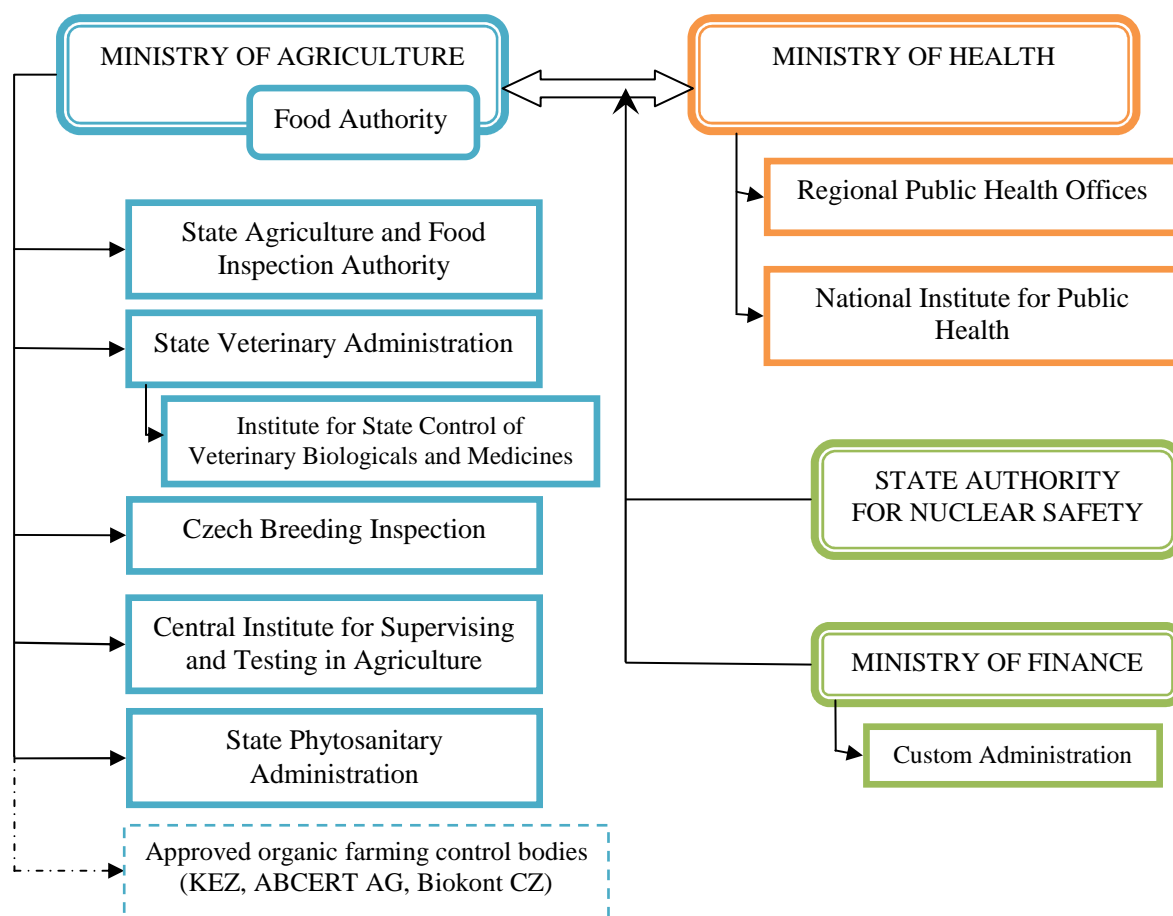
<sup>13</sup> Its competence arises from the Act No 154/2002 Coll., as amended.

<sup>14</sup> Its competence arises from the Act No 324/2006 Coll., as amended. State Phytosanitary Authority is not competent authority in accordance with Regulation on Official Controls. It was mentioned above that plant health is not subordinated to legal definitions in Regulation on Official Controls. But some aspects of official controls are applied to the plant health area, e.g. MANCPs. Therefore, authority dealing with plant health is an inseparable component of the national control system.

<sup>15</sup> Their competence arises from the Act No 110/1997 Coll., as amended and the Act No 258/2000 Coll., as amended. There is National Institute for Public Health established by Ministry of Health as a state contributory organisation which provides scientific support to public health protection authorities.

<sup>16</sup> Regulation (EC) (see footnote 4) and the Act No 242/2000 Coll., as amended.

<sup>17</sup> KEZ (beneficiary association), ABCERT AB (German company with branch in the Czech Republic), Biokont CZ (limited liability company)



Obrázek 1Czech National Control System

#### 4. FEED SAFETY AND CENTRAL INSTITUTE FOR SUPERVISING AND TESTING IN AGRICULTURE

The competent authorities for performing official controls shall meet a number of operational criteria. How some important requirements on official controls are satisfied is documented on feedingstuff controls which are primary organised by Central Institute for Supervising and Testing in Agriculture (CISTA).

It is necessary to say that CISTA is an experienced player within this area. CISTA has looked after feedingstuff area since the fifties of the last century. Nowadays there are two acts which stipulated a legal base of CISTA competence in this area. The Act No 147/2002 Coll. on CISTA, as amended, is a general legal regulation which lays down among others that CISTA performs administrative proceedings and carries out other administrative activities, expert and testing tasks and control and monitoring activities in accordance with special acts, the feedingstuff area is mentioned in letter b) of article 2 (1). The Act No 91/1996 Coll. on Feedingstuffs, as amended, is a special act which sets forth CISTA powers to supervise compliance with obligations imposed by this Act and by Community legal regulations<sup>18</sup>.

<sup>18</sup> They include those rules which are directly applicable on natural persons and legal entities. Regulation (EC) No 183/2005, Regulation (EC) No 1831/2003, Regulation (EC) No 999/2001, Regulation (EC) No 1774/2002,

CISTA follows triennial control plan which is included in MANCP. Moreover there is drawn up a control plan for each year extra. Recently, there were made some changes in CISTA organisation structure with the purpose of improved implementation of article 4 (2) letter a) and (4) Regulation on Official Controls; requirements on effectiveness, impartiality and consistency of official control could be ensured in better way. The Official Control Section was established and three divisions were formed within this Section. Staff of Division of Agricultural Inspection which is decentralized into 6 regional departments carried out on spot controls, on farms and in establishments. Division of Feedingstuff and Soil Safety prepares control plan, performs supervising execution and provides other related administrative or expert activities. The third one, Division of Animal Production, is responsible for feedingstuff biological testing<sup>19</sup>.

CISTA control staff is assisted by CISTA National Reference Laboratory (NRL) which is official laboratory according to the article 12 Regulation on Official Controls. NRL carries out the analysis of samples taken during the controls. NRL is accredited in accordance with ISO17025 by the Czech Accredited Institute (compare with Art. 12 (2) letter a) Regulation on Official Controls). Moreover, two of NRL departments<sup>20</sup> have been designated as national reference laboratories for Community reference laboratory in compliance with article 33 Regulation on Official Controls.

However, some special control tasks, which are connected with feed safety, are performed in cooperation with other competent authorities. State Veterinary Administration is responsible for controls on imported feedingstuffs of animal origin. CISTA in cooperation with State Veterinary Administration carry out controls on animal by-products (just on feedban and aspects related to feedingstuffs). The other one, Institute for State Control of Veterinary Biologicals and Medicines performs controls on medicated feed. CISTA should also cooperate with Customs Administration in the field of imports of plant origin feed. Effective coordination of above mentioned activities is ensured by Food Authority of the Ministry of Agriculture.

Suitably qualified and experienced control staff together with adequate laboratory capacity should help to perform officials control in effective and appropriate way. Most of CISTA control staff has university degree in relevant expert field. CISTA organises regularly trainings and seminars for its staff on new legislation or control proceedings. The guideline for the qualification of the staff was drawn up for this purpose. The aptitude for multidisciplinary cooperation (see Art. 6 letter c) Regulation on Official Controls) could be found in integration of controls in feed, soil and fertilizer area at the primary production level (on farms) in future.

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Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Regulation (EC) No 178/2002. For details see <http://eur-lex.europa.eu/en/index.htm>.

<sup>19</sup> Biological testing means efficiency and safety determination of feedingstuff or additive. It is not very appropriate that CISTA performs biological testing because CISTA simultaneously control results of biological testing when the feed business operator applies for permission to produce or to distribute feedingstuff extracted with using of new technological procedure. There is no security that the control impartiality is ensured in adequate way.

<sup>20</sup> Regional Department of NRL in Brno in area of heavy metals in feedingstuffs and Regional Department of NRL in Opava in areas of feed additives and mammalian tissue presence in feedingstuffs

Feedingstuff controls are planned and carried out on a risk based analysis<sup>21</sup> in compliance with article 3 (1) Regulation on Official Controls. Division of Agricultural Inspection carries out both routine and targeted controls. Routine controls are focused on industrial production, primary production, transport and imports<sup>22</sup> in general whether the conditions setting down in approval or registration are satisfied and whether relevant legal requirements are complied with (e.g. feed hygiene, labelling). Routine controls include all types of products (compound feedingstuffs, additives, premixtures, feed material) without exception. Targeted controls are concern with problematic areas. Nowadays dioxine, mycotoxine or genetic modified organisms are the objects of targeted controls. There are also carried out extraordinary controls, which emerge from complaints or RASFF<sup>23</sup> notifications. If it is necessary, additional controls are carried out in order to verify compliance with imposed correct measures or to prove repeated breaches of relevant legislation. Finally, monitoring of undesirable, prohibited and polluted substances (e. g. heavy metals, persistent organic pollutants, dioxine, mycotoxine, antibiotics, growing stimulators) in feedingstuffs in accord with Commission recommendations is performed by Division of Feedingstuff and Soil Safety. Number of controls in general depends on CISTA personnel capacity and on number of controlled establishments. It is possible to state that controls covered whole feed chain from primary production to distribution of feedingstuffs in compliance with article 3 (3) Regulation on Official Controls.

Controls itself are carried out according to the Act No 552/1991 Coll. on State control, as amended, which lays down the principal rules for control activities, and the Acts on feedingstuffs and on CISTA, which lay down other specifics for feedingstuff area. These legal regulations ensure legal powers for CISTA staff to carry out official controls (see Art. 4 (2) letter e) Regulation on Official Controls). Control staff shall be free from any conflict of interest and the impartiality of official controls shall be ensured (see Art. 4 (2) letter b) and (4) Regulation on Official Controls). It is set down in article 10 of the Act on State control that controls must not be performed by persons that could be prejudiced in relation to controlled persons or to control objects. Furthermore there is applied controlled rotation of control staff from inspection to inspection in CISTA for this purpose. It is not obvious from the legal regulations whether the controls are carried out without prior warning (see Art. 3 (2) Regulation on Official Controls). There is only prescribed that the start of control and the enter into establishment shall be notified to controlled person. The consistency and unique control quality is ensured by many guidelines and methodologies which afford unified base for control performance considering current law.

Official controls are usually carried out in the form of inspections, audits or verifications. Monitoring is also applied as mentioned above<sup>24</sup>. All sampling and analysis methods used by

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<sup>21</sup> There are four main criteria for risk categorisation: type of feedingstuff, production scope, type of establishment and previous control results.

<sup>22</sup> It was mentioned above that controls on imports of animal origin feed are performed by the State Veterinary Administration. Import of plant origin feed is probably not so usual. Moreover, the Czech Republic is not a typical point of entry. That is why there are no available documents on import control performance and rather poor cooperation between CISTA and Custom Administration.

<sup>23</sup> Rapid Alert System for Food and Feed (see <http://www.bezpecnostpotravin.cz/Index.aspx?ch=552&typ=1&val=71298&ids=0>)

<sup>24</sup> Compare with articles 2 (containing definitions) and 10 Regulation on Official Controls.



NRL are validated<sup>25</sup> and tested in proficiency tests. Three final samples<sup>26</sup> should be always taken in order to comply with article 11 (5) and (6) of Regulation on Official Controls. The provisions of Decree No 124/2001 Coll. conform to it.

The protocol is drawn up on each control containing control findings, drawbacks and broken provisions of legal regulations. Controlled person has to be informed on protocol content and to receive a copy of it. Control protocols as well as laboratory analyses are recorded in database and connected to database of registered or approved business operators. Records are available for control staff and serve for following control planning.

If the control detects any non-compliance, it is the reason for taking an action in order to be ensured that the remedy will be done by business operator. The article 18 of the Act on Feedingstuffs, which creates legal power to impose corrective measure to CISTA staff, refers to Regulation on Official Controls as for types of corrective measures. Provision of written notification of the decision to the operator concerning the action and imposing measures as well as information on rights of appeal against such decision is ensured by the Act on Administrative Procedure. Imposition of corrective measure shall be without prejudice to administrative or criminal liability application. Sanctions (fines) for infringements are laid down in the Act on Feedingstuffs. Whether they are effective, appropriate and dissuasive in compliance with article 55 (1) Regulation on Official Controls it is hard to say. It depends on more aspects than only fine rate. In case of extraordinary situations when the risk to human health deriving from feed is ascertained (e.g. rejection of feed consignment from third country) CISTA notifies it through RASFF. For this purpose CISTA has developed methodical instruction.

Achieving the objectives of Regulation on Official Controls shall be supported by internal or external audits<sup>27</sup> which each competent authority including CISTA shall undergo. The purpose of audit system is to verify whether official controls are carried out as intended, effectively implemented and suitable to achieve the objectives of the relevant legislation including compliance with MANCP. In this context CISTA has adopted following measures:

- New independent Division of Audit and Quality Management was established and is directly subordinated to Director General;
- ISO 9001 will be implemented by the end of 2009 in CISTA.

Besides, Community general and specific audits are carried out by Commission experts in all Member States. These audits verify that official controls take place in Member States in accordance with MANCPs and in compliance with Community law.

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<sup>25</sup> Decree No 124/2001 Coll. lays down requirements on sampling and laboratory testing principles with respect to Community law.

<sup>26</sup> The first sample is used for analysis in labs. The second one is controlled if the controlled person asks for the second analysis. The third sample is being kept in case of infringements or of appeals.

<sup>27</sup> Audit means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives (see Art. 2 (6) Regulation on Official Controls).

## 5. CONCLUSION

It is evident that official control performance in feedingstuff area is ensured in an appropriate way. Not only CISTA flexibly adapts to new requirements on official controls. There could be mentioned some problematic points, e.g. import control or cooperation with Custom Administration or “real” control impartiality. In 2006 there was drawn up the country profile on how control systems for food and feed safety, animal health, animal welfare and plant health are organised in the Czech Republic. It should be updated in this year. Feedingstuffs area is one of areas free from any deficiencies. Maybe only implementation of article 7 Regulation on Official Controls should be truly criticized. *The competent authorities shall ensure that they carry out their activities with a high level of transparency. For that purpose, relevant information held by them shall be made available to the public as soon as possible.* Of course the confidentiality principle shall be kept in some justified cases. However, public must have access to information on the control activities of the competent authorities and their effectiveness. Access to information at the request is ensured by relevant legislation<sup>28</sup> in the Czech Republic. But active access to above mentioned information, e.g. through websites of CISTA or Ministry of Agriculture, is dismal. It is not possible to find there the Annual report on the Implementation of MANCP or MANCP itself<sup>29</sup> or the Annual report on CISTA activities or other relevant information<sup>30</sup>.

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<sup>28</sup> The Act No 106/1999 Coll. on Free Access to Information, as amended. The Act No 123/1998 Coll. on the Right to Environment Information, as amended.

<sup>29</sup> Compare with <http://www.food.gov.uk/foodindustry/regulation/europeleg/feedandfood/ncpuk>

<sup>30</sup> Compare with <http://www.szpi.gov.cz/cze/cinnost/kontrola/default.asp?cat=2184>