Comments of the Ministry of Health to the Draft Report of a mission carried out in the Czech Republic from 26 May to 04 June 2008 in order to evaluate the systems in place to control the Salmonella risk in the table egg sector.

To separate articles of the draft of the final report (return, statement):

Summary

Totally untrue is the statement that in the Czech Republic, there has not so far been performed a corresponding epidemiological investigation in relation to the occurrence of the salmonellosis and the veterinary authorities are never engaged to investigation of foodborne diseases. The team of the mission on the basis of the visit of the only one region effected the general conclusion which was applied to the whole Czech Republic. SVS (State Veterinary Administration) is engaged in the investigation every time it is relevant. Such case occurred in 2006 in the region of Central Bohemia when there the salmonellosis disease was investigated with 14 people in the company catering. KHS then contacted the responsible SVS officer in the respective region.

Concerning the relatively high occurrence of salmonellosis in comparison with the EU average, it is necessary to point out that the report system in frame of EU is not unified and the data are therefore incomparable. In the year 2007, from 18,000 reported occurrences of salmonellosis, only 3.7% had epidemiological character. With the largest part, it did not come off any connection with the consumption of a particular type of food.

According to the EFSA standpoint adopted on July 9th, 2008, at the level of EU, there has existed a variety of different approaches for determination of particular foodstuffs which caused a foodborne disease of human, however, none of them is sufficient on its own. Hence, it is not evident what the team of the mission considers to be the "corresponding epidemiological investigation". On top of that we assume that these issues already exceed the original focus of the mission, then "Evaluation of the systems in place to control the Salmonella risk in the table egg sector".

Article 5.2.1

We then propose to adjust the sentence in the first paragraph in the following form: "One more control body Czech Agriculture and Food Inspection Authority (CAFIA) of the Ministry of Agriculture is in charge of controls of eggs at retail level."

We further propose to replace the second paragraph with the following text:

In frame of the Ministry of Health are solved the issues of the food safety and salmonellosis in humans by the section of the Chief Public Health Officer, Public Health Protection. Department. This department, among others, deals with the methodical guidance of 14 Regional Public Health Protection Departments. The territorial jurisdiction of the Regional Public Health Protection Department is geographically divided into smaller units, formerly called districts. Districts have local offices which are part of the Regional Public Health Protection Departments and these are directly governed by the Director of the Regional Public Health Protection Department.

Article 5.2.2

Incorrectly is also mentioned an information about the mutual cooperation of Regional Public Health Protection Department and State Veterinary Administration. According to 63 of the Law no.258/2000 Col. about the Protection of public health, the competent authorities immediately report to one another any occurrence of contagious disease from animals on man and when carrying out any measures against infections they fully cooperate. Authorities of veterinary administration report to the bodies of protection of public health even a death of an animal from such infection. On regional basis infectious foodborne diseases are investigated by Regional Public Health Protection Department staff - unit of the food hygiene in cooperation with the department of epidemiology and the regional office of State Veterinary Administration. Ministry of Health is informed about the situation. Within every region there is established an infection commission compounded of representatives of Regional Public Health Protection Department and State Veterinary Administration which solves the issues concerning infections which may affect a higher volume of population.

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Communication between the Regional Public Health Protection Department and State Veterinary Administration proceeds on several levels:

- 1. In case of a sudden occurrence of outbreak when there is as a bacteria causing disease or there is a suspicion on a food of an animal origin, the information is from operative reasons passed on to by the fastest communication means accessible, i.e. via telephone or e-mail.
- 2. In other cases, the SVA is informed in the form of regular weekly reports. As evidence there are weekly reports from the 9th, 16th and 29th week which contain information about occurrences of salmonellosis in 2007. These reports were sent to SVA by email, which is considered a formal way of communication.

Members of the team were during the visit of the Regional Public Health Protection Department submitted the report and as well it was possible to verify that SVS really regularly receives the reports. Therefore, it is quite incomprehensible, why the team of the mission brings in that SVA has never been informed about cases of salmonellosis diagnosed on people.

Further we do not agree with the statement that SVA gets to know about salmonellosis cases on the basis of periodical reports whose frequency may range to the extent of weeks, months or a year. Weekly reports are carried out always, similarly are carried out the monthly statements and annual reports. SVA therefore receives the information within one week at the latest, not on the basis of the annual report as it is stated in the conclusion of the Article 5.3. Also this was explained to the team of the mission.

5.3.

Not all but most salmonellosis is reported by the doctors, hospitals or laboratories and further confirmed bacteriologically.

Therefore we propose to omit the sentence: "Data concerning sporadic and epidemic episode of salmonellosis are stored at a district level." In reality, the data is saved in a database EPIDAT, access to which only has an entitled worker on any organizational level.

Data about sporadic and epidemiological occurrences are sent from the Local Office to the Regional Public Health Protection Department which further sends it to the Ministry of Health and The National Institute of Public Health then carries out its centralization and statistic scoring.

It is not true that eggs and egg products has never been analyzed. In frame of monitoring of dietary exposure - Mikromon project, the occurrence of selected pathogenic bacteria including bacteria Salmonella spp. in foodstuffs from market is being monitored. Results of this monitoring are then transferred to SVA at the regional level.

Concerning taking of samples in relation to the investigation of salmonellosis and foodborne diseases generally, it is necessary to take into account the fact that the involved person generally visits the doctor sometimes even with several-day delay. Then another two days are needed to assess bacteria Salmonella in the swab of the involved person. After this time (4-5 days) it is almost impossible to track the suspicious food, nevertheless the samples of foodstuffs on the place are taken to be available including swabs from the environment. In any case, the investigation is always carried out. The fact that the foodstuffs are in the time of the investigation mostly consumed is difficult to influence in any way.

RPHD have, according to the Law no.258/2000 Col., the possibility to order an business operator taking and storing of samples of served dishes, in case it is needed for ensuring safety of served dishes or for reasons of suspicion on arising of an infectious disease from dishes and then determine the scope and time of fulfillment of this responsibility.

It is impossible to agree with the remark that the only way the SVA learns about salmonellosis disease on people stays the periodical report. As mentioned above, in case of emergency, SVA is informed immediately by any accessible communications means.

In the last paragraph, the team of the mission mentions, that in the case of one epidemic in 2007, RPHD identified as possible vehicle an egg but because eggs did not have overdue expiry date, further investigation was not carried out. Hereto cannot take a standpoint to this issue, because it is not evident which epidemic was meant.

5.7

The second sentence in the first paragraph misquotes, that the Public Health Protection Department of Ministry of Health (PHD) is responsible for the checks in the area of catering; correct is that RPHD is the responsible body because the Ministry of Health does not carry out official checks.

In the paragraph "Catering" we propose to shorten the sentence in the following form: "The RPHD officials are in charge of control in catering." Correct handling with the eggs is the responsibility of the business operator not the supervisory body.

To the remark that until now it was not counted with the special task focused on taking egg samples and samples of egg products we mention that there has been no reason to this. Incidence of salmonellosis is in the Czech Republic quite high, however, the number of salmonellosis in catering is very low, e.g. in 2007 there were only 6 outbreaks. On that account the supervisory body did not consider necessary to focus its activity in this direction. Eggs as well as meat are generally considered a risk food and it is the responsibility of the business operator to have established such techniques including thorough heat treatment which ensures that the final dish will be safe. On this account is more efficient the preventive approach of checks of established procedures based on principles of HACCP.

Targeted tasks focused on particular questions are proclaimed by the Ministry of Health every year. In previous years it was e.g. monitoring the occurrence of bacteria Listeria monocytogenes in product which support its growth, further there were tasks focused on frozen products, vegetable salads, non-pasteurized fruit juices, ice-creams, etc. In 2008 it was decided, mainly in concurrence on NSCP/s realized by SVA and on the basis of the results of Mikromon monitoring it was decided to carry out monitoring of occurrence of salmonellas in catering. Additionally, the focus of EC mission has been also taken into consideration. In any of the egg and egg products samples taken there was not found any trace of bacteria Salmonella. Another task focused on monitoring of occurrence of salmonella in catering is planned for 2009.

It is not true that the supervisory body has not made a follow-up check in relation to the foodborne outbreak. Just the check, at which the mission team was present, was the follow-up check in this facility. During the check in relation to the epidemic, all deficiencies which could have resulted in the occurrence of the disease were removed immediately. Only the check of air-conditioning regulation was carried out at the day of the visit of the mission. The supervisory authority however assumes that the air conditioning, in this case, did not present the risk for foodstuffs. Quoted Regulation 882/2004, article 8, point 3 requires that the competent authorities introduce procedures of verification of the effect of official checks that have been carried out and to ensure that the corrective measures are accepted in case of need. The way of the introduction of these procedures here at the regulation does not mention. Thereby that the corrective measure was accepted immediately and the business operator removed the deficiencies without delay, yet in the time of the check, it is possible to regard the check as effective.

5.7.1

In the draft of the report it is stated that the traceability system has been established recently, on the basis of the recommendations of the supervisory body. With this it is impossible to agree because the traceability system in this premise was introduced already in 2004 as a part of procedures based on HACCP principles. At that time, according to national Decree No.107/2001, there was a duty of premises from certain capacity of produced dishes to have such procedures established. Possible mixing of the eggs of different ranks was not considered as an insufficiency by the supervisory body because the premises have the sole supplier of eggs. Its traceability then is not baffled by mixing of different batches. Beyond that, Article 18 of the Regulation 178/2002 determines that business operator must be able to identify the company which delivered the particular food to them. This duty was fulfilled by the business operator by submitting the necessary delivery documentation and labels by which are the carriage boxes for eggs equipped. According to the opinion of the supervisory body, the business operator then fulfilled the request of monitoring within the range of Reg.178/2002.

Concerning the missing stamps on some eggs, we would like to state that the eggs are purchased in mass packages of 180 pcs. Each box is labelled. EU Council Regulation 1028/2006 in Article 28 tolerates a deviation of 20% of eggs with illegible stamping, in the report here at is not mentioned what percentage of eggs was unlabelled.

The report further mentions alleged bad hygienic practice at storing eggs on the premises, however, it is not evident wherein the team of the mission sees the bad hygienic practice. Eggs were stored in a separate, clean cool room equipped by thermometer, records about monitoring of temperature were part

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of the HACCP procedures. Eggs were carried to production parts to a special sector where they are broken in special boxes earmarked to this purpose. Handling with the eggs is carried out in the way to minimize the risk of food contamination and the supervisory body considers the requirements of the Annex of Rag. 852/2004 as fulfilled.

6.

In the conclusions it is wholly untruly stated that there does not exist any cooperation among supervisory bodies concerning monitoring and control of salmonellosis. Above mentioned there are several cases which contradict this statement.

To the second point of the conclusions we mention that the Public Health Protection. Department of the Ministry of Health really does not carry out full epidemiologic investigation because this activity is commended to the Regional Public Health Protection. Department. But not even in this case it is possible to agree with the conclusion. It is also unclear what the team of the mission understands under a concept of "complete epidemiological survey". About as good as it can be, the investigation is carried out every time including the sporadic occurrences without apparent or demonstrable epidemiologic context, of course, completeness of gained data can differ among single cases because it is affected by many factors.

8.

To recommendation No. 1: Cooperation with SVA will be formalized in detail. Mutual meeting is planned where the extent of the performed epidemiological investigation of each supervisory authority will be specified. Due date: till the end of 2008.

To recommendation No. 2: A legislative measure will be considered.

To recommendation No. 6: Within the official inspections it is always required to remove deficiencies according to the requirements of Amendment II Reg. 852/2004 and this is furthermore verified by the form of follow-up checks.