THE ZOONOSES REGULATIONS – NEW APPROACHES TO REDUCING ZOONOTIC PATHOGENS

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SUMMARY

The zoonoses regulations consist of two legal acts, i.e. Regulation (EC) 2160/2003 on the control of *Salmonella* and other specified zoonotic agents, which is direct applicable in each member state, and the Directive 2003/99/EC. They are amended by specific regulations and on the food safety side by Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs. This regulation defines process hygiene and food safety criteria. Targets set by the zoonoses regulation upon the data derived through baseline studies according to the zoonoses directive can result in stricter microbiological food safety criteria according to the regulation on microbiological criteria in foodstuffs.

Keywords: zoonoses, zoonotic agents, monitoring, food safety

INTRODUCTION

The so called zoonoses regulations of the European Community consists mainly of two legal acts, i.e. Regulation (EC) No 2160/2003 (EC, 2003b) on the control of *Salmonella* and other specified zoonotic agents, which is direct applicable in each member state, and the Directive 2003/99/EC (EC, 2003a) on the monitoring of zoonoses and zoonotic agents, which is a guidance act to be implemented in each member state. Meanwhile also more specific regulations have been issued with specific targets like *Salmonella* in laying hens (Regulation (EC) No 1168/2006) (EC, 2006). The goals of those legal acts are two-fold. First of all the current situation concerning important zoonotic agents within the Community should be evaluated by monitoring programs, including baseline studies. Secondly targets for prevalence rates should be set in order to achieve a reduction in the prevalence of the major zoonotic pathogens. The success of those methods will again be monitored at each step, so that targets can be set lower over time. The first goal (monitoring) is described by the Directive, the second one by the Regulation and its amendments. In the following, the approaches of the Directive and the Regulation will be described and methods and targets will be discussed.

On the food safety side the Commission Regulation (EC) No 2073/2005 (EC, 2005) on microbiological criteria in foodstuffs completes the picture. In this Regulation microbiological criteria in the process line and the endproduct are set for the main zoonotic agents and foodstuffs. Depending on the sampling site process hygiene criteria (during processing) and food safety criteria (for the endproduct) are defined. Thus, the zoonoses regulations and the Regulation on microbiological criteria in foodstuffs are linked and fill the gap between the efforts for animal

health and food safety in the primary production and the food safety issues in the food producing and marketing sector.

DIRECTIVE 2003/99/EC – THE MONITORING DIRECTIVE

The goal of the Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents is to ensure that zoonoses and zoonotic agents, their respective antibiotic resistances and foodborne outbreaks are monitored in an epidemiological way. Changing tendencies over time should be detected and possible sources be identified. The data should be sampled and analysed in a Community zoonoses report. This has been done also previously, but the analysis of the data was not systematic and there was no common approach within the member states (Hartung, 2004). Those data should then be used for a scientific microbiological risk analysis according to Codex Alimentarius (CAC, 1999).

The existing systems of the member states could be used, however if necessary, harmonisation is possible. Indeed, the responsibility to create and publish the Community zoonoses report was transferred from the EC Commission to the European Food Safety Authority (EFSA), which was established according to the basic Regulation (EC) No 178/2002 (The General Food Law) in the year 2003 (EFSA, 2007). In each member state a standardised sampling of relevant data should take place and the results should be forwarded in a standardised format to the EFSA database. EFSA will then compile a "Community Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Antimicrobial Resistance in the European Union" for each year (EFSA, 2007). The EFSA expert panel on Biological hazards will give advice on the final report (EFSA, 2007). In Germany also a national report on the epidemiological situation of zoonoses, zoonotic agents, antimicrobial resistance and foodborne outbreaks is issued (Hartung, 2006).

There are also routine monitoring programmes implemented in member states concerning the antibiotic resistance in relation to zoonotic agents. Especially resistance patterns of zoonotic agents from animals reared for food production and from food itself are registered. Trends in the change of those resistance patterns should be detected and also the early detection of new, emerging resistances. This includes where possible also the emergence of new resistance mechanisms. In addition, differences in different geographic regions should be detectable.

The quality of these data greatly depends on the representativity of the isolates and the sample size (n). The latter factor is the denominator for the precision of the analysis.

Antibiotic resistance can be monitored successively in three areas. The monitoring can include zoonotic agents (e.g. *Salmonella* spp., *Campylobacter jejuni* and *C. coli*) from food at the retail level (incl. pork meat, beef, poultry meat, food containing raw eggs). Another source are isolates from clinically healthy animals (used for food production) concerning the same agents. In addition clinically ill animals (used for food production) can be sampled similarly.

Coordinated control programs of all member states complete the data set initiated by the monitoring Directive 2003/99/EC. So far coordinated control programs started for *Salmonella* spp. in laying hens and broiler. They will be followed by programmes dealing also with other animal species like turkey and fattening pigs and other zoonotic agents.

Those baseline studies should deliver prevalence data, which are comparable between member states and should state the real "base" line for future considerations. This baseline will serve then as the basis for future targets to be implemented by the control regulation, the Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified zoonotic agents. In the first years experience with the control programmes has to be gained. In the future those programmes should

be mandatory in order to reach the implemented target. In Germany the baseline study for *Salmonella* spp. in broiler chicken has been recently performed and published (BfR, 2006).

REGULATION (EC) NO 2160/2003 – THE CONTROL REGULATION

Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified zoonotic agents sets the scene for the establishment of Community targets, for reducing the prevalence of zoonotic agents with public health significance in animals used for food production. The targets should include as defined in the Regulation the maximum time limits within which the targets shall be reached, the definition of epidemiological units, the definition of the testing schemes necessary to verify the achievement of the targets and, where relevant the definition of the agents with public health significance. Before proposing rules on specific control methods, the Commission should consult the European Food Safety Authority (EFSA). An excerpt from the Regulation on the time limits is given in Table 1.

Table 1. Maximum time limits within which the targets for zoonotic agents should be reached according to Regulation (EC) No 2160/2003

1. Zoonosis or zoonotic agent	2. Animal population	3. Stage of food chain	4. Date by which target must be established (*)	5. Date from which testing must take place
All salmonella serotypes with public health significance	Breeding flocks of *Gallus gallus*	Primary production	12 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Laying hens	Primary production	24 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Broilers	Primary production	36 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Turkeys	Primary production	48 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Herds of slaughter pigs	Slaughter	48 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Breeding herds of pigs	Primary production	60 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4

(*) These dates are based on the assumption that comparable data on prevalence will be available at least six months before the establishment of the target. If such data were not available, the date for the establishment of the target would be postponed accordingly.

REGULATION (EC) NO 2073/2005 – THE FOOD SAFETY REGULATION

The Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs translates the foodborne pathogen targets defined by the zoonoses control regulation (Regulation (EC) No 2160/2003) into food safety criteria. The regulation differentiates between process hygiene criteria and food safety criteria. Process hygiene criteria apply for all stages of the production process until the food leaves the process line for the retail level. Those criteria are intended to control the process hygiene. Failing of the criterion must lead to an improvement in process hygiene like intensified cleaning and disinfection. Those criteria include also indicator organisms like *E. coli*. Food safety criteria apply solely at the retail level, where the endproduct is presented to the consumer. It concerns only foodborne pathogens like *Salmonella* spp. When a criterion is not met at this stage, revocal from the market is necessary or at least heat treatment of the product, when it has not been brought to the market.

An example concerning *Salmonella* spp. in broiler for the relationship between the zoonoses directive, the zoonoses regulation and the regulation on microbiological criteria following Table 1 can be given as follows:

Within primary production should have been performed in 2006, targets should be set in 2007 following the baseline study and control actions should start in 2009. In parallel the regulation on microbiological criteria in foodstuffs is in force since the beginning of 2006 with the criterion of absence of Salmonella spp. in 10g at the retail level. With the beginning of 2010 and in parallel to the above mentioned timeframe the criterion is absence in 25g at retail level, i.e. a stricter criterion is applicable.

In conclusion targets set by the zoonoses regulation upon the data derived through baseline studies according to the zoonoses directive can result in stricter microbiological food safety criteria according to the regulation on microbiological criteria in foodstuffs.

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