

## Food-borne zoonoses, the EU zoonosis legislation and the prospects for food safety and consumer protection during primary animal production

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### Lebensmittelübertragene Zoonosen, die EU – Zoonosengesetzgebung und Ausblicke auf Lebensmittelsicherheit und Konsumentenschutz im Rahmen der primären Tierproduktion

**Zusammenfassung.** Zoonosen sind Erkrankungen, die naturgemäß zwischen Tier und Mensch übertragen werden können. Die Kontrolle von Lebensmittel-relevanten Zoonosen innerhalb der Europäischen Union ist eine Grundvoraussetzung für die Sicherheit im internen Handel und repräsentiert demnach einen wichtigen Baustein in der politischen Agenda. Bedauerlicherweise war bis vor Kurzem das Schaffen eines klaren Überblicks über das derzeitige Vorkommen von durch Lebensmittel verursachten Zoonosen und die Prävalenz der diese hervorrufenden Agentien wegen des Fehlens von verlässlichen Überwachungs- und Dokumentationsprogrammen beeinträchtigt. Gleichzeitig wurde deutlich, dass europaweit nur begrenzter Erfolg in Hinsicht auf die Kontrolle wichtiger durch Lebensmittel übertragener Erreger wie *Salmonella* spp. verzeichnet werden. Die Europäische Union hat eine Gesetzgebung verabschiedet, die diese Situation beheben und die Kontrolle von durch Lebensmittel übertragenen Zoonosen in der Primärproduktion gewährleisten soll. Dieser Beitrag diskutiert die Anreize zur Einführung der EU-Richtlinie RL 2003/99/EG und EU-Verordnung VO (EG) 2160/2003, fasst ihre Kernaussagen zusammen und erörtert die Hauptauswirkungen beider Gesetzestexte auf die Prävention von durch Lebensmittel übertragenen Zoonosen. Schlussfolgernd gibt es in Bezug auf die humane Salmonellose einen Grund für vorsichtigen Optimismus, für andere durch Lebensmittel verursachte Zoonosen besteht jedenfalls noch Handlungsbedarf.

**Summary.** Zoonoses are diseases that are transmitted naturally between animals and humans. The control of food-borne zoonoses within the European Union is a prerequisite for assuring a functional internal market and consequently represents an important item on the political agenda. Unfortunately, until recently, gaining a clear view of the current incidence of food-borne zoonoses and the prevalence of its causative agents has been frustrated by the absence of reliable monitoring and reporting systems. Similarly, it has become clear that, Europe wide, one has witnessed only limited success with regard to the control of important food-borne agents such as *Salmonella* spp. The European Union has adopted legislation to remedy this situation and to control food-borne zoonoses in primary production. This contribution discusses the incentives for introducing EU Directive 2003/99/EC and EU Regulation No. 2160/2003, summarises their essentials and discusses major ramifications of both pieces of legislation for the prevention of food-borne zoonoses. It is concluded that there is reason for cautious optimism concerning human salmonellosis, while for other food-borne zoonoses there should be a call for action.

**Key words:** Zoonoses, food safety, EU legislation, *Salmonella*, veterinary public health.

### 1. Introduction

Zoonoses are diseases and disease agents that are transmitted between animals and humans in a natural way and they constitute a major part of the communicable disease burden. It appears that zoonoses represent the majority of emerging infectious diseases. Several transmission pathways exist for zoonoses, including those via food or drinking water, direct animal contacts or those mediated through insect or arthropod vectors, rodents or aerosols. In addition, zoonoses can be transmitted from person to person or from animal to animal.

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One or more 'new' zoonoses emerge every year. This implies that the public health authorities must remain vigilant and, if necessary, need to formulate appropriate control measures. Recent examples include SARS (severe acute respiratory syndrome), and HPAI (highly pathogenic avian influenza). Older examples of emerging zoonoses include enterohaemorrhagic disease caused by VTEC (verotoxinogenic *Escherichia coli*), salmonellosis caused by *Salmonella enteritidis* transmitted through eggs, and campylobacteriosis caused by *Campylobacter jejuni* and *Campylobacter coli*. Although the latter are examples of zoonoses transmitted via foods, none of the mentioned zoonoses are exclusively food-borne.

On the 1<sup>st</sup> of January 1993, the European Union (EU) initiated its internal market program involving free movement of capital, labour, services and goods, including foodstuffs, animal products and live animals. During the following decade the EU found itself faced with several serious animal health and food safety problems such as the bovine spongiform encephalopathy (BSE) epidemic, outbreaks of classical swine fever and foot and mouth disease, and became increasingly concerned about the persistent problem of endemic food-borne zoonoses such as salmonellosis and campylobacteriosis. The latter were often originating from foodstuffs placed on the market within the EU. It became clear that control of food-borne zoonoses was a prerequisite for assuring a good functioning internal market, not only for reasons of public health but also because national prevention strategies of zoonoses were inadequate and gave rise to unfair competitive advantages in the food trade.

Preceding the formulation of new legislation with regard to zoonoses and their control, the European Commission sought advice from its 'Scientific Committee on Veterinary Measures relating to Public Health (SCVMPH, whose tasks have currently been taken over by the European Food Safety Agency [EFSA], more in particular by EFSA's panels on biological hazards and contaminants). In its 2000 Opinion on Food-borne Zoonoses the SCVMPH concluded that there was a potential for significant improvement of the present food surveillance, control and inspection procedures, which – based on present knowledge – could revert the increasing trend in zoonotic food-borne diseases. The measures taken for combating zoonoses up to that moment were rated as insufficient. Hence, the SCVMPH suggested: i) introducing a new, more effective zoonosis monitoring system, ii) various measures that would create conditions to reduce the prevalence of zoonoses, and, iii) to consider adopting a number of new control measures [1].

In the past few years, the EU legislative bodies (Commission, Council and Parliament) have responded forcefully to this challenge by adopting new legislation for the control of zoonoses all along the food chain. This reflects that free movement of goods (including foodstuffs and live animals) and food safety assurance are linked political priorities.

The purpose of this paper is to review the current situation with regard to major food-borne zoonoses and

their control and to illustrate how, particularly in Northern Europe with regard to *Salmonella*, considerable progress has already been made. Also, it is discussed why and how further progress with regard to the EU *Salmonella* situation might be feasible in the years to come. In addition, the readership is familiarised with the recently issued EU legislation, that has come into force as of December of 2007. In the following the essential elements are presented.

## 2. Food-borne zoonoses in Europe and the inconsistencies in the detection and reporting of these

The primary objective of food-borne zoonotic pathogen control is to reduce the incidence of human disease. Ideally, this is achieved by elimination of the pathogen at the most appropriate stage(s) in the food chain. Where this is not feasible the alternative is to incrementally reduce the risk at various stages of production by introducing 'hurdles', i.e. taking measures that limit growth of or partially eliminate pathogens. Obviously, the latter should be combined with consumer information on the residual risks prevailing and how to manage these. However, certain pathogens occur ubiquitously or are rapidly spread over Europe as a result of the expansion of travel and/or trade within the EU or with third countries (see Tables 1 and 2). This challenges the efficacy of the various national programs to control zoonoses.

Food safety policies should be set in relation to the 'appropriate level of protection' (ALOP) [7]. In a number of cases the primary food safety initiatives do not directly relate to human disease but are rather targeted at achieving a tolerable level (i.e. concentration or prevalence) of the pathogen in food and/or in animals. Risk reduction should be achieved through integrated initiatives from animal feed mills through to the point of consumption of foods of animal origin. One instrument to improve food safety is meeting so-called 'food safety objectives' (FSO) [8]. An FSO is defined as the maximum frequency (prevalence) or concentration of a hazard in a food at the time of consumption that provides – or contributes to – the appropriate level of protection. 'Performance objectives' (PO), similar to FSO's, relate to the acceptable frequencies or concentrations of pathogens in the food chain before the point of consumption. Consequently, the conceptual tools for a modern food safety strategy should now be in place.

As regards the monitoring and surveillance systems (MOSS) of zoonotic pathogens, a major problem has been – and continues to be – that the methods of detection and reporting are not harmonised for most zoonotic agents of concern. As a consequence, prevalence data of the infection in animals, food contamination and incidence data of the disease in humans are generally not comparable within the EU. This is illustrated by Table 2 based on Community Zoonosis Reports from 1999 and 2000 [9, 10].

Moreover, the number of other (mainly non food-borne) zoonotic pathogens (e.g. tularemia) are, as of the year 2005, being collected on the Community level by the European Centre for Disease Control (ECDC),

**Table 1.** Human salmonellosis incidence in the 1997–2006 period (total number of cases per 100.000 inhabitants) in Austria, Finland and Sweden; for the latter two countries figures are broken down into proportion (%) of cases contracted domestically or through travel [2–6]

Year	Austria	Finland		Sweden			
	Total <sup>a</sup>	Total	Domestic (%)	Travel (%)	Total	Domestic and unknown (%)	Travel (%)
1997	94	56	27	73	53	22	78
1998	87	50	18	82	52	15	85
1999	88	49	26	74	58	23	77
2000	88	49	12	88	55	19	81
2001	90	53	15	85	53	19	81
2002	104	43	19	81	44	24	76
2003	103	41	15	85	42	28	74
2004	91	41	15	85	40	21	79
2005	65	45	18	82	40	20	80
2006	62	46	17	83	44	27	73

<sup>a</sup> A systematic breakdown ('domestic/travel') of Austrian figures is only available from the province of Styria for the year 2002. These figures exclude cases of *S. typhi* and *S. paratyphi* (reportedly exclusively associated with travels to Africa, South America, Asia) and are only based on analysis of serovars sent in by a limited number of 'primary laboratories'. Although said data suggest otherwise specific questioning of patients clearly indicate that the majority of cases is travel-associated (Dr. Christian Kornschober, Austrian Agency of Health and Food Safety, Graz, Austria; pers. comm.).

**Table 2.** Numbers of human VTEC / HUS cases in selected EU countries; taken from the Community Zoonoses Reports for the years 1999–2000 [9, 10]

Country <sup>a</sup>	VTEC cases 1999		VTEC cases 2000		HUS cases 1999		HUS cases 2000	
	Non-0157	0157	Non-0157	0157	Non-0157	0157	Non-0157	0157
Austria	28	2	20	3	2	2	2	3
Belgium	34	19	–	–	9	0	–	–
France	41	8	34	2	41	8	34	2
Germany	–	–	–	–	–	–	–	–
Portugal	–	–	–	–	–	–	–	–
Greece	–	–	–	–	–	–	–	–
England/Wales	–	1084	–	896	–	–	–	–

<sup>a</sup> Possible sources for discrepancies with regard to reporting include:

- In the 99/00 reports France made no distinction between VTEC and HUS, while Germany, Portugal and Greece did not report any case
- Belgium: no cases in 2000, although several EHEC cases occurred (van Hoof, pers. comm.)
- Germany, England & Wales reported no HUS cases for 1999/2000 although several reports were mentioned in literature.

while other viral zoonoses such as tick-borne encephalitis (TBE) are not routinely collected. Also, varying protocols and methods are used for sampling, analysis and reporting of one and the same zoonotic agent and/or disease between and within member states. Therefore, – the more so because member states do not consistently distinguish between diseases acquired domestically or those contracted during travel abroad – the currently available incidence data on human food-borne zoonoses from different EU countries are of limited value for comparisons between member states and also between years. Yet, it is particularly this type of information on human incidence coupled with information on prevalence in foodstuffs and primary production that informs the risk assessments for intra-community trade. A more appropriate approach to monitoring food-borne zoonoses in the EU is to meet the following objectives: i) to follow epidemiological trends in live animals and food; ii) to estimate the true incidence and disease

burden in each member state; iii) to compare data between EU member states; and iv) to detect early outbreaks of human diseases. In this regard, the EU monitoring programs ought to be targeted towards the major food-borne zoonotic agents such as *Salmonella*, *Campylobacter*, *Yersinia* and VTEC. A common definition of cases, terminology, sampling schemes, laboratory protocols and methodology is needed. Finally, through baseline studies monitoring is to be harmonised in terms of sampling procedure (at which point in the food chain, type of sample, number of samples and sample size, laboratory procedure).

### 3. Zoonosis legislation in the EU

#### 3.1 The situation during the period 1994–2004

Council Directive 92/117/EC, also referred to as the Zoonoses Directive [11], introduced requirements for

the surveillance of *Salmonella* in poultry breeding flocks and for monitoring and reporting of certain zoonoses on a national and EU level. This directive outlined reporting requirements for the following diseases: tuberculosis caused by *Mycobacterium bovis*, brucellosis (and agents thereof), salmonellosis (and agents thereof), trichinellosis, campylobacteriosis, echinococcosis, listeriosis, rabies, toxoplasmosis and yersiniosis; the reporting of *Escherichia coli* O157 was voluntary, whilst data on *Cryptosporidium*, viral zoonoses other than rabies and viral food-borne infections were not reported. This information was collected in the various member states, subsequently collated by the Community Reference Laboratory which was the German Federal Institute for Risk Assessment (BfR) and in the period 1994–2004 issued as the annual Community Zoonosis Report (within the EU generally referred to as ‘Trends and Sources of Zoonoses’).

The purpose of the annual Community Zoonosis Report was to provide reliable information on the human incidence of the defined zoonoses, as well as information on the prevalence of the associated zoonotic agents in animals and foodstuffs so as to facilitate risk management. However, the experience of one decade of reporting has shown that both detection and reporting methods were neither standardised nor harmonised.

Another point of concern has been that two parallel reporting systems for communicable diseases and zoonoses in humans were in place, i.e. one based on the afore-mentioned Directive 92/117/EEC, the other on Council Decision 2119/98/EC, which regulated the reporting of contagious diseases in humans including zoonoses [12]. This situation created confusion and superfluous work requirements for the member states. Following the advice of various stakeholders the European Commission (based on the road map outlined in the White paper on Food Safety as discussed by Daelman [13]) proposed a revised zoonosis legislation, which was adopted by the Council of Ministers and the European Parliament. Including a detailed presentation of the actual legislation would not fit the framework of this contribution. Instead, we will discuss its relevant elements and add some observations from the scientific perspective.

### 3.2 The new approach

European Parliament and Council have agreed on two legal acts on zoonoses, the *Directive* 2003/99/EC on the monitoring of zoonoses and zoonotic agents, (amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC), and the *Regulation* No. 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents, both of which were ultimately adopted in their final form on the 17th of November 2003 and were implemented during 2004 [14, 15].

In addition, the Community has adopted Regulation No. 178/2002, often referred to as the General Food Law, that laid down the general principles and requirements of food law and established the European Food Safety Authority (EFSA). Furthermore, the Community

adopted the ‘hygiene package’ consisting of 4 Regulations (No. 852, 853, 854 and 882/2004) that represent implementing legislation for the General Food Law.

With regard to preventive human medicine a major improvement has been the establishment of the new European Centre for Disease Control (ECDC) that commenced its activities in 2005. The remit and tasks of ECDC are laid down in Regulation No. 851/2004, a major one being the publishing of an annual epidemiological report on communicable diseases including zoonoses within the EU. The ECDC has a much more active role in risk analysis than has EFSA. For example, it facilitates the exchange of best practices for disease control and the operation of an early warning system for epidemics. ECDC also issues recommendations on risk mitigation strategies such as vaccination programs and occupational health protection procedures for operatives when handling birds with suspected avian influenza infections.

From the moment all these pieces of legislation came into force, the member states were to notify the EU Commission which competent authorities were responsible for their implementation. When more than one were involved the member states were obliged to ensure a good co-operation between them (Chapter I of Zoonoses Directive 2003/99). Experience has shown this to be a challenge.

#### 3.2.1 The new Zoonosis Directive

The Zoonosis Directive includes three elements of legislation dealing with: i) monitoring of zoonoses and zoonotic agents and antibiotic resistance in farm animals and food, but also wildlife and feed, including co-ordinated baseline studies, ii) investigating food-borne disease outbreaks; and iii) submitting to the EU Commission and to the European Food Safety Authority (EFSA) national ‘trends and sources’ reports annually.

#### Monitoring of Zoonoses (Chapter II) and Antibiotic Resistance (Chapter III)

As of the year 2005 EFSA produces the Community report on the monitoring of zoonoses and antibiotic resistance. EFSA has subcontracted the actual data collection to the Danish National Food Institute, and the collection of the report of food borne outbreaks to the German Federal Institute of Risk Assessment (BfR, Berlin).

The Zoonosis Directive identified in its Annex I two categories of zoonoses, i.e., category A and category B (see Table 3). In the case of category A zoonoses the monitoring of the disease as well as its agents is mandatory. Zoonoses and their agents ranked under category B are only then to be reported if the epidemiological situation requires this in a member state. Nevertheless, initially the reporting systems are based on the former system, considering an evolution is foreseen with implementing decisions to be taken in the years to come. For example the report on zoonoses for 2005 included BSE, avian influenza, cysticercosis, Q-fever and sarcocystosis [16].

It is interesting to note that rabies, yersiniosis and toxoplasmosis (monitoring of which diseases was still

**Table 3.** Category A and Category B zoonoses, as defined in Annex I of the EU Zoonosis Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents [15]

**Category A.**

Zoonoses and zoonotic agents to be included in monitoring

- brucellosis and agents thereof
- campylobacteriosis and agents thereof
- echinococcosis and agents thereof
- listeriosis and agents thereof
- salmonellosis and agents thereof
- trichinellosis and agents thereof
- tuberculosis due to *Mycobacterium bovis*
- verotoxigenic *Escherichia coli*

**Category B.**

List of zoonoses and zoonotic agents to be monitored according to the epidemiological situation

1. Viral zoonoses
  - calicivirus
  - hepatitis A virus
  - influenza virus
  - rabies
  - viruses transmitted by arthropods
2. Bacterial zoonoses
  - borreliosis and agents thereof
  - botulism and agents thereof
  - leptospirosis and agents thereof
  - psittacosis and agents thereof
  - tuberculosis other than in point A
  - vibriosis and agents thereof
  - yersiniosis and agents thereof
3. Parasitic zoonoses
  - anisakiasis and agents thereof
  - cryptosporidiosis and agents thereof
  - cysticercosis and agents thereof
  - toxoplasmosis and agents thereof
4. Other zoonoses and zoonotic agents

obligatory under the old Directive 92/117/EC) are now classified category B zoonoses.

As regards antibiotic resistance the Directive stipulates in Annex II that for monitoring to be useful, at least information is to be generated on: 1) the animal species included in monitoring, 2) the bacterial species and/or strains included in monitoring, 3) the sampling strategy used in monitoring, 4) the antimicrobials included in monitoring, 5) the laboratory methodology used for the detection of resistance, 6) the laboratory methodology used for the identification of microbial isolates, and, finally 7) the methods used for the collection of the data. It is also specifically required that the member states ensure that the monitoring system provides relevant information with regard to a representative number of isolates of *Salmonella* spp., *Campylobacter jejuni* and *Campylobacter coli* from cattle, pigs and poultry and food of animal origin derived from those species. However, more

specific implementing decisions are foreseen for this monitoring during the next 5–10 years as, for example, surveying cattle and poultry for *Campylobacter coli* does not make sense. It appears that indicator bacteria for antimicrobial resistance such as *Escherichia coli* and *Enterococcus* sp. will also be monitored during the next years. Major concerns are the findings of extended spectrum betalactamase (ESBL) intestinal bacteria in patients and methicillin-resistant *Staphylococcus aureus* (MRSA) in live animals and foodstuffs as well as in patients.

### Investigating food-borne disease outbreaks (Chapter IV)

A new requirement for the competent authority is to ensure that samples of suspect foodstuffs in a disease outbreak are preserved for further investigation. This investigation could include the epidemiological profile, the foodstuffs potentially implicated and the potential causes of the outbreak. Furthermore, the following data are to be reported to the Commission: a) the total number of outbreaks over a year, b) the number of human deaths and illnesses in these outbreaks, c) the causative agents of the outbreak, including, where possible, serotype or other definitive description of the agent; where the identification of the causative agent is not possible the reasons should be stated, d) foodstuffs implicated in the outbreak and other potential vehicles, e) identification of the type of place where the foodstuff incriminated was produced/purchased/acquired or consumed, and, finally, f) contributory factors, for example, deficiencies in food processing hygiene. This is the only remaining reporting requirement for human diseases in this legislation.

### Exchange of information (Chapter V)

By the end of May of each year, the member states are to report their data to the Commission. The Commission subsequently forwards the reports to the EFSA, that evaluates the various pieces of information and produces a consolidated report by the end of summer of that year on the situation in the entire EU in the preceding year. In this report EFSA shall also include the reports from the European Centre for Disease Control (ECDC) that collates the reports from the human health network from contagious diseases based on Council Decision 2119/98 and Regulation 851/2004. Furthermore, ECDC reports additional information as required by Council Directive 64/432/EEC [17], i.e. on tuberculosis and brucellosis. The Community reports on zoonoses and communicable diseases [18] are in the public domain and available for downloading at the EFSA and ECDC websites, respectively.

It should be noted that in the first report an extensive *status praesens* was to be formulated (i.e. for every zoonosis/zoonotic agent). Follow-up reports are focused on the changes from the initial situation as well as on data on the susceptible animal populations (number of herds and number of animals) and the number and description of the laboratories involved in monitoring activities.

Moreover, the Council of Ministers in agreement with the European Commission and Parliament requested EFSA to issue an opinion on the first Community summary report issued by EFSA [19]. The main conclusions were that i) salmonellosis and campylobacteriosis were the most commonly reported food-borne zoonoses, ii) the *Salmonella* problem is to a large extent caused by consumption of eggs and poultry meat contaminated with *Salmonella*, and iii) there is a need for a common strategy on data collection, monitoring and reporting to improve the usefulness of the data presented in the Community Summary Report.

### 3.2.2 The Zoonosis (or Salmonella control) Regulation

The reporting under the former Directive 92/17/EC strongly suggested that the majority of reported cases of food-borne zoonotic disease in humans originated from *Salmonella* and *Campylobacter*, as concluded in the SCVMPH opinion of 2000 [1]. During the last 5 years the salmonellosis situation in the EU has to some extent improved as evidenced by the decreasing trend in the number of cases. This is undoubtedly largely the result of several countries having implemented control programs. For instance, in Denmark such programs exist for pigs and for layers. The latter are based on serology and taking appropriate measures in heavily infected herds and on implementing a test and destruction strat-

egy [20] or on vaccination as practised in the United Kingdom for layers. This suggests that the control measures implemented in recent years have been more effective than the ones issued decades ago.

Also, Finland and Sweden have already rather effective national *Salmonella* control programs in place, the results of which illustrate that much can be achieved (see Tables 4 and 5).

The data from Finland and Sweden indicate a pre-harvest prevalence of 0.01–0.59% during the last decade. Although it is hard to ascertain the particular effects of each single element of these programs, the results are important.

For instance, the Swedish ‘test and removal’ approach (consisting of the surveillance of the breeding pyramids, of feeding stuffs production and primary production, coupled with the consistent elimination from the food chain of all products from which *Salmonella* is isolated) has been followed over a period of a total of 12 years since Sweden joined the EU. Obviously, the success of these programs remains dependent of constant updating of the policy as the structure of primary production changes and the costs for clean-up of holdings increase.

The aim of the Finnish national *Salmonella* control programme is to ensure that the prevalence of *Salmonella* is below 1% in production animals and in foods of animal origin. All *Salmonella* serotypes are included and the measures are the same, independent of serotype. Positive detection of *Salmonella* consistently leads to tak-

**Table 4.** Results of the Salmonella monitoring program in Finland and Sweden at farms and slaughterhouses; based on the annual national zoonoses reports for the years 1996–2006 [21, 22, 23]

Species	Type of sample	Finland			Sweden		
		Number of samples	Number of positive	Prevalence (%)	Number of samples	Number of positives	Prevalence (%)
Cattle	Lymph node	33538	49	0.15	35300	23	0.06
	Carcase surface	35186	52	0.15	35300	8	0.02
Swine (sows and fattening)	Lymph node	68723	90	0.13	63100	81	0.13
	Carcase surface	70349	30	0.04	63100	7	0.01
Flocks of laying hens	Faeces	27703	15	0.05	8710	43	0.49
Broiler and turkey flocks	Faeces	38430	227	0.59	35055	26	0.07
Poultry	Neck skins	NA	NA		45600	15	0.03

NA not available.

**Table 5.** Results of the Salmonella monitoring program in Finland and Sweden in cutting plants [21, 22, 23]

Sample origin	Sample type	Finland			Sweden		
		Number of samples	Number of positive	Prevalence	Number of samples	Number of positives	Prevalence (%)
Beef	Crushed meat <sup>a</sup>	28359	30	0.11	25500 <sup>b</sup>	2	0.01
Pork	Crushed meat	34400	8	0.02	25500	2	0.01
Poultry	Crushed meat	8488	30	0.35	11100	0	0

<sup>a</sup> ‘Crushed meat’ is composed of meat scraps originating from the processing – and other equipment. Such samples reveal the true exposure following the last cleaning and disinfectant cycle. <sup>b</sup> In Swedish figures the sample origin (beef or pork) was not recorded separately, total numbers have been split over animal species.

ing measures based on legislation to prevent the spread of infection and to identify the source of infection. In poultry production, all broiler and turkey flocks are tested for the presence of *Salmonella*. The test results of each broiler or turkey flock within four weeks before slaughtering should be informed to the slaughterhouse and to the meat inspection veterinarian. The *Salmonella*-positive flocks are slaughtered at the end of a working day and the plant is cleansed and disinfected after slaughtering. If the meat inspection veterinarian has not received this information before slaughtering the flock is considered to be *Salmonella*-positive.

Recently, the Swedish Board of Agriculture carried out a review of the Swedish *Salmonella* control program [24]. The main conclusions were that, assuming unchanged or improved food safety, possibilities for a more cost efficient control program could be identified. The most important conclusions of this review were that: i) all changes in the *Salmonella* control program should be risk based, ii) all food business operators are responsible for food safety, including freedom from *Salmonella*, which should be emphasized, iii) a voluntary biosecurity program should be introduced for cattle and pigs, iv) cost sharing should be introduced into the *Salmonella* reimbursement system; if there is third party negligence it should be possible to reclaim the costs, v) clean up and disinfection procedures of *Salmonella* infected herds can be improved, and finally, vi) the administrative burden of the control program can be eased.

A regular review is needed for keeping *Salmonella* control programs up-to-date, cost efficient and relevant for stakeholders. An evaluation of the Finnish *Salmonella* program has shown that the program is economically feasible for society [25]. The total annual costs of the program were calculated to be 0.02 €/kg broiler meat. Taking into account the costs of the program and the public health costs, the benefit-cost ratio was 4.0 compared to a situation without the program.

The fact that the European Community implements a *Salmonella* control does not mean that the member states are forced to strictly adhere to a fixed format. A fair degree of flexibility is built-in in the Regulation. Each member state shall propose its specific national program to the Commission for approval through a 'comitology' procedure (i.e. the Commission proposes and the member states approve by qualified majority in the Standing Committee on the Food Chain and Animal Health (SCFCA)).

The major control policy of the EU is to define *Salmonella* prevalence targets in primary production for each member state to be based on findings from the baseline studies, while leaving it up to the member states to design programs to attain these targets within 3 years. Nevertheless, such control programs have to be approved by the Commission. In this way the objectives for food safety are clear and to be timely achieved, while the approach to reach these objectives remains flexible. For member states with a high *Salmonella* prevalence in the baseline studies, the EU will initially define prevalence targets that aim at relative reduction, i.e. a 50% reduction of prevalence over 3 years. An initial chal-

lenge was to establish harmonised monitoring systems throughout the Community that would allow measuring the compliance of the targets. However, this has successfully been resolved with the coordinated baseline studies. From December of 2004 to December of 2008 a number of food animal species targets will be established consecutively, i.e. first chicken (breeders, layers, broilers) then turkeys, then pigs (slaughter, breeder stock). Table 6 (based on Annex I of the Regulation and implementing legislation) illustrates this scheme.

The industry organisations that in many member states are already actively involved in reducing the prevalence of *Salmonella* may integrate their control programs in these national programs, obviously subject to critical evaluation by the individual member states and, ultimately, subject to the Commission's approval. Annex II of the Regulation provides the general criteria for control programs as well as criteria for food and feed producers entering these programs. It is the ultimate goal of the Commission, from 2011 onwards not to allow the trade of fresh poultry meat unless '*Salmonella* is absent in 25 grams'. It should be noted that this requirement for *Salmonella* in poultry meat is also included as one element of a broader legislation (particularly Regulation 2073/2005) laying down microbiological criteria in general. In said Regulation [which deals with both processing and end product microbiological criteria for food stuffs (including *Salmonella*)] stipulates that the criteria for meat and products thereof should take into account the expected improvement in the *Salmonella* situation at the level of primary production.

The criteria for the public health importance of the *Salmonella* serotypes are defined in Annex III of the Regulation. The following four criteria should determine the public health significance of *Salmonella* serotypes, that represent the primary targets of the Regulation: i) the most frequent *Salmonella* serotypes (top 5 or top 10) in human salmonellosis on the basis of data collected through the EC monitoring system, ii) the route of infection (i.e. the presence of the serotype in relevant animal populations and feed), iii) whether any serotype shows a rapid and recent ability to spread and to cause disease in humans and animals, and, finally, iv) whether any serotype shows increased virulence, for instance as regards invasiveness, or resistance to relevant therapies for human infections. Initially for a 3 year transition period the 5 most important *Salmonella* serotypes (*S. enteritidis*, *S. hadar*, *S. infantis*, *S. typhimurium*, *S. virchow*) as revealed by the human reporting system will be targeted while an extension to other serotypes will be based on an assessment of the benefits and costs of controlling that *Salmonella* type.

Although this approach to assessing the public health significance (i.e. monitoring the 'historic frequency') appears to be meaningful for purposes of setting priorities in combating human salmonellosis in Europe, a word of caution is timely. It should by no means lead to erroneously concluding that the non-prevalence of certain other serotypes would indicate that these are avirulent or insignificant to public health,

**Table 6.** Community targets for the reduction of prevalence (PV) of *Salmonella* of public health importance that are to be established pursuant to Article 4 [Regulation No 2160/2003] adapted from Official Journal of the European Union 12.12.03 L 325/11] [15] with a view of starting pre-harvest controls in EU Member States (MS)

Animal population	Baseline study published	Results (prevalence all <i>Salmonella</i> )	Community target prevalence and serotype	Deadline for target to be reached
Breeding flocks of <i>Gallus gallus</i>	Spring 2005	5.1 % (flock prevalence) 2.8% ( <i>S. enteritidis</i> , <i>hadar</i> , <i>infantis</i> , <i>typhimurium</i> and <i>virchow</i> )	Com Reg 1003/2005 < 1% for <i>S. enteritidis</i> , <i>hadar</i> , <i>infantis</i> , <i>typhimurium</i> and <i>virchow</i>	December 31, 2009
Laying hens	October 2004 – September 2005 Results published EFSA website June 2006	30.8 % (holding prevalence) 20.3% ( <i>S. enteritidis</i> and <i>typhimurium</i> )	Com Reg 1168/2006 < 2% for <i>S. enteritidis</i> and <i>typhimurium</i> Relative reductions for those MS with PV > 40% (40% relative reduction) PV 20% to 39% (30% relative reduction) PV 10% to 19% (20% relative reduction) PV < 10% (10% relative reduction)	To be established during 2008 on the basis of baseline study (the relative reductions shall be achieved during 2008) NB! December 2009 eggs must originate from flocks not under restrictions for <i>Salmonella</i> [Annex II (D)]
Broilers	October 2005 – September 2006 Results published EFSA website April 2007	23.7% flock prevalence 11% ( <i>S. enteritidis</i> and <i>typhimurium</i> )	Target to be established 36 months after entry into force (December 2006)	
Turkeys	October 2006 – September 2007 (results to be published EFSA website)		Target to be established 48 months after entry into force (December 2007)	
Herds of fattening pigs	October 2006 – September 2007 (results to be published EFSA website)		Target to be established 48 months after entry into force (December 2007)	
Breeding herds of pigs			Target to be established 60 months after entry into force (December 2008)	

particularly so because virulence is known to vary over time, whilst commercially available methods for determining virulence of *Salmonella* serotypes are rare.

The implementation of the Regulation will have far-reaching consequences for trade. Intra-community trade will only be possible provided flocks/herds have the mandatory health certificate by the specific deadlines mentioned in Annex I of the Regulation. For a transitional period, member states may be authorised to demand that the dispatching member state fulfils criteria of the importing member state. Third countries wishing to trade must comply and must have similar control programs in place that also need to be accepted by the Commission. The implications for third countries are currently difficult to analyse.

#### 4. Discussion

In comparing the recommendations of the SCVMPH with the political translation as formulated in the EU Zoonosis and Food Safety legislation, it is striking that the bold decisions taken have a rather provisional character and that many of the procedures and time frames seem, for the time being, to be based on reasonable as-

sumptions rather than on hard facts. This is the result of political compromises, having to deal with very complex systems in real time (i.e. with the infrastructural differences in the food industry and/or the differing rates of success in controlling food-borne zoonoses across the EU) and are associated with the very absence of reliable EU-wide information that could have inspired a more definitive decision. Consequently, many implementing decisions have been left for decision-making at a later stage. Yet, it is quite clear that the Commission considers food safety to be a pre-requisite for a well functioning market and that building consumer confidence in the European Community represents a priority.

In the following sections we will discuss the first achievements of the programs, its inherent weaknesses and other concerns.

#### First results

The baseline studies for *Salmonella* in primary production (particularly those of eggs & broilers) have revealed large differences in the prevalence both between various EU member states and within one and the same



member state [26, 27]. For example, whilst for broilers the average prevalence of *Salmonella*-positive flocks in the entire EU was 23.7%, the *Salmonella* prevalence varied considerably amongst member states, i.e. from 0% to 68.2%. This means that in the EU one in four broiler flocks being raised during the one-year period of the baseline survey was *Salmonella*-positive. Similarly, whereas the average *Salmonella* detection rate in laying hen holdings in the entire European Union was 30.8%, it ranged from 0% to 79.5% in different member states. The baseline studies represent the basis for the associated risk management policy, i.e. to design *Salmonella* control programs to be implemented with a view to reduce the Community *Salmonella* prevalence to target values in the range of 1–2% and to include an increasing number of *Salmonella* serotypes in monitoring and surveillance programs.

Also, within certain member states the results of baseline studies for layers and broilers indicate pre-harvest prevalences of *Salmonella* varying significantly over consecutive years, e.g. in the reporting period a prevalence of 30% whereas in the previous years prevalences in the order of 3% were reported. These observations illustrate how the new monitoring approach allows for getting a more reliable picture of the extent of the *Salmonella* problem in Europe and how generated data may serve as an instrument for convincing the public health authorities to further promote harmonized monitoring of food-borne hazards and animal disease and thus a more cost-efficient risk management.

Underpinning these strategies are preventive measures such as the competitive exclusion method developed by Nurmi and Rantala [28] – successfully applied in Finland – which is a good example of the positive impact scientific research has had on *Salmonella* prevention in poultry production.

### Weaknesses of the approach

Monitoring of many important zoonoses are not mandatory according to the new Zoonosis Directive. To develop good prevention methods for these pathogens at the European level the number of Category A zoonoses and zoonotic agents should be increased. For example, all over Europe yersiniosis is emerging as one of the more important food-borne pathogens.

It should also be noted that, at least as far as the Zoonosis Regulation is concerned, only few animal species are targeted. This should be no big surprise when one realises that the most frequent food-borne diseases such as salmonellosis and campylobacteriosis are primarily transmitted through poultry and pigs, both species being produced in industrial animal husbandry systems where infection pressure might be higher.

For gaining insight in the situation regarding non-food-borne zoonoses with both veterinary and medical significance, such as rabies, the current regulation offers little. This similarly applies to diseases such as tularemia, tick-borne encephalitis, and echinococcosis, for which annual surveys would also be helpful. It is therefore a positive development that ECDC has in its annual

epidemiological report included some of these zoonoses such as hepatitis A, Q-fever, tularaemia, Puumala haemorrhagic fever with renal syndrome, and West Nile fever.

The decision to allow the use of different detection methods when monitoring for instance *Salmonella* in pigs should be questioned. For instance, Article 12 of the Regulation reads: 'Alternative methods may be used if they have been validated in accordance with internationally recognised rules and offer equivalent results to those obtained by international standardisation bodies, as reference method ...' The wording 'at least equivalent or superior' would have been better. In the current legal situation it is entirely conceivable that the authorities will be faced with a cascade of not necessarily optimal tests. The fact that, the detection methods improve constantly, should have been the very motivator to – at least for a limited period of time – use one and the same test and once the decision is made to change the method, to rely on the superior one as the method of choice. If the major incentive for changing the legislation was the lack of standardisation and harmonisation, it is regrettable that test alternatives that could frustrate a true comparison between member states are still permitted. We wish to note this unsatisfactory situation, as it represents a challenge and in our opinion should in the next 5–10 years be remedied, so veterinary and public health objectives are not compromised.

Since the results of national reporting have to be collated and analysed before they are forwarded to EFSA, the information is delivered at least 6 (sometimes more) months after the year has ended. This results in considerable delays before the Community Report can be issued. For instance, the Community Zoonoses report for 2005 was published in May 2007. Consequently, the results are inevitably retrospective. In our view, efforts to accelerate this process are needed. Setting clear priorities and focusing on the major food-borne threats could be helpful. Another priority should be to detect emerging risks within the Community as the early warning systems of ECDC and the emerging risks monitoring become operational during 2007–2008. To this end, the rapid alert (RASFF) system for foodstuffs and feed should be integrated in the early warning systems on emerging risks.

The geographical separation between the agencies involved in the reporting of zoonoses is far from optimal. Whereas up to 2004 only one reference laboratory was responsible, the Community zoonoses reporting is currently conducted by two Community expert agencies, one [the European Centre for Disease Control (ECDC) in Stockholm] dealing with the reporting of communicable diseases in humans, the other [the European Food Safety Authority (EFSA) dealing with food safety, while risk management responsibilities for food safety remain with the European Commission in Brussels. Both reporting agencies have different priorities (justified as these may be), but we fear that this situation may interfere with the efficiency of the communication between these agencies as well as with the quality of zoonoses reporting. To achieve a well-functioning

risk management process all three parties need to collaborate intensively. It should remain a priority for EFSA and ECDC to act as independent and impartial agencies, serving the Community's interest by providing scientific opinions that are in agreement, not tainted by political arguments and including transparent analyses of risks, costs and benefits. This represents our major concern for the future zoonosis control in Europe.

Finally, the split of the reporting systems on the national level in human, veterinary and food elements represents a counterproductive approach in terms of a 'farm-to-fork' strategy. Whereas the most valuable outcome of the former zoonoses reports was that EU member states got an overview of the zoonoses situation in their respective countries all along the food chain, this is no longer guaranteed in its future form, as the amalgamation of the various reports will only be done on the community level.

### Financial concerns

How to handle the enlargement of the EU (as of the 1<sup>st</sup> of May 2004 with 10 new member states and during 2006 with Romania and Bulgaria) has been a point of some concern. The EU enlargement has strained the resources in all Community institutions and a clear focus and setting of priorities were needed. So far, it appears that this enlargement has been rather uneventful. Great emphasis was given to training and upgrading of veterinary and food safety services and of food industries. Having made the collection of comparable data on *Salmonella* in poultry and pigs a priority appears in retrospect to have been justified, as this production system will be subject to Community targets in the immediate future. To ensure that coordinated monitoring is effective, the new zoonosis legislation provides the legal basis for the Community to pay 50% of the costs for testing, provided monitoring is conducted according to the technical and financial guidelines and is completed in time.

The animal and food industry have expressed mixed feelings with regard to the new legislation. Regardless how keen industry may be to do away with zoonoses motivated by their legal obligation to produce safe food in the framework of Hazard Analysis Critical Control Point (HACCP) production schemes, it is clear that the costs incurred are considerable. Nevertheless, by leaving it to the member states and food industry to design their control programs, it should be possible to implement the control programs in a flexible and cost-effective manner adapted to the local conditions.

### 5. Concluding remarks

The Community zoonoses control strategies are work in progress and it is only possible to judge the impact on a preliminary basis. However, the annual decreases in incidence of human salmonellosis should be considered an encouraging sign that the revised policy might function. If this is indeed the case a reduction in the number of cases of food borne salmonellosis within the EU of more than 50% could be achieved within the next 5–10

years. This prediction is based both on the FAO/WHO risk characterisation of *Salmonella* in eggs and broiler chickens [29] and on a more recent report by de Jong and Eckdahl [30] on layers where a linear relationship between the pre-harvest prevalence of *Salmonella* and human risk of salmonellosis was found.

This having been said, it must be conceded that – with the exception of transmissible spongiform encephalopathy (TSE) and baseline studies for *Salmonella* in poultry breeders, layers, broilers, slaughter hogs and piglet production – the monitoring of other food-borne zoonoses has not yet been harmonised in particular for foodstuffs. For several pathogens such as VTEC, *Listeria*, *Yersinia* and *Campylobacter* and for antimicrobial resistance, there is a lack of comparable data on the prevalence in primary production and foodstuffs in the EU. This is a serious impediment to risk assessment and management with regard to intra-community trade and consumer protection. Moreover, initiating sentinel monitoring projects with the aim to validate current monitoring systems for human incidence needs to be seriously considered.

The new zoonosis legislation obliges the member states to provide reliable information to the Community services. For this to be realised, the national competent authorities along the food chain need to collaborate and exchange information. At present, the latter is complied with to a variable degree only. It is a justified concern that it will still take considerable time before this situation will be remedied. However, in some member states (e.g. in Finland) the control and supervision of the food chain has been vested with one agency, which has simplified collaboration.

It is helpful that risk management within the European Commission services is clustered in one Directorate General (DG SANCO) that encompasses the entire food chain from animal feed through to the consumer table and consumption, that the zoonoses data from the food and veterinary sides are submitted by one competent authority per member state (albeit that the data on the human incidence are now reported separately) and finally, that these data are collated, analysed and published. It is clear, however, that unless the exchange of information is complete, it will be difficult to judge the magnitude of endemic zoonoses, detect emerging diseases or to recognise and control outbreaks of both. A formal collaboration between medical, veterinary and food/feed supervision is a prerequisite for this. Unfortunately, to date, the interface between these factions is all but seamless. In this regard, the prospects for improvement could be better.

The new zoonosis legislation represents the first steps towards refocusing food control system to address the most significant risks for public health. The cornerstone is the integrated approach, where information from all along the food chain is fed back and forward, where flock or herd-based data are combined with the results of inspection of individual animals and foods, and where communication between all those professions dedicated to public health is intensified. We believe that these processes can elevate the standards of

food safety and consumer protection, and, if properly implemented, may ensure that the Community market for foodstuffs and animal products will enjoy increased consumer confidence.

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