



EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on a review on the European Union Summary reports on trends and sources zoonoses, zoonotic agents and food-borne outbreaks in 2009 and 2010 – specifically for the data on Salmonella, Campylobacter, verotoxigenic Escherichia coli, Listeria monocytogenes and foodborne outbreaks

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SCIENTIFIC OPINION

Scientific Opinion on a review on the European Union Summary Reports on trends and sources zoonoses, zoonotic agents and food-borne outbreaks in 2009 and 2010 – specifically for the data on *Salmonella*, *Campylobacter*, verotoxigenic *Escherichia coli*, *Listeria monocytogenes* and foodborne outbreaks¹

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ABSTRACT

The European Union (EU) Summary Reports on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2009 and 2010 – specifically for the data on *Salmonella*, *Campylobacter*, verotoxigenic *Escherichia coli*, *Listeria monocytogenes* and foodborne outbreaks was reviewed. The main conclusions and recommendations are reported. Comparison between EU Member States (MSs) was found to be difficult due to the differences of the methods used, sampling schemes and reporting systems. Methods, sampling schemes and reporting systems among MSs should therefore be harmonised. When comparing MS-specific trends, the impact of sample sizes, weight of samples and methodologies should be considered, as these variables could otherwise lead to misinterpretation of the data. Incidence data alone do not provide a full picture of the public health burden of zoonotic diseases. Fatalities provide another important insight. Ultimately, summary measures of public health such as disability adjusted life years (DALYs) and cost-of-illness estimates should be presented. Travel information was found to be still incomplete in many MSs. For many pathogens this hampers source attribution. To better understand the public health problems related to food and animal sources in the EU, it is desirable to differentiate between travel within and outside the EU. This would also be useful to better evaluate the public health impact of EU-wide food safety measures. Whenever possible the data/results should be analysed using proper statistical tools. When data do not allow for this, the text should be kept to presenting the data without implying any patterns or trends.

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KEY WORDS

Review, European Community Summary Reports, 2009, 2010

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SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Biological Hazards (BIOHAZ) to deliver a Scientific Opinion on a review on the European Union (EU) Summary Reports on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2009 and 2010 – specifically for the data on *Salmonella*, *Campylobacter*, verotoxigenic *Escherichia coli*, *Listeria monocytogenes* and foodborne outbreaks.

Comparison between EU Member States (MSs) is difficult due to the differences of the methods used, sampling schemes and reporting systems. Methods, sampling schemes and reporting systems among MSs should be harmonized.

Data on human cases were reported via The European Surveillance System (TESSy) to ECDC by the 27 MSs and three EEA/EFTA countries (Iceland, Lichtenstein and Norway). Switzerland reported human cases directly to EFSA. The completeness of reporting varied between both MSs and pathogens.

The data reported to ECDC did not provide for an accurate picture of the epidemiological situation in the EU as they did not account for underreporting and under-ascertainment. The ratio between true cases and reported cases is known to vary widely between MSs and between pathogens, making comparisons extremely difficult. These limitations also affect the accuracy of risk assessment and attribution studies and furthermore may lead to inappropriate estimates of the cost-benefit ratio of interventions.

Incidence data alone do not provide a full picture of the public health burden of zoonotic diseases. Fatalities provide another important insight. Ultimately, summary measures of public health such as disability adjusted life years (DALYs) and cost-of-illness estimates should be presented.

Trends in reported cases are assumed to provide insight in the changes in disease incidence, and thus for the evaluation of control programs. Supporting evidence for the assumption that the sensitivity of surveillance systems does not change over the years has not been provided. Evaluation of the public health impact of food safety programmes is further hampered by a lack of risk factor information.

Travel information is still incomplete in many MSs. For many pathogens this hampers source attribution. To better understand the public health problems related to food and animal sources in the EU, it is desirable to differentiate between travel within and outside the EU. This would also be useful to better evaluate the public health impact of EU-wide food safety measures.

Whenever possible the data/results should be analysed using proper statistical tools. When data do not allow for this, the text should be kept to presenting the data without implying any patterns or trends. This also relates to use of words or phrases like “only” and “very low” contamination in e.g. RTE turkey and bovine meat, respectively. Such words imply an acceptance of the contamination level, which is outside the scope of the report. Phrases like “lower or higher than” are only considered appropriate to use when comparing trends from e.g. year to year, if supported by proper statistical analyses.

When comparing MS-specific trends, the impact of sample sizes, weight of samples and methodologies should be considered, as these could otherwise lead to misinterpretation of the data. In addition data from MSs, where sample unit and sample size were unspecified could be presented in an annex.

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BACKGROUND AS PROVIDED BY EFSA

The Directive 2003/99/EC establishes the system on EU-wide data collection for zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks. The Directive assigns EFSA the tasks analysing the data and publishing in collaboration with ECDC annual EU Summary Reports on trends and sources zoonoses, zoonotic agents and food-borne outbreaks.

Each year substantial quantities of data are received from the Member States and part of this data monitoring and reporting is harmonised by EU legislation or by EFSA specifications. The analyses of the data at supra-national EU level are challenging due to different epidemiological situations in the Member States and also because the data are not always directly comparable between the countries and years.

The scientific panels of BIOHAZ and Animal Health and Welfare (AHAW) have been in the past consulted about the European Union Summary Reports from years 2004 and 2005, and two opinions from the panels have been issued on this review (EFSA Journal (2006) 403, 1-62 and EFSA Journal (2007) 600, 1-32). It would be appropriate to repeat this review of the EU Summary Reports for 2009 and 2010 data collections (EFSA Journal (2011) 9(3):2090 and EFSA Journal (2012) 10(3):2597) in order to further improve the scientific quality of the reports, the data collection and the analyses carried out.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The BIOHAZ panel is asked to:

- Review the European Union Summary Reports on trends and sources zoonoses, zoonotic agents and food-borne outbreaks in 2009 and 2010. This review should in particular focus on data i.e. *Salmonella*, *Campylobacter*, verotoxigenic *Escherichia coli*, *Listeria monocytogenes*, food-borne outbreaks and other food-borne zoonoses, including current analyses of available data;
- Evaluate the appropriateness of the data collected at EU level;
- Consider what data are needed at EU level to provide an accurate picture of the epidemiological situation in the EU and the Member States;
- Assess if the analyses methods used in the report are appropriate;
- Consider if collection of sampled based data for the reports aim instead of aggregated data would improve the quality and analyses of data at EU level;
- Consider if the data collection should be extended to additional zoonoses, or zoonotic or microbiological agents;
- Propose any improvements to the data collection, the presentation of the data and their analyses and to the way harmonised monitoring is done.

ASSESSMENT

1. Introduction

EFSA is charged with coordinating the annual reporting of zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks in the European Union under Directive 2003/99/EC as well as analysing and summarising the data collected.

Each year EFSA in close collaboration with the European Centre for Disease Prevention and Control (ECDC) analyses the data and publish a European Union (EU) Summary Report on trends and sources zoonoses, zoonotic agents and food-borne outbreaks based on the results.

In order to improve the scientific quality of the EU Summary Reports it is appropriate to consult the relevant EFSA scientific panels regarding the best set of data to be collected and the analyses to be carried out.

Consequently, EFSA invites the scientific panel on Biological Hazards (BIOHAZ) to review the EU Summary Reports on trends and sources zoonoses, zoonotic agents and food-borne outbreaks in 2009 and 2010, specifically for the relevant diseases that are within the scope of the BIOHAZ Scientific panel, i.e. *Salmonella*, *Campylobacter*, verotoxigenic *Escherichia coli*, *Listeria monocytogenes*, food-borne outbreaks and other food-borne zoonoses (EFSA, 2011a; 2012a).

2. Review of the 2009 and 2010 European Union (EU) Summary Reports

2.1.1. Human data in general

Data on human cases were reported via The European Surveillance System (TESSy) to ECDC by the 27 EU Member States (MSs) and three EEA/EFTA countries (Iceland, Lichtenstein and Norway) for all diseases discussed in these documents. Switzerland reported human cases directly to EFSA. Graph SU1 presented comparative data on the reported incidence of zoonoses in the EU in a useful format. *Campylobacter* and *Salmonella* have remained by far the most frequently reported zoonoses in humans. More detailed information was provided in pathogen-specific chapters. Trend analyses were presented at EU-level when data were available. In addition, informative analyses on the breakdown of trends per MS have been provided. The completeness of reporting varied: in 2009 all 27 MSs plus three non-MSs reported data on *Salmonella*, one MS did not report data on *Listeria*, two MSs did not report data on *Campylobacter*, *Trichinella*, and *Echinococcus*, three MSs did not report data on VTEC and *Yersinia*. Fewer countries reported data on *Toxoplasma*. The results were adequately summarized in Chapter two.

The data reported to ECDC did not provide for an accurate picture of the epidemiological situation in the EU as they did not account for underreporting and under-ascertainment. The ratio between true cases and reported cases is known to vary widely between MSs and between pathogens, making comparisons extremely difficult. These limitations also affect the accuracy of risk assessment and attribution studies and furthermore may lead to inappropriate estimates of the cost-benefit ratio of interventions. Tam et al. (2012), in the UK IID-2 study, have described a cohort-based approach to estimate multipliers for a range of intestinal pathogens. Havelaar et al. (2012a) have described a modelling approach based on comparative risks of Swedish travellers to different EU MSs to estimate multipliers for salmonellosis and campylobacteriosis. Their results have been used in several EFSA Opinions (EFSA, 2008a; 2008b; 2011b; 2011c). ECDC is addressing this problem in the Burden of Communicable Diseases in Europe (BCoDE) project (ECDC, 2012).

Trends in reported cases are assumed to provide insight in the changes in disease incidence, and thus for the evaluation of control programs. Supporting evidence for the assumption that the sensitivity of surveillance systems does not change over the years has not been provided. The reports both mentioned problems related to differences in methodology applied in different MSs, related to changes in the number of MSs reporting, etc. Further information on health care-seeking behaviour of patients in different MSs and further information on the operation of the health care systems (sample submission, analysis for specific pathogens, sensitivity and specificity of laboratory methods, effectiveness of reporting systems etc.) should be available to allow more meaningful comparisons on reported data. Other possible explanations such as changes in food preparations and consumption patterns might also be responsible for at least a part of the observed changes in observed disease incidence, but are not specifically addressed. More data are needed on details of surveillance systems to better interpret and possibly standardize the reported data. Sero-epidemiology is an alternative, surveillance-system independent tool to evaluate the exposure of populations to intestinal pathogens, and thus the impact of food safety interventions. The applicability of sero-epidemiology is currently being explored by ECDC.

Evaluation of the public health impact of food safety programmes is further hampered by a lack of risk factor information which makes it very difficult to interpret observed trends.

Incidence data alone do not provide a full picture of the public health burden of zoonotic diseases. Fatalities provide another important insight and from data presented in the report, *Listeria* is the cause of most deaths related to reported cases.

Ultimately, summary measures of public health such as disability adjusted life years (DALYs) and cost-of-illness estimates should be presented (Gkogka et al., 2011; Havelaar et al., 2012b). This is the aim of the ECDC BCoDE project (Kretzschmar et al., 2012). Where available, specific data on health

care usage (GP visits, hospitalisation, severe sequelae such as Guillain-Barré syndrome and haemolytic-uraemic syndrome) - an indication of severity - could be included in the EU Summary Reports.

Travel information is still incomplete in many MSs and for many pathogens this hampers source attribution. To better understand the public health problems related to food and animal sources in the EU, it is desirable to differentiate between travel within and outside the EU. This would also be useful to better evaluate the public health impact of EU wide food safety measures.

2.2. *Salmonella*

The *Salmonella* data were for the most part well-presented and relevant in both reports. It may be worth considering omitting the introductory section, which seems to reproduce text book material. If retained in future EU Summary Reports, the introduction section would benefit from a more critical appraisal of known facts about the organism and the methods of characterisation. For example, in both reports it is stated that 'more than 2,500 serovars of zoonotic *Salmonella* exist. This is not strictly correct. Although >2500 serovars have been *identified*, less than 1000 (and probably less than 500) have been isolated from animals and can therefore be regarded as truly 'zoonotic'. Indeed, many of the more exotic serovars, which have for the most part been initially identified in developing countries, have only been observed in humans. Furthermore it should be realised that the incubation period for human salmonellosis can extend for up to 72 hours or even more, depending on the ingested dose and other factors such as the vehicle of infection and the immune status of the host. Additionally, in the reports there was inconsistency in the use of 'serovar' and 'serotype' throughout the documents. Both terms have been used – 'serovar' is now considered the most appropriate term. The paragraph describing the most common sources of *S. Enteritidis* and *S. Typhimurium* should not be mentioned in the introduction as a matter of fact. This may be the current epidemiological situation, but this may change over time. The sources of different serovars should be discussed in a section devoted for taking stock of the epidemiological situation and observed trends – a concluding section on *Salmonella*, where all major findings are discussed.

2.2.1. Salmonellosis in humans

Salmonellosis is the second most frequently reported zoonosis in EU and the reported incidence continues to decrease. The reported incidence has been presented in a Table and trends over five years were visualized for the EU and for each reporting MS in graphs and analysed statistically for trend, which is very informative. Major differences in reporting MSs, that may affect overall trend, have been noted. The data collected were case-based, except for two MSs reporting aggregated data. The presentation of data is considered appropriate. The countries providing no case-based data could be excluded from the Table and be presented as a footnote. Strong deviations in reported cases per 100.000 among MSs were neither noted nor explained or discussed, i.e. several MSs reporting less than 10 cases per 100,000. Such countries could be excluded from calculating the total EU incidence.

Information on domestic/imported origin of cases has been presented in tabular form. As there are still many MSs with no or incomplete information, presenting an EU average is not very informative. Furthermore, there is strong geographical variation in the domestic or imported origin of cases, which is not reflected in an EU average. Collecting travel information on reported cases should be a priority in all MSs (see also 2.1.1).

The data on seasonality were presented in a single graph combined with serovar distribution in 2009, and combined with age distribution in 2010. It is not clear why these differences in presentation have been chosen. Whether seasonality differs between MSs or geographical regions has not been evaluated. Age distribution of cases could be discussed more extensively. There was detailed information on (evolution of) serovar distribution and time trends, which assists in understanding overall trends in more detail.

2.2.2. Data on *Salmonella* in foods

Data on *Salmonella* in food have been presented in Tables by animal species of origin i.e. broilers, turkeys, table eggs, pig meat etc. For each animal species, the results were presented by reporting MSs in a single Table and divided into results obtained at slaughter, processing/cutting plant and retail. A total percentage of *Salmonella*-positive samples for reporting MSs has been given at the bottom of each Table. Such an overall *Salmonella*-positive sample percentage is difficult to interpret as it includes results from a mixture of surveys with different sampling designs, sampling sizes, sampling approaches, etc. Also, there is a risk that readers are interpreting this as the “EU average”, which is even less meaningful, since not all MSs reported data. One purpose of a total average should be to analyse any significant trends occurring from e.g. one year to the next, although without harmonised monitoring schemes this is not possible.

The results have been mostly described by “eyeballing”. Some general remarks have been made such as “data from the MSs reporting investigations at different sampling stages, showed that samples tested at slaughter were found to be more contaminated than samples tested later in the food chain”. Such an observation may leave a false impression that the products at retail are less contaminated, while the explanation may rather be due to the variations in sampling strategies (including what the individual sample is actually representing: carcass, pork chop, minced meat etc.) as described above. Also, the observation is not true for all MSs.

Overall, whenever possible the data/results should be analysed using proper statistical tools. When this is not possible, the text should be kept to presenting the data without implying any patterns or trends. This also relates to use of words or phrases like “only” (e.g. only 0.6% positive samples of egg products) and “very low” (e.g. very low (0.8% and 0.4%) contamination in RTE turkey and bovine meat, respectively), which imply an acceptance of the contamination level, which is outside the scope of the report. Phrases like “lower or higher than” is considered appropriate to use when comparing trends from e.g. year to year, if supported by proper statistical analyses.

There was a specific paragraph dealing with non-RTE foods, but what is meant by this has not been adequately explained. In principle it should include all products sold at retail that are not RTE foods, but then the results from the Tables were not in accordance with what is described in the text. The relevance of including a paragraph describing the results of sampling non-RTE food should be considered, as it is assumed that these are already in the Tables in some form. If it is decided to retain this paragraph, a better explanation should be provided.

The Tables describing the RTE foods are useful. The use of a “total proportion of *Salmonella*-positive samples” is considered to be more meaningful to apply here than for the other Tables, although interpretation should be done with caution due to the factors described above.

When comparing MS-specific trends, the impact of sample sizes should be considered. For instance in Figure SA6, the occurrence of *S. Enteritidis* in table eggs from six MS over three years has been presented and discussed in the text. From the figure some countries (e.g. Greece), appear not to have had *S. Enteritidis* in table eggs in the three-year period, whereas in Germany a declining trend was observed. When looking at the sample sizes in Table SA11 (EFSA, 2011a), it can be seen that many more samples were collected in Germany. It is very likely that if a similar number of samples had been collected in Greece, the apparent prevalence would have been different from zero. This possibility is supported by the finding of *S. Enteritidis* in laying hen flocks in Greece (Table SA22). The consideration of sample sizes is particularly important when dealing with food sources, where the expected number of *Salmonella*-positive samples is low, such as is the case with table eggs.

In the food Tables, sample weight (or sample area in cm²) has been indicated, but the impact that the different sample weights/sizes may have on the results was not discussed. An example of this is in the description of bovine RTE foods, where Poland was highlighted as having the highest proportion of

positive samples. In contrast to all other MSs in this Table, Poland took 200 g samples, which would be expected to result in higher positivity.

In Table SA16, it is not clear why there is a category called “Vegetables” and another named “Fruit and vegetables”, and if investigations of vegetables were reported in both.

2.2.3. Data on *Salmonella* in animals

The section began with a short description of the species for which harmonised monitoring, national control programmes and targets are implemented. A new Table inserted in this section, listing for each animal species (or production type) which serovars are targeted, what the targets are and how many MSs that have met the targets, is recommended. Such information has, of course, been presented under the respective animal species, but an overview Table is considered useful. Due to the harmonised monitoring and, if the production type exists in the MSs, all MSs report data, the use of EU total average is considered appropriate and the overall presentation of the results was clear and useful. The description of the target set for laying hens (EFSA, 2011a, p. 65) fails to describe the serovars that have been targeted (i.e. *S. Enteritidis* and *S. Typhimurium*). The data collected at the flock level were also clearly described, but in several places these were referred to at the sample level - e.g. “The MSs reported between 0 % and 10.9 % samples positive with *S. Enteritidis* and/or *S. Typhimurium*” (EFSA, 2011a; Table SA22, p. 67). This should be ‘flocks’ as more than one sample is collected per flock and a single *Salmonella*-positive sample results in a flock being declared *Salmonella*-positive.

No harmonised monitoring currently exists for *Salmonella* in pigs and cattle, as well as other farm species. The data reported were therefore sparse and the possibility to make for instance trend analyses is restricted to a very few MSs which report annual results from a national control programmes. The text describing these results was therefore kept short without many interpretations, which is considered appropriate.

2.2.4. Data on *Salmonella* in feeds

This section has briefly described the overall *Salmonella* findings in feed materials and compound feeding stuff. The focus has been on compound feeding stuffs presumably because this is the feed ready to be fed to the animals. A large proportion of the feed materials is also fed directly to the animals without further treatment. This includes, for instance, oil-based products such as soy and rape, which are recognised sources of *Salmonella*. A large proportion of these feed materials are imported from outside EU. Some are processed further at feed plants, but some are distributed directly to e.g. pig and cattle farms. More information (if available) on the serovar distribution in feed materials (particularly the oil-based products) could be useful, and may shed light on the origin of some of the *Salmonella* findings in animals that tends to occur in clusters in a group of MSs and/or over a shorter time period.

2.2.5. Evaluation of the impact of *Salmonella* control programmes in poultry

Overall, the included figures and analyses are considered appropriate. Further in-depth data analysis could follow the recommendation in EFSA (2011b) “The establishment of active surveillance of human salmonellosis in all Member States is recommended, including harmonised typing of human *Salmonella* isolates and efforts to quantify the level of under-ascertainment and underreporting”. In the very last paragraph in the 2010 report possible explanations to the reduction in both human cases and *Salmonella*-positive *Gallus gallus* flocks has been provided. Here voluntary and compulsory vaccination have been underlined as factors possibly contributing to the reduction, and were the only factors specifically mentioned (except for “other hygiene-based control measures”). It may have been more appropriate to have also mentioned the general the control of *Salmonella* in breeding flocks. For an assessment of the usefulness of vaccination for control of *Salmonella* in poultry reference should be made to: Opinion of the Scientific Panel on Biological Hazards on a request from the Commission related to the use of vaccines for the control of *Salmonella* in poultry (EFSA, 2004).

The 2010 report also referred to the EFSA Opinion on laying hens, stating that 65% of all human salmonellosis cases can be attributed to the laying hen reservoir (EFSA, 2010a). This is not the correct reference. The reference should have been EFSA (2011b). Also, the inclusion of published confidence limits when referring to such model results would have been worthwhile.

Finally, this section may have been better placed following the description of the results from the harmonised monitoring in poultry.

2.2.6. *Salmonella* serovars

The report would benefit from including MS-specific data on the serovar distribution in humans. This would aid the comparison of the serovar distribution through the food chain and be valuable for assessing the trends and dynamic of human salmonellosis as well as evaluating the effect of control efforts in the food chain. As recommended in EFSA (2011b) “Close monitoring of the serovar distributions in humans and broilers should be strengthened to identify the emergence of serovars of public health significance”, and emerging serovars could be identified more explicitly in future EU Summary Reports.

In the 2010 report, a decrease of 2,088 cases of *S. Typhimurium* was described. The 2009 figures included isolations of the monophasic *S. Typhimurium* strains but this was not the case for the 2010 data report, where these strains were reported separately (EFSA, 2011a; 2012a). This means that the actual decrease from 2009 to 2010 was considerably less than the above mentioned figures showed.

It should also be kept in mind that when isolates of major serovars such as *S. Enteritidis* and *S. Typhimurium* are decreasing in numbers, the relative importance of other serovars may increase without necessarily representing an absolute increase. When discussing the trend of specific serovars in human, the absolute numbers should therefore also be considered.

In relation to the phage typing data both reports have not fully considered the genetic ‘make-up’ of certain phage types and the implications on the figures presented. For example, in the 2009 data report (EFSA, 2011a), in relation to serovars in humans (p. 92, para 6), for *S. Typhimurium* it should be realised that DT193 is a composite phage type which is comprised of at several ‘clades’ or ‘clones’, which are for the most part unrelated and can only be distinguished by molecular subtyping. Additionally ‘RDNC’ and ‘NT’ (Table SA33) are not distinct phage types. ‘RDNC’ means ‘reacts but does not conform’, and is a conglomeration of strains with different phage reactions which have not been assigned to a recognised phage type; ‘NT’ means ‘not typeable’ and the same considerations as those to ‘RDNC’ apply – i.e., both ‘RDNC’ and ‘NT’ can represent several unrelated strains. These two types should therefore be included at the bottom of Table SA33, possibly just before ‘Other’, or even combined with ‘Other’. It should also be noted that ‘U302’ (p. 93, para 1, line 2) is not a definitive phage type. The considerations on ‘RDNC’ and ‘NC’ also apply to the *S. Enteritidis* phage typing data (Table SA31, p. 87-88). As explained above, ‘RDNC’ is not a single phage type and should therefore should be included at the bottom of columns in Table SA33 (p. 94).

The same criticism can be extended to human TESSy data the 2010 report, where in Table SA31 (p. 91) the TESSy returns included ‘RDNC’ as a phage type for both *S. Enteritidis* and *S. Typhimurium* (ranked as numbers 5 and 3, respectively in Table SA31), and NT as a phage type for *S. Typhimurium* (ranked as number 8).

For human salmonellosis, the 2009 report would have benefited from mentioning of the appearance of *S. Typhimurium* DT191 in 2009. It is clear from Table SA33 (p. 94) that this type emerged in significant numbers in humans in 2009 but was not seen in isolates from food animals. The number of infections identified (237) is quite substantial. A short note about the reservoir of this phage type – corn snakes fed on imported frozen infant mice imported into the EU from the USA - (Harker et al, 2011), would have been informative, particularly as the type does not appear in the ‘top ten’ in the 2010 data report (EFSA, 2012a), following the implementation of international control measures.

For the non-human sources, available serovar data were presented in the order: meat, primary production and feed. The resulting serovar distributions were used to make comparisons of the serovar distributions between the different links in the food chain and to humans. These comparisons were also discussed further in the last section “Overview of *Salmonella* from farm-to-fork”.

Apparently, two different data sets were available for the serovar distributions; the serovar Tables in which only the serovar distribution have been reported and the prevalence Tables, which also included the number of units tested. For the outside reader, this distinction is not clear and the limitations of both data sets for providing representative serovar distribution should be better described.

The serovar distribution for *Gallus gallus* (presumably from the serovar Tables) has not distinguished between the broiler and laying hen reservoir, making the comparison of the serovar distribution between the different links in the food chain and to humans difficult. Because of this limitation, the overall comparisons have put more emphasis on the serovar distribution in broiler meat. Since less than half of the MSs reported data from investigations of broiler meat in 2009 and 2010, this may lead to misinterpretation of the data. For instance in the 2010 report, *S. Kentucky* was mentioned as associated with broilers (p. 108). From the Tables the dominance of *S. Kentucky* in broiler meat was driven only by a single country and relied on relatively few samples. Indeed, from a more detailed scrutiny of the data reported at the flock level through the harmonised monitoring, the prevalence of *S. Kentucky* can be seen to be higher in turkeys than in broilers (EFSA, 2012b).

Serovar distributions to the extent possible were based on data from harmonised monitoring, where also the prevalence (proportion positive) was taken into account. Comparison of serovar distributions across the food production chain is therefore recommended.

The 2010 EU Summary Report (EFSA, 2012a) provided a helpful commentary on the newly-emerging monophasic *S. Typhimurium*-like strains (p. 100). This is particularly relevant since, as stated, the current tetra-resistant DT193/DT120 epidemic strain cluster has spread beyond its initial porcine source and in 2010 has been identified in other food-animal reservoirs, including poultry. The information in this commentary is also useful, since the mechanism of reporting of monophasic *S. Typhimurium* differs between countries, with some countries reporting such strains by phage type (DT120/DT193), and not as ‘monophasic’, or by antigenic structure. Thus the information presented in Table SA31 (p91) included isolates of both DT193 and DT120 in the *S. Typhimurium* phage types listed for both years. As it is highly probable that a significant number of isolates of these phage types were monophasic, the proportion of such monophasic isolates is likely to be considerably in excess of those reported in 2010 as ‘*S. Typhimurium* monophasic’ (EFSA, 2012a; Table SA30, p90).

As recommended in EFSA (2010b) “The antimicrobial resistance pattern should be determined and reported in a harmonised way for human, animal and food isolates, according to European guidelines”.

According to EFSA (2008b) “Data gathering for purposes of attribution should be question driven and by representative sampling. Baseline studies, as carried out under the Zoonoses Regulations, are an important development. It is recommended that all *Salmonella* isolates from cases of human illness and a representative set of isolates from all main animal species entering the food chain is serotyped in all MSs and that at least the common serotypes such as *S. Enteritidis* and *S. Typhimurium* are subtyped using harmonised and appropriate methods.” For *Salmonella*, serotyping is universal for all countries, whilst many countries in the EU also use the same schemes for the phage typing of *S. Enteritidis*, and most for *S. Typhimurium*. Harmonised molecular typing based on pulsed field gel electrophoresis (PFGE) is now widely in use in many countries world-wide but less useful for attribution purposes. For attribution purposes sequence-based methods, such as Variable Number of Tandem Repeats (VNTR) analysis are being harmonised for *S. Typhimurium* and *S. Enteritidis* and the results should be more amenable to transfer between countries. If possible, reporting of molecular subtypes of *S. Enteritidis* and *S. Typhimurium* based on VNTR analysis is recommended for future EU Summary Reports.

2.2.7. Overview of *Salmonella* from farm-to-fork

This section has provided a comprehensive overview of the presented *Salmonella* data and also included references and discussions to additional data or reports considered important for the interpretation of the data. No specific comments or recommendations are made for this section, but points mentioned previously should also be considered and included when developing this section for future EU Summary Reports.

2.2.8. Conclusion and discussion

The *Salmonella* data were for the most part well-presented and relevant in both the 2009 and 2010 EU Summary Reports (EFSA, 2011a; 2012a). Consideration should be given to omitting the introductory section, which seems to reproduce text book material. If retained in future EU Summary Reports, the introduction section would benefit from a more critical appraisal of known facts about the organism and the methods of characterisation.

The sources and/or reservoirs of different *Salmonella* serovars should be discussed in a section devoted to the epidemiological situation and observed trends. This could be discussed in a concluding section on *Salmonella*, where all major findings are discussed.

A total percentage of *Salmonella*-positive samples in food for reporting MSs was very difficult to interpret as it included results from a mixture of surveys with different sampling designs, sampling sizes, sampling approaches, etc., and there is a risk that it will be misinterpreted as the “EU average”. One purpose of a total average is to analyse trends, but without harmonised monitoring schemes this is not possible.

Description of trends should be supported by proper statistical tools. When data do not allow for this, the text should be kept to present the data without implying any patterns or trends. When comparing MS-specific trends, the impact of sample sizes and weight of samples should be considered, as it could otherwise lead to misinterpretation of the data.

For the *Salmonella* data from animals, inclusion of a new Table listing for each animal species (or production type), which serovars are targeted, what the targets are and how many MSs that have met the targets is recommended.

The appropriate epidemiological unit (e.g. sample, flock or herd) should be used when presenting the data in the text.

More information (if available) on the serovar distribution in feed materials (particularly the oil-based products) would be useful, as this may shed light on the origin of some of the *Salmonella* findings in animals that tends to occur in clusters in a group of MSs and/or over a shorter time period.

The EU Summary Reports would benefit from including MS-specific data on the serovar distribution in humans. This would aid the comparison of the serovar distribution throughout the food chain and be valuable for assessing the trends and dynamics of human salmonellosis as well as evaluating the effect of control efforts in the food chain.

The presentation of *Salmonella* subtypes (e.g. phage types) should be considered carefully, taking into account the actual meaning of the notations given to the subtypes. Particularly, the strains given the notation “RDNC” or “NT” should be recognised as strains for which it was not possible to assign a distinct phage type. Such strains should be reported in the bottom of the Tables.

The serovar distributions should, to the extent possible, be based on data from harmonised monitoring, where also the prevalence (proportion positive) is taken into account when comparing serovar distributions across the food production chain.

If possible, reporting of molecular subtypes of *S. Enteritidis* and *S. Typhimurium* based on VNTR analysis is recommended for future EU Summary Reports.

2.3. *Campylobacter*

2.3.1. *Campylobacteriosis* in humans/reported cases

Campylobacteriosis is the most frequently reported zoonosis in EU and the reported incidence continues to increase. The reported incidence has been presented in a Table and trends over five years were visualized for the EU and for each reporting MS in graphs and analysed statistically for trend, which is very informative. Major differences in reporting systems, that may affect trend, have been noted. The data collected were case-based, except for one MS reporting aggregated data; one MS did not report any cases in 2009 and only one case in 2010. Two MSs did not report campylobacteriosis in both years. The presentation of data was appropriate but the countries providing no case-based data could be excluded from the Table and be presented as a footnote. Strong deviations of reported cases per 100.000 were neither noted nor explained, i.e. several MSs reporting less than ten or even less than one case per 100,000. Such countries could be excluded from calculating the total EU incidence.

Table CA3 on domestic/imported origin of cases in the 2009 report was discontinued in the 2010 report. In the 2010 report, available travel information was provided in text form. This is appropriate as in many MSs, travel information is still incomplete or fully absent. Collecting such information should be a priority in all MSs (see also 2.1.1).

The data on age-specific distribution from a subset of MSs has been presented as a graph in an appropriate way. The seasonality has also been appropriately shown as a graph, indicating the number of confirmed cases per month for the whole EU (with few exceptions). The presentation of cumulative data for the whole EU may be less informative than an analysis by region because the seasonality differs between MSs (geographical regions). It could be at least amended by adding individual graphs for each MS or for representative regions.

Species distribution was given in text form. There was a lack of speciation for a large proportion of cases (51% in 2009 and 51.8% in 2010). Data on speciation per MS would be useful in addition to the aggregated results. No subtype data have been reported although according to EFSA (2010c) “To provide a better understanding of the molecular epidemiology of campylobacteriosis and a better basis for source attribution in the EU, it is recommended that a representative collection of isolates from humans and putative reservoirs (in particular food-producing animals but also other domestic and wild animals) is obtained and subjected to genotyping in all MSs”. Currently the most appropriate method of genotyping appears to be MLST. Storage of the isolates and their DNA is recommended, so that in the future, potentially improved subtyping methods could be applied. This should be regarded as a matter of urgency as a baseline is needed before EU-wide controls are considered in the broiler meat production chain.

2.3.2. *Data of Campylobacter* in animals and food

2.3.2.1. *Data on Campylobacter* in animals

Data from poultry, pigs, cattle and other farm animals as well as pets were reported. The Tables on prevalence in broilers and other poultry and in pigs comprised data on animal-based sampling and flock/herd-based sampling together.

The EU-wide baseline survey for poultry has been presented separately from the above mentioned data in the 2009 data report (EFSA, 2011a) and comprised prevalence data of *Campylobacter*-colonised broiler batches.

For cattle a great variety of descriptions has been given, representing dairy cows, meat production animals, calves, other age groups or unspecified. Thus a comparison is very difficult. In addition also

for cattle data sets have been divided in animal-based and herd-based data. Only for animal-based data were there enough samples were provided from MSs. Therefore, a comparison between MSs in relation to herd-based data was not possible.

No data from other farm animals that allow reporting of prevalence have been provided. In addition data were mainly derived from clinical investigations from sheep and goats.

For cats and dogs data from several MSs were available with appropriate sample sizes but the origin of the samples was not specified. Furthermore clinical and diagnostic samples have been included, which makes interpretation difficult.

The *Campylobacter* species distribution for broilers, cattle and pigs has been given as a graph, including unspecified isolates. Consideration should be given to show the contribution without inclusion of the unspecified isolates.

2.3.2.2. Data on *Campylobacter* in food

Data from poultry, pig and bovine meat as well as from other foodstuffs have been presented.

Data for fresh broiler poultry meat were presented in a Table with different sections for slaughter, processing plants and retail. Sample units were mostly single samples, but in general sample size varied between 1g and 25g. For some countries specific explanations were given regarding seasonality (e.g. Denmark). Seasonality was not in general included in the analysis, as data were not available on that basis. Data for fresh non-broiler poultry meat have been presented in a similar Table, but only a few MS reported for this category.

In the 2009 EU Summary Report the EU-wide baseline survey was presented separately from the above mentioned data and comprised prevalence data on broiler carcasses as well as quantitative data from broiler carcasses.

The data for fresh pig meat and bovine meat were similarly presented as for fresh poultry meat. Only data from few MSs were presented in the Tables, as not all MSs did collect such data. Furthermore, only the sample size (N) for Germany and the Netherlands (for fresh pig meat) and for Germany (only in 2009), Luxembourg (only in 2009) and the Netherlands (for fresh bovine meat) was appropriate to calculate percentage positives.

Meat products from broiler, turkey, pig and bovine meat were summarised in one Table, although only data from two to three MSs could be included in the analysis. Almost all products proved to be negative, but the sample size for this calculation was very small per country and product.

Other foodstuffs comprised cows' milk, other milk and dairy products. Only five (four in 2010) MSs reported for cows' milk with a reliable sample size. The data for other milk products were not interpretable as the origin of the milk was not specified. Dairy products were in some cases specified and comprised mainly cheese. The number of samples was very low.

The species distribution of *Campylobacter* in fresh broiler meat has been provided as a graph, including unspecified isolates. Consideration should be given to showing the contribution without inclusion of the unspecified isolates.

2.3.3. Conclusion and discussion

For comparisons, only flock-based data should be considered for poultry. Animal-based data are not meaningful, considering the high (up to 100%) intra-herd prevalence of infected poultry flocks. To facilitate comparison also for pigs herd-based data should be considered. Only few MSs reported in that way.

Data from minor species (other farm animals) can be useful in the context of source attribution; samples from clinical infected animals cannot be used for this purpose. In other cases, especially when only few MSs are reporting, the data could be considered for presentation in an annex. The inclusion of pet animal data is relevant but the sampling from non-clinical sources should be encouraged. Samples which would allow an estimation of real prevalence would be welcome.

Concerning the distribution of *Campylobacter* species in animals and food (poultry) a second graph giving the distribution of all isolates properly identified to the species level would be instructive. Otherwise the real prevalence of the identified species will be underestimated. The comprehensive graph (including unspecified isolates) could be moved to an annex.

Seasonality should be considered where possible, both for animal sampling and food: in 2009 only data from Norway on the sampling season was available. Seasonality can greatly influence the results, as is also already stated in the EU Summary Reports. Sample based reporting which allows inclusion of seasonality is recommended.

In general, data from MSs with unspecified sample unit and sample size could be presented in an annex.

The distribution of positive samples throughout the food chain for the different animal species is informative. It should be kept in mind that all kind of samples are included (animal, herd and single samples) and therefore an interpretation should be made accordingly. Information on sampling technique variations etc., would also be helpful.

General trends over a five-year period have been given for human cases of campylobacteriosis. In the 2010 EU Summary Report a graph on fresh broiler meat was also provided. Such a trend analysis is useful but should be interpreted considering the rationale of data reporting.

2.4. *Listeria*

2.4.1. Listeriosis in humans

The reported incidence of listeriosis was low compared to other zoonotic and foodborne pathogens, but the reported number of fatal cases was the highest of any of the agents in both EU Summary Reports. The reported incidence has been presented in a Table and trends over five years were visualized for the EU (only for MSs with data from five consecutive years) and for each reporting MS in graphs and analysed statistically for trend, which is very informative. There were fluctuations but no clear trend in the five-year period. Major differences in reporting MSs, which may affect overall trend have been noted. The data collected were case-based, except for two MSs reporting aggregated data and one MS not reporting in both years. The presentation of data is appropriate. Those countries providing no case-based data could be excluded from the Table and be presented as a footnote. Strong deviations of reported cases per 100.000 between MSs are neither noted nor explained - i.e. several MSs reporting less than 0.1 cases per 100,000.

Information on domestic/imported origin of cases has been presented in the text, but was missing for approximately 25% of all cases. Where data were available, the majority were from domestic cases.

Data on seasonality have not been presented. Approximately 60% of cases occur in the elderly (65+) while cases in infants accounted for 4 % in 2009 and 6% in 2010 (EFSA, 2011a; 2012a). Complete data on age distribution has not been provided. Cases in pregnant women have been indicated under 'transmission routes' but whether such information was complete, or how pregnant women were exposed, has not been clearly stated. The basis for assessing the transmission routes for confirmed cases and providing this information is unclear and the data are incomplete. The data do not provide a basis for the evaluation of the public health impact of food safety programmes. Fatalities have been reported, but not foetal deaths or abortions.

2.4.2. Data on *Listeria* in animals and food

2.4.2.1. *Listeria* data in animals

Listeria is common in animals and nature. Several MSs reported data on *L. monocytogenes* in animals especially in cattle, sheep and goats. These data were not especially relevant since the risk of listeriosis is linked to contamination (mostly from processing environment) of ready-to-eat foods which support the growth of the organism, and not to the prevalence in animals.

2.4.2.2. *Listeria* data in food

Compliance with microbiological criteria

Data reported reflect the requirements of the Regulation 2073/2005 (European Commission, 2005), and investigations have focused on testing RTE foods for compliance with these limits.

There are some weak points in the assumptions made for the evaluation of the compliance to the Regulation 2073/2005. For example it is assumed that products except hard cheeses and fermented sausages are able to support growth of the pathogen. Depending on their physicochemical characteristics (pH, aw, presence of antimicrobials etc) however, many of these products may not support growth of *L. monocytogenes*. An effective evaluation of the compliance to the safety criteria requires the combination of the prevalence and concentration data with data on the physicochemical characteristics of the products (mainly pH, water activity (a_w)) as well as the remaining shelf life of the products after the time of analysis. The need for the above information has been taken into account in the *L. monocytogenes* baseline survey (BS) in certain ready-to-eat foods for 2010/2011 (Commission Decision, 2010).⁴

All data in the report were presented in a qualitative form (i.e. percentage of products with <100 cfu or >100 cfu). Such data do not provide a clear picture of the risk of listeriosis. Based on the dose-response relationship of *L. monocytogenes* (Figure 2) the risk of listeriosis is mostly related to products with high concentrations of the pathogen. For example, assuming a mean serving of 50-100 grams, the risk of listeriosis for the normal population is significant for products with *L. monocytogenes* concentration higher than 10^3 - 10^4 cfu/g. Thus it is important to analyze the actual concentration of the pathogen in RTE products and especially the percentage of products with high concentrations.

Comparison between annual data is affected by the selection of products that are analyzed in relation to their ability to support growth of the pathogen. For example, in one year more products that are able to support growth are analyzed higher concentration and non-compliance levels are expected.

The fact that data may not be comparable between MS due to differences in sampling and testing schemes should be stressed.

In all Tables averages have been estimated for the total samples at both processing and retail stages. This provides an erroneous picture since the safety criteria are different for the two stages. Averages should be estimated for the processing and retail stage separately. In addition it is not clear if these

⁴ A *Listeria monocytogenes* baseline survey (BS) in certain ready-to-eat foods (2010/2011) has been undertaken (Commission Decision, 2010). Ready-to-eat food categories chosen were those that have been linked to human listeriosis cases and where *L. monocytogenes* is most often reported according to the results from the "EU summary Reports on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks", also over 100 cfu/g (= legal safety limit), namely: Packaged (not frozen) hot or cold smoked or gravad fish, Soft or semi-soft cheeses, excluding fresh cheeses: Packaged heat-treated meat products, which have been handled and vacuum or MAP packaged after heat treatment. Testing of all three RTE categories will be performed at the end of shelf-life and for smoked/gravad fish: also tested immediately after sampling. Details of pH, and aw will be provided and all samples will be analysed with an enumeration method. Thus this one-year BS (2010/11) will provide additional valuable information on occurrence of *L. monocytogenes* in RTE food categories which are perceived as being at high risk, growth/no growth characteristics of packaged smoked or gravad fish and modelling to estimate the compliance with *L. monocytogenes* food safety criteria.

averages are weighted or not. All figures should be presented separately for the processing and retail stage as in the case of Figure LI3 since the safety criteria are different for the two stages.

2.4.3. Conclusion and discussion

More data are required for an effective analysis of origin (domestic/imported), seasonality and age distribution of listeriosis cases. In general the assessment of the transmission routes for confirmed cases is incomplete. The data on listeriosis in humans do not provide any basis for the evaluation of the food safety programmes impact (i.e. safety criteria of EU Reg. 2073/2005) on public health. Data on the occurrence above or below a certain limit of *Listeria* in foods have their limitations in relation to conclusions on the compliance with the safety criteria, risks, comparison between MSs and in relation to trend analyses.

2.5. VTEC

2.5.1. Data on VTEC in humans

Reports of verotoxin-producing *Escherichia coli* (VTEC) infections are less frequent than those of other bacterial zoonoses in the EU but such infections are of particular concern due to their severe nature and as causative agents of haemolytic uraemic syndrome (HUS). The reported incidence has been presented in a Table and trends over five years have been presented graphically, as well as the results of statistical analysis for trend, which is very informative. The reported incidence in the EU has increased for four consecutive years, but this fails to reach statistical significance over a 5-year period. To what extent this increase is due to better detection and reporting, compared to real trends in disease incidence is not clear. Major differences in reporting MSs, that may affect overall trend, have been noted. The data collected were case-based, except for three MSs where the reporting system is not aggregated; two MSs did not report VTEC. The presentation of data was appropriate. Considerable differences in reported cases per 100.000 between MSs were only briefly discussed.

A separate figure has presented information on seasonality of VTEC infections, separately for O157 and non-O157 serogroups. Detailed Tables have presented further information on serogroups and associated virulence characteristics (more commonly named virulence factors). The importance of non-O157 strains is not well known due to differences in surveillance and laboratory methods. Harmonisation of isolation of non-O157 strains is needed to better support decisions on the control of VTEC at EU level. Further detailed serogroup information has been presented for cases associated with HUS. It is confusing that colour codes and the order of specific serogroup was different between 2009 and 2010. It is not clear how many cases were identified as HUS compared to only diarrhoeal cases. Active HUS surveillance is recommended to get better data on the burden of this important sequela.

No information on domestic/imported origin of cases was presented. The data on seasonality were presented in a single graph combined with serogroup distribution in 2009, and combined with age distribution in 2010. It is not clear why these differences in presentation have been chosen. Whether seasonality differs between MSs or geographical regions is not evaluated. Age distribution of cases could be discussed more extensively. There was detailed information on serogroup distribution and time trends by MSs, which is informative to understand overall trends in more detail.

In a similar way to the reporting of RDNC and NT in the *Salmonella* Tables (see earlier), consideration should be given to moving the types classified as 'Not Typeable (NT)' (EFSA, 2012a, Table VT3, p. 165), to the bottom of the Table rather than as number two in the 'top ten serogroups reported each year'. NT is likely to be a heterogeneous collection of strains, and to give it such prominence in the Table is misleading.

An analysis of the serogroups for the presence of virulence genes has been presented in the 2010 EU Summary Report (EFSA, 2012a), which is highly informative.

2.5.2. Data on VTEC in animals and food

2.5.2.1. VTEC data in animals

Twelve countries reported isolations of VTEC from food animals (cattle and sheep) in 2009 and sixteen in 2010 (EFSA, 2011a; 2012a). A wide range of serogroups were identified in those countries where serogrouping was undertaken.

2.5.2.2. VTEC data in food

Twenty MSs reported data on VTEC in food for 2009 and nineteen MSs and one non-MS for 2010 (EFSA, 2011a; 2012a). In 2009, 9,285 bovine meat samples were investigated of which 2.3 % were VTEC-positive and 0.7 % VTEC O157-positive. In 2010, twelve MSs reported testing of 8,566 bovine meat units (from investigations of 25 or more samples) of which 0.5 % were VTEC-positive and 0.1 % VTEC O157-positive.

Comparison between MSs is difficult due to the differences in the methods, sampling schemes and reporting system. For example in Table VT4 (EFSA, 2011a) where the VTEC in fresh bovine meat was presented for the same description of samples (i.e. fresh) the sample weight included both surface and weight sampling (i.e. 400 cm² or 25g). It is not clear if the samples were carcasses, primary cuts or final products. In the case of carcasses the sampling stage has not been defined. The sampling stage can be important due to the significant effect of certain processing steps (i.e. chilling) on VTEC prevalence.

The reported percentage of samples positive to VTEC O157 for bovine fresh meat at slaughter, cutting/processing plant in Spain for 2009 was 14.9% (EFSA, 2011a). In contrast the respective prevalence in Spain for the years 2006-2008 was less than 1.3% whilst in 2010 it was 0% (EFSA, 2012a). This huge deviation needs to be discussed.

For most MS no information has been provided for other serogroups other than O157.

The change in prevalence of VTEC in fresh bovine meat during the years 2006-2010 has not been presented. Such information is important for trend analysis. For such analysis the differences in methods, sampling schemes and reporting systems among MSs should be taken into account.

2.5.3. Conclusion and discussion

Comparison between MSs is difficult due to the differences on the methods, sampling schemes and reporting system. Methods, sampling schemes and reporting system among MSs should be harmonized.

Analyses should be extended to serogroups other than O157.

Consideration should be given to moving the types classified as 'Not Typeable (NT)' (EFSA, 2012a; Table VT3, p. 165), to the bottom of the Table rather than as number two in the 'top ten serogroups reported each year. NT is likely to be a heterogeneous collection of strains, and to give it such prominence in the Table is misleading.

A trend analysis on the change in prevalence of VTEC in fresh bovine meat during the years 2006-2010, within MSs, could be presented, if data allows.

An analysis of the serogroups for the presence of virulence genes has been presented in the 2010 EU Summary Report (EFSA, 2012a), which is highly informative.

2.6. *Yersinia*

2.6.1. Yersiniosis in humans

Yersiniosis in the EU has shown a statistically significant decreasing five-year trend but is still the third most frequently reported zoonotic infection. The reported incidence has been presented in a Table and trends over five years were presented in the text, as well as the results of statistical analysis for trend. Major differences in reporting MSs, that may affect overall trend, have been noted. It would be interesting to know if the decrease in trend is seen in all age groups. The data collected were case-based, except for three MS where the reporting system was not aggregated; two MSs did not report *Yersinia*. The presentation of data is appropriate. Considerable differences in reported cases per 100.000 were only briefly discussed. Relatively good speciation and travel information data were available; about half of the strains were serotyped in 2010 but hardly any were biotyped. Such information was not provided in the 2009 report (EFSA, 2012a; 2011a).

2.6.2. Data on *Yersinia* in animals and food

In 2009 and 2010, only six and seven MSs respectively reported data on *Yersinia* in pig meat and products thereof (EFSA, 2011a; 2012a).

In 2010, four MSs submitted data regarding the testing of animals for *Yersinia*. The results of the reported data for animals in 2008-2010 have been shown. Four MSs provided data regarding *Yersinia* in pigs in 2010, with an overall proportion of *Yersinia* spp. and *Y. enterocolitica*-positive units of 12.3 %. Most of the porcine isolates that tested positive for *Y. enterocolitica* in 2010 were reported together with serotype information (EFSA, 2012a).

The BIOHAZ Panel concluded in an earlier report (EFSA, 2007) that the best and most reliable indicator of *Y. enterocolitica* pathogenicity is the biotype as the various biotypes are either pathogenic or non-pathogenic. The serotype alone is not a reliable marker of *Y. enterocolitica* pathogenicity because several serotypes are common to both pathogenic and non-pathogenic strains. Most of the porcine isolates that tested positive for *Y. enterocolitica* in 2010 were reported, together with serotype information (EFSA, 2012a).

2.6.3. Conclusion and discussion

Since only a few MSs report data on *Yersinia* spp. and *Y. enterocolitica* and since sample types and levels are not specified in most cases the data are not very useful for comparison between countries. In the future it is suggested that harmonized data on herd level (number of positive herds) and prevalence data for pig carcasses at the end of the slaughterline should be collected. In addition it is recommended that all strains are sero- and biotyped (EFSA, 2007).

2.7. *Trichinella*

Trichinella is a well-known parasitic zoonosis, involving twelve species and four genotypes (whereby the EU Summary Report mentions only three) (Gottstein et al., 2009). *T. spiralis*, *T. britovi*, *T. native* and *T. pseudospiralis* are considered to be the species circulating in Europe. However, *T. murelli* has also been reported from an outbreak in Europe caused by imported horse meat not originating from Europe, but so far is not regarded as a species native to Europe. The 2009 report contained an extensive section on this zoonotic parasite (EFSA, 2011a).

2.7.1. Trichinellosis in humans

There were 748 confirmed cases out of 1073 reported cases in the EU, which is a slight increase to the years before. Whether this may also be related to better reporting was not discussed. The highest human infection rates were in certain geographical areas. Also the data for some localized outbreaks were provided, which is useful in assessing the impact of individual outbreaks. The number of cases was found to have markedly decreased in the 2010 EU Summary Report (EFSA, 2012a): with 223 confirmed cases out of 394 reported cases.

The Table also listed the number of imported cases, which is valuable information. If possible the probable origin of these cases could be indicated, as this would be helpful. Data were given either on case-based reports or aggregated data or sometimes not specified.

The infections in different age classes have been shown.

Two countries did not provide information on human cases: Denmark (*Trichinella* is not a notifiable disease in humans) and Greece. Therefore, there were no results on trichinellosis from these two countries; information as to whether there are no cases would have been useful. The diagnostic methods for *Trichinella* in humans are not harmonized and not clearly listed for the individual countries.

There were no data on human infection in the French DOMs overseas and some Spanish and Portuguese islands in the 2009 EU Summary Report (EFSA, 2011a). No map was shown for 2010 (EFSA, 2012a).

2.7.2. Data on *Trichinella* in animals

Data on the infection in animals were clearly presented for pigs, farmed wild boar, wild boar and other wildlife. The infection was very low in farmed pigs and the infection rate has not noticeably changed over the years. Also *Trichinella* was found in solipeds but this information was only reported in the text and not in a Table, even though testing has been systematically done. Information on which type of farms the infected pigs came from has not been provided; such information may be helpful with regards to the development of risk-based surveillance in farmed pigs.

A harmonized monitoring scheme was also proposed by the EFSA scientific report: “Development of harmonised schemes for the monitoring and reporting of *Trichinella* in animals and foodstuffs in the European Union, EFSA January 2012” with useful suggestion for the harmonization of testing.

Especially in the Eastern EU regions wild life is heavily infected, and racoon dog appear to be an important reservoir. No testing is done on a regular level.

A risk-based assessment is currently undertaken in the frame of Scientific Opinions related to meat inspection by EFSA (EFSA, 2011d; EFSA, 2011e).

2.7.3. Overview of *Trichinella* from farm-to-fork

There was a positive correlation between the number of positive pigs and wild boar and the number of human cases, indicating that there is a relationship between consumption of pork and infection.

2.7.4. Conclusion and discussion

The 2009 report contained an extensive section on *Trichinella*, which was overall well presented. A large collection of data was presented but there is still no completely harmonized monitoring scheme for this organism. Data on different *Trichinella* species and genotypes are often lacking. More information on the origin in the human and animal cases would be useful for control purposes.

Whilst the number of human infections increased in 2009 in comparison with the numbers in the previous report, they decreased in the 2010; possible reasons for this decline were not discussed.

Reservoirs of *Trichinella* are in the wild animals such as wild boar, foxes and racoon dogs, which are currently not tested on a regular basis in all MSs. If the aim is to have a continuous surveillance as indicator to the risk then wild life should be in focus. Missing data from individual MSs should be collected.

The presentation in the maps could be improved by either a different colour code or even better be differently patterned. The maps are difficult to read, especially when printed out in black and white. It

would be helpful to have a different annotation system to clearly refer to the Tables in the annex, as well as within the text.

2.8. *Toxoplasma*

Toxoplasma is commonly found in a wide number of animal species as well as humans and has a global distribution. Seropositive rates differ among European countries (Papadimitrakis et al. 2009). *Toxoplasma* infections in pregnant women may lead to abortions, stillbirth or congenital disease (hydrocephalus, intra-cranial calcifications, chorioretinitis). Toxoplasmosis acquired later in life is asymptomatic or causing mild illness in most cases, but is increasingly also recognized as an important agent of ocular disease. Because consequences of toxoplasmosis are life-long the disease burden is high; for example, in the Netherlands *Toxoplasma* was ranked first among 14 enteric pathogens, using DALYs as risk metric (Havelaar et al, 2012b). In addition, *Toxoplasma* was ranked as a medium risk in the meat inspection opinion on swine (EFSA, 2011d).

2.8.1. Toxoplasmosis in humans

The data on humans were difficult to interpret, since some countries monitor toxoplasmosis whereas others do not. It is not clear from the Table To2 in the 2009 report whether only congenital cases have been reported or which other cases are included (EFSA, 2011a). In the 2010 report (EFSA, 2012a) only congenital toxoplasmosis was supposed to be reported due to a change of the case definition (Commission Decision, 2008). Not only congenital cases but also ocular toxoplasmosis can also be a problem. Only disease in children was reported, even though consequences in the infected babies can develop later in life.

Data on seropositivity were not reported. Screening in pregnant women is undertaken, in some countries on a regular basis, and in others voluntarily. These data should be presented.

Information on source attribution is needed to focus management activities.

In some countries, where congenital toxoplasmosis is notifiable (EFSA, 2011a; p.375), the data do not appear in the Table on human cases. Because of the high burden in MS, a more systematic surveillance of clinical and subclinical cases is needed.

2.8.2. Data on *Toxoplasma* in animals

Data from the animals were presented. It was clear from 18 MSs who reported data that infections were ubiquitous.

Regrettably comparisons between countries are difficult. It may not be possible to compare between countries due to possible different diagnostic techniques, which are not always clearly stated. Serology in cattle is not a valid source of information as it does not correlate with infection or viable oocysts. More specific information is needed for the attribution of the source of the parasite. Information on viable tissue cysts as well as information on infection in cats as shedders of the oocysts in the environment would be needed to identify the food which represents a risk factor as possible transmitter of the parasite.

Findings of *Toxoplasma* in sheep and goats, where the level is almost 25%, should be given greater prominence (see Table 3.11.2. Table TO3 (EFSA, 2011a, section 3.11.2). In other animals the prevalence was relatively low with the exception of cats where it was higher. Because of their structure the Tables reporting the *Toxoplasma* infection in animals were not very easy to read, since animal types were included in lines and were difficult to find. Perhaps a more elegant solution could be found. The high incidence of toxoplasma in sheep and goats should be highlighted in discussions.

2.8.3. Conclusion and discussion

Data from humans and animals needs to be harmonized by using standardised sampling and diagnostic techniques. For humans, this includes data on incidence and disease burden. The case definition has to be very clear and the different types of toxoplasmosis infection and disease clearly differentiated. Congenital cases should perhaps be presented separately from seropositive data and cases of ocular toxoplasmosis. More information is needed related to the source attribution of the infection. This is important for management options.

2.9. Food-borne outbreaks

The reporting of investigated food-borne outbreaks has been mandatory for EU MSs since 2005. Starting from 2007, harmonised specifications on the reporting of these outbreaks at EU level have been applied. The food-borne outbreak investigations and reporting systems at national level are not harmonized within EU MSs. Differences in the numbers and types of reported outbreaks, as well as causative agents, may therefore not necessarily reflect levels of food safety between MSs, but may rather be indicative of the differences in the efficiency and sensitivity of the national systems for identifying and investigating food-borne outbreaks. Data from 2009 and 2010 provided information on the total number of reported food-borne outbreaks attributed to different causative agents, including food-borne outbreaks in which the causative agent was unknown (EFSA, 2011a; 2012a).

The 2009 specifications for food-borne outbreak reporting defined the strength of evidence that could link cases to a food vehicle drawing a distinction between “verified” and “possible” food-borne outbreaks. Detailed data were only reported for verified food-borne outbreaks, defined as those in which the causative agent had been detected in the food vehicle or where the food vehicle had been identified by analytical epidemiology. This approach has some limitations, including lack of acknowledgement that the nature of evidence is not necessarily correlated with its strength. Another difficulty is the reluctance, for legal reasons, of some MSs to identify a particular food vehicle as “verified”. Because of these limitations, EFSA has revised the food-borne outbreak reporting specifications (EFSA, 2010d). Thus in 2010 (EFSA, 2012a), the distinction between ‘verified’ and ‘possible’ food-borne outbreaks was abandoned in the reporting; instead, outbreaks were categorised as ‘strong evidence’ or ‘weak evidence’ outbreaks based on the strength of evidence implicating a suspect food vehicle. In the former case, i.e. where the evidence implicating a particular food vehicle was strong, based on an assessment of all available evidences, a detailed dataset was reported for food-borne outbreaks. In the latter case, i.e. where no particular food vehicle was suspected or for foodborne outbreaks where the evidence implicating a particular food vehicle was weak, only a limited dataset was reported. This included the number of outbreaks per causative agent and the number of human cases hospitalisations and deaths. In the report the term ‘weak evidence outbreak’ also covered the outbreaks for which no particular food vehicle was suspected.

2.9.1. Conclusion and discussion

Taking into account the weakness of the non-harmonised outbreak investigation and reporting system at the national level and thereby the different level of details in the reported data, the data were in general dealt with in a sufficient and comprehensive way in the 2009 and 2010 EU Summary Reports (EFSA, 2011a; 2012a).

The usefulness of attributing outbreaks, where toxin-producing bacteria like *Bacillus*, *Staphylococcus* and *Clostridium* are the causative agents, to specific categories of raw foods could be discussed. Species need to be defined when presented in the report. Outbreaks involving these toxin-producing bacteria are mostly caused by inappropriate procedures during processing and storage and not or to a lower degree to the presence in a particular raw food like meat, egg and milk. Therefore at least as an addition it could be informative to attribute outbreaks from these specific organisms to the settings where these infections are acquired. Also, it would be interesting to gain knowledge about to what extent outbreaks (from all organisms) are caused by industrial processed foods compared to food handled and prepared at restaurants, in households and similar settings.

For *Salmonella*, where much data are available, it could be relevant to see whether there was a correlation between the number of countries with high prevalence of *Salmonella* in eggs, poultry and other meat and the number of outbreaks caused by these sources. This could be done by using the source attribution approach based on outbreak data, as described by Pires et al. (2010).

Another suggestion for improvement of future reports would be to link the discussion on the specific food-borne outbreaks (*Salmonella*, *Campylobacter*, VTEC, viruses, parasites etc.) to the general data and chapters where the general data on these pathogens are discussed.

GENERAL CONCLUSIONS AND RECOMMENDATIONS

Comparison between EU Member States (MSs) is difficult due to the differences of the methods used, sampling schemes and reporting systems. Methods, sampling schemes and reporting systems among MSs should be harmonized.

Data on human cases were reported via The European Surveillance System (TESSy) to ECDC by the 27 MSs and three EEA/EFTA countries (Iceland, Lichtenstein and Norway). Switzerland reported human cases directly to EFSA. The completeness of reporting varied between both MSs and pathogens.

The data reported to ECDC did not provide for an accurate picture of the epidemiological situation in the EU as they did not account for underreporting and under-ascertainment. The ratio between true cases and reported cases is known to vary widely between MSs and between pathogens, making comparisons extremely difficult. These limitations also affect the accuracy of risk assessment and attribution studies and furthermore may lead to inappropriate estimates of the cost-benefit ratio of interventions.

Incidence data alone do not provide a full picture of the public health burden of zoonotic diseases. Fatalities provide another important insight. Ultimately, summary measures of public health such as disability adjusted life years (DALYs) and cost-of-illness estimates should be presented.

Trends in reported cases are assumed to provide insight in the changes in disease incidence, and thus for the evaluation of control programs. Supporting evidence for the assumption that the sensitivity of surveillance systems does not change over the years has not been provided. Evaluation of the public health impact of food safety programmes is further hampered by a lack of risk factor information.

Travel information is still incomplete in many MSs. For many pathogens this hampers source attribution. To better understand the public health problems related to food and animal sources in the EU, it is desirable to differentiate between travel within and outside the EU. This would also be useful to better evaluate the public health impact of EU-wide food safety measures.

Whenever possible the data/results should be analysed using proper statistical tools. When data do not allow for this, the text should be kept to presenting the data without implying any patterns or trends. This also relates to use of words or phrases like “only” and “very low” contamination in e.g. RTE turkey and bovine meat, respectively. Such words imply an acceptance of the contamination level, which is outside the scope of the report. Phrases like “lower or higher than” are only considered appropriate to use when comparing trends from e.g. year to year, if supported by proper statistical analyses.

When comparing MS-specific trends, the impact of sample sizes, weight of samples and methodologies should be considered, as these could otherwise lead to misinterpretation of the data. In addition data from MSs, where sample unit and sample size were unspecified could be presented in an annex.

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