Regulatory Issues Associated with Preharvest Food Safety: European Union Perspective

LIS ALBAN

Danish Agriculture and Food Council, DK-1609 Copenhagen V, Denmark

ABSTRACT Free movement of safe and wholesome food is an essential aspect of any society. This article contains an updated description of the regulatory issues associated with preharvest food safety within the European Union. Salmonella, Campylobacter, Trichinella, antimicrobial resistance, and bovine spongiform encephalopathy are dealt with in detail. Moreover, Cysticercus bovis/Taenia saginata, Toxoplasma, Yersinia, verotoxigenic/shigatoxigenic Escherichia coli, Listeria, and foodborne viruses are briefly covered. The article describes how the focus in the European Union is changing to involve a supply chain view with a focus on cost-effectiveness. The precautionary principle—as well as the use of private standards as an instrument to ensure compliance—is dealt with. In addition, actions in the pipeline are presented and discussed.

FOOD SAFETY AND THE NEED FOR SURVEILLANCE AND CONTROL IN THE EUROPEAN UNION Free movement of safe and wholesome food is an essential aspect of the internal market within the European Union. This contributes significantly to the health and well-being of citizens and to their social and economic interests. A high level of protection of human life and health should be assured in the pursuit of community policies while allowing for flexibility when appropriate (1). These lines describe the overall policy in the European Union. The policy is practiced through different parts of the European Union regulatory framework, which is described below.

The responsibility for the progress of food safety is split between the European Union (EU) Commission, which makes legislation as risk managers, and The European Food Safety Authority (EFSA), which provides independent scientific support and advice to the EU Commission as risk assessors. EFSA provides support and advice to the EU Commission on the risks to human and animal health related to zoonotic hazards in the environment, in the food chain, and in animal populations. EFSA takes an integrated approach to its work, involving a number of its scientific panels and units if there is a concern about the food chain. The scientific panels assess the risk related to a given activity or hazard and produce opinions about questions received from the EU Commission. Moreover, independent scientists contribute through a number of working groups, for instance, a working group on antimicrobial resistance. Input is also received and discussed with a number of stakeholders such as the European Livestock and Meat Trading Union (UECBV), the Liaison Center for the Meat Processing Industry (CLITRAVI), the European Poultry Industry (AVEC), and Copa-Cogeca (the union of European farmers and their cooperatives). Based on data collected and reported by the individual member states, European Union summary reports on

Received: 12 August 2014, Accepted: 4 August 2015, Published: 9 September 2016
Editors: Kalmia Kniel, Department of Animal and Food Science, University of Delaware, Newark, DE; Siddhartha Thakur, North Carolina State University, College of Veterinary Medicine, Raleigh, NC
Correspondence: Lis Alban, lia@lf.dk
© 2016 American Society for Microbiology. All rights reserved.
zoonotic infections, foodborne outbreaks, and antimicrobial resistance are produced in collaboration between EFSA and the European Center for Disease Prevention and Control (ECDC). EFSA’s scientific panels review the annual reports and make recommendations on prevention and measures. The output of all EFSA’s work is presented on their website (http://www.efsa.europa.eu).

According to EFSA (2, 3), several zoonotic hazards are capable of causing disease in humans. These are *Campylobacter*, *Salmonella*, *Yersinia*, verotoxigenic *Escherichia coli* (VTEC) (also known as shigatoxigenic E. coli [STEC]), *Toxoplasma gondii*, *Listeria monocytogenes*, *Coxiella burnetii* (Q-fever), *Brucella*, *Trichinella*, West Nile fever, bovine tuberculosis, and lyssavirus (rabies). *Campylobacter*, *Salmonella*, and *Yersinia* account for the majority of human cases (Fig. 1). All hazards on this list are foodborne except for *C. burnetii*, lyssavirus, and West Nile virus.

The importance of a zoonosis as a human infection does not depend solely on the incidence in the human population. The severity of the disease and the case fatality are also important factors affecting the relevance. Therefore, despite the relatively low number of cases caused by VTEC/STEC, *Listeria, Echinococcus, Trichinella*, and lyssavirus (rabies), these hazards are considered important in the European Union due to the severity of the illnesses they cause and thereby higher case fatality risks (2, 3).

Generally speaking, poultry is considered the source of the majority of human campylobacteriosis cases— consumption of poultry meat attributing to 20 to 30% of cases, while 50 to 80% may be attributed to the poultry reservoir seen as a whole in the European Union (4). Poultry meat and eggs are also a significant source of human *Salmonella* infections, although improvements are being seen as a result of setting targets for *Salmonella* in poultry production in the European Union (2). Furthermore, a nonnegligible proportion of the human cases of infection with *Salmonella, Yersinia*, and *Trichinella* can be ascribed to pork. For *Toxoplasma*, pork is one among several sources, and the proportion of human cases caused by pork is unknown. Finally, VTEC/STEC is primarily ascribed to cattle/beef and other ruminants as well as vegetables.

Apart from the zoonotic infections listed in Fig. 1, there is concern in the European Union about the development of antimicrobial resistance due to the use of antimicrobials in livestock. It is feared that this might result in treatment failure and/or prolonged treatment in humans infected with resistant bacteria. Drug-resistant bacteria are estimated to be responsible for 25,000 human deaths annually and cost European Union member states more than €1.5 billion annually (5). In most of these cases the specific impact of the resistance is unknown, because the fatalities are related to a combination of advanced age, comorbidity, lack of immune

FIGURE 1 Reported number of confirmed human cases of zoonoses in the European Union in 2010 and 2012. Modified from references 2 and 3. *Tuberculosis caused by Mycobacterium bovis. **No data available for 2012.*
competence, and the disease course itself (e.g., dehydration after diarrhea). An example of this is, e.g., seen in humans infected with macrolide-resistant *Campylobacter*, as described by Alban et al. (6).

Despite of a plethora of actions taken to ensure food safety in the European Union, a large number of human cases of foodborne illness occur annually. In times of economic crisis, resources are even more limited than usual, hampering implementation of additional preharvest control programs. Hence, the feasibility of improvements in areas such as food safety is related to the economy in the livestock industry—unless governments can or will pay. A global economic crisis will not motivate farmers or abattoirs to implement costly changes that will further minimize the risk related to the animals or the products thereof. Hence, it is a challenge to ensure food safety in a cost-effective way. Still, this is aimed for continuously within the European Union.

The following sections present the most important parts of the regulatory framework in the European Union and discuss actions taken in member states that are forerunners within food safety. In addition, actions in the pipeline will be presented and discussed. Ultimately, food safety policy is a result of a combination of consumers’ perception and what is feasible, and in the European Union the latter means what the member states can agree to.

The focus will be on pig/pork, cattle/beef, poultry meat, and eggs. Bovine spongiform encephalopathy (BSE) will also be covered.

**REGULATORY FRAMEWORK IN THE EUROPEAN UNION**

In the European Union, most legislation is framed as either a regulation or a directive. Regulations have general application; they are binding and directly applicable in all member states. In contrast, a European Union directive sets out the objective or the policy which should be attained. Each member state must then pass the relevant legislation to give effect to the terms of the directive within a certain time period.

**The General Food Law and the Associated Parts of Legislation**

Regulation 178/2002—called the General Food Law—deals with the general principles, requirements, and procedures regarding food. The core of the entire European Union food safety legislation can be found in article 14, where it is stated that food shall not be placed on the market if it is unsafe (1). Because it is a regulation, it applies directly in all member states.

The General Food Law was introduced to ensure free movement of safe and wholesome food while avoiding distortion of competition. Previous to the adoption of this regulation, the food laws differed between the individual member states with respect to concepts, principles, and procedures. It was the intention to approximate these concepts, principles, and procedures to form a common basis for the measures governing food and feed. Moreover, it was found necessary to ensure that consumers, other stakeholders, and trading partners had confidence in the decision-making process underpinning food law, including the scientific basis and the structures and independence of the institutions protecting health and other interests. An example of this is that the establishment and duties of EFSA are stipulated in the General Food Law. The BSE crisis taking place during the years up to 2002 probably also contributed to the need for a common, clear, fair, and effective food law.

The parts of the regulatory framework that deals specifically with preharvest food safety are the Zoonosis Directive 2003/99/EC, the Zoonosis Regulation 2160/2003, and the Hygiene Package (Fig. 2). The following will describe the Zoonosis Directive, the Zoonosis Regulation, and selected parts of the Hygiene Package—as well as the food law.

**Control of *Salmonella* and Other Foodborne Zoonotic Agents**

The Zoonosis Directive 2003/99/EC sets the general requirement for monitoring zoonoses and zoonotic agents (7), whereas the Zoonosis Regulation 2160/2003 states that common targets and control programs for the reduction of *Salmonella* in poultry and pig production will be set on the European Union level (Annex I of the regulation) (8). Other foodborne zoonotic agents or other animal populations should be addressed, if necessary. The regulation foresees that target setting should take place at the level of primary production and/or, where necessary, at other appropriate stages of the food chain. In other words, testing should be performed at the herd level or of carcasses at the slaughterhouse (8). It is stated in the regulation that the member states are to implement the control program. Annex II lists general requirements for national control programs.

For pigs, no preharvest target has been set so far. It is specified that testing should cover all *Salmonella* serotypes with public health significance for both breeding and finishing pigs. Even though this is a regulation, not all member states have established a
preharvest monitoring program for finishing pigs. However, at least Belgium, Finland, Germany, The Netherlands, Sweden, and the United Kingdom have monitoring programs in place; see Baptista (9) for a thorough presentation of the various programs in the European Union. Only few member states apart from the Scandinavian countries have a surveillance program implying that actions are taken on results obtained from preharvest surveillance. In Denmark, finishing pigs from herds with a high prevalence of Salmonella are subjected to sanitary slaughter, which mainly consists of hot water decontamination (10). Moreover, an industry-driven penalty scheme is in place for finishing pig herds, in which a certain percentage of the carcass value is deducted from the finishers originating from herds with a moderate or a high level of Salmonella (10).

For cattle, no specific regulation on or requirement for preharvest testing for Salmonella is in place at the European Union level. Moreover, the prevalence of Salmonella in beef is sporadic to low and of limited concern in the European Union in general (3). However, this may change due to the severity of the disease in humans caused by the host-adapted Salmonella enterica serotype Dublin, which accounts for the majority of isolates from cattle and beef (11). Reductions in prevalence among cattle are possible, but it is difficult to keep the infection at a low within-herd prevalence without risking new outbreaks and consequential food safety issues and production losses related to outbreaks. Thus, eradication of Salmonella in cattle is aimed for in the Scandinavian countries, which are the only member states which have nationally organized control efforts in place. In Sweden, eradication is aimed for through very strict handling of infected premises by veterinary authorities, followed by repeated bacteriological culturing of samples from all animals on the premises before the herd can be considered free from infection (12, 13).

S. Dublin mainly causes disease in calves but also causes abortions, and it has been shown that veal producers who purchased calves from Salmonella test-positive dairy herds were more likely to deliver infected animals to slaughter (14). The Danish approach therefore aims at eradicating S. Dublin from the cattle population through stepwise regional eradication with strict movement restrictions and mandatory, documented effective action plans for elimination of S. Dublin in

**FIGURE 2** Graphical description of the European Union regulatory framework for food safety: the Food Law, the Zoonosis Directive, the Salmonella Regulation, and the Hygiene Package (Regulations 852, 853, 854, and 882); other relevant legislation (Regulations 2073, 2074, and 2075 from 2005); and the new regulations 216, 217 and 218 from 2014, which have updated the older parts of the legislation.
test-positive herds (15). All cattle herds are classified by use of serology. Owners of test-positive herds have to implement a risk-based action plan to eliminate *S. Dublin* and have to document the effect of this plan by serological testing of indicator groups of animals. The Danish Veterinary and Food Administration imposes official restrictions on infected herds. This requires, among other things, that the animals are accompanied for slaughter by an official passport and slaughtered late in the day under tightened hygienic precautions, at lowered line-speed, and carcasses are subjected to microbiological testing; *S. Dublin*-positive carcasses are either heat-treated or condemned (16).

For poultry and eggs, testing should cover all *Salmonella* serotypes with public health significance (Regulation 2160/2003). Regulation 646/2007 has set a target for broilers of 1% prevalence of *S. enterica* serotype Enteritidis and *S. enterica* serotype Typhimurium, which constitute the majority of human cases ascribed to poultry. The target for table egg layer flocks is 2% or below as laid down in Regulation 1168/2006 (17). The target had to be reached by 31 December 2011 (18). Moreover, Regulation 200/2010 specifies that the maximum percentage of adult breeding flocks of *Gallus gallus* remaining positive for *S. Enteritidis, S. enterica* serotype Infantis, *S. enterica* serotype Hadar, *S. Typhimurium*, and *S. enterica* serotype Virchow (the relevant *Salmonella* spp.) is to be 1% or less (19). European Union data show a continued decrease in the numbers of human salmonellosis cases, which is likely to be mainly related to the successful *Salmonella* control programs in fowl (3).

Denmark has had intensive *Salmonella* control programs since the 1990s, and a zero strategy (eradication) is in place for production of eggs and broilers, implying actions against all serotypes. The target of 1% *Salmonella*-positive broiler flocks was reached in 2000, and the prevalence in table egg laying flocks has been lower than 2% since 2004 (20). In 2007, Denmark applied to the European Union for special guarantees for *Salmonella* in table eggs, a position attained by Sweden and Finland at the time of their accession into the European Union in 1995 (21). In 2012, special guarantees for *Salmonella* in table eggs were granted to Denmark, implying that eggs placed on the market should be of the same high standard (22). Hence, in the European Union a member state will be able to benefit from actions taken to deal effectively with a food safety challenge.

**The Precautionary Principle**

The General Food Law (Regulation [EC] 178/2002) specifies that risk assessments should be undertaken to ensure confidence in the scientific basis for the food law in general, except where this is not appropriate to the circumstances (1). Moreover, according to Article 6 in the regulation, risk assessment will be based on the available scientific evidence and undertaken in an independent, objective, and transparent manner (1).

Article 7 in the General Food Law sets rules for how and when the precautionary principle should be used:

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Hence, the precautionary principle makes it possible to introduce preliminary actions that should be in place until sufficient knowledge is collected to assess the risk. There may not always be agreement about what sufficient knowledge is.

Compared to earlier regulations, the General Food Law induced a shift in primary responsibility for food safety: from veterinary authorities to the so-called food business operators (FBO), who can be farmers, meat processors including abattoir owners, and retailers. Moreover, focus has shifted from control of food safety at the company level to the supply chain level, which implies the production chain from stable to table (23). However, the shift in responsibility to the FBO is somewhat contradicted in Regulation (EC) 854/2004, which specifies in detail what the official control should consist of in relation to meat inspection. According to this regulation, almost no responsibility is delegated to the FBO (24).

**General Rules on Hygiene: for the FBOs**

Regulation (EC) 852/2004 lays down the general rules on hygiene to be followed by the FBOs (25). According to the regulation, FBOs who carry out any stage of production, processing, and distribution of food after primary production must implement and maintain procedures based on hazard analysis and critical control
point (HACCP) principles. Such an HACCP program is based on the following elements: (i) conduct a hazard analysis, (ii) identify critical control points, (iii) set critical limits, (iv) establish monitoring procedures, (v) establish corrective actions, (vi) establish record-keeping procedures, and (vii) verify that the HACCP works (Table 1).

As a part of an HACCP, a measure of compliance is conducted. This might consist of a test determining the number of coliform bacteria (indicating growth or not of a specific bacteria), or more commonly it could be an indirect measure such as the temperature. To identify where in the food production process interventions can be done, a risk analysis needs to be conducted. A risk analysis consists of the following four elements: (i) hazard identification, (ii) risk assessment, (iii) risk management, and (iv) risk communication. Figure 3 shows how the different elements of an HACCP relate to risk analysis, as suggested by Mellor (26).

**Specific Rules on Hygiene for the FBOs**

Regulation (EC) 853/2004 states the specific hygiene rules for products of animal origin (21). This includes the concept of food chain information. In brief, this relates to information about the animal such as:

1. The status of the holding or the regional animal health status
2. The health status of the animals
3. Veterinary medicinal products and compliance with withdrawal periods
4. Occurrence of disease that may affect the safety of the meat
5. Results of any analysis taken that may be of relevance for protection of public health
6. Relevant reports about previous ante- and post-mortem inspections of animals from the same holding, including reports from the official veterinarian
7. Production data, when this might indicate the presence of disease
8. Name and address of the private veterinarian normally attending the farm

The slaughterhouse operator may be provided with the main part of the information listed above through a standing arrangement or a quality assurance scheme. Record-keeping of relevant food safety information is a part of an HAACP system, as described in Table 1.

According to Regulation (EC) 853/2004, slaughterhouse operators must not accept animals onto the slaughterhouse premises unless they have been provided with relevant food chain information. Slaughterhouse operators must be provided with the information no less than 24 hours before the arrival of animals at the slaughterhouse, except in specific circumstances such as emergency slaughter, slaughter of horses, or where ante-mortem inspection has taken place at the farm (21). However, today the competent authority may permit the information to arrive less than 24 hours before the animal arrives. This makes it possible for smaller abattoirs to receive the information by paper upon the arrival of the animal (27).

The regulation also describes requirements for dairies, abattoirs, and cutting plants and for maintenance of hygiene, e.g., by setting maximum limits for the temperature during production.

**Microbiological Criteria and Salmonella**

Regulation (EC) 2073/2005, concerning microbiological criteria, sets the requirement for the level of food safety that the FBO should provide by use of his or her own control program. The regulation specifies how surveillance and monitoring should be conducted for carcasses and the meat products thereof as well as a variety of other food items of animal origin (28). The regulation operates with two kinds of criteria: process hygiene criteria and food safety criteria. For each criterion, it is specified how

| TABLE 1 | Relations between various elements of hazard analysis of critical control points (HACCP) and risk analysis – according to Mellor (26) |
|---|---|---|---|---|
| Element of HACCP | Hazard identification | Risk assessment | Risk management | Risk communication |
| Conduct a hazard analysis | X | | | |
| Identify critical control points | X | | | |
| Set critical limits | X | | | |
| Establish monitoring procedures | | X | | |
| Establish corrective actions | | X | | |
| Establish record-keeping procedures | | | X | |
| Verification that HACCP works | | | X | |
many samples should be taken and how often. This includes a description of the sampling plan \((n = \text{number of samples, and } c = \text{number of samples above } m)\), acceptable limits (a maximum of \(c/n\) values are observed between \(m\) and \(M\), and no value exceeds \(M\)), analytical reference methods, stage where a specific criterion applies, as well as action in case of unsatisfactory results. Moreover, the reactions to findings above the specified limits are described; for process hygiene criteria, corrective measures must be taken in the production line, whereas for food safety criteria, recall of products is required (28).

For pig carcasses, five swab samples are to be taken and analyzed for Salmonella per week, and the results are evaluated over 10 weeks. Until June 2014, the limit for this process criterion was five positive out of the 50 samples. Today, the limit is three out of 50 (29). If more positives are found, corrective measures must be taken along the production line. This implies that prevalence up to 6% (3 positive out 50 samples) is accepted on the carcass.

For poultry and turkeys, the initial process criterion was 7 out of 50 samples, reflecting a generally higher prevalence in poultry compared to pigs. In 2011, the criterion was changed to a food safety criterion requiring the absence of S. Enteritidis and S. Typhimurium in 25 g fresh poultry meat.

For cattle carcasses, the process criterion is 2 out of 50 samples, reflecting a generally low prevalence of Salmonella in beef.

For minced meat, the criterion is a food safety criterion. Here, absence in the five weekly samples is required for both pig, beef, and poultry meat. If Salmonella-positive samples are found, the food product should be recalled. This also applies to minced meat that is to be heat-treated prior to consumption. This reflects that eating habits vary in the European Union; in some member states minced pork would never be eaten raw, whereas in other member states raw minced pork is considered a delicacy.

Salmonella is known to be present occasionally on the carcass (which is why prevalence up to 6% is accepted in the European Union). However, Salmonella does not disappear when the meat is being processed, e.g., into minced meat. Hence, the criterion set for carcasses may not be considered that ambitious, whereas the criterion set for processed meat such as minced meat intended to be heat-treated prior to consumption is so ambitious that it is difficult for the processors to comply.

**Trichinella**

Until 2014, Regulation (EC) 2075/2005 laid down the specific rules on official controls for Trichinella in meat (30). Susceptible livestock includes pigs and horses as well as wild boar and other game species that are destined for human consumption. Until June 2014, it was mandatory to test all these animals for Trichinella as a part of meat inspection. Exemptions could be made for a holding or a category of holdings that had been officially recog-
nized by the competent authority as free from *Trichinella* or for a region where the risk of *Trichinella* in domestic swine was officially recognized as negligible. Belgium and Denmark were the only member states which were granted the status of areas with negligible risk (31, 32).

In most parts of the world, pig production has changed. Today many pigs are raised indoors under high levels of biosecurity, hampering the transmission of *Trichinella*. This is supported by European Union and U. S. data (33, 34). Eventually, this led to a change in European Union regulation toward lifting the requirement for testing pigs raised under so-called controlled housing conditions in integrated production systems. This calls for a very high degree of biosecurity and requires a type of animal husbandry where after weaning, swine are kept at all times under conditions controlled by the FBO with regard to feeding and housing. The animals must be reared indoors after weaning, there must be no contact with wildlife, and effective rodent control must be in place. A set of procedures laid out in Chapter I of Annex IV of the regulation must be followed (32) (Table 2).

All carcasses from holdings not officially recognized as applying controlled housing conditions will be systematically examined for *Trichinella*. Moreover, at least 10% of slaughtered carcasses from each holding officially recognized as applying controlled housing conditions will be examined for *Trichinella*. This will last until the member state has demonstrated that historical data on continuous testing carried out on the slaughtered swine population provide at least 95% confidence that the prevalence of *Trichinella* does not exceed 1 per million in that population. Denmark and Belgium are exempted from the 10% testing because of their negligible risk status in accordance with Regulation 2075/2005 (32).

The testing of pigs from noncontrolled housing can be interpreted as a sentinel because these pigs are believed to be of relatively high risk. Testing the high-risk pigs will form part of both a continuous documentation of disease freedom and an early warning system allowing fast and effective risk mitigation in case of possible findings (31). The possibility of stopping testing pigs from controlled housing will most likely lead to a decrease in the number of *Trichinella* tests. However, the full implementation will await acceptance from important trade partners from countries outside the European Union. Therefore, a country like Denmark, which exports >90% of its pork production will continue testing almost all pigs. Denmark’s challenge shows the importance of international recognition regarding surveillance for animal health. Currently, work is being conducted in the international organization Codex Alimentarius to identify internationally accepted methods of surveillance for *Trichinella* (see later section).

**TABLE 2** List of requirements that food business operators must meet to obtain official recognition of holdings as applying controlled housing conditions – modified from Annex IV, Chapter 1 in Regulation (EC) 2015/1375

<table>
<thead>
<tr>
<th>Issue</th>
<th>Specific requirement</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Housing</strong></td>
<td>The operator must have taken all practical precautions with regard to building construction and maintenance in order to prevent rodents, any other kind of mammals, and large carnivorous birds from having access to buildings where animals are kept.</td>
<td></td>
</tr>
<tr>
<td><strong>Rodent control</strong></td>
<td>The operator must apply a pest-control program, in particular for rodents, effectively to prevent infestation of pigs. The operator must keep records of the program to the satisfaction of the competent authority.</td>
<td></td>
</tr>
<tr>
<td><strong>Buying feed</strong></td>
<td>The operator must ensure that all feed has been obtained from a facility that produces feed in accordance with the principles described in Regulation (EC) No 183/2005 of the European Parliament of 12 January 2005 and of the Council laying down requirements for feed hygiene.</td>
<td></td>
</tr>
<tr>
<td><strong>Storing feed</strong></td>
<td>The operator must store feed intended for <em>Trichinella</em>-susceptible species in closed silos or other containers that are impenetrable to rodents. All other feed supplies must be heat-treated or produced and stored to the satisfaction of the competent authority.</td>
<td></td>
</tr>
<tr>
<td><strong>Disposal of dead animals</strong></td>
<td>The operator must ensure that dead animals are collected, identified, and transported without undue delay.</td>
<td></td>
</tr>
<tr>
<td><strong>Rubbish dump</strong></td>
<td>If a rubbish dump is located in the neighborhood of the holding, the operator must inform the competent authority. Subsequently, the competent authority must assess the risks involved and decide whether the holding is to be recognized as applying controlled housing conditions.</td>
<td></td>
</tr>
<tr>
<td><strong>Purchase of piglets</strong></td>
<td>The operator must ensure that piglets coming onto the holding from outside and pigs purchased are born and bred under controlled housing conditions.</td>
<td></td>
</tr>
<tr>
<td><strong>Identification of pigs</strong></td>
<td>The operator must ensure that pigs are identified so each animal can be traced back to the holding.</td>
<td></td>
</tr>
<tr>
<td><strong>Introduction of new animals</strong></td>
<td>The operator may introduce new animals onto the holding only if they come from holdings also officially recognized as applying controlled housing conditions.</td>
<td></td>
</tr>
<tr>
<td><strong>Access to outdoor facilities</strong></td>
<td>None of the animals has access to outdoor facilities unless the food business operator can show by a risk analysis to the satisfaction of the competent authority that the time period, facilities, and circumstances of outdoor access do not pose a danger for introduction of <em>Trichinella</em> in the holding.</td>
<td></td>
</tr>
</tbody>
</table>
BSE

BSE is under control in the European Union. By June 2015, 22 member states had obtained the status of negligible BSE risk by the World Organization for Animal Health, and the remaining 6 member states had the status of controlled risk (35). This is a result of having effective bans in place for many years regarding the use of mammalian protein as feed for livestock. This has opened up for discussion of the need to continue removing specified risk material (SRM). The position that it is unnecessary to remove SRM from cattle in areas or member states with negligible BSE risk was prevalent at the time the original version of the European Union TSE Regulation 999/2001 was adopted (Annex V, paragraph 1) (36). However, this was changed later, which can be seen in the consolidated version of Regulation 999/2001 (37). So today, SRM must still be removed in member states with negligible risk of BSE—but not in countries outside the European Union exporting to the European Union.

The EU Commission has developed a so-called roadmap for BSE (38), according to which a review of the necessity to remove SRM is on the agenda. Until recently, the intestines from duodenum to rectum (both inclusive) and of all ages of cattle were defined as SRM. In May 2015, new legislation (European Union Regulation 2015/728) was adopted that reduces the SRM from the intestine to the last 4 m of the small intestines. This brings the European Union list of SRM closer to international standards. Furthermore, a new European Union regulation (Regulation 2015/1162) came into force (August 2015) revising the definition of SRM for member states with a negligible risk of BSE. Hence, from now on, these member states only have to remove the skull including the eyes, the brain, and the spinal cord as SRM from cattle over 12 months of age. This means the intestines will no longer have to be dealt with as SRM for these member states.

The economic gain related to lifting the feed ban cannot be quantified easily, because it depends on the commercial possibilities. Most likely, the gain will be substantial; currently, there is a large number of products that need to be rendered by use of a resource-demanding and costly process. If these products can be manufactured and sold instead, then they will represent both an economic gain and a cost saving. For example, if the spinal column is no longer considered SRM, then T-bone steaks can be sold again. This used to be a highly valued cut. Cattle intestines have previously been used for human consumption, and this would again be considered a possibility if the SRM requirements are lifted.

There used to be a demand for human consumption for cattle brains, in particular, in Southern Europe, but it is doubtful whether this interest can be re-established (39). In fact, cattle brains will continue to be considered SRM.

Antimicrobial Use and Resistant Bacteria

In 2001, the EU Commission launched its first European Union strategy to combat the threat of antimicrobial resistance. This led to the banning of the use of antimicrobials as growth promoters in 2006 (40). Moreover, it set requirements for data collection and monitoring and supported actions in the areas of research and raising awareness. For example, a specification for the harmonized monitoring of antimicrobial resistance in *Salmonella* and *Campylobacter* was published by EFSA in 2007. Since then these data have been collected and published on EFSA’s website.

In November 2011, the EU Commission outlined a 5-year action plan against the rising threats from antimicrobial resistance (5). According to the action plan, policy-makers need to protect consumers from risks related to the food chain and to establish the best control options to reduce such risks. Moreover, the EU Commission considers that the ongoing efforts are insufficient and that a holistic approach is needed to mitigate the risk. A total of 12 key actions are aimed for in the action plan. Among these are promoting the appropriate use of antimicrobials in humans and animals, focusing on medicated feed, promoting microbiological diagnosis and follow-up report, putting in place effective prevention, and developing new effective antimicrobials or alternatives for treatment of infections in humans and animals. Moreover, the monitoring systems for antimicrobial use and resistance should be strengthened in all member states—in both human and animal medicine—and prevention and control of infections in animals should be enhanced. The European Medicine Agency is running the European Surveillance of Veterinary Antimicrobial Consumption, which calculates the consumption of antimicrobials in milligram per kilogram of animal produced for each member state (41). These data show that there is a substantial variation in the consumption of antimicrobials across the member states (Fig. 3).

**ACTIONS IN THE PIPELINE IN THE EUROPEAN UNION**

As noted in Fig. 1, *Salmonella* and *Campylobacter* constitute the main foodborne hazards in the European Union. It is being increasingly acknowledged in the
European Union member states that Salmonella and Campylobacter require risk management.

**Salmonella**

The European Union strategy for Salmonella began with poultry, which was ascribed to the highest number of human cases. No further actions are expected for poultry, because of the recently set production targets. The coming years will probably show a positive impact on human health related to achieving these targets.

Currently, the focus is on pigs, which are the second-largest source of Salmonella in humans in the European Union. The discussion is currently dealing with the question of where to go for control: preharvest, postharvest, or both. Initially, the focus was on preharvest measures and therefore also on monitoring or surveillance of pig herds. The idea was to increase awareness among farmers about the status of the animals.

However, as highlighted by Alban et al. (10), if there is no focus on the abattoir, the actions taken against Salmonella preharvest might easily be wasted. This was clearly shown in the EFSA baseline study for finishing pigs, where for two member states the prevalence of Salmonella was higher in the pork leaving the abattoir (measured as the proportion of Salmonella-positive carcasses) than the prevalence in the pigs entering the abattoir (measured as the proportion of lymph-node-positive samples) (42). This probably reflects a lack of focus on what can be done at the abattoir to prevent Salmonella contamination and cross-contamination.

The EU Commission is currently considering how to move on. Scientific cost–benefit analyses of actions taken preharvest have indicated that the feasibility of managing and reducing Salmonella in breeding and slaughter pigs was neither easy nor clear, and did not show larger benefits than costs (43, 44). A subsequent cost–benefit analysis of postharvest measures also showed that none of the actions considered were cost-effective (45). So far, the only step taken politically has been a tightening of the microbiological process hygiene criterion for carcasses as described in “Regulatory Framework in the European Union,” above.

As stated earlier, only a few member states have plans in place for cattle, probably because beef and milk are already dealt with sufficiently to prevent human infection. Moreover, no targets are being discussed regarding the prevalence of Salmonella in cattle in the European Union.

**Campylobacter**

No regulation is in place for Campylobacter in the European Union. A recently conducted cost–benefit analysis pointed to the importance of improved on-farm biosecurity, such as fly screens as suggested by Hald et al. (46), and best practice hygiene at the slaughterhouse as feasible ways of reducing the exposure of humans to Campylobacter in broilers (47). However, such requirements depend on continued commitment from the producers and the slaughterhouses. Political discussions are underway concerning how to move on. Regulatory actions will most likely involve the use of process criteria, and such criteria will be set by the EU Commission. However, flexibility might be sought because the prevalence of Campylobacter varies enormously between European Union member states; in some member states between-flock prevalence above 70% is seen. When setting a criteria for Campylobacter, the concentration might be used instead of the prevalence, e.g., by use of a limit of 1,000 CFU/g. Before setting such a target, the impact on production will be estimated, i.e., the number of batches that will be subjected to heat treatment or freezing. Meanwhile, individual member states have regulations in place aiming at reducing consumer exposure.

In Denmark, a national mandatory surveillance program is in place. The Danish Action Plan describes measures implemented preharvest, such as biosecurity which is regulated in details, not only in the national legislation but also by a quality assurance system, owned and driven by the industry, called KIK. The KIK scheme is based on national and European Union legislation as well as international published literature and practical inputs from the farmers (http://www.danskslagtefjerkrædk/Aktiviteter/Kvalitet_i_Kyllingeproduktionen.aspx). Campylobacter flock prevalence is monitored by cloacal swab samples collected at the slaughterhouse. Each flock is sampled. Moreover, national surveillance of fresh, chilled broiler meat at slaughterhouses is in place involving weekly sampling of whole legs that are analyzed quantitatively. The Action Plan also covers surveillance of fresh broiler meat intended for retail, both produced in Denmark and imported. This is covered by the so-called case-by-case program, which was initiated in 2006 as an intensified nondiscriminatory control of Salmonella and Campylobacter in fresh meat (48).

Other sources and routes may contribute to the number of people acquiring a Campylobacter infection. Source account models are being developed to increase the knowledge about the relative importance of the various reservoirs. According to Boysen and Hald (49), the cattle reservoir has been found to be the second most important reservoir in Denmark. High Campylobacter jejuni prevalence has been reported in cattle, but very low prevalence has been found in Danish beef. Thus, if
cattle should bear the second highest responsibility in relation to human campylobacteriosis, routes other than meat should be considered.

**Trichinella and Other Zoonotic Parasites**

The need for surveillance for *Trichinella* in pigs to ensure food safety and international trade is being debated internationally. Various approaches to surveillance are suggested or in place in the European Union, the United States, the World Organization for Animal Health, and Switzerland. The difference relates to the choice of test (serology/digestion), the target prevalence by which freedom from infection should be demonstrated, and the requirements for housing conditions for the pigs that do not need to be tested. According to Schuppers et al. (50), the programs do not recognize each other as providing an equivalent level of protection for consumers. However, a common set of guidelines would be helpful to ensure free trade. The question is whether it is possible to identify a globally agreed level of consumer protection.

The Codex Committee on food hygiene in collaboration with the European Union and the World Organization for Animal Health is currently developing a set of guidelines for *Trichinella* surveillance. An electronic working group for *Trichinella* was organized in March 2012 and is led by the European Union and New Zealand, and this working group is close to finding a common standard for *Trichinella* testing about which there will be consensus. Please see the website of Codex Alimentarius for the latest version of this work (http://www.codexalimentarius.org).

It is being debated to what extent *Taenia saginatal Cysticercus bovis* should be considered a food safety hazard. Viable cysticerci present in beef may result in infection of humans with tapeworm (51). Although this condition is not associated with pain or discomfort, it is perceived as disgusting. The infection is not notifiable in the European Union, and no data are available that can be used to assess the number of human cases with sufficient precision. Still, in some member states the presence of *C. bovis* found at meat inspection is considered nonnegligible. Due to the European habit of consuming raw or less than well-done beef, there is a risk of becoming infected with tapeworm. How to deal with this risk is currently being discussed at the Codex level—in the same working group that is discussing *Trichinella*. One solution may be risk-based surveillance aimed at targeting animals, herds, or cuts with the highest risk of harboring *C. bovis* (51).

*Toxoplasma* is known to be associated with rodents and cats, and therefore outdoor-reared pigs have a higher risk of *Toxoplasma* than pigs reared indoors on farms with rodent control and indoor-living cats. A risk assessment has shown that meat destined for production of raw or lightly cured products intended to be consumed without further heat treatment (such as salami) represents a risk to humans (52). It may be suggested to use the concept of controlled housing to divide pig herds into controlled (low-risk) and noncontrolled (high-risk) subpopulations. That would make it possible to freeze meat from noncontrolled housing destined for such ready-to-eat products as a way to mitigate the potential risk related to *Toxoplasma*.

**Other Zoonotic Hazards**

In the European Union, no definite actions have been decided upon regarding *Yersinia*, *Toxoplasma*, VTEC/STEC, *L. monocytogenes*, and viruses. The considerations regarding feasible control are presented in the following.

Although *Yersinia* is number 3 on the list of zoonotic hazards causing human illness (Fig. 1), no specific risk-mitigating regulations are in place in the European Union. Recently, scientific investigations have been made into the use of multidiagnostics whereby a single sample of blood taken from a pig at slaughter can be used to divide herds into among others *Yersinia*-positive and -negative. However, *Yersinia* is commonly found in pig farms, and eradication from the pig population does not seem to be realistic. The presence of *Yersinia* on a carcass is related to fecal contamination. The focus could therefore be on the hygienic measures taken in the abattoir. For example, there is discussion concerning to what extent we are dealing with *Yersinia* when we are preventing the spreading of *Salmonella* during slaughter. EFSA has suggested introducing a 4-year survey for *Yersinia* in the European Union. Such European Union surveys would ensure collection of comparable data enabling trend analyses as well as risk factor studies—similar to what has been undertaken for *Salmonella* (53). However, so far there is no acceptance of such a survey in the European Union.

VTEC/STEC is associated with ruminants. Within the European Union, outbreaks related to consumption of raw milk, among other sources, have occurred in England and Scotland, although the largest recent outbreak occurred in 2011 and was related to fenugreek sprouts (54). It is not known how to control the spread of VTEC/STEC among cattle or other livestock. Therefore, the focus is on how to control the hazard post-harvest. Here, pasteurization of milk (55) and cooling of meat resulting in a low surface temperature combined...
with a dry surface have a documented risk-mitigating effect (56). According to Regulation 853/2004, an unbroken cooling chain is required (25). Since 2013, operators of bovine slaughterhouses can use lactic acid on whole carcasses, half-carcasses, or parts of bovines with the objective being to reduce the microbiological surface contamination. This is in line with U.S. post-harvest procedures for decontamination (57).

In 2014, the EU Commission initiated a work aimed at developing guidelines for how to deal with food contaminated with VTEC/STEC. The discussion between the Commission and the meat-producing stakeholders (represented by the European Livestock and Meat Trading Union) concerned the criteria for when to submit meat for heat treatment and the practical difficulties arising due to lack of rapid analytical methods. If the finding of stx genes in meat destined for ready-to-eat products or dishes that are not fully heat-treated would become the foundation for the risk assessment, then a large quantity of meat would have to be destined for heat treatment for no reason because stx genes alone will not cause outbreaks; not just stx genes, but also eae genes—limited to serogroups O157, O111, O26, O103, O145, and O104—have to be present in the same live bacteria. Therefore, the first step of the analysis would be bacteriological enrichment and detection of stx and eae genes associated with the aforementioned serogroups. The next step will be confirmation of the simultaneous presence of the genes in the same isolated live bacteria (58). Such an analysis is at present so time-consuming that it will create substantial losses to the abattoirs and make it nearly impossible to put freshly minced meat on the market. Other classification approaches were therefore also being discussed. However, the EU Commission have recently given up the guidelines due to these technical constraints.

In the European Union, the preharvest regulation of L. monocytogenes is indirect and uses indicators. For milk, this includes requirements set to (i) somatic cell counts aimed at controlling mastitis, (ii) general hygiene practices, and (iii) measures directed against microbial development in the milk, including requirements for temperature, time, and total viable counts, both upon collection and prior to heat treatment (21). The remaining actions are industry-driven such as good silage production methods, good milking techniques, correct equipment, and cleaning of equipment. Moreover, Listeria is regulated postharvest; for meat products, milk, cheese, fish, etc. microbiological criteria are defined (28).

Foodborne viruses are the second most important cause of foodborne outbreaks in the European Union after Salmonella. In 2009, they were responsible for 19% of all outbreaks in the European Union, causing over 1,000 outbreaks and affecting more than 8,700 individuals. There is no legislation in place to mitigate this risk. EFSA has provided advice on possible measures to control and prevent the spread of these viruses. Focus is on the prevention of contamination rather than removal of the virus from contaminated food. More specifically, norovirus and hepatitis A virus play a role in fresh produce, ready-to-eat foods, and bivalve mollusks such as oysters, mussels, and scallops. Thorough cooking is currently the only efficient way to remove or inactivate norovirus or hepatitis A virus from these products. Moreover, hepatitis E is highly prevalent in pigs across Europe, and there is some evidence of transmission through food, although human clinical cases are rare in the European Union. Meat or liver should also be completely cooked to ensure effective removal of the potential presence of hepatitis E virus. To prevent hepatitis E infections, EFSA also recommends that people with liver diseases or immune deficiencies and pregnant women should be advised against eating under-cooked meat and liver from wild boar and pork (59).

**Antimicrobials and the Associated Risk of Development of Resistant Bacteria**

The European Union action plan against the rising threats from antimicrobial resistance that is described in the section “Regulatory Framework in the European Union” will lead to initiatives in the various member states at a varying speed because of the different situations and approaches in the member states. The EU Council conclusions from 2012 regarding antimicrobial resistance calls on the EU Commission and the member states to take the necessary steps to implement the action plan (60).

To get an idea of what measures, more specifically, will be put in place, attention might be directed to Denmark, which—together with Sweden—has been ahead of the rest of the European Union regarding mitigation of the risk related to the use of antimicrobials in livestock. These experiences, good as well as bad, will probably act as an inspiration for the European Union with respect to how to mitigate the risk related to antimicrobials in livestock. In the following, the legal framework in place in Denmark is described in brief.

- Restricted use of extemporaneously prepared medicines (the cascade rule; imposing mandatory first priority to medicinal products approved for the relevant species, subsidiary approved for other species).
The veterinarians’ profit when distributing medicines is limited to a maximum of 5 to 10% at sales.

Livestock herds are recommended to have a veterinary advisory service contract with a veterinary practitioner.

Prescriptions made by veterinarians are limited to a maximum of 5 days of treatment in production animals. Exceptions are granted only if a veterinary advisory service contract is made between the veterinarian and the farmer. In such cases, up to 35 days of treatment is allowed for a diagnosed disease or a disease that was expected in the pigs, calves, and poultry, on the basis of the veterinarian’s knowledge of the herd.

Treatment is allowed only in diseased animals or animals in a well-defined incubation period (metaphylaxis); prophylactic use is illegal.

Mandatory recording of medicines used, and drugs delivered and prescribed by the veterinary practitioners to farmed animals. This information must be available for inspection by veterinary officials for 3 years.

Mandatory reporting to the Vetstat database.

Pharmacies and the pharmaceutical industry are prohibited from offering economic incentives to veterinarians or others for the purpose of increasing product sales.

Restricted use of fluoroquinolones and cephalosporins in livestock either officially or through industry-driven bans. This includes among others that the injection is restricted to use by the veterinary practitioner only. Furthermore, it is mandatory to conduct susceptibility testing in relation to use for production animals, documenting the need. It is mandatory to notify authorities of the use of fluoroquinolones.

Treatment guidelines have been developed regarding use of antimicrobial agents in cattle and pigs.

The Yellow Card scheme endorsed by the Danish Veterinary and Food Administration imposes preventive measures in pig herds using more than twice the average national consumption. Permit limits are gradually being adjusted. Please see Alban et al. (61) for an extended description of the Yellow Card scheme. (Source: modified from DANMAP [62].)

**Meat Safety Assurance Programs**

The primary purpose of meat inspection is to provide consumers with healthy meat. The meat inspection procedures were developed about 100 years ago, when tuberculosis and brucellosis played a major role in human health. Since then, the picture has changed as *Campylobacter, Salmonella,* and *Yersinia* today represent the most significant causes of zoonotic infections in humans, as noted in Fig. 1. In the European Union it is being asked whether the existing meat inspection process provides the optimal protection, what the costs are, and how we can do better. This implies a political and scientific focus on the modernization of meat inspection in the member states, the European Commission, and EFSA. The EU Council asked the EU Commission to look at how a risk-based approach could be incorporated increasingly into the legislation. This applies to which hazards are to be covered by meat inspection and how such hazards should be monitored/surveyed. The EU Commission then asked EFSA to clarify these two issues scientifically. EFSA sent out two reports regarding pigs in September 2011. The first report concerned the identification of infectious agents (hazards) that are relevant for food safety in relation to pigs and pork (63). The next report identified so-called harmonized epidemiological indicators (metrics) for the hazards that are identified as being relevant to food safety (64). Similar reports have been made for poultry (in 2012), ruminants (in 2013), sheep and goats (in 2013), and solipeds (in 2013). Please go to http://www.efsa.europa.eu for all reports.

According to these reports, the main food safety hazards associated with pork are *Salmonella,* *Yersinia,* *Toxoplasma,* and *Trichinella.* None of these can be dealt with macroscopically at meat inspection (63), and only *Salmonella* and *Trichinella* are covered by existing regulations as described above. As also stated above, EFSA developed a list of epidemiological indicators, meaning ways an indication of the presence (or prevalence) of each of the individual hazards can be obtained (64). The list was primarily based on scientific considerations, and not on economic and practical concerns. The approach taken by EFSA was to look broadly at surveillance and thus not only on what happens in a slaughterhouse in connection with the meat inspection. The indicators were divided according to location in the production line: in the herd, during transport to the slaughterhouse, at the slaughterhouse, or by biosecurity audits of the herds. The latter can be seen as similar to the concept of controlled housing used in the *Trichinella* regulation and referring to top biosecurity. EFSA recommends the establishment of pork safety assurance frameworks that cover the entire production chain from stable to table (63). A similar line
of thinking has been used for cattle/beef and poultry/poultry meat.

The concept of food chain information can be used for such safety assurance programs. For example, currently, all cattle must be inspected for *C. bovis* by making incisions into the masseter muscles even in regions where the prevalence is very low. A recent Danish study has shown that female cattle are at higher risk of *C. bovis* compared to males, probably because females are grazed more often and live longer than males, resulting in more exposure to the parasite. If only females are inspected, almost the same number of positive cattle are found as when all cattle are inspected. Hence, gender can be used as food chain information determining the kind of meat inspection to which the carcass is subjected (51). The future of meat inspection for bovines is currently being discussed between the EU Commission and the member states. As of mid-2015 it is unknown whether changes will be introduced. In particular, *C. bovis* and bovine tuberculosis are being discussed. It is feared that a visual-only inspection will lead to poorer detection of these zoonotic agents. This can be compensated for by the use of risk-based sampling of high-risk subpopulations as well as using several years of surveillance, as described by Calvo-Artavia et al. (51, 65) and Foddai et al. (66).

By June 2014, the European Union meat inspection regulation for pigs was changed, making visual-only the customary way of conducting inspection if food chain information is exchanged routinely between the farmer and the abattoir (67). Palpation will now take place only upon suspicion. Suspicion could arise if any abnormalities are seen during ante-mortem or postmortem inspection or if epidemiological data or food chain information indicates that palpation or incision is necessary. It is expected that visual-only inspection will be gradually implemented during the coming years in most European Union member states. Again, concern about reactions from importing trade partners outside the European Union may play a role in the speed of the implementation.

**Private Industry Standards**

Private standards might act as food safety assurance frameworks as suggested by EFSA. Such standards are gaining increasing importance by combining different aspects of food production that are of interest to customers and consumers. Private standards are built on top of international and national legislation (Fig. 4). They constitute an effective way of dealing with food safety, because they ensure implementation of legislation and new requirements while also providing documentation for trade partners. The specific requirements in the standard are customer-driven. One possible drawback is that use of standards is more costly when herds and abattoirs are numerous and small compared to few and large.

In Denmark, a private standard has been developed for pig production. This standard is called the DANISH Product Standard, and it defines the requirements for the production of Danish pigs. It is accredited to an international standard called EN45011. Compliance with the standard is checked by an independent third party, who visits every pig farm at least once every 3 years. During the visit, compliance with all requirements is checked in detail. The main focus of the DANISH Product Standard is the key areas affecting animal welfare, meat safety, and traceability in the primary production of pigs. Detailed requirements are described for each of the following areas, and an example of what it covers is given for each area:

1. **Pig identification and traceability:** Pigs for slaughter must be tattooed and ear-marked if exported.
2. **Feed:** Antimicrobial growth promoters are not allowed.
3. **Herd health and use of medicine:** Treated animals must be clearly identified, and withdrawal periods after antimicrobial treatment should be complied with.
4. **Treatment of sick or injured pigs:** Diseased pigs are placed in hospital pens.
5. **Housing and equipment:** Bedding must not be harmful to the pigs. Therefore, it is forbidden to
use peat unless it has been heat-treated or specifically approved by the Danish SPS-Health status department.

6. **Outdoor production**: Pigs kept outdoors must be fenced with an inner and outer fence.

7. **Feed and water provision**: There should be free access to clean and fresh drinking water for pigs >14 days old.

8. **Management**: All pigs >28 days old have to be inspected at least once a day.

9. **Delivery of pigs**: Pigs may be held for a maximum of 2 hours in mobile collection pens.

If the inspector finds conditions not in accordance with the above-listed requirements, he might take one of the following three actions, depending upon how serious the lack of compliance is:

1. Record a critical comment in the auditing report with a requirement for immediate action.
2. Ask producer to submit follow-up documentation in the form of a photo or a note showing that the condition is corrected.
3. Revisit within 3 months. If conditions have not been put right by this time, the approval is lost.

More information and appendices for the DANISH Product Standard can be found at [http://vsp.lf.dk/~media/Files/DANISH/DANISH%20produktstandard/Produkt_Standard_UK.pdf](http://vsp.lf.dk/~media/Files/DANISH/DANISH%20produktstandard/Produkt_Standard_UK.pdf).

**CONCLUSION**

Within the European Union, it is being recognized that *Salmonella* and *Campylobacter* need to be addressed specifically. For *Salmonella* in poultry, the experience is that setting targets in the primary production arena results in a lower number of human cases, whereas for *Salmonella* in pigs it is crucial to focus on the abattoir. For *Campylobacter*, no easy risk-mitigating strategies exist. The focus here should first be on identification of feasible instruments. Moreover, the role of the environment in the transmission of *Campylobacter* is being increasingly acknowledged, although not much is known about the exact pathways leading to exposure of humans.

For *Trichinella*, testing has to take place in only the noncontrolled housing compartment, meaning outdoor-reared pigs or pigs reared on farms with poor biosecurity. For BSE, changes related to how to deal with SRM are in the pipeline, because the vast majority of member states in the European Union are considered to have a negligible risk of BSE.

There is no direct preharvest regulation of the zoonotic hazards *C. bovis*, *T. saginata*, *Toxoplasma*, *Yersinia*, STEC/VTEC, *Listeria*, and foodborne viruses. Discussion of how to deal with these hazards in the future is ongoing.

To ensure food safety, further focus should be on the entire production chain. For each commodity, it should be carefully considered which hazards need to be covered by surveillance and how. Subsequently, control points should be identified. This should involve measurements of either the hazards themselves or the production systems, where this makes sense and is most cost-effective.

To combat the risk related to antimicrobial resistance, the focus in the European Union will be on prudent use, treatment guidelines, and restriction of use of critically important antimicrobials such as fluoroquinolones and cephalosporins. Detailed monitoring of use in individual animal species and age groups is expected because without such knowledge no targeted effort can be made.

Traditional meat inspection provides limited public health compared to the resources invested. Meat inspection is therefore being modernized within the European Union, emphasizing a simple and targeted approach to ensure cost-effectiveness.

All these needs can be addressed by the use of quality assurance schemes based on private standards incorporating public requirements and make use of appropriate food chain information. Such schemes should be accepted internationally.

The precautionary principle can and should be used where needed, but actions taken should be of limited duration and of a proportionate dimension in order not to distort trade. Moreover, risk managers including politicians should be willing to lift restrictions when the risk is declining (as noted for BSE) to ensure cost-effective protection of food safety implying no unnecessary waste of resources while safeguarding consumer confidence.

The European Union consists of 28 member states, and the rules that are set are minimum rules, which can be complied with by most member states. In general, flexibility is allowed as an acceptance of the wide variety of productions systems, climatic conditions, and traditions that exists in the different member states. This flexibility also makes it possible for individual member states to set higher standards, where this is judged reasonable.

Finally, it should be emphasized that it is the FBO’s responsibility to place safe products on the market.
Agreements on targets and method freedom will act as incentives to identify cost-effective and feasible means.

ACKNOWLEDGMENTS
Several people have contributed to this chapter: Annette Cleveland Nielsen, Annette Lychau Petersen, Gudrun Sando (the Danish Veterinary and Food Administration), Maj-Britt Albrechtsen, Mie Nielsen Blom, Jan Dahl, Claus Heggum, Vibeke Møgelmose, Annette Dressing, Mariannande Sandberg, Lene Lund Sørensen, Flemming Thune-Stephensen (the Danish Agriculture and Food Council), Erik Rattenborg (SEGES), Lene Trier Olesen (Arla Foods Amba), and Liza Rosenbaum Nielsen (University of Copenhagen).

The author declares a conflict of interest: The author is working for an organization that gives advice to the agricultural sector of Denmark, including farmers and abattoirs.

REFERENCES

