EUROPEAN COMMISSION



Brussels, XXX [...](2011) XXX draft

COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT

Accompanying the document

Commission Regulation laying down detailed rules on a Salmonella food safety criterion in fresh meat of fowl of Gallus gallus and turkeys

EN EN

EUROPEAN COMMISSION



Brussels, xxx SEC(2010) xxx

COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT

Accompanying the document

Commission Regulation laying down detailed rules on a Salmonella food safety criterion in fresh meat of fowl of Gallus gallus and turkeys

EN

Section 1: Procedural issues and consultation of interested parties

ORGANISATION AND TIMING

The lead Directorate-General for this initiative is the Directorate-General for Health and Consumers (DG SANCO).

The Impact Assessment Steering Group (IASG) was established with the following DGs nominating representatives: SANCO, AGRI, TRADE and SG. The IASG first met on 25 May, with subsequent exchanges of views by e-mail and a second meeting held on 17 March 2010. A final consultation was carried out electronically in December 2010.

The Impact Assessment was submitted in December 2010 and the Impact Assessment Board was consulted on 26 January 2011.

CONSULTATION AND EXPERTISE

External expertise

External expertise from the European Food Safety Authority (EFSA) was used to analyse the data on the *Salmonella* prevalence in fresh poultry in the period 2004-2007 and to estimate potential non-compliance under a number of possible options for detailed rules (See Tables 9 and 11).

A questionnaire was sent to the Member States (MS) and European stakeholders organisations at the end of May 2009. General information on consumption, production data and impact of recalls and outbreaks, information on experiences with existing food safety criteria and information on expected impact of the new criterion in fresh poultry meat was requested.

Replies were received from competent authorities of 18 Member States and Switzerland, from 11 stakeholders' organisations and from 4 individual food business operators (FBOs). The outcome is summarised in Annex 1.

Consultation of competent authorities

Exchanges of views on the detailed rules for the *Salmonella* criterion in fresh poultry meat and its potential impact took place in legislative working group meetings with Member States, Switzerland and Norway on 6 and 7 April, 18 May 2009, 17 June, 1 July and 9 September 2009. The discussions on the detailed rules of the *Salmonella* criterion for fresh poultry meat with the Member States started 16 June 2010 in the meeting of Chief Veterinary Officers (CVOs). A draft proposal for Regulation laying down the *Salmonella* criteria for fresh poultry meat has been discussed in the meeting of Commission working group on microbiological criteria for foodstuffs on 25 June, 13 July, 8 September, 8 October and 29 October 2010.

Consultation of European stakeholders' organisations

On 23 January 2009, a meeting was organised with Association of Poultry Processors and Poultry trade in the EU (a.v.e.c.), the European Farmers and European Agri-Cooperatives

(COPA-COGECA) and the Retail, Wholesale and International Trade (EuroCommerce) mainly to request information on the potential economic impact of a criterion.

In April 2009, all members of the SANCO Stakeholders Consultation Forum have been invited to indicate their interest in participating to consultation meetings. The final consultation group consisted of a.v.e.c., the International Federation of Organic Agriculture Movements (IFOAM), the European Feed Manufacturers' Federation (FEFAC), the European Rural Poultry Association (ERPA), the European Consumers Organisation (BEUC), the European Livestock and Meat Trading Union (UECBV), COPA-COGECA and EuroCommerce. The group was consulted on 4 June and 3 September 2009. All stakeholders remained updated on the progress of a draft proposal during 2010. Official letters on the issue were received from a.v.e.c., COPA-COGECA and EuroCommerce between the beginning of 2009 and the end of 2010.

Consultation of international partners

Since the adoption of Regulation (EC) No 2160/2003, third countries have been reminded at several occasions on the application of the *Salmonella* criterion in fresh poultry meat from 2011 on.

Following technical agreement on a draft Regulation in the Standing Committee of the Food Chain and Animal Health at the beginning of 2011, a WTO (SPS) consultation will take place. In the meantime, requests for information are addressed bilaterally.

<u>OPINION OF THE IMPACT ASSESSMENT BOARD ON THE DRAFT IMPACT ASSESSMENT REPORT</u>

The Impact Assessment Board concluded on 31 January 2011 that the draft impact assessment report provides sufficient evidence to justify policy action. The main recommendations for improvements were a better explanation of the wider legal and policy context, a further indication of the rationale behind the options examined, an amelioration of the presentation of health impacts with text to justify scores, a justification of the ranking of options and certain issues on the procedure and presentations.

All these main recommendations have been taken into account in this final version by introducing additional paragraphs.

Section 2: Problem Definition

BACKGROUND

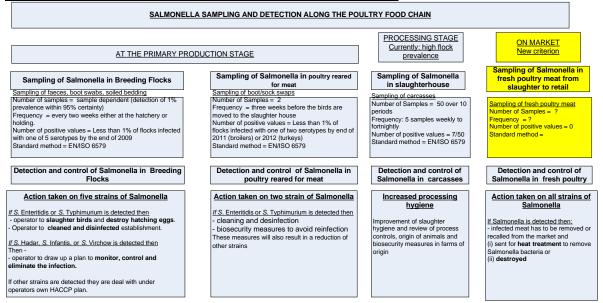
In 2003 the European Parliament and Council adopted a legislative measure on the control of *Salmonella* and other specified food-borne zoonotic agents in food (Regulation (EC) No 2160/2003). The legislation sets targets for reduction of *Salmonella* prevalence in animal populations considered at risk:

- Salmonella control was first introduced in breeding hens as they were considered to be an important source of infection for their offspring (laying hens and broilers). Legislation established monitoring regimes and targets for reduction in flocks and the destruction of eggs if flock infected with certain serotypes.
- Secondly, controls were introduced in flocks of layers, eggs being by far the most important cause of salmonellosis outbreaks in humans. Legislation established monitoring and targets for reduction in flocks and the destruction of eggs if flock infected with certain serotypes.
- Next in the farm to fork approach is poultry meat as it was the second most reported source of salmonellosis infection when the Regulation was adopted. Monitoring and targets for reduction already apply, now to be completed by trade restrictions if the meat is still contaminated. Due to the success of measures further up the chain poultry meat has became a less important source of salmonellosis infection. However, in order to ensure progression with the reduction programme it is considered important that the requirement laid down in the overarching legislation (for a food safety criterion) is introduced at the end of the chain.
- Finally, the Commission is currently cost/benefit analyses are done on the feasibility of *Salmonella* control in pigs.

The aim of this particular policy is to ensure that *Salmonella* reduction measures further down the chain are being observed and that Europe's overall levels of human salmonellosis are reduced. This impact assessment focuses on establishing a harmonised *Salmonella* food safety criterion¹ in fresh poultry meat (i.e. chicken and turkeys) and the trade restrictions set for non-compliant poultry meat. It is not considered that individually the policy will have a significant direct impact on public health through withdrawal of food on the market but, indirectly, the testing and the actions that follow a positive finding should over time improve hygiene along the supply chain.

¹ Regulation (EC) No 2073/2005 define the food safety criterion as the acceptability of the batch and if *Salmonella* is present in any of the sample units tested, the batch has to be withdrawn from the market or, if not yet at retail level, may be submitted for further processing.

IMPLEMENTATION OF THE LEGISLATION TO DATE



As regards poultry meat, a *Salmonella* process hygiene criterion for poultry carcases was introduced on 1 January 2006 at the processing stage before *Salmonella* control programmes started at primary production in accordance with Regulation (EC) No 2073/2005 on microbiological criteria in foodstuffs². Such process hygiene criterion indicates the acceptable functioning of the production process. It has no impact on meat placed on the market (no withdrawal or recall resulting in a limited economic impact) and intended to be a first step towards *Salmonella* control while the prevalence in flocks was still high.

By the adoption of Regulation (EC) No 2160/2003, the Parliament and Council required however that the Commission moved to a stricter food safety approach with market restrictions when a reduction of *Salmonella* in flocks had to be achieved. The new criterion is a food safety criterion defining the acceptability of a product or a batch of foodstuff. It is applicable to products ready to be placed on the market or which are already in the market. Samples can be taken from slaughter until the end of shelf-life.

Salmonella food safety criterion already exist for meat preparation, meat products (e.g. chicken nuggets) and minced meat derived from fresh poultry meat (5 samples per batch, no tolerance).

See Annex 2 for further information on the measures introduced to control the prevalence of *Salmonella* along the poultry food chain.

WHAT IS THE ISSUE OR PROBLEM THAT MAY REQUIRE ACTION?

As outlined above, Regulation (EC) No 2160/2003 establishes targets for reduction of *Salmonella* in poultry along the food chain, trade restrictions on animals and food (i.e. meat) and considers a harmonised approach to sampling regimes for food businesses operators to test for *Salmonella* presence. Targets for reduction and the sampling requirements for the first two steps in the food chain (breeding flocks and broilers/turkeys) have already been put in place.

_

² OJ L 338, 22.12.2005, p. 1.

This impact assessment focuses on the harmonised sampling rules for the application of the food safety criterion for the final stage requiring, according to the Regulation, the absence of *Salmonella* in 25 grams of the fresh poultry meat from the end of 2010. In order to meet this criterion, detailed rules i.e. sampling schemes and analytical methods need to be set. However, there is a discrepancy between the timing needed to achieve *Salmonella* reduction target in flocks and the date of application of the food safety criterion at the fresh meat stage.

The differences in the prevalence of *Salmonella* in flocks in the Member States were illustrated during baseline surveys before control programmes started. Table 4 in Annex 2 provides the results, showing that substantial time may be needed to reduce *Salmonella* in flocks in certain Member States. Too early application of the food safety criterion could be problematic for economic operators and other stakeholders The Regulation identifies the possibility to adjust the targets or/and sampling criteria in light of its costs and benefits analysis, changes to the scientific risk assessment and trends in incidence.

This impact assessment analyses in terms of costs and benefits various sampling methods for testing *Salmonella* presence in fresh poultry meat.

HUMAN SALMONELLOSIS AND FOOD-BORNE SOURCES

Human salmonellosis

Salmonella is an important source of food-borne diseases in humans in the EU. Human salmonellosis can range from a mild (characterised by the acute onset of fever, abdominal pain, nausea and sometimes vomiting) to severe gastroenteritis and in some patients, invasive disease, which can be life-threatening. Salmonellosis might also result in long-term and sometimes chronic sequelae e.g. arthritis.

According to the EFSA/ECDC report on monitoring of zoonoses in 2008³ (the "2008 zoonoses report"), the decreasing trend in the notification rate of salmonellosis cases in humans continued. However, salmonellosis still remained the second most commonly reported zoonotic disease in the EU. There were a total of 131,468 reported cases of human salmonellosis in the EU 27. Although it is considered that these figures only represent part of the real number of cases. Estimates from a UK and Dutch study⁴ suggest that the real number of cases could be 3.2 to 13.9 times higher. Recently, EFSA adopted an opinion⁵ indicating that the underascertainment ratio of clinical illness at EU level range between 5 and 100 in different Member States.

The EU notification rate was 26.4 cases per population of 100,000, varying from 2.9 to 126.8 confirmed cases per population of 100,000. DE accounted for 32.6% of all reported cases, whereas the notification rate was highest in Slovakia.

.

³ The ECDC/EFSA Community Summary report on trends and Sources of zoonoses and zoonotic agents and food-borne outbreaks in the EU in 2008, The EFSA Journal (2010), 1496. http://www.efsa.europa.eu/en/scdocs/scdoc/1496.htm

⁴ Extracted from: Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission on a quantitative microbiological risk assessment on *Salmonella* in meat: Source attribution for human salmonellosis from meat (the EFSA Journal (2008) 625, 1-32)

⁵ Scientific opinion on a quantitative estimation of the public health impact of setting a new target for the reduction of Salmonella in laying hens, adopted during the meeting of the EFSA BIOHAZ Panel on 9 and 10 March 2010.

Detection in food-borne sources

MSs continue to report *Salmonella* findings from investigations of poultry meat. The overall proportion of positive samples in fresh broiler meat was 5.1% at EU level varying between 0% and 75.5 % in MSs (source: 2008 zoonoses report). The main sources identified in verified outbreaks of salmonellosis were eggs and egg products (40.8%), followed by inadequately heat treated bakery products (13.5%), pig meat and products thereof (7.1%), mixed or buffet meals (6.3%) and poultry meat and products thereof (3.9%)⁶.

Public health cost of salmonellosis caused by poultry meat

In the EFSA opinion (referred to in footnote 4), extrapolation of Dutch research data to the EU27, resulted in an estimation of the total cost of all *Salmonella* infections between 0.2 and 3 billion Euro per year. Extrapolation of other studies in UK and Finland results in an annual cost of food-borne *Salmonella* of \leq 400-900 million per year. Based on the above outbreak investigations and additional national studies referred to in Annex 3, it is estimated that poultry meat contributes to 4 to 10% of human salmonellosis creating a burden of \leq 16 to 90 million per year. More details on these estimations can be found in Annex 3. *S.* Enteritidis and *S.* Typhimurium remain the most frequently reported serovars (81% of all known serovars in human cases).

UNDERLYING DRIVERS OF THE PROBLEM ARE:

- 1. The problem with salmonellosis in the EU leading to significant public health impacts;
- 2. Short timing for the application of targets further up the food chain, possibly resulting in a possible disproportionate economic impact when applying of the food safety criterion at the fresh meat stage;.
- 3. Too short timing for the establishment of national control programmes (NCPs) at the MS level necessary to monitor trends and current situation of *Salmonella* zoonosis. Hence, any evaluation or/and assessment of trends and developments of *Salmonella* is not possible yet;
- 4. The need to consider a risk to consumers of *Salmonella* contamination at the fresh poultry meat stage; and
- 5. Diversity and freedom of choice for sampling methods (from very stringent to of the minimal standards) risk poultry market distortion both within and outside the EU.

WHO IS AFFECTED, IN WHAT WAY, TO WHAT EXTENT?

What products are affected?

The food safety criterion of absence in 25g gram of *Salmonella* will apply to fresh poultry meat (e.g. whole raw chicken and turkey carcasses, raw chicken and turkey cuts – breasts, thighs, legs etc.) either sold by refrigeration or by frozen means. The criterion will also not cover ducks, guinea fowl, partridge or other game birds.

⁶ The Community Summary Report on Food-borne outbreaks in the EU in 2007, *The EFSA Journal* (2009), 271

⁸ 4% -10% of the total cost of food-bourne Salmonella estimated to be approx. €400-900 million)

Which stakeholders?

Implementing a food safety criterion of 25 gram absence of *Salmonella* at the end of the food chain and applying its detailed harmonised sampling regimes will affect not only for FBOs but also regulators which in turn might affect to a certain degree end food chain actors - consumers.

The food safety criterion in the basic Regulation (EC) No 2160/2003 applies to meat placed on the market. The criterion therefore applies to **wholesalers** and **retailers** within the EU and third country traders who will be impacted if fresh poultry meat is found to be contaminated with *Salmonella* within the frame of voluntary self-checks or official controls. This application to the final suppliers of poultry meat ensures fair competition between meat produced in the EU and imported meat.

Minimum requirements for sampling will only be laid down for poultry **slaughterhouses and processing (cutting) plants**. As FBOs are responsible for sampling and testing, they will have to bear relevant costs (i.e. collection samples and submitting them to approved laboratories for testing of, administrative costs), which might either increase or decrease depending on, among others, frequency of sampling, a number of samples per batch or a sampling method in general to be applied.

It is likely that, the positive samples identified for the food safety criterion at the fresh meat stage will also have an indirect affect on the **primary production sectors** further up the food chain. Detecting *Salmonella* in fresh poultry meat will result in FBOs identifying the source and putting in place further measures on primary producers to ensure improved food safety and quality.

The proposal is not directed to **Competent Authorities** (**CAs**). They are, however, responsible for verification of the compliance of the food safety criterion, and control and monitoring of the *Salmonella* presence.

Consumers as the end user in the food chain might also be affected by this criterion in two ways. Firstly, a stringent criterion will result in an increase in a number of withdrawals or recalls of poultry meat contaminated with *Salmonella*, which in turn might reflect in the loss of consumer confidence to poultry meat in general and shifting to substitutes (i.e. red meat), not always perceived as a source of salmonellosis but often considered as less healthier from a nutritional point of view. However, consumers in certain Member States, in particular in the north of Europe, generally feel more ensured on the safety of poultry meat as withdrawals or recalls demonstrate the official controls are able to detect and withdraw risks (outcome of discussion with Member States). Secondly, stricter rules for *Salmonella* control at the fresh meat stage will result in measures all over the production chain to decrease *Salmonella* prevalence, which shall lead to a reduction of human salmonellosis cases.

See Annex 4 for further information on the poultry market and consumption patterns.

HOW WOULD THE PROBLEM EVOLVE, ALL THINGS BEING EQUAL?

By the end of 2010, the criterion in the Regulation (EC) No 2160/2003 applies. Each food business operator would need to consider how they would interpret the requirement – absence in 25g – and establish a sampling regime to be compliant with the requirement. In order to allow for uniformed application and verification, Member States' national control authorities might establish guidelines for FBOs on sampling in order to meet the criterion absence in 25 grams.

As currently the prevalence of *Salmonella* varies significantly from Member State to Member State (see Table 1), applying a non-harmonised criterion could have variable impacts across the European Union. In addition, if the requirement comes into effect with non-harmonised rules there is a potential that food businesses operators could introduce different sampling regimes and therefore find different amounts of *Salmonella* contamination at the fresh meat stage. The effect of such event is assessed under option 1.

Table 1: *Salmonella* prevalence (% positive samples) in fresh broiler meat at retail, 2004-2008 (source: 2008 zoonoses report)⁹.

	2008	2007	2006	2005	2004
Austria	7.8	5.8	-	-	-
Belgium	11.4	9.2	7.5	2.2	13.5
Bulgaria	0.3	-	-	-	-
Estonia	-	-	10.3	11.8	-
Germany	10.8	8.5	-	-	12.9
Greece	15.6	11.6	-	18.2	0
Latvia	8.2	3.0	-	11.5	7.3
Lithuania	16.2	-	-	-	-
Luxembourg	5.9	6.7	6.6	0	0
Netherlands	7.7	8.1	8.4	9.4	7.4
Slovenia	0.6	2.3	-	-	7.4
Spain	3.6	10.2	3.4	3.8	9.7
United Kingdom		-	3.6	4.0	3.9

Disparities between the contamination rates in meat and in prevalences in flocks (as illustrated in Table 4 in Annex 2) across Member States may reflect efforts taken so far by the Member States in controlling *Salmonella* in the poultry production chain.

<u>DOES THE EU HAVE THE RIGHT TO ACT – TREATY BASE, 'NECESSITY TEST'</u> (SUBSIDIARITY) AND FUNDAMENTAL RIGHTS LIMITS?

The Commission has the legal obligation to lay down detailed rules in accordance with the provisions in Regulation (EC) No 2160/2003. Food safety is largely an EU competence and food safety criteria such as this *Salmonella* criterion is an exclusive EU competence. Harmonised detailed rules on the food safety criterion are needed to guarantee correct competition and similar acceptance of food on the internal market, and to provide uniform conditions in the whole EU for import from third countries.

⁹ The 2008 zoonoses report of EFSA only provides data from these Member States on monitoring of fresh poultry mea tat retail. EFSA only included data if at least 25 samples per Member States were taken to ensure a significant meaning of the percentages. Results from sampling at other stage of the food chain from other Member States are also in the 2008 zoonoses report.

Due to various food crisis food standards have been harmonised at the EU to ensure confidence in EU markets. Standardising the methods for detection for major risks to human, animal and plant health promotes harmonised protection across the Community. In the absence of harmonised detailed rules, MSs may apply different detailed rules and may not be ready to accept controls made in other MSs, fragmenting the internal market. The Commission also has the task to ensure the same high level of food safety standards apply in all Member States and therefore the principle of mutual recognition can not be used in this case.

Section 3: Objectives

WHAT ARE THE GENERAL POLICY OBJECTIVES?

The general objective of the Regulation is to ensure safe food for consumers and improve public health by establishing safe guards to control *Salmonella* at critical points all along the food chain.

The general policy objective for this initiative is also to ensure that the efforts being carried out earlier in the food chain to achieve the reduction target in flocks, are not being compromised by not adequately control at the fresh meat stage.

WHAT ARE THE SPECIFIC/OPERATIONAL OBJECTIVES?

The specific objectives to achieve that aim include:

- Ensuring that consumers have reasonable assurance that fresh poultry meat placed on the market becomes gradually free from relevant *Salmonella*;
- Establishing harmonised detailed sampling schemes and analytical methods to ensure the functioning of the internal market and third country trade without placing unnecessary burdens on businesses and any other parties;
- Ensure consistency with other European Union objectives in particular commitments relating to sustainable production and the small business act;
- Ensure the compliance with the Commission's "from farm to fork" / "from stable to table" strategy (food safety along the food chain).
- Ensure that, where possible, the detailed rules (analytical method, sampling method, sampling frequency, ...) have been aligned with the provisions in Regulation (EC) No 2073/2005 for practical reasons, for reduction of sampling costs and for consistencies across the legislative piece.
- Ensure the possibility for a risk-based adjustment of the sampling frequency similar to the one for the existing *Salmonella* criteria for carcases e.g. reduction of sampling frequency when previous results were favourable and a risk-based reduction in small establishments subject to the discretion of the Member States.

<u>UNDERLINE THE CONSISTENCY OF THESE OBJECTIVES WITH OTHER EU</u> POLICIES AND, IF APPLICABLE, HORIZONTAL OBJECTIVES

The general objectives identified above, especially regarding the EU action to ensure consumer and human health protection are compatible with the EU Charter of Fundamental Rights.

Section 4: Policy options

WHAT ARE THE POSSIBLE OPTIONS FOR MEETING THE OBJECTIVES AND TACKLING THE PROBLEM?

<u>Policy Option 1 – Do nothing</u> – allow the absence of *Salmonella* in 25 grams criterion in fresh come into force at the end of 2010 without applying harmonised rules for its application amongst FBOs. Although this option is in contradiction with the basic requirement laud down by the European Parliament and the Council, its impact was assessed as it represents the Commissions' "do nothing" option.

<u>Policy Option 2 – Apply the absence of 25 grams criterion with harmonised sampling rules – apply the absence of all *Salmonella* in 25 grams criterion from the end of 2010 but set detailed rules for FBOs about how the criterion should be applied and monitored.</u>

<u>Policy Option 3 – Apply the absence criterion to only the 2 most significant serotypes of Salmonella</u> with harmonised sampling rules as a transitional measure – apply the absence of Salmonella in 25 grams criterion to the serotypes that pose the largest risk to public health, e.g. the serotypes that already have marketing restriction further up the food chain (Salmonella Typhimurium and Salmonella Enteritidis)

<u>Policy Option 4 – Apply the absence criteria but to 10 grams rather than 25 grams, with harmonised sampling rules</u> as a transitional measures – reduce the sensitivity of testing. Due to its support from the most relevant stakeholders, the impact of this option was assessed despite the contradiction with the basic requirement (25 grams) and analytical constrains (no ISO method).

<u>Policy Option 5 – Apply a tolerance</u> allowing meat on the market in which *Salmonella* is present in 1 of the samples taken.

<u>Policy Option 6 - Postpone the coming into force date until the prevalence is low - The existing process hygiene criterion would remain applicable in this option.</u>

All options can be laid down by the regulatory procedure with scrutiny (Article 5a §3(a) of Council Decision 1999/468/EC, as amended by Council Decision 2006/512/EC).

WHICH OPTIONS HAVE BEEN DISCARDED AT AN EARLY STAGE AND WHY?

No policy option has in principle been excluded beforehand. During consultation stakeholders raised concerns about the socio-economic impacts of a target being set at the fresh poultry meat level and have suggested that the primary legislation be revised in order to remove the food safety criterion. The primary legislation, however, gives no flexibility the Commission to lay down these rules or not.

According to legal advice, the Member States, the European Parliament and Council could bring an action before the Court of Justice against the Commission for failure to act in case no detailed rules are laid down.

In addition, removal of the criterion completely would prevent the overall policy objective to ensure safe food for consumers by establishing safe guards at critical points all along the food chain being achieved. It is considered that certain policy options identified above are a better alternative to minimise the socio-economic impacts without jeopardising the policy objective of consumer safety.

Other non-regulatory actions were considered during the development of the impact assessment and the evaluation of the preferred option. Consideration as to whether campaigns on good hygiene and meat preparation in kitchen as an alternative to legislation were considered but due to the diversity in cooking practices and consumption habits across the EU it was considered that the principles of subsidiarity would work better in order to achieve significant additional public health benefits.

During the consultations, three Member States contested the sampling of neck skins in slaughterhouses for the purpose of this food safety criterion, proposing sampling at a later stage on chicken breast or parts. This option was not maintained because

- Ø FBOs are used to neck skin samples (existing process hygiene criterion)
- Ø It allows to make a link with the farm of origin
- Ø It is considered by EFSA as the most appropriate sample for monitoring of fresh meat
- Ø It is preferred by a qualified majority of Member States
- Ø It is the earliest sample of fresh meat that can be taken, maximising the time for analysis

Section 5: Analysis of impacts

This section explores the likely economic and social impacts of each of the options identified above within the EU and wider.

The main focus of the economic impacts will be on FBOs. The majority of the costs in applying the food safety criterion with detailed sampling and testing rules, will be borne by FBOs. Regarding social and health impacts, this IA will try to identify potential disadvantages and benefits, in the short and long term, for consumers, resulting from application of the criterion.

The costs of sampling and analysis depend mainly on the number of analysis carried out, as the time related to collect one or several samples from a batch is similar and is not expected to make a big difference to the cost.

It should be noted that the estimations in this section do not differentiate between organic/free range and conventional production because no specific data could be provided by stakeholders organisations dealing with organic/free range production. Sampling costs are the same but losses in case of withdrawal or recalls are higher. A cost difference of 100 % for organic production would not be an exception.

Organic and free range represents less than 5 % of the poultry production but differences between Member States exist. During baseline surveys, the flock production type was not significantly associated with the prevalence of *Salmonella* spp. in broilers. The *Salmonella* prevalence was almost twice as high in free range turkeys compared to conventional ones.

The following impacts were assessed to the extent possible for the different options:

- Ø Economic impact for food business operators including sampling and testing costs, cost because of withdrawal and recalls, loss of sales, switches of suppliers
- Ø Impact on the internal market
- Ø Impact on third country trade
- Ø Verification costs for competent authorities
- Ø Social impact for food business operators and consumers.

Apart from testing costs (sampling and analysis), the uncertainty on the assumptions and the variation of data estimations provided by stakeholders made analysis and accurate estimation of costs extremely difficult (e.g. conflicting data from stakeholders, the spread of the EFSA estimation of human burden etc).

Therefore, not all impacts could be calculated into detail. Where estimations are provided they should be interpreted with care. It should also be taken into account that estimations are based on 2008 data and do not taking into account progress made due to the *Salmonella* control programmes in flocks.

It should be highlighted that the direct impact from withdrawal of incompliant meat on human salmonellosis is expected to be limited. This is due to the short "use-by" dates for meat placed fresh on the market (80%) and therefore most of the batch may be consumed before the results of analysis are available. A far more important indirect effect is, however, expected as the possible withdrawal creates an incentive to the downstream actors such as farmers and slaughterhouses to take the appropriate preventive measures. In addition, incompliant batches will be traced back to the farm of origin where measures will be taken to prevent contamination of following flocks.

It is obvious that both the public health and economic impact (from withdrawals and subsequent actions) will be most significant in those Member States currently having a high prevalence in poultry meat and flocks (See Table 1 above).

In addition, regardless of the option chosen, a risk-based adjustment of the sampling frequency will be considered as the existing *Salmonella* criteria allow a risk-based reduction of sampling frequency e.g. fortnightly when previous result were favourable and a risk-based reduction in small establishments. However, for ease of comparison for each of the different options in the Impact Assessment (and to limit the number of variables when carrying out quantitative calculations) the same sampling frequency (weekly) was used. The impact of fortnightly sampling is, however, illustrated in option 2.

Detailed estimations are therefore put in Annex 5 while a more qualitative approach and relative comparison are used in the analysis of the options below.

1. POLICY OPTION 1 – DO NOTHING

If the Commission does not lay down the detailed sampling schemes and analytical methods as requested by the Regulation then only the criterion 'Salmonella: absence in 25 grams' in fresh poultry meat will apply. Not establishing harmonised detailed sampling rules will allow freedom for Member States and FBOs to decide on criterion's interpretation establishing adequate sampling schemes to ensure the requirement is met. Therefore FBO in the different MS will operate under different conditions and the results will be uneven and not comparable. This will affect intra-Community trade and lead to a re-nationalisation of the poultry meat market. In addition there will be also a distortion in the border controls on imports

The intra-Community trade of poultry meat is more than 20% of the 11.5 million tonnes produced and has a value of 4.4 billion € The value of imported poultry meat that could be affected is about 350 million €

Estimated sampling costs for FBOs: 8 to 71 mio €

Estimated sampling costs for competent authorities: 1.25 mio € This cost for the verification of compliance already exists today and will remain the same in all options. Therefore it is not repeated in the next options.

Estimated other economic costs (e.g. recall and withdrawal): 8 to 64 mio €

The public health impact of this option depends on the approach taken at national level, is therefore unpredictable and may vary between the Member States.

Position of stakeholders on this option

Neither the competent authorities of Member States nor private stakeholders organisations support for this option. They insist on a harmonised EU approach in order to avoid trade difficulties.

2. POLICY OPTION 2 – APPLY THE ABSENCE CRITERION WITH HARMONISED SAMPLING RULES

Implementing detailed sampling rules on the absence of all *Salmonella* in fresh poultry meat, all FBOs across Europe will be required to carryout out the same sampling regime on fresh meat. For the estimation of the impact, different options for harmonised sampling regimes from one batch of chickens per week or fortnightly for each relevant FBO, have been considered as well as different numbers of samples per batch. As reference point for the estimations, 5 samples per batch was used being the same approach as all current *Salmonella* food safety criteria for other food.

This option, requiring action in case of the detection of any type of *Salmonella*, may have a high economic impact.

Estimated sampling costs for FBOs: 36 mio €

Estimated other economic costs: 33 mio €

Since this is the option with the highest economic impact, the incentive for downstream actors to take preventive measures (indirect impact on public health) is strong; a quick achievement of the public health objective e.g. a maximum reduction of human salmonellosis through the consumption of poultry may be expected. The largest impact is expected in countries with the highest prevalence in poultry (Hungary, Spain, Portugal and Poland).

This option is used as reference for the other harmonised options below in a relative comparison of the impact. The option was used as reference being the originally planned EU approach and being most close to the requirement on meat in Regulation (EC) No 2160/2003 as well as existing *Salmonella* criteria in food.

Position of stakeholders on this option

Denmark and BEUC are strongly insisting on this option which is also the favourite one of Sweden and Finland but these two Member States accept that this option may be premature for other Member States¹⁰. Other Member States and private stakeholders are very reluctant, considering the economic impact too high as long as low *Salmonella* prevalences in flocks have not been achieved.

3. POLICY OPTION 3 – APPLY THE ABSENCE CRITERION TO ONLY MOST SIGNIFICANT SEROTYPES OF SALMONELLA

S. Enteritidis and S. Typhimurium strains represent 81% of all know Salmonella food poisoning in the EU. Whilst this assessment of risk is based on evidence across the food chain (eggs, meat of other species, ...) and not directly related to poultry meat cases, the key strains that cause food poisoning in humans are the focus of this option. This option, therefore, only requires the absence of S. Enteritidis and S. Typhimurium in the 25 gram samples.

In this option, sampling costs slightly increase because serotyping is required.

Limiting the market restrictions to these 2 serotypes, representing in 2008 14.9 % of all serotypes in broiler meat (2008 annual zoonoses report), would result in a 6 to 7-fold (100/14.9 reduction of the economic impact, except sampling cost, compared to option 2.

At the same time, the impact on public health may be the same as in option 2 since the biosecurity and hygiene measures taken to control the two *Salmonella* serotypes will also reduce the other *Salmonella* serotypes.

Estimated sampling costs for FBOs: 39 mio €

Estimated other economic costs: 4.9 mio €

The economic impact of this option is reduced compared to option 2. Therefore, the incentive for downstream actors to take preventive measures is somehow reduced. It is therefore expected that achievement of a maximum reduction of human salmonellosis through the consumption of poultry will take some more time than in option 2 but be achieved in a relatively short period.

3.1. Position of stakeholders on this option

All Member States except Denmark and France and all private stakeholders except the consumers' stakeholders can support this option. It can be considered as a compromise with a

¹⁰ Finland and Sweden obtained special guarantees at their accession because of the very low *Salmonella* prevalence and the very strict national control programmes in all food producing animals (Commission Regulation (EC) No 1688/2005 of 14 October 2005 implementing Regulation (EC) No 853/2004 as regards special guarantees concerning *Salmonella* for consignments to Finland and Sweden of certain meat and eggs). The new food safety criterion will therefore have no economic impact on these Member States.

balanced approach between costs and public health benefit. It is also in line with the focus on these two serotypes at control in flocks.

4. POLICY OPTION 4 – APPLY THE ABSENCE CRITERIA BUT TO 10 GRAMS RATHER THAN 25 GRAMS

Another option is the reduction of the sample size from 25 to 10 grams. Accordance to the European reference laboratory on *Salmonella*, this option will reduce the detection rate by 2.5 fold but the sampling costs will remain the same as in option 2.

It is expected that the economic impact, apart from sampling, of this option will be 2.5-fold reduced compared to option 2.

Estimated sampling costs for FBOs: 36 mio €

Estimated other economic costs: 13.2 mio €

Since the economic impact of this option is similar to option 3, a similar effect on human salmonellosis is expected.

Position of stakeholders on this option

Most Member States and private stakeholders can support this option. It can be considered as a compromise with a balanced approach between costs and public health benefit. It is considered less risk targeted than option 3 which focuses on the 2 most important serotypes of public health significance. It may be perceived by consumers as an unacceptable compromise on food safety.

5. POLICY OPTION 5 – APPLY A TOLERANCE ALLOWING MEAT ON THE MARKET IN WHICH SALMONELLA IS PRESENT IN 1 OF THE SAMPLES TAKEN.

A less ambitious food safety criterion with a certain tolerance could be considered.

During its meeting on 10 and 11 March 2010, the EFSA adopted a technical report on the link between *Salmonella* criteria at different stages of the poultry production chain¹¹. The report indicates that 19 to 36 samples must be analysed if a tolerance of 1 positive sample is accepted in order to be equally ambitious from a consumer protection perspective with the prevalence in fresh poultry meat observed in 2008.

Sampling costs, as FBOs would be obliged to take between 19 to 36 samples instead of 5, are very high in this option.

There is also a risk for a loss of confidence of the consumer in poultry meat and competent authorities accepting the presence of *Salmonella* in poultry meat. The impact on public health may be very low since the tolerance level may be in several Member States higher than the current prevalence.

Estimated sampling costs for FBOs: 136 to 257 mio €

-

¹¹ EFSA Journal 2010; 8(3):1545. [65 pp.]

Estimated other economic costs: 9.4 mio €

It is expected that this option will hardly create any incentive to prevent salmonellosis along the productions chain.

Position of stakeholders on this option

During discussions most Member States and private stakeholders do not support this option, mainly because of the high sampling costs.

6. POLICY OPTION 6 – DELAY THE COMING INTO FORCE DATE UNTIL THE PREVALENCE IN FLOCKS IS LOW

There is no change in costs of sampling or in social/economic impact compared to the current situation.

Salmonellosis in humans is considered an accepted risk in this option but may reduce if actions at earlier stages proceed (e.g. targets for reduction in flocks). However, there is hardly any incentive for such actions. This option has the highest chance of all options for outbreaks and loss of consumer's confidence due to such outbreaks.

It will not provide incentive to progress in control measures along the food chain, while exposing EU producers to import pressure produced at lower standards.

Estimated sampling costs for FBOs: 12 mio €(current costs).

Estimated other economic costs: 0 mio €

It is expected that this option will hardly create any incentive to prevent salmonellosis along the productions chain.

Position of stakeholders on this option

Preferred option of most stakeholders and could be supported by several of Member States. Strongly opposed by BEUC, Denmark, Finland and Sweden. It should be taken into account that FBOs had already 7 years to take the necessary steps (adoption in 2003, application end 2010), which can be used as an argument against this option e.g. by the European Parliament (the regulatory procedure with scrutiny of the European Parliament applies).

Member States informed not to apply the food safety criterion until harmonised detailed rules have come into force in the course of 2011, being in practice a postponement of the coming into force by 6 to 12 months.

Section 6: Comparing the options

Objectives Options	Ensure that consumers have reasonable assurance that fresh poultry meat placed on the market is free from relevant <i>Salmonella</i>	Establishing a harmonised sampling scheme to ensure the functioning of the internal market and third country trade without placing unnecessary burdens on businesses	Ensure consistency with other European Union objectives in particular commitments relating to sustainable production and the small business act	Ensure the compliance with the Commission's "farm to fork" strategy
Policy Option 1 – Do nothing	No harmonised rules, completely dependent of Member States initiatives	Major disruption of internal market and third country trade expected	Completely dependent on MS initiatives. It may be expected that Member States will take into account sustainable production and small business act	Not ensured (no measures for meat on the market)
Policy Option 2 – Apply the absence criterion	Mostly achieved	Achieved	May not be ensured (important economic impact)	Ensured
Policy Option 3 – Apply the absence criterion to the 2 most significant serotypes of Salmonella	Largely achieved. Meat cwith other serotypes will not be taken from the market but measures taken at previous stages will reduce all serotypes.	Achieved	Ensured	Ensured
Policy Option 4 – Apply the absence criteria but to 10 grams rather than 25 grams	Largely achieved. The lower detection rate will still be a trigger to encourage measures taken at previous stages and reducing exposure to all serotypes.	Achieved	Ensured	Ensured
Policy Option 5 – (n = 19-36, 1 positive)	Not achieved	Not achieved.	Achieved	Not ensured
Policy Option 6 – Postponement of date	Not achieved	No harmonisation or disruption of trade.	Achieved unless the increased risk of outbreaks result in loss of consumer's confidence	Not ensured (no measures for meat on the market)

<u>INDICATE HOW POSITIVE/NEGATIVE IMPACTS HAVE BEEN WEIGHED FOR</u> EACH SHORT-LISTED OPTION.

For each option, all costs of sampling by FBOs and competent authorities, the additional costs for FBO (record keeping, etc.) and the economic losses were calculated. Losses of sales because of a loss of consumers' confidence has not been taken into account because such losses may as well happen by recalls of contaminated food (may increase due to this initiative) as by outbreaks (will reduce due to this initiative). Figures provided on such losses are extremes and very exceptional in practice based on experience gained for existing food safety criteria (almost always due to outbreaks not because of recall).

All options, except a postponement of the date of application are expected to trigger sufficiently all food business operators to reduce the exposure of humans to *Salmonella*. Major differences between the options on this benefit are not expected.

<u>PRESENT RESULTS OF THE WEIGHING AND PRESENT THE AGGREGATED AND DISAGGREGATED RESULTS.</u>

In Table 2, the 6 options are being compared. As regards harmonised options 2 to 5, only a weekly sample frequency with 5 samples is maintained for clarity and because considered most relevant. Prudence is needed in the interpretation of these figures, however the relative effect of options 3 and 4, compared to option 2 is valid.

Table 2: Overall costs (mio €)

Option	Sample	Overall ch	nange	Additional	Cost of recall/	Total
	regime	in cost	of	cost (100 €per	withdrawal	additional
		samplin	ıg (FBO)	(considering	costs
					detection rates)	
		FBO	CA			
1	Lower limit	-3.4	0	0.55	8	6.4
	Upper limit	59.8	0	0.55	64	125.6
2	weekly	2.6	0	0.55	33	58.9
3	5 samples	24.0	0	0.55	4.9	34.3
4		27.6	0	0.55	13.2	39.1
5		124-246	0	0.55	9.4	135-257
6		0	0	0	0	0

Details on the estimations are in Annex 5.

<u>INDICATE IF THE ANALYSIS CONFIRMS WHETHER EU ACTION WOULD HAVE AN ADDED VALUE.</u>

Since option 1 (no EU action) completely depends on the initiatives of Member States, its economic impact varies enormously and can either be lower or higher than the different options at EU level. It can be assumed that most Member States in case of option 1 will choose for a lower impact with an outcome close to the impact in options 3 or 4. No significant reduction of cost is therefore expected from the absence of an EU action, while a very important value will be the establishment of a harmonised sampling scheme to ensure the functioning of the internal market and third country trade without placing unnecessary burdens on businesses.

<u>HIGHLIGHT THE TRADE-OFFS AND SYNERGIES ASSOCIATED WITH EACH OPTION.</u>

Option 1 carries a serious risk of trade disruption by the application of different rules in the Member States. It may also result in differences in the acceptance of exposure to food safety hazards between Member States.

Option 2 is completely in line with the legal action of the Parliament and the Council taken in 2003 by adopting of the Regulation (EC) No 2160/2003 following a commitment to reduce the number of *Salmonella* cases in humans in a harmonised way. There is however a risk that the economic impact of such option is disproportionate to the public health benefit, in particular when the prevalence in flocks is still high.

Option 3 significantly reduces the economic impact while still considered risk based since it focuses on the 2 most significant *Salmonella* serotypes. The aim of Regulation (EC) No 2160/2003 is still achieved; in particular meat should only be place on the market with a reasonable assurance that it is free from relevant *Salmonella* serotypes.

Option 4 provides also a useful alternative in case the economic impact of option 2 is currently considered to high. This option is however less risk based than option 3. In addition it is in contradiction with the basic provision in Regulation (EC) No 2160/2003 and the EN/ISO standard for analysis (both referring to 25 g).

Option 5 has a very high sampling cost without increasing public health protection.

Option 6 may not sufficiently trigger actions at previous stages of the food chain to achieve a public health benefit and is in contradiction with the legal provisions on the date of coming into force.

RANK THE OPTIONS IN TERMS OF THE VARIOUS EVALUATION CRITERIA.

Table 3: Overall ranking of options

Option	Limitation of	Harmonisation	Public health	Legal/political	Analytical
	costs	of trade	impact	aspects	aspects
3	++	++	+	++	+
4	++	++	+	+	-
	' '				
2	-	++	++	++	++
6	+++	++	-	-	Not relevant
5	-	-	-	+	-
1	-/+	-	-/+	-	-/+

Meaning of scores used:

- Limitation of costs: see Table 2
- Harmonisation of trade: -: no harmonisation; ++: full harmonisation.
- Public health impact: -: hardly expected; +: expected over a certain period; ++: high and quick impact; -/+: unpredictable (depending ion individual Member States decision).
- Legal/political impact: -: amendment of basic legislation needed by regulatory procedure with scrutiny turning around the original requirement laid down by the Parliament and the Council; + amendment of basic legislation needed by regulatory procedure with scrutiny slightly deviating somehow from the original requirement; ++: no amendment of basic requirement needed.
- Analytical aspects: -: very expensive (option 5) or against ISO-standard for analysis; +: ISO standard available, but additional serotyping needed; ++: ISO standard available; -/+: unpredictable.

When ranking the options, harmonisation of trade was considered as predominant and a high weight was given to the scores on legal/political aspects. None of the options was however excluded for legal reasons because amendments subject to regulatory procedure with scrutiny are possible. Further ranking was based on the balance between costs and public health impact.

PREFERRED OPTION.

Based on the information currently available the following detailed rules proposed:

- Ø Option 3 focussing on S. Enteritidis and S. Typhimurium.
- Ø 5 samples per batch using the same samples as for the existing process hygiene criterion
- Ø Weekly sampling with the possibility to reduce to fortnightly based on favourable outcomes of previous samplings. Reduction of sampling frequency is also allowed in small establishments on the basis of a risk analysis.

These detailed rules provide the best balance between costs and public health benefits. As highlighted before all options establishing harmonised rules for the food safety criterion, with the exception of the postponement of date of coming into force, are expected to place adequate pressure on the poultry supply chain to ensure that salmonella controls are improved. As a more strict application of the criterion (e.g. more samples or more *Salmonella* strains) is unlikely to bring significantly higher public health benefits but may place large additional burdens on the supply chain it is considered - in order to minimise the economic and social impacts of the application of the criterion - that option three is the preferred option.

The detailed rules are supported by all Member States except 2 and all stakeholders except by consumers stakeholders.

Section 7: Monitoring and evaluation

WHAT ARE THE CORE INDICATORS OF PROGRESS TOWARDS MEETING THE OBJECTIVES?

The following indicators will be used:

- 1. Prevalence of Salmonella in poultry flocks and poultry meat
- 2. Prevalence of Salmonella in humans
- 3. Salmonella outbreaks linked to poultry meat
- 4. Consumption of poultry meat
- 5. Prices of poultry meat
- 6. Intra-Community trade of poultry and poultry meat
- 7. Import of poultry meat
- 8. Export of poultry meat.
- 9. Number of withdrawals or recalls per reason (outbreak, non-compliance) and costs, to the extent information is available.

<u>WHAT IS THE BROAD OUTLINE FOR POSSIBLE MONITORING AND EVALUATION ARRANGEMENTS?</u>

Indicators 1 to 3

A harmonised annual monitoring has already been laid down in flocks of broilers and turkeys as part of the *Salmonella* control programmes.

Monitoring of *Salmonella* in poultry meat is mandatory in accordance with the provisions in Directive 2003/99/EC and must be reported to the Commission. EFSA must analyse them.

The European Centre for Disease Prevention and Control (ECDC) collects data on human salmonellosis in accordance with Decision 2000/96/EC.

The results from all the above monitoring and the evaluation of the results are evaluated and published annually in a common report on zoonoses monitoring of EFSA and ECDC (See http://www.efsa.europa.eu/EFSA/ScientificPanels/ZOONOSES/efsa_locale-1178620753812 1211902602478.htm

The indicators 4 to 8

These indicators are monitored and published be Eurostat.

The indicator 9

Availability to be discussed with the Member States and Stakeholders.

Annex 1

Summary of questionnaire

Answers were received from:

- Ø Competent authorities of Austria (AT), Romania (RO), Latvia (LV), Slovenia (SI), Lithuania (LT), Finland (FI), Czech Republic (CZ), Slovak Republic (SK), Sweden (SE), Denmark jointly with Danish Poultry Council (DK+)), Estonia (EE), France (FR), Germany (DE), Netherlands (NL), Luxembourg (LU), Bulgaria jointly with Association of meat processors in Bulgaria and Bulgarian poultry union (BG+), Hungary jointly with Baromfi Termék Tanács (Hungarian Poultry Product Board) (HU+) United Kingdom together with British Poultry Council and British Retail Consortium (UK+), and Switzerland(HE)
- Ø Stakeholders: a.v.e.c., British Retail Consortium (BRC), Austrian poultry stakeholders organisations (AT stake), European poultry and Game Association (EPG), National Farmers' Union UK (NFU), Fédération des Industries Avicoles France (FIA), Dutch member of Eurocommerce (NE), a German (DE) retailer, 3 Slovenian food business operators (FBO SI 1-3), a Swiss (HE) FBO and those mentioned above (jointly with competent authorities)

A. General questions:

(1) What percentage of poultry meat consumed in your country is placed on the market as "fresh meat" including frozen meat but excluding meat preparations, meat products?

If possible, what is the % of the different categories of fresh poultry meat (with skin, without skin, offal) placed on the market?

Replies (all from 2007 or 2008)

	Fresh meat	With skin	Without skin	Offal
AT	Not known			
RO	95	95	0	5
LV	Not available			
LT	70	76	20	4
FI	15			
CZ	95	73	24	3
SK	40	62.5	37.5	12.5
SE	14-16	40	60	
EE	No data			
FR	45 (only chicken)	75	25	?
DE	75			
NL	80	30	69	1
HE	50 (broilers), 20 (turkey)			
DK+	71	68	30	2

BG+	35-40	70				10
UK+	53	68.5 (47% wh	ole birds)	31.5		Not known
FIA		70		30		
NE	18.2	27		55		1
EPG	75 (DE)	No further differentiation possible				
FBO SI 1		69.6	27.4		3	
FBO SI 1		80	17.3		2.7	
FBO SI 3		91	7.4		1.6	
FBO HE	75	75 25			<1	
AT stake	90	40-50	10-20		30-3	5

(1) What is the mean weight of a batch of fresh poultry meat? A batch is defined in Article 2(e) of Regulation (EC) no 2073/2005. In practical terms within the frame of this questionnaire, a batch should be considered as the amount of meat that should be withdrawn from the market if not in compliance with a food safety criterion, assuming that the whole batch is still available.

Replies:

	Overall		With skin		Without skin	Offal
AT	Not known					
LV	22-62 tonnes					
LT	30 tonnes					
FI	Daily production					
CZ			20-120 tonne	S	7-36 tonnes	1-5 tonnes
SK	45 tonnes					
DE	26-88 tonnes					
UK+C	Batch is flock (50	0-50	0,000 birds) or	sla	nughter batch (2,0	000 birds) or retail
	packs with same d	late	code (on evera	ge	150,000 units)	
DK+	62 tonnes					
EPG	Enormous variation	on				
BRC	Different ways of	inte	rpretation by r	eta	ilers	
avec	20-120 tons					
NE		20	0-3000 kg	2	0 x 550 kg	100 to 3000 kg
FBO SI 1	17 tons					
FBO SI 2	22.5 tons					
FBO SI 3	34 tons (daily					
	prod.					
FBO HE	20-80 tons					

(2) Do you have published information on the costs of human salmonellosis? If so, please forward electronically with the complete questionnaire or provide reference.

Replies:

o SE: Sundström K 2007: 80 million SEK per year

o UK+: 1,200€per case visiting GP.

o DK+: 9.6-22.5 million € in 2001

o NL:

Information for the Netherlands found can be the web http://www.rivm.nl/vtv/object_document/o7902n22451.html. This suggests there were 43,381 cases of human salmonellosis in the Netherlands, of which 27,531 were foodborne. There were 47 deaths, of which 29.8 foodborne. The disease burden was 1,053 DALYs of which 668 foodborne, and the total costs 10.8 million euro, of which 6.9 million foodborne. Among the foodborne cases, the numbers attributed to poultry meat was as follows: 4130 cases (http://www.rivm.nl/vtv/object_document/o7901n22451.html); 100 **DALYs** (http://www.rivm.nl/vtv/object_document/o7903n22451.html). Costs and deaths are not presented in disaggregated form on the website but can be calculated proportionally: 1 million € and 4.5 deaths. Further details will be provided in an RIVM report that will be published shortly.

- o NE: 1000-1500 € see: www.rivm.nl/infectieziektenbulletin/bul111/salm.html
- (3) Do you have published quantitative data on the social-economic impact of
 - Food-borne outbreaks in certain meat (poultry or others)

Replies:

RO	No salmonellosis outbreaks in 2008 due to certain meat products
LV	17 outbreaks
DK+	No
FR	1095 outbreaks in 2007 (all causes), 42 outbreaks (3.8%) due to poultry meat, 8 (0.7%) to Salmonella
FIA	1 outbreak (poultry meat) by S. <i>Enteritidis</i> and 2 by S. <i>Typhimurium</i> in France in 2006.
NE	25,000 to 105,000 €

• Recall because of non-compliance with a microbiological criterion

DK+	No
UK+	£10,000 to 1 million
BRC	£ 100,000-£1 million
EPC	600,000 to 1 million €per 100 tonnes fresh poultry meat

(4) What is your estimation of the social-economic impact (in €) as regards poultry meat per food-borne outbreaks due to such meat or by (future) recall/withdrawal because of non-compliance with the new criterion?

Replies:

AT	Not known
LT	200€per case
DE	Depends on daily production
DK+	Outbreaks linked to poultry meat are rare in DK, so minimal social-
	economic impact
UK+	£100,000 to 1 million
FIA	If no market for all Salmonella positive flocks: 22.320.000 €per month in
	France
NE	1 €per kg returned
DE retailer	15,600€per product per company
FBO SI 3	95,200€
FBO HE	800,000€

(5) What it the number of approved food business operators of fresh poultry meat in your country (see: http://ec.europa.eu/food/food/biosafety/establishments/list_en.htm):

	Slaughterhouses	Processing plants	Distributors
AT	30	26	Not known
RO	29	229	100
LV	2	4	44
SI	4	4	1
LT	14	118	88
FI	21 (of which 17 low	70 (all meat)	
	capacity ones)		
CZ	37	436	No data
SK	10	61	
SE	25	28 (all meat)	
EE	4	2	17
FR	430	566	26,200 retail stores
DE	89	202	No data
NL	35	292	439
LU	0		
HE	5	229	unknown
BG+	28	39	
HU+	73	84 (all meat)	
DK+	11	6	493 (authorised/registered)
UK+	98	400	No data

BRC	450 in UK		
FIA	830	566	26,200
NE	35	294	No info
FBO HE	2	0	
AT stake	30	26	unknown

B. Questions related to existing Salmonella food safety criteria on poultry

- (1) Samples taken by the **food business operators** in 2008 within the implementation of:
 - (a) Food safety criterion **1.5** in Annex I chapter 1 of Regulation (EC) NO 2073/2005 (*Salmonella* in **minced meat and meat preparations** made from poultry meat intended to be eaten cooked)

	Samples	Recalls	% meat recalled	
RO	170	0		
LV	29% of batches	Not available	5%	
LT	202	4	100%	
SK	535	0		
SE	1234 incl. taken by	0		
	CA			
EE	306	0		
FR		3 withdrawals, 0 recalls		
DE	5 samples per week	Not obtained		
LU	4	0		
HE	907			
BG+ (7(a) &	6162	10%	90%	
(b))				
DK+	60	0	0	
UK+	1-5% of batches	5 reported withdrawals,	90-100% of frozen	
	being 1,000-5,000	no recalls	withdrawals	
	samples			
FIA			1%	
NE	2 x 5 per week	0	8%	
FBO SI 1	427	0	0	
FBO SI 2	535	0	0	
FBO SI 3	54	0	0	
FBO HE	100%	0		

(b) Food safety criterion **1.9** in Annex I chapter 1 of Regulation (EC) NO 2073/2005 (*Salmonella* in **meat products** made from poultry meat intended to be eaten cooked)

Replies:

	Samples	Recalls	% meat recalled	
RO (2008)	530	0		
LT	21	0		
SK	105	0		
EE	No such products on			
	the market			
FR		3 withdrawals with 2	700 kg	
		recalls (only duck meat)		
DE	Not obtained	Not obtained		
LU	2	0		
HE	456			
BG+	See above			
DK+	?	0	0	
UK+	Very limited market	0		
FIA			1%	
NE	5 per week	0	8%	
FBO SI 1	1379	0	0	
EPG (7(a) &	DE: 5 samples per week, most is consumed before test results are known			
(b))				
FBO SI 2	265	0	0	
FBO SI 3	0	0	0	
FBO HE	150	0		

- (2) Samples taken during official controls in 2008 within the implementation of:
 - (a) Food safety criterion **1.5** in Annex I chapter 1 of Regulation (EC) NO 2073/2005 (*Salmonella* in **minced meat and meat preparations** made from poultry meat intended to be eaten cooked)

	Samples	Recalls	% meat recalled
RO	195	0	
LV	43	-	9.3%
SI	480	2	0 (no more on market)
LT	9	0	
SK	37	-	2.7%
CZ	6x per year		
SE	1234 incl. taken by	0	
	CA		
EE	36	1	0% (already sold)
FR	280	3	0

DE	463		
NL	110	15	0
LU	31		
HE	179	5 (all imported)	
BG+	725	10%	
HU+	141	0	0%
DK+	263	14 (all frozen import)	100%
UK+	0 (not including		
	imports)		

_

(b) Food safety criterion **1.9** in Annex I chapter 1 of Regulation (EC) NO 2073/2005 (*Salmonella* in **meat products** made from poultry meat intended to be eaten cooked)

	Samples	Recalls	% meat recalled
AT	66	7	7 (batches?)
RO	228	0	
SI	57	0	0
LT	0	0	
SK	226	-	
CZ	12x per year		
EE	No products on		
	market		
FR	180	0	
DE	285	1	
NL	1	0	0
LU	5		
BG+	910		
HU+	161	No data	11.8%
DK+	3	0	
UK+	0 (not including		
	imports)		

C. Questions related to the potential new Salmonella food safety criteria in fresh poultry

1. How many batches (or % of all batches) would you like/estimate that food business operators sample in your country per year for the implementation of the new criterion if to be carried out within the frame of HACCP.

Replies:

AT	10%
LV	10%
FI	0, sampling at farms
EE	To be based on risk or capacity
SK	24 batches a year
CZ	From the positive flocks
DE	Based on HACCP principle of a risk based approach
NL	Based on HACCP principle of a risk based approach
BG +	10%
DK+	One batch per week
UK+	Based on HACCP principle of a risk based approach. Higher for turkeys than
	for broilers
BRC	Based on HACCP principle of a risk based approach
DE retailer	Weight based
EPG	Based on HACCP principle of a risk based approach
FBO HE	500 to 1000

2. Should a minimum number of samples to be taken by the food business per year be laid down in Community legislation:

	YES/NO	If YES, number/year
AT	No	
LV	No	
LT	Yes	As in Regulation (EC) No 2073/2005 (1 per week)
FI	Yes	As in Regulation (EC) No 2073/2005
CZ	No	
SK	No	
SE	Yes	As in Regulation 2073/2005 + meat of all positive flocks
EE	Yes	Based on batches produced/slaughtered previous year
FR	Yes	As in Regulation (EC) No 2073/2005
DE	No	
NL	Yes	As in Regulation (EC) No 2073/2005
HE	Yes	Risk based and proportional
BG+	Yes	According to capacity and weekly number of batches
HU+	Yes	2-52 according to capacity

DK+	Yes	As in Regulation (EC) No 2073/2005
UK+	Yes	As in Regulation (EC) No 2073/2005 as starting point
NE	No	
DE retailer	No	
FBO SI 1/2	No	
FBO SI 3	Yes	52
FBO HE	No	
AT stake	No	

3. How many batches (or % of all batches) should be officially sampled in your country for the verification of the implementation of the new criterion:

Replies:

AT	No
LV	20%
LT	200
FI	No calculations yet
SE	No minimum requirement
CZ	From positive flocks
EE	No minimum requirement
FR	No minimum requirement, risk based decision
DE	No minimum requirement
BG+	10%
HU+	350 (broilers) + 240 (turkeys)
DK+	No minimum requirement, risk based decision
UK+	No minimum requirement. Verification can be by other means e.g. retail
	survey
DE retailer	Up to industry to ensure product safety
FBO HE	0
AT stake	0

4. Do you consider that there is a market for the industrial heat treatment of fresh poultry meat in your country if the meat does not comply with the food safety criterion?

ricpiics.				
	YES/NO	Reduction	of	Cost of waste management
		value		
LT	Yes	No data		200€per tonne
FI	Yes			
CZ	Yes if <10%	60%		100€ if unpacked, 400-500€ if
				packed

SK	No		
SE	No		
EE	No		
FR	No		
DE	No		150€per tonne
NL	No		170-270€ per tonne (unpacking
			by hand (100-200€) + destruction
			(70€per tonne)
HE	No		
BG+	No		
HU+	Very limited	20-30%	
DK+	Yes if <5%	30%	70€per tonne
UK+	Very limited	50%	Depends on ABP category
FIA	No		
NE	No		
DE retailer	No		
EPG	No		
BRC		If possible: 33%	Depends on ABP category
NFU	Very limited un		
	UK		
FBO SI 1/2	No		
FBO HE	No		400-500€per tonne
AT stake	No		

5. Can you quantify the estimated impact of recalling non-compliant meat from the market due to loss of consumers confidence:

	YES/NO	
LV	No	
LT	No	
FI	No	
CZ	No	
SK	No	
SE	No	Instead an increased confidence is expected
EE	No	
FR	No	
DE		If 10% reduction of consumption: 270,000,000€
NL	Yes (but	1.8 million € per recall (0.1% decline of consumption per
	uncertain)	recall)
BG+	No	
DK+	No	

UK+		Quoted Deloitte report: Loss of 50% of consumers fore more
		than 9 months
FIA		300,000 to 500,000 €per recall
NE	YES	1 about 1 €per kg
NFU		30% drop of sales, recall costs: twice the value of the product
FBO SI 1/3	No	
FBO SI 2	100,000€	
FBO HE	No but very	
	high	
AT stake	No	

6. What is your estimation of the mean cost of sampling for the *Salmonella* criterion in fresh poultry meat: total cost expressed per analysis including (additional) sampling cost, administrative cost (reporting result):

	Total	Analysis	Sampling	Administration
AT	60€			
LV	196€			
SI	23.75€			
LT	10.43-14.50€			
CZ		23€ + 27€ for		
		serotyping		
SK	20 (FBO)-25 (official			
	sample) €			
SE	10-20€			
EE	104.3€	15.3, serotyping: 79€	10€	
FR	30€	+ 60€ if		
		indentification and		
		typing		
DE		35-40€+ serotyping:	65€	
		55-105€		
NL	83.43-118.40€	83.43-118.40€+ 60€	50€	Re-inspection:
		for serotyping		220€
LU	30.26€			
HE	100€			
BG+		20€ rapid test: 13€	7.5€h/person	
HU+	60€	20€	40€	
DK+	DK+ 15(FBO sample)-26€			
	(official sample)	and typing		
UK+	15-25€ (FBO); 25-			
	35€(official sample)			
FIA	25-30 €			

NE		13€ + 110€ for		
		serotyping		
DE retailer		40€	65€	
BRC		£10-20		
NFU		£19.55		
FBO SI 1	50€	29.69€		
FBO SI 2	29.69€			
FBO SI 3	9.7-10.2€			
FBO HE	50€			
AT stake	150€			

D. Other information you consider relevant for the impact assessment:

EPG: A reduction of 10% of consumption of fresh poultry meat means a turnover lost of 270 million €(90,000 tonnes)

Avec:

- Ø Of all fresh chicken meat 70% is presented as fresh, 30% as frozen.
- Ø 20% of sale is whole chicken,
- Ø 75% of boneless breast chicken filet is sold as fresh 25% as frozen

FI: In Finland the new criterion is not expected to increase present costs. Majority (75%) is placed on market as meat preparations and extended control programme is already applied.

CZ: CZ indicates that since most poultry meat is fresh, there would be a need for freezing and storage before contaminated meat can be subjected to heat treatment

FR: General comments on draft impact assessment

- It does not seem that it is realistic to apply, from the end of 2010, the same criteria for all fresh poultry meat. The *Salmonella* prevalence of poultry meat products is still high in several member states and economic consequences are suspected to be important for FBO concerned. In any case, the types and categories of fresh meat products taken into account need to be described (whole carcases, cut meat with skin such as legs or wings, cut meat without skin such as chicken breast).
- The number of human salmonellosis directly linked to consumption of poultry meat is very low. Other cases are related to cross contamination but their importance is not known. The actual impact of a criterion absence of *Salmonella* sp. in 25g of fresh poultry meat on public health should be estimated.
- We agree with the opinion expressed by the stakeholders on the fact that a criterion is not necessarily contributing to reduce *Salmonella* prevalence at prior stages. On the contrary, if a criterion is too rigorous and difficult to met, FBO might use decontamination process (chemical decontamination) in order to comply with the limit of the criterion. This solution would not be in accordance with the general principles of EU regulations, which emphasize on preventive control measures.
- We propose a more progressive approach based on the following points :
 - distinction between the different categories of products, in particular with or without skin, because poultry meat without skin are less contaminated and a more rigorous criterion could already be set for these products;
 - first, only S. Enteritidis and S. Typhimurium serotypes could be taken into account; expansion to all serotypes could be done secondly (schedule shall be specified)
 - Salmonella enumeration analytical method will be soon available (ISO standard method); it would be interesting to develop surveys in order to obtain quantitative data on the level of contamination and to assess the impact of cross contaminations.

DE:

The draft impact assessment is currently limited to the detailed rules of the *Salmonella* food safety criterion. It should be extended to additional harmonised measures to reduce the risk from *Salmonella* by the consumption of fresh poultry meat, in particular:

- Logistic slaughter
- Amend Regulation (EC) No 854/2004 in order to solve a practical problem due to a gap in categorisation of meat. Apart from the categories "unfit" and "fit for fuman consumption", a categories "it for human consumption on condition that..." should be created.
- Validation of practical PCR methods. Permission to use methods which are validated at national level as reference methods
- Minimum criteria to develop HACCP-based auto-control systems in poultry slaughterhouses

UK+

The questionnaire needs to reflect the different ways that batches failing the criteria can be removed from the market. According to regulation 2073/2005 unsatisfactory batches should not be placed on the market or should be removed from the market according to reg 178/2002. In Reg. 178/2002 removal can be withdrawal or recall and which should be determined according to risk.

With reference to this questionnaire when estimating the effect/cost of withdrawal or recall at different sampling stages if the stage is the whole carcass which is then portioned extra costs and practical difficulties will be incurred if it is required to trace all the parts of the carcass that have been placed on the market and likewise if other parts of the carcase are required to be traced if for example breast portions test positive.

FIA:

It was very difficult for us to answer the questionnaire because the situation between the individual companies differ substantially.

We don't have the answers for some questions. There are some difficulties with the "batch" definition. It depends of the procedure of the different companies.

It is essential to precise the sampling method and the typology of the product on this Regulation. We suggest deep muscle for sampling procedure; In fact product with skin will be always consumed cooked.

We make progress and we purpose also to stay focus on *Salmonella* Enteritidis and Typhimurium in the first time and after look at the others serotypes.

We purpose also a quantitative method approach.

Annex 2

<u>CONTROL MEASURES TO REDUCE THE PREVALENCE OF SALMONELLA ALONG</u> THE POULTRY FOOD-CHAIN.

Breeding flocks of chicken (Gallus gallus)

In 2005 the Community introduced a reduction target for the prevalence of *Salmonella* requiring all MSs to achieve a prevalence of *Salmonella* of <1% of five serotypes by the end of 2009. Under Member States' National Control Programmes (NCPs), Member States, farmers and food business operators (FBOs) have been working towards a reduction of prevalence of *Salmonella* in their breeding flocks to achieve the target. In line with Regulation (EC) No 2160/2003 and in order to monitor progress towards the target a harmonised sampling criterion was established for FBOs. The criterion sets out the method for sampling, the frequency of sampling, the number of samples, and the number/types of positives allowed.

The 2008 monitoring data demonstrated (using the data collected by FBOs and official control sampling) established that 0.9% flocks in Member States were found to be infected with the five main serotypes demonstrating the most were on track to achieve the target. However in two Member States the percentage of infected flocks was still slightly above 5%.

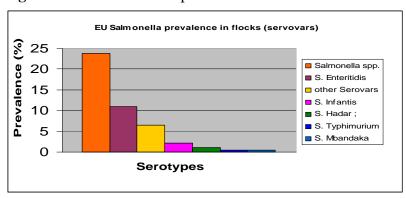
Broilers Flocks

A baseline survey to establish the prevalence of *Salmonella* in broiler flocks was carried out between October 2005 and September 2006¹². Results are summarised in Table 4. At Community level 23.7% of flocks tested positive for *Salmonella*. To address the high prevalence at broiler level a reduction target for *Salmonella* Enteritidis and *Salmonella* Typhimurium of 1% or less by the end of 2011 was set by Commission (Regulation (EC) No 646/2007 of 12 June). As with the approach taken for breeding flocks, since 1 January 2009, Member States have adopted NCPs to outline the methods they will be using to reduce *Salmonella* in broiler flocks. Again detailed rules for FBOs' sampling – the method for sampling, the frequency of sampling, the number of samples, and the number/types of positives allowed - have been laid down.

The baseline survey in 2005-2006, demonstrated that the presence of *Salmonella* spp. in the EU was significant however big variations were observed among MSs, from 0% in SE and 0.1% in FI to 68.2% in HU, 58.2% in PL, 43.5% in PT and 41.b2% in ES. The flock prevalences for MSs for the 2 targeted *Salmonella* serotypes accounted for 11%, ranging from 0% (FI, IE, SE) to 28.2% (ES), 32.4% (PL) and 39.3% (PT).

¹² Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline survey on the prevalence of *Salmonella* in broiler flocks of *Gallus gallus*, in the EU, 2005-2006. The EFSA Journal (2007) 98, 1-85

Figure 2: % of Salmonella positive flocks in the EU for all and targeted (5 and 2) serotypes



Source: EFSA, 2007

Note: With 95% confidence level, CIs are: 23%-24,5% - Salmonella spp.; 10.2%-11.6% - S. Enteritidis; 0.4%-0.5% - S. Typhimurium; 2.0%-2.4% - S. Infantis; 0.3%-0.5% - S. Mbandaka; 1.0%-1.3% - S. Hadar; 6.2%-6.9% - other serovars.

Table 4: Percentage of positive flocks of broilers and turkeys during harmonised baseline surveys

% of Salmonella positive flocks (Baseline surveys 2006-2007)							
		ilers		keys			
	All Salmonella	SE+STM (target)	All Salmonella	SE+STM (target)			
Austria	5,4	1,3	25,5	0,4			
Belgium	12,4	2,0	17,8	7,1			
Bulgaria	no results	no results	0,0	0,0			
Cyprus	9,1	1,7	57,6	0,0			
Czech Republic	19,3	9,6	42,7	18,4			
Denmark	1,6	0,3	4,0	0,0			
Estonia	2,0	1,7	no flocks	no flocks			
Finland	0,1	0,0	0,0	0,0			
France	6,2	0,5	13,3	3,8			
Germany	15,0	1,6	9,2	2,6			
Greece	24,0	3,2	16,5	0,0			
Hungary	68,2	5,1	78,5	3,6			
Ireland	27,6	0,0	27,6	0,0			
Italy	28,3	2,3	38,8	6,1			
Latvia	6,2	5,1	no flocks	no flocks			
Lithuania	2,9	2,9	5,3	1,5			
Luxembourg	no results	no results	no flocks	no flocks			
Malta	no results	no results	no flocks	no flocks			
Netherlands	7,5	1,0	14,1	1,5			
Poland	58,2	32,4	26,9	4,2			
Portugal	43,5	39,3	6,3	0,0			
Romania	no results	no results	no results	no results			
Slovenia	1,6	1,6	21,2	4,7			
Slovak Republic	5,7	3,3	22,9	0,0			
Spain	41,2	28,2	56,3	2,8			
Sweden	0,0	0,0	0,0	0,0			
United Kingdom	8,2	0,2	32,2	4,6			
EU (weighted)	23,7	11,0	30,7	3,8			

EFSA Report: *Trends and Sources of Zoonoses and Zoonotic Agents in the European Union in 2007* presents the study carried out during the years 2004 to 2008 and demonstrates that, for MSs that provided data consistently (11 MSs) the mean prevalence for top two serotypes seem to decrease slightly but these trends were not statistically significant.

Breeding turkeys

A baseline study on turkeys was carried out between October 2006 and September 2007 in all MSs to obtain reference value for a regulation setting a reduction target for *Salmonella* (2 top serotypes) of 1% or less of flocks infected. According to EFSA report, the EU weighted prevalence of all serotypes was 13.6%, ranging widely from 0% to 82.1% in reporting MSs (14). Three MSs isolated 2 top serotypes that accounted for the EU prevalence of 1.7%, varying from 0% to 8.3% within MSs.

Fattening turkeys

According to the baseline survey (see Table 4), the EU prevalence of *Salmonella*-positive fattening flocks was 30.7%, varying among MSs from 0% to 78.5%. 13 MSs reported findings of top serotypes (S.E. and S.T.) in production turkeys with an EU weighted prevalence of 3.8% with a range of 05 to 18.4% between MSs. The EU prevalence *of Salmonella* for S.E. and S.T. accounted for 4.3% and 6.8% respectively, with the highest rates, above 20%, in BE, DE (S.T.) and CZ and LT (S.E.).

General provisions on poultry meat

General rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules are laid down in Regulation (EC) No 852/2004 on the hygiene of foodstuffs¹³, Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin¹⁴ and Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption¹⁵. These "hygiene Regulations" take into account the implementation of procedures based on the principles of Hazard Analysis and Critical Control Points (HACCP) and the application of good hygiene practice to control contamination at primary production, cross-contamination and development of pathogens during slaughter, processing, storage and distribution.

Specific provisions to control Salmonella in poultry meat

Salmonella food safety criteria in foodstuffs have already been laid down in Commission Regulation (EC) No 2073/2005. The Regulation (EC) No 2073/2005 lays down the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures of the hygiene Regulations. Following unsatisfactory results when testing against the criteria, the measures laid down Regulation (EC) No 2073/2005 must be taken by the food business operators including the withdrawal or recall of the product or batch in the case of a food safety criterion.

¹³ OJ L 139, 30.4.2004, p. 1, as corrected by OJ L 226, 25.6.2004, p. 3

 $^{^{14}\,}$ OJ L 139, 30.4.2004, p. 19, as corrected by OJ L 226, 25.6.2004, p. 22

¹⁵ OJ L 139, 30.4.2004, p. 81, as corrected by OJ L 226, 24.6.2004, p. 83

A Salmonella food safety criterion already applies since 1 January 2006 on the minced meat, meat preparations and meat products. Additionally, a process hygiene criterion for Salmonella on carcases of broilers and turkeys is laid down. It includes a certain tolerance but shall be revised in the light of the changes observed in Salmonella prevalence. If the process hygiene criterion is not met, corrective actions are required in order to maintain the hygiene of the process, including the status of the incoming birds, but it is without consequences for products placed on the market.

Finally, all *Salmonella* serotypes must be excluded by extensive testing in meat from poultry, excluding meat preparations and mechanically separated meat, intended for Finland and Sweden in accordance with Commission Regulation (EC) No 1688/2005 of 14 October 2005 implementing Regulation (EC) No 853/2004 as regards special guarantees concerning *Salmonella* for consignments to Finland and Sweden of certain meat and eggs¹⁶. These Member States obtained the special guarantees at their accession because of the very low *Salmonella* prevalence and the very strict national control programmes in all food producing animals.

٠

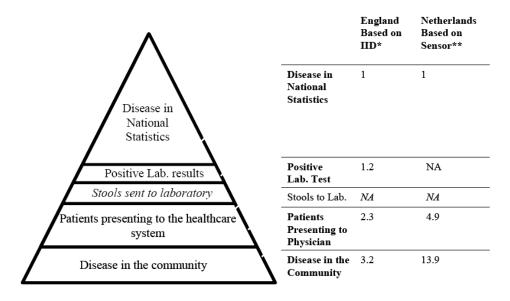
¹⁶ OJ L 271, 15.10.2005, p. 17

Annex 3

1. HUMAN SALMONELLOSIS

Human salmonellosis is usually characterised by the acute onset of fever, abdominal pain, nausea and sometimes vomiting. In some patients the infection may be more serious and the associated dehydration can be life-threatening. Salmonellosis has also been associated with long-term and sometimes chronic sequelae e.g. arthritis. According to the EFSA/ECDC Community report on trends and sources of zoonoses, zoonotic agents in the EU in 2008 (the (2008) zoonoses monitoring report), there were over 131,468 reported cases of human salmonellosis in the EU 27. These figures only represent a part of the real number of cases estimated 3.2 to 13.9 times higher respectively in a UK and Dutch study as illustrated in Figure 3¹⁷.

Figure 3: Surveillance pyramid showing the multipliers for *Salmonella* in England and the Netherlands



Notes: *IID = Infectious Intestinal Disease Study; **Sensor & Netherlands Institute for Primary Health Care (NIVEL) Studies; NA = not available

Mortality reported during outbreaks in the zoonoses monitoring reports is about 1 per 1000 cases. Reported hospitalisation during outbreaks is about 15 to 20% (source: zoonoses monitoring reports).

The following extrapolation of the burden was made in the Scientific Opinion on a quantitative estimation of the public health impact of setting a new target for the reduction of Salmonella in laying hens, adopted during the meeting of the EFSA BIOHAZ Panel on 9 and 10 March 2010: "The costs of salmonellosis and sequels (excluding post-infective irritable bowel syndrome) in the Netherlands were estimated at 11 million € per year (Haagsma et al., 2009). Extrapolating these estimates would result in a disease burden of 0.2-0.5 million DALYs (Disability

fuman salmonellosis from meat (the EFSA Journal (2008) 625, 1-32)

41

¹⁷ Extracted from: Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission on a quantitative microbiological risk assessment on *Salmonella* in meat: Source attribution for

Adjusted Life Years) per year for the EU27 and total costs between 0.2 and 3 billion € per year."

In a Report on the "Economic impacts of the Finnish Salmonella Control programme for broilers" the following costs per case were used, including productivity losses: deaths: 1,234,793 €, hospitalised cases: 1,924 €, outpatient cases: 452 € and unreported cases: 145 €

The Finnish estimations and data from the EU 2007 zoonoses monitoring report can be used to calculate the costs of all salmonellosis cases in the EU per year (Table 5):

Table 5: Extrapolation of burden to the EU27

	Cost (€) per case	Cases	Total cost (€)
Outpatient cases	452	134,837	60,946,155
Hospitalised cases	1,924	26,967	51,885,133
Deaths	1,234,793	154	190,158,122
Unreported cases	145	1,078,693	156,410,485
			459,399,895

In the UK, the cost of salmonellosis was estimated at $1,200 \in \text{per}$ case visiting a general physician being, by extrapolation at EU level, $1,200 \times 154,099$ reported cases x 2.3 to 4.9 (see figure 1) = 425 to 906 million \in for all salmonellosis cases.

In the Netherlands, the total cost of salmonellosis was estimated at 10.8 million € with 47 deaths in 2006. About 10% was attributed to poultry meat ¹⁹. As poultry meat consumption in the Netherlands represents 3.15% of the EU 27 consumption, extrapolation results in a cost of 34 million € and 149 deaths due to poultry meat.

495 different serotypes were isolated from human cases in 2007, *Salmonella* Enteritidis and *Salmonella* Typhimurium representing respectively 64.5 and 16.5%. All serotypes are considered of potential public health significance in several EFSA opinions although a relative classification may be possible.

In summary, an overall cost of salmonellosis at EU level is estimated by EFSA between 0.2 and 3 billion Euro, being most likely about 400 to 900 million € based on additional Finnish and British studies.

-

¹⁸ EELA Publikationsserie 02/2003 ISSN: 1458-6878

¹⁹http://www.rivm.nl/vtv/object_document/o7902n22451.html,http://www.rivm.nl/vtv/object_document/o7901n 22451.html, http://www.rivm.nl/vtv/object_document/o7903n22451.html

2. FOOD-BORNE SALMONELLOSIS

The vast majority of salmonellosis are food-borne infections, mainly caused by foodstuffs derived from animals. The Commission requested the EFSA in 2007 to evaluate the relative contribution of different meat categories to cases of food-borne *Salmonella* infections in humans. So far, mainly outbreak investigation allows a certain quantification of the contribution of different foodstuffs. In 2008, the main sources identified in verified outbreaks were eggs and egg products eggs and egg products (40.8%), followed by inadequately heat treated bakery products (13.5%), pig meat and products thereof (7.1%), mixed or buffet meals (6.3%) and poultry meat and products thereof.

Based on these data and attribution studies such as the Dutch ones described above, it can be estimated that 4 to 10% of salmonellosis can be attributed to poultry meat and products thereof.

3. POULTRY MEAT AS SOURCE OF INFECTION

Poultry meat on the market can be contaminated with Salmonella due to:

- contamination of meat by faecal content at slaughter if the poultry is derived from an infected flock;
- cross-contamination of meat during slaughter or processing due to poultry batches slaughtered before and originating from infected flocks.

Cooking of poultry meat by the final consumer is common practice and only rarely poultry is consumed raw. However, inappropriate handling *Salmonella* contaminated meat in domestic kitchens significantly influences the risk for human disease. In particular, thorough cooking is not always ensured and cross contamination of ready-to-eat food (e.g. salad vegetables) by contaminated poultry meat before it is cooked is risky.

Overall, 4.6% to 6.8% of fresh broiler and turkey meat was contaminated with *Salmonella* in the period 2004 to 2008 (2008 zoonoses monitoring report). The EFSA analysed the data on the occurrence of *Salmonella* in fresh broiler and turkey meat reported by the Member States for the years 2004-2007 more into detail. Sufficient data were missing to evaluate the occurrence of *Salmonella* in frozen poultry meat compared to meat that has never been frozen. Only one MS reported data on the occurrence of *Salmonella* in poultry offal, with no positive findings. Based on the data of another MS, the occurrence of *Salmonella* appeared to be higher in broiler meat with skin (6.6%) than in skinned broiler meat (3.6%). The prevalence on neck skin samples collected in slaughterhouses in 2008 by all Member States within the frame of a harmonised baseline survey²¹, also revealed significant high prevalence (data will be published in the next weeks) than the overall prevalence on fresh meat in the period 2004 to 2008. Consistent trends in prevalence in fresh poultry meat collected at the slaughterhouse, at processing or at retail were not observed. There was a substantial variation in the occurrence of *Salmonella* in fresh poultry meat between Member States. Generally, fresh meat from turkeys was more often found *Salmonella* positive than fresh meat from

٠

²⁰ http://www.efsa.europa.eu/en/scdocs/scdoc/1496.htm

²¹ Commission Decision 2007/516/EC. OJ L 190, 21.7.2007, p. 25.

broilers. The data available are not directly comparable between Member States and therefore the results have to be interpreted with care and considered indicative.

The 2008 zoonoses monitoring report shows a large variation of serotypes found in broiler meat in the EU with major differences between Member States. The 5 most frequent ones were *S.* Infantis: 40.1%, *S.* Enteritidis: 12.5%, *S.* Parathyphi B. var. Java: 6.9%, *S.* Kentucky: 6.3% and *S.* Typhimurium: 2.4% all belonging to the 10 most frequently reported serotypes in human salmonellosis.

Annex 4

WHO IS AFFECTED, IN WHAT WAY, TO WHAT EXTENT? continued...

Breakdown of Poultry Market in the EU.

Fresh poultry meat²² production and trade in Europe and with third countries

Poultry meat in EU27 has gained importance even though the growth rates have been quite modest since 2003. However, strong internal and export demand have fuelled increased poultry production. The EU27 produces over 11 million tonnes of poultry meat a year, reporting an estimated annual turnover of around 20 billion euros and employing more than 500 000 people. Making the poultry sector the second largest one after pork. Chicken production accounts for 8.5 mio tonnes that covers 74% of total poultry meat, whereas turkey meat is produced in amount to 1.8 mio tonnes in the EU. Since 2003 broiler meat production has reported a steady increase while turkey meat production has been on a slight decreasing trend.

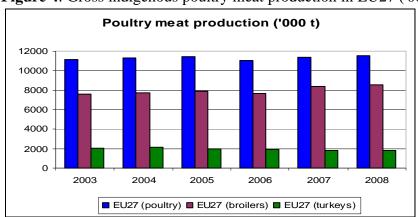


Figure 4: Gross indigenous poultry meat production in EU27 ('000t)

Source: Avec Annual Report 2009

Main producers in Europe

77% of total EU poultry meat is produced within 7 MSs –FR, UK, DE, ES, PL, IT and NL.

According to GAIN, majority of these leading producers are expected to report a slight production growth from 2009 on, mainly due to the increased domestic demand (UK, DE) or reduced feed costs (PL).

<u>FR</u> – the poultry sector in France is worth around 6 bln euros a year. Poultry meat production is around 1.9 million tonnes half of which is chicken. Exports accounts for one billion euros, 45% of which is traded with other EU countries. FR remains the largest EU exporter to third countries, with exports of whole frozen chickens to Saudi Arabia nad Yemen.

_

²² Fresh poultry meat can be marketed frozen, unfrozen or quick-frozen."Fresh meat" is defined in Annex I, point 1.10 of Regulation (EC) No 853/2004 and in Council Regulation No 1234/2007 of 22 October 2007 as meat that has not undergone any preserving process other than chilling (-2to +4 °C), freezing (-12 to -2°C) or quick-freezing (-18 to -12 °C), and that constitutes the raw material for minced meat, mechanically separated meat, meat preparations and meat products. However, this processed meat is not covered by this IA since food safety criteria set in Commission Regulation No 2073/2005 already apply to them.

<u>UK</u> - poultry meat production in the UK is around 1.6 million tonnes, of which 275 000 were exported.

<u>Germany</u> - poultry sector in Germany is worth around 1.1 billion euros a year. Poultry meat production is around 1.2 million tonnes. Export business is practically zero. DE exports account for over 30000 tonnes. Russia, followed by Ukraine continues to be the main destination for German exports broilers.

<u>ES</u> - the poultry sector in the Spain is worth around 1.67 billion euros a year (including live birds and eggs). Poultry meat production is around 1.05 million tonnes of which only 85 000 tonnes is exported. ES is not a major importer either. Its major suppliers are DE and FR, though the biggest source of imports remains Brazil.

<u>IT</u> - poultry sector in Italy is worth around 3.5 billion euros a year. Poultry meat production is around 675 600 million tonnes of which 63 273 tonnes are exported.

<u>Hungary</u> – the total number of poultry is 40 million including over 30 million chickens. EU countries buy 75 percent of exports, most going to Germany but Austria, Belgium, the UK and the Netherlands also import.

<u>The Netherlands</u> - the poultry sector in the Netherlands is worth around 1.6 billion euros a year (including live birds and eggs). Poultry meat production is around 600 000 of which just over half is exported mainly to the UK and Germany.

Intra EU27 trade

Intra community trade of fresh poultry meat is estimated to be around 2.2 million with another 1 million being trade outside of the union with third country trade partners.

The EU27 poultry meat trade balance is exposed to slight fluctuations, being positive in 2008 and slightly negative in 2009. However, over last several years trade balance has been rather stable in light of stable imports and exports. According to GAIN forecasts, a negative trend will continue until 2015, though only steady changes are foreseen.

Extra EU27 imports

Brazil and Thailand remain the largest suppliers of broiler meat to the EU27, followed by Argentina and Chile. Chile entered the import scene only in 2008 when the development of its poultry industry led to an almost doubling of EU chicken meat imports (frozen chicken breasts and salted chicken cuts).

The EU became a net importer of poultry meat in 2008 after a tariff rate quota was established for Brazil and Thailand as a result of a WTO ruling. The EU faces increased export market competition from the U.S. and Brazil in Russia, the Ukraine and the Middle East. The EU industry struggles with high feed and energy costs and environmental and animal welfare regulations.

Extra EU27 exports

EU broiler exports face strong competition on the world market from Brazil and the strong Euro is also affecting trade. In last few years Russia²³ has remained the primary destination

²³ In 2008 and 2009 the Russian import ban on some poultry plants due to alleged sanitary concerns is having a negative impact on trade, which might lower in overall EU27 broiler exports. Source: GAIN

for EU27 broiler meat exports, followed by Saudi Arabia, Ukraine, Benin and Vietnam, which are growing markets for EU poultry meat.

EU poultry meat is reportedly replacing US poultry meat imports in the new EU domestic markets, particularly in Romania and Bulgaria.

In the perspective of next 5-6 years, according to a.v.e.c. projections, poultry meat market is expected to grow, though steadily. As Figure 2 illustrates, production of poultry meat, including chicken meat will be increasing on average 1% every year. Trade balance seems to be stable, however, a.v.e.c. calculations present an downward trend in favour of imports from a growing number of suppliers.

EU citizens will consume more and more poultry meat, to reach to an amount of nearly 25 kilos in 2015 (while 19.7 kilos of chicken meat).

Consumers

Consumption in EU27 has increased steadily since 2003 to reach 11.2 mio tonnes in 2008. In average, an EU citizen consumes around 23 kilos yearly, however several MSs report significantly higher levels of consumption per capita from 27 kilos (UK, RO) up to app. 32 kilos in IE, PT, HU, ES. Of total poultry meat consumption per capita, 17 kilos accounts for broilers and 3.5 kilos for turkeys. EU consumption of poultry meat is expected to grow slowly in 2009 and 2010.

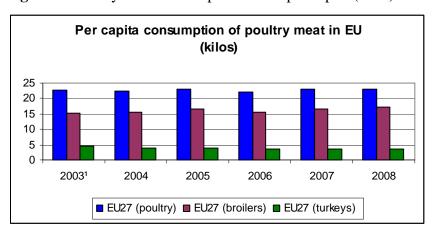


Figure 5: Poultry meat consumption in EU per capita (kilos)

Source: Avec Annual Report 2009

It is worth noting that such MSs as AT, UK report a significant increase in broilers consumption in expense of turkeys. The reason of a shifting away form turkey meat is that chicken is perceived to be tastier and more convenient to use. Chicken meat is also considered a healthier source of protein than other meats, and in addition it remains a staple among the general population and is especially important to the growing EU27 Muslim population. It is observed that processors opt more for broilers than turkeys as processing yields on carcasses are higher. It should be also noted that chicken meat remains competitive not only to turkey meat but also to red meat as chicken meat is its relatively low cost replacement.

Table 6: Poultry meat market in the EU27, 2003-2008

	2003	2004	2005	2006	2007	2008
	EU-15		EU-25		EU	-27
Gross production	8.987	10.921	10.998	10.648	11.385	11.503
Total Exports	1.275	1.300	1.240	1.2 4 0	1.050	1.150
Total Imports	1.100	500	640	650	820	840
Consumption	8.700	10.350	10.550	10.250	11.150	11.200
Consumption per capita,k	22,7	22,5	22,9	22,1	23,1	23,1
Rate of self-sufficiency %	103	106	105	105	101	102

Source: Avec, Annual Report 2009.

Annex 5 MORE DETAILED ANALYSIS OF THE IMPACT OF DIFFERENT OPTIONS

Table 7: Overview of data used and assumptions made.

Data/Assumption	Source (see more details in text below)		
Number of approved slaughterhouses in the EU: 1800 Number of additional processing (cutting) plants: 3700	List of approved establishments provided by MSs		
Amounts of poultry meat produced: 11.5 mio tonnes (a)	a.v.e.c. 2009 annual report		
% of <i>Salmonella</i> contaminated poultry meat: 5.1% (b) based on official controls, 1 sample per batch	EFSA 2008 annual report		
587 000 tonnes Salmonella contaminated in 2008	(a) x (b)		
Detection rates rates if the number of samples per batch is amended: Ø 5(.1) % if one sample per batch Ø 17.4 % if 5 individual samples per batch Ø 40.7 if 50 samples per batch pooled per 5 for analysis	EFSA 2008 annual report + unpublished EFSA estimations		
20% of batches tested per sampling day			
20% of positive batches recalled or withdrawn	Questionnaire; represents the % of frozen poultry meat on the market		
Overall loss when recalled or withdrawn: 2€kg	Questionnaire		
Overall cost of <i>Salmonella</i> detection: 50€if only one analysis, 25€ if at least 5 analyses Serotyping: 100€per test	Questionnaire, reference laboratories		

1. POLICY OPTION 1 – DO NOTHING

If the Commission does not lay down the detailed sampling schemes and analytical methods as requested by the Regulation then only the criterion 'Salmonella: absence in 25 grams' in fresh poultry meat will apply. Not establishing harmonised detailed sampling rules will allow for freedom for Member States and FBOs to decide on criterion's interpretation establishing adequate sampling schemes to ensure the requirement is met. Thus, an important level of variation between MSs and FBOs is likely to exist.

1.1. Economic Impact

1.1.1. Food Business Operators

Sampling and testing

Samples will be taken by slaughterhouses and processing plants in their own establishments based on their own risk management interpretation of "Salmonella: absence in 25 grams" and their HACCP plan.

All slaughterhouses already have the obligation to sample carcases in the frame of the existing process hygiene criterion (5 samples per week, reduction of frequency is allowed based on favourable previous results and in small establishments). The basic current cost of testing for this *Salmonella* process hygiene criterion can be estimated at: 1800 (approved slaughterhouses for poultry x 52 (weekly sampling) x 5 (number of analyses per week or fortnightly) x 25 \in (cost per analysis) is 12 mio \in New additional sampling is only required in the 3700 processing plants which are not slaughterhouses.

Since no harmonised rules are laid down in this option, a variation in sampling regime for the new criterion must however be considered e.g. from twice a week to once per month in slaughterhouses and processing plants, resulting in a variation of a total sampling cost between 8 and 71 mio \in This cost per analysis shall be completed with a possible administrative costs (i.e. familiarisation with legislation, if necessary, keeping records of tests results, producing records for inspection) that are estimated at average $100 \in$ per year, or 5500 establishment x $100 \in$ $5500 \in$ $5500 \in$ $5500 \in$ $5500 \in$

Withdrawal and Recalls

Due to the length of time between the sampling and the result to be known, most of this meat will already be on the market for sale. As it will no longer be compliant with the criterion, it will need to be removed from the market. When a food is already on the market, the FBO has to take measure to withdraw the product. When the product has already reached the final consumer, the FBO is required to put in place measures to inform the consumer and recall the product. When a food is unsafe and is part of a batch of food, it shall be presumed that all the food in that batch is unsafe. Estimates from business on the cost of withdrawing and recalling a product range have highlighted that, in a worse case scenario, a recall could be in the range of 650.000 €to 1.000.000 € including the further cost of extra transport, destruction, human resource, advertising, waste treatment etc. As highlighted above, the impact the food safety criterion will have on each FBO will vary depending on their self-assessed sampling regime and their subsequent levels of detection.

Fresh meat, except if frozen, cannot be stored before placing on the market until the results of testing are known. This is similar for minced meat and meat preparations for which a *Salmonella* food safety criterion exists since the beginning of 2006. The questionnaire revealed that removal of contaminated minced meat and meat preparations is very exceptional in practice unless frozen. This is because the "use by" date is very short after marketing and often has passed before removal is possible. It is expected that, once the *Salmonella* criterion applies to fresh poultry meat, the same practical issues will occur. Removal of meat because of non-compliance may be possible in the case of frozen meat (20% of all fresh poultry meat on the market, including the imported one) but rare in all other cases.

This practical issue will limit the social economic impact of the measures but is expected to remain a sufficient trigger to encourage measures to reduce *Salmonella* prevalence at all previous stages of the food chain, being the general objective of this initiative.

Meat that is withdrawn or recalled can either be used in industrial heat-treated products (e.g. cooked meat products) or destroyed. Stakeholders have argued that there is a limited market for poultry industrial heat treatment and that this market will probably not accepted contaminated meat. It is therefore unlikely that, even at half the value, the retailer will be able to sell the fresh poultry meat for heat-treated products. More likely the revenue from these contaminated meat and the cost to remove it for the market will be lost. The overall loss of value is estimated at 2 €per kg poultry meat²⁴.

A total amount of 587,000 tonnes is expected to be theoretically recalled or withdrawn However, EFSA estimated that by taking 5 samples per batch in stead of 1, the detection rate increases by 17.4/5 = 3.5 fold (see Table 9). In summary, the following estimation can be made.

- § 20% of batches are tested per sampling day. The mean batch size of this 20% is assumed to be similar to the overall mean batch size. Therefore 20% of batches is considered to represent 20% of production of meat.
- § 1 to 8 sampling days per month (20 production days per month), meaning 5 to 40% of production days per year.
- § Recall or withdrawal in practice only possible in frozen meat (20% of market)
- § 3.5-fold increase of detection rate compared to 1 sample per batch

Overall loss = 587,000, 000 kg x 20% x 5-40% x 20% x 2 \notin kg x 3.5 = 8 to 64 mio \notin

Loss of sales

As outlined above, application of the food safety criterion and the need to sample for *Salmonella* presence will have an impact on sales as non-compliant food will have to be withdrawn from the market. Recalling and withdrawing food may have a negative impact on consumer confidence as consumers equate recalls with unsafe food. This loss of confidence may translate into a reduction in the total demand for poultry meat and therefore FBOs will be forced to drop their prices. The impact the food safety criterion will have on each FBO will vary depending on their sampling regime and their subsequent levels of detection.

In practice, based on the experience with existing food safety criteria (see replies to questionnaire), a loss of confidence due to recall or withdrawal is very rare and may even result in certain Member States in an increase of confidence in the food safety controls of competent authorities. Loss of confidence is more likely to occur in the case of an outbreak of clinical salmonellosis. There were 15 and 18 verified outbreaks reported due to poultry meat in the EU respectively in 2007 and 2008. The purpose of the new criterion is to reduce these outbreaks and may therefore contribute to the prevention of a loss of consumers` confidence.

Because of different perception of consumers to withdrawals or recalls (loss of increase of confidence) and because the food safety criteria may have as well a favourable (less outbreaks) or negative (negative perception of recalls/withdrawals) effect on consumers

.

²⁴ a.v.e.c. estimate: 1.5€per kg of leggs/drumstick until 2.5€per kg of breast fillet

confidence and losses of sales, it is very difficult to estimate these losses and uncertainty on this impact is high.

Switches in suppliers

FBOs - in order to minimise the likelihood of non-compliant meat during sampling and save on the costs of recalling, heat treating or destroying meat - may switch their primary production suppliers to get better guarantees of *Salmonella* free meat. It is expected that in this option, competent authorities in Member States with a high prevalence in flocks may tend to implement less ambitious detailed rules for the food safety criterion in order to limit its economic impact. Switches in suppliers will therefore be less pronounced than in other options with a harmonisation of detailed rules at EU level.

Internal Market

To mitigate the costs and to prevent substantial withdrawals and loss of sales some FBOs in some countries (i.e. those will a high *Salmonella* prevalence) are likely to establish fairly liberal sampling regimes. This could have a knock-on effect on trade with FBOs not respecting each others testing regimes and blocking intra-Community and third country trade. In addition, it might undermine the policy's intentions of reducing the presence of *Salmonella* in fresh poultry meat.

Third Country trade

A non-harmonised sampling approach will create major difficulties for third countries wanting to import poultry meat since they will have to apply with different detailed rules for the criterion depending on the importing Member State.

Import figures of fresh poultry meat are in Table 8. Controversy exists on whether the application of the criterion in fresh meat would result in an economic advantage or disadvantage for the Member States compared to third countries. It might be easier for Member States to comply with the criterion in poultry meat produced in the EU since *Salmonella* is being reduced at farm level. This is not the case in most third countries. Additionally, imported poultry meat is frozen, allowing storage of the batch until the result of *Salmonella* testing is known or resulting in long shelf-life with increased removal. On the other side, stakeholders' organisations claim that poultry meat intended for the EU market will be screened prior to shipment. If *Salmonella* is detected, the meat will not be sent to the EU but placed on the market of the third country (not having a *Salmonella* criterion for poultry meat) without losses.

Table 8: EU imports of poultry meat are provided (Source: a.v.e.c.)

	2004		2005		2006		2007		<u>2008</u>	
	tonnes	%	tonnes	%	tonnes	%	tonnes	%	tonnes	%
Brazil	163389	78,3%	225152	89,5%	134372	86,5%	136980	83,1%	128629	83,0%
Thailand	20469	9,8%	1638	0,7%	89	0,1%	95	0,1%	37	0,0%
Chile	9856	4,7%	11620	4,6%	11476	7,4%	10723	6,5%	11738	7,6%
Argentina	6505	3,1%	9658	3,8%	7037	4,5%	12416	7,5%	11629	7,5%
Israel	1709	0,8%	2148	0,9%	1700	1,1%	3624	2,2%	2262	1,5%
Croatia	257	0,1%	77	0,0%	28	0,0%	25	0,0%	81	0,1%
USA	21	0,0%	1	0,0%	20	0,0%	91	0,1%	84	0,1%
Uruguay	48	0,0%	25	0,0%	25	0,0%	0	0,0%	49	0,0%
Others	6316	3,0%	1245	0,5%	513	0,3%	829	0,5%	393	0,3%
Total EU 27	208570	100,0%	251564	100,0%	155260	100,0%	164783	100,0%	154902	100,0%

80 to 90% of imported fresh poultry meat is from Brazil, 4.5 to 7.5% from Chile. All this import is frozen.

1.1.2. *Competent Authorities (CAs):*

Competent authorities need to carry out inspections for the verification of the implementation of the provisions, including testing, by the food business operators. Currently, between 20 and 28,000 official samples are taken in the EU each year in fresh poultry meat. The cost of this official sampling is, if 25,000 samples per year in the EU at 50 €batch = 1,250,000 €

Member States and private stakeholders expressed their reluctance to a minimum sampling frequency for official controls. This is in line with the EU approach in which the primary responsibility for food safety rests with the FBOs and CA are only responsible for the verification of the correct application by the FBOs. The cost of continuing the current sampling frequency by CA has therefore been taken into account in all options and is not further addressed below.

1.2. Social Impact

1.2.1. Food Business Operators

Loss of production regions/methods

If FBOs do not respect one another's sampling regimes and switch suppliers this could result in the loss of rural activities in certain production regions (e.g. countries with a high prevalence of *Salmonella* in live flocks). No data are, however, available to estimate this impact in detail.

1.2.2. Consumers

Salmonellosis

The approach laid down in Regulation (EC) No 2160/2003 is to create an incentive, encouraging the control of *Salmonella* at previous stages of the food chain (targets in flocks, increased slaughter and processing hygiene). The criterion will, therefore, result in a gradual reduction of exposure by poultry meat compared to the current situation without trade restrictions on contaminated meat with a final effect of €16 to 90 million. The effect on the previous stages of the food chain is an indirect effect on public health over a longer period and is expected to be far more important than the direct impact on public health by the removal of contaminated meat. Data are missing to estimate the time needed to obtain the final effect.

2. POLICY OPTION 2 – APPLY THE ABSENCE CRITERION WITH HARMONISED SAMPLING RULES

Implementing detailed sampling rules on the absence of all *Salmonella* in fresh poultry meat, all FBOs across Europe will be required to carryout out the same sampling regime on fresh meat. For the estimation of the impact, different options for harmonised sampling regimes from one batch of chickens per week or fortnightly for each relevant FBO have been

considered as well as different numbers of samples taken and analysed per batch. As reference point for the estimations, the current basic sampling requirement for the *Salmonella* process hygiene requirement and for all existing *Salmonella* food safety requirements for other food is considered: 5 samples on a weekly basis. The method used to detect *Salmonella* shall be consistent with the other *Salmonella* food safety criteria (EN/ISO 6579).

2.1. Economic Impact

2.1.1. Food Business Operators

Sampling and testing

The total cost for sampling and testing at a weekly one batch by taking 5 samples per batch can be estimated at 5500 establishments x 5 samples per week x 25€per sample x 52 weeks = 36 mio € As no additional samples need to be taken in slaughterhouses due to the existing sampling for the existing process hygiene criterion (cost 12 mio €), the costs represents a 24 mio €increase to be carried by processing plants.

Withdrawal and Recalls -

The costs can be estimated in a similar way as in option 1, however, with a fixed harmonised sampling frequency.

- § The overall loss of value is estimated at 2 €per kg poultry meat
- § Amount of 587,000 tonnes
- § 20% of batches per sampling day are tested.
- § 1 sampling day per week, meaning about 20% of production days
- § Recall or withdrawal in practice only possible in frozen meat (20% of market)
- § 3.5-fold increase of detection rate compared to 1 sample per batch

Overall loss = 587,000, 000 kg x 20% x 20% x 20% x 2€kg x 3.5 = 33 mio €

Loss of sales

The costs are likely to be the same as those identified in option 1. It might be reduced if retailers switch sales.

Switches in suppliers

Without the ability to interpret the sample criterion in a flexible way, FBOs may switch their primary production suppliers to get better guarantees of *Salmonella* free meat. Table 1 suggests that certain countries and producers could see a large impact on their trade (Lithuania, Greece, Belgium and Germany). In addition, Hungary has a prevalence of all *Salmonella* of around 71% (2008 zoonosis report). Given that it is a large trader of chicken to the other Member States, applying the new harmonised criterion could have a significant impact on its trade possibilities.

Internal Market and Third Country Trade

In contrast with option 1, this option will guarantee open trade between MSs and with third countries since the same provisions will apply as regards the presences and control of *Salmonella*. There may be reluctance to purchase poultry meat or live poultry for slaughter in countries with a high *Salmonella* prevalence in flocks.

The criterion may facilitate export to third countries requesting the absence of *Salmonella* e.g. Russia, who is the most important importer from the EU followed by Japan, China and Saudi Arabia. It is not allowed to export food that is not complying with the EU criteria even if there are no such criteria in the third country of destination. The total export from the EU of fresh poultry meat in 2008 was 0.86 million tonnes with a value of about €90 million.

2.2. Social Impact

The social impact may be the same as in option 1. It is however expected that the spread in the estimations is much smaller due to the harmonisation of rules.

2.3. Variation on the sampling regime and detection rates

Within the option the impact of variations in the sampling regime and their impact on detection rates and cost were calculated in order to estimate the impact of different detailed rules.

The EFSA estimated the detection rate for different true levels of prevalence in batches (0.1 to 50%). Below is the one for a true prevalence of 5% which is very close to the observed prevalence of 5.1%

Table 9: EFSA estimates on impact of sampling regime on the sampling costs and detection rates (expected prevalence) when the observed prevalence is 5% (1 sample)

Number of samples tested per	Increase of sampling costs	Detection rate
batch		
1	x 0.2	5
5	x 1	17.4
50	x 10	40.7

Based on the EFSA estimates and the differences in sampling frequency and sampling regime, costs for different scenarios are estimated in Table 10.

Table 10: Overall estimation of the burden in option 2 applying different regimes and frequency of sampling

Sampling frequency			50 €per	Additional cost (100 €per	Cost of recall/ withdrawal	Total additional		
		New cr	riterion	Current cost (repealed)		FBO)	(considering detection rates)	costs
		FBO	CA	FBO	CA			
fortnightly	1	7.2	1.25	-6	-1.25	0.55	4.7	2.0
	5	17.8	1.25	-6	-1.25	0.55	16.5	24.5
	50 (pooled per 5)	36	1.25	-6	-1.25	0.55	38.6	64.4

Weekly	1	14.3	1.25	-12	-1.25	0.55	9.4	13.8
	5	35.8	1.25	-12	-1.25	0.55	33	58.9
	50 (pooled per 5)	71.5	1.25	-12	-1.25	0.55	77.2	138.8

3. POLICY OPTION 3 – APPLY THE ABSENCE CRITERION TO ONLY MOST SIGNIFICANT SEROTYPES OF SALMONELLA

S. Enteritidis and S. Typhimurium strains represent 81% of all know Salmonella poisoning in the EU. Whilst across the food chain (eggs, meat of other species, ...) and not directly related to poultry meat cases, the key strains that cause food poisoning in humans are the focus of this option. This option with therefore only require the absence of S. Enteritidis and S. Typhimurium in the 25 gram samples.

3.1. Economic Impact

3.1.1. Food Business Operators

Sampling and testing

Compared to the previous options, this option requires further serotyping after the detection of *Salmonella* in order to exclude other serotypes. Such serotyping (100 €per test) will have to be applied on the 5.1% positive samples. It results in an overall increase of sampling cost of about 10%. The total sampling costs for the reference approach (5 samples weekly) would be 39 mio € including the current one of 12 mio €

Withdrawal and Recalls

Limiting the market restrictions to these 2 serotypes, representing in 2008 14.9 % of all serotypes in broiler meat (2008 annual zoonoses report), would result in a 6 to 7-fold (100/14.9) reduction of the economic impact compared to option 2. In the reference approach this cost can be estimated at 4.9 mio €

Loss of sales -

Similar to the effect on withdrawal and recalls a 6 to 7 fold reduction of the loss of sales can be estimated compared to option 2.

Internal Market and Third Country Trade

Variation between Member States on the prevalence of S. Enteritidis and S. Typhimurium has been described (2008 zoonosis report). There may therefore be a reluctance to purchase poultry in countries with a relatively high prevalence of these two serotypes. High prevalence was only noticed in small Member States with a low number of *Salmonella* isolates.

There are no separate data on the frequency of *S*. Enteritidis and *S*. Typhimurium from third countries. Similar prevalences as in the Member States may be assumed.

3.1.2. *Competent Authorities (CAs):*

This option increases the sampling cost by 10%. However, as serotyping is already done voluntarily by the CA it is unlikely to pose any additional cost on them.

3.2. Social Impact

3.2.1. Food Business Operators

Loss of production regions/methods

Similar to the effect on withdrawal and recalls, a 6 to 7 fold reduction of the loss of sales can be estimated compared to option 2.

3.2.2. Consumers

<u>Salmonellosis</u>

Similar to the effect on withdrawal and recalls a 6 to 7 fold reduction of the loss of consumers confidence can be estimated compared to option 2. The impact on public health may be the same as in option 2 since measures taken to control the two serotypes at previous stages of the food chain will also reduce other serotypes.

4. POLICY OPTION 4 – APPLY THE ABSENCE CRITERIA BUT TO 10 GRAMS RATHER THAN 25 GRAMS

Another option is the reduction of the sample size from 25 to 10 grams. Accordance to the Community reference laboratory on *Salmonella*, this option will reduce the detection rate by 2.5 fold but the sampling costs will remain the same.

Table 11: Detection rates (% of contaminated meat) estimated in this option

Number of samples tested per	Increase of sampling costs	Detection rate
batch		
1	x 0.2	2
5	x 1	7.0
50	x 10	16

4.1. Economic Impact

4.1.1. Food Business Operators

Sampling and testing

Same as in option 2.

Withdrawal and Recalls -

As the detection of *Salmonella* is 2.5-fold reduced in a 10 gram sample it is expected that the need to withdraw or recall products will be 2.5-fold reduced being 13.2 mio €for the reference approach.

Loss of sales -

Similar to the effect on withdrawal and recalls a 2.5-fold reduction of the loss of sales can be estimated compared to option 2.

Internal Market and Third Country Trade

Similar to the effect on withdrawal and recalls a 2.5-fold reduction of the loss of sales can be estimated compared to option 2.

4.2. Social Impact

4.2.1. Food business operators

Loss of production regions/methods

Similar to the effect on withdrawal and recalls a 2.5-fold reduction of the loss of sales can be estimated compared to option 2.

4.2.2. Consumers

Salmonellosis

Similar to the effect on withdrawal and recalls a 2.5- fold reduction of the loss of consumers confidence can be estimated compared to option 2. The impact on public health may be the same as in option 2 since measures will in any case be taken to control *Salmonella* at previous stages of the food.

5. POLICY OPTION 5 – APPLY A TOLERANCE ALLOWING MEAT ON THE MARKET IN WHICH SALMONELLA IS PRESENT IN 1 OF THE SAMPLES TAKEN.

A less ambitious food safety criterion with a certain tolerance could be considered as a transitional.

5.1. Economic Impact

5.1.1. Food Business Operators

Sampling and testing

The number of samples to be taken per batch if one positive sample is accepted, is 19 to 36 taking into account the 2008 EU prevalence in poultry meat and in order to be equally ambitious from the consumers health perspective with the prevalence in fresh poultry meat observed in 2008. If a reduction of prevalence is anticipated (progress made in reduction of *Salmonella* in flocks because of targets), the number of samples must be increased. The cost of analysis of such approach with a tolerance would therefore increase 19/5 = 3.8 to 36/5 = 7.2-fold compared to option 2, being respectively 136 to 257 mio \in

Withdrawal and Recalls –

Detection rates (% of meat not in compliance with this option) would be the same as if 1 sample is taken with a zero-tolerance in option 2 with the same cost of recall and withdrawal.

Loss of sales -

Similar loss of sales can be estimated compared to option 2 (one sample).

Internal Market and Third Country Trade

Since this option is in contradiction with the EFSA opinion and it includes a tolerance on the prevalence higher than current prevalences in a lot of Member States, these Member States

are expected not to support the option on their territory. It may only be accepted if a based on Member State/third country decision and limited to the domestic market. Major trade difficulties are therefore expected.

5.2. Social Impact

5.2.1. Food business operators

Loss of production regions/methods

See effect on withdrawal and recalls.

5.2.2. Consumers

Salmonellosis

Similar to the effect on withdrawal and recalls.

6. POLICY OPTION 6 – DELAY THE COMING INTO FORCE DATE UNTIL THE PREVALENCE IN FLOCKS IS LOW

6.1. Economic Impact

6.1.1. Food Business Operators

Sampling and testing

There will be no additional sampling costs but the current application of the *Salmonella* process hygiene criterion should be continued. This cost is 12 mio €

Withdrawal and Recalls

No costs of withdrawal or recalls because no food safety criterion.

Loss of sales

No loss of sales.

Internal Market and Third Country Trade

No effects.

6.2. Social Impact

6.2.1. Food business operators

No influence compared to current situation.

6.2.2. Consumers

Salmonellosis

Salmonellosis in humans is considered an accepted risk in this option but may reduce if actions at earlier stages proceed (e.g. targets for reduction in flocks). However, there is hardly any encouragement for such actions. This option has the highest chance of all options for outbreaks and loss of consumer's confidence due to such outbreaks.