Quantitative Microbiological Risk Assessment of *Salmonella* in pigs: an EFSA initiative towards constructing a European QMRA approach.

Robinson, T.P., Hugas, M.

Biological Hazards Unit, European Food Safety Authority, Largo N. Palli 5/A, I-43100 Parma, Italy.

*corresponding author: tobin.robinson@efsa.europa.eu*

**Summary**

To date, the scientific opinions of EFSA's Scientific Panel on Biological Hazards (with the exception of those on BSE/TSE) are mainly based on qualitative and in some cases semi-quantitative risk assessment. As a first step towards developing a European approach on Quantitative Microbiological Risk Assessment (QMRA), EFSA is now preparing to carry out a QMRA on *Salmonella* in pigs, at a European level, via a consortium of European institutes funded through a grant.

**What is EFSA?**

EFSA was established by the European Parliament in 2002 following a series of food scares in the 1990s (BSE, dioxins,...) which undermined consumer confidence in the safety of the food chain. EFSA's two main areas of work are: Risk Assessment and Risk Communication. Risk management measures and the operation of food control systems are not within EFSA's remit and remain the responsibility of the European Commission and Member States.

EFSA's Scientific Committee, its Scientific Expert Panels and other expert groups provide risk assessments on all matters linked to food and feed safety, including animal health and welfare and plant protection. EFSA's Scientific Expert Panels provide the European Commission, the European Parliament and Member States with a sound scientific basis on which to base legislation and policies related to food and feed safety. The Authority is also consulted on nutritional issues in relation to Community legislation.

EFSA is committed to ensuring that all interested parties and the public at large receive timely, reliable, objective and meaningful information based on the risk assessments and scientific expertise of its Scientific Committee and Expert Panels. Communicating its own initiatives and ensuring collaboration and coherence across the Member States are crucial to maintaining consumer confidence in the risk assessment process.

**Elaborating a strategy on QMRA at the European level**

To date, the scientific opinions of EFSA's Scientific Panel on Biological Hazards (with the exception of those on BSE/TSE) are mainly based on qualitative and in some cases semi-quantitative risk assessment. However, in September 2004, EFSA launched a project tender to formulate a strategy for QMRA at the European level taking into account: i) the expectations from interested parties, ii) the advantages and disadvantages of the application of QMRA at European level, iii) the available resources at European level and iv) existing international experience. The conclusions from this project were:

- There is broad support in the European Commission, among Member States and scientists for development of QMRA at the European level. EFSA is considered to be the appropriate organisation to organise the process on a European scale.
- QMRA is expected to promote structured, evidence-based decision making in food safety and to improve the transparency of the process. This will result in better risk communication and help to build trust among stakeholders. Careful consideration of regional differences is a prerequisite for QMRA studies at the European level.
- Three important tasks were identified for EFSA:
  - creating a network of European institutes for QMRA
  - harmonisation of QMRA
  - developing and maintaining databases to support QMRA
- EFSA can build its QMRA activities on completed and on-going work in Member States and may aim to organize the process on a European scale, while keeping a community perspective and
taking into account the needs of Member States. It needs to be aware of the diversity in Europe, both with respect to technical development as well as to cultural and consumption habits.

- It is expected that there will be a limited number of questions that require full farm-to-fork risk assessments. More questions requiring quantitative assessment of specific stages in the food chain are anticipated.
- A structured, interactive process is necessary to assure a purpose-oriented QMRA process and to prevent wasting of scarce resources.

A variety of applications of QMRA will be required, such as in helping risk managers to set priorities for control at different stages of production, to establish control measures and to defend them in an international context and towards stakeholders.

The development of a strategy for conducting QMRA at European level is a challenge and will require taking into account the limited resources available, time constraints, the risk of duplication of existing or ongoing national QMRA studies, the needs of the individual Member States and regional variations (e.g. nutritional habits, local products, and prevalence variability). The effective interaction between risk assessors and risk managers is also an essential factor.

As a first step, and taking into account the conclusions from the project formulating a strategy for QMRA, and in response to a demand from the Commission, EFSA is proposing to fund a collaborative project to carry out a QMRA on *Salmonella* in pigs, from the farm to the table, involving a consortium of European institutes. This will be carried out through Article 36 of EFSA’s founding regulation, that provides for networking with organizations operating in the field of EFSA’s mission. Funding for the consortium will be in the form of a grant, details of which can be found on the EFSA website (http://www.efsa.europa.eu/en/about_efsa/cooperation.html). The list of competent organisations with which EFSA may collaborate with through this type of funding have also been published on the EFSA website (http://www.efsa.europa.eu/ etc/medialib/efsa/about_efsa/cooperation/art_36_cooperation/1065.Par .0005.File.dat/Art36_list.pdf).

**QMRA Salmonella in slaughter and breeder pigs**

A total of 192,703 human cases of salmonellosis were reported in the EU in 2004, food being the main source of infection. It is estimated that several thousand people die each year in the EU due to salmonellosis. Eggs and egg products, poultry meat and pig meat are the main source of outbreaks in humans from products of animal origin.

Commission Regulation (EC) No. 2160/2003 lays down provisions for the control of *Salmonella* and other specified food-borne agents. The scope of the Regulation is limited to agents which pose a public health concern. The Regulation required that the Commission targets for the reduction of the prevalence of Zoonoses and zoonotic agents at the level of primary production and where appropriate, at other stages of the food chain. Target setting in poultry populations (breeding hens, laying hens, broilers and turkeys) is ongoing. However, the current provisions also require the setting of targets for *Salmonella* in live pigs within a fixed time schedule.

In view of this future cost/benefit analysis, it seems appropriate to carry out quantitative risk assessments on *Salmonella* in slaughter and breeder pigs. In accordance with Article 15 of Commission Regulation (EC) No. 2160/2003, EFSA shall be consulted before a target for reduction is set. Therefore EFSA, in particular its Panel on Biological Hazards, is requested to carry out this quantitative microbiological risk assessment. The cost/benefit analysis itself is not part of this mandate.

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Background of the call for proposals

EFSA is seeking proposals from the competent bodies identified in the approved list of competent organizations approved by the Management Board on the 20th December 2006 to carry out a quantitative microbiological risk assessment (QMRA) on *Salmonella* in slaughter (fattening) and breeder pigs.


The objectives of this Call for proposals are as follows:

A QMRA model that covers the whole food chain is required, beginning with a baseline model for the farm-to-fork-chain, including risk characterisation. While slaughter (fattening) pigs are the main object of this risk assessment, the role of piglets as a source of *Salmonella* also needs to be considered. During transport and lairage, cross-contamination might occur, both between-animal and between-batches (i.e. between-herds) due to carry-over of *Salmonella* on surfaces from one day to the next. The model will concentrate on primary production through to raw pig meat and raw pig meat products arriving in the kitchen. The model will also include (a) module(s) accounting for preparation and consumption of raw pig meat and raw pig meat products, and a dose response model, thus allowing numbers of human cases to be assessed.

Variability at all stages of the farm to fork chain, in and between Member states is a major consideration and needs to be explored. The end point of the QMRA will be, where possible, human cases of salmonellosis, which will, where possible, be compared with human incidence data. In addition, intermediate outputs such as prevalence/numbers on pork meat and antibody detection in meat juice should also be included and compared with surveillance data from both animals and meat. All assumptions on which the assessment is based and the uncertainties will be clearly identified, as will data gaps, with a view towards improving surveillance.

Terms of reference

The QMRA will address the terms of reference given by the European Commission, described below:

- The expected reduction of *Salmonella* cases in humans (or pig meat at retail) by a reduction (e.g. 5- or 10-fold) of *Salmonella* prevalence in slaughter pigs (based on bacteriology in lymph nodes or serology at slaughter).
- The sources of infection for fattening pigs at farm level.
- The reduction of the prevalence in slaughter pigs by the most important potential treatments or control measures at farm level.
- The impact of transport, lairage and slaughter processes on contamination of carcasses.
- The expected reduction of *Salmonella* cases in humans (or pig meat) by the most important control measures during transport, at lairage or during the slaughter process.

If quantitative data are not available and if such data can be generated with the limited resources and in the limited time of this project, then such data generation may also be included in the proposal.

EFSA also intends that the QMRA should build on existing models as much as possible and take into account:

- The variation in primary production within the EC, including factors such as herd size, access to the external environment, etc. Likewise, variations in slaughter practices and related primary production types should be characterised.
- Different behaviour between different serotypes of *Salmonella enterica*, if known should be taken into account.
- Differences in preparation and consumption within the EU, in the amount of pork and pork products consumed, and also in the major types of products consumed should be considered. Whereas most pork is eaten cooked, some traditional pork and pork products are consumed raw. Poor hygiene and differences in handling raw pork in the kitchen may lead to different probabilities of cross-contamination and undercooking and should also be considered.

For further details of this and future collaborations funded by EFSA through Article 36 grants, the corresponding page on EFSA's website should be consulted (http://www.efsa.europa.eu/en/about_efsa/cooperation.html).

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