

Opinion of the Scientific Committee on Veterinary Measures relating to Public Health on the 9th Code of Federal Regulations Part 304 et seq. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule. **20 July 1998**

TERMS OF REFERENCE

The Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) received a request to review the requirements of the new U.S. regulation on "Pathogen reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; final rule" and to comment on the scientific validity and practicality of the requirements.

An opinion was requested before June 1998.

BACKGROUND

The Food Safety and Inspection Service (FSIS) established requirements applicable to meat and poultry slaughtering establishments designed to reduce the occurrence and numbers of pathogenic microorganisms on meat and poultry products, reduce the incidence of food-borne illness associated with the consumption of those products and provide a new framework for modernisation of the current system of meat and poultry inspection.

The new regulations, known as the "US Megareg":

1 - require that each establishment develops and implements written Sanitation Standard Operating Procedures (Sanitation SOPs);

2 - require that all meat and poultry establishments develop and implement a system of preventive controls designed to improve the safety of their products, known as HACCP (Hazard Analysis and Critical Control Point);

3 - require regular microbiological testing by slaughter establishments to verify the adequacy of the establishments' process controls for the prevention and removal of faecal contamination and associated bacteria;

4 - establish pathogen reduction performance standards for *Salmonella* that slaughter establishments and establishments producing raw ground products must meet.

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1. THE FACTUAL CONTENT OF THE “US MEGAREG” – SUMMARY OF PROPOSALS

1.1 Summary of the US Megareg requirements

The Food Safety and Inspection Service (FSIS), US Department of Agriculture (USDA) issued on July 25, 1996 a new wide-ranging rule «Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) systems; Final Rule» (Federal Register, 9th code, part 304 et seq), the so-called Megareg. The final rule was the result of a thorough, interactive rule-making process on a 1995 FSIS proposal. FSIS had solicited extensive public comment and encouraged dialogue between FSIS and interested parties on the many policy and technical issues involved in the proposal. The implementation of the regulation has been gradual, beginning with the larger plants from 26 January 1998, and is still ongoing in smaller plants.

The purpose of the Megareg is to establish new requirements for all meat and poultry plants to improve food safety and begin the long-awaited modernisation of USDA's meat and poultry inspection system. The carcass-by-carcass inspection system, however, is still in place, but may be subject to change in the future.

In the following, the US Megareg, as presented by FSIS, will be described.

1.1.1 Background to the US Megareg

As is the case in other countries, food-borne disease is an important public health problem in the United States. Data from the Center for Disease Control and Prevention (CDC) suggest that food-borne microbial pathogens account for up to 7 million cases of food-borne illness each year, and up to 7,000 deaths. Of these, nearly 5 million cases of illness and more than 4,000 deaths may be associated with meat and poultry products. The seriousness of the problem was illustrated by the outbreak of food-borne illness that occurred in several western states in early 1993. The outbreak was attributed to undercooked hamburgers contaminated with *Escherichia coli* O157:H7, that were served at a chain of fast-food restaurants. This particular outbreak led to hundreds of cases of illness and four deaths. USDA's review of the outbreak concluded that the food safety system in place at that time did not adequately address the risk of microbial contamination.

A number of different bodies had called for changes in the inspection system to address microbial pathogens more specifically and make the system more prevention-oriented. Because of newer knowledge on microbial hazards, the FSIS realised that the existing system of slaughter inspection relied largely on organoleptic (sensory) methods and did not provide sufficient public health protection, since it did not adequately target and reduce pathogenic microorganisms on raw meat and poultry. Furthermore, it did not integrate systematic, preventive process control into the production process to make all meat and poultry products as safe as possible. It was assumed that implementation of the Megareg would help to correct these deficiencies.

1.1.2 The main content of the US Megareg

The Megareg requires all slaughter and processing plants to adopt the system of process control aimed at preventing food safety hazards known as Hazard Analysis and Critical Control Points (HACCP). To verify that HACCP systems are effective in reducing contamination with harmful bacteria, FSIS has set pathogen reduction performance standards for *Salmonella* spp. that slaughter plants and plants that produce raw, ground meat and poultry will have to meet. In addition, slaughter plants will be required to conduct testing for generic *E. coli* to verify that their process control systems are working as intended to prevent faecal contamination, the primary source of contamination with harmful bacteria. FSIS also requires plants to adopt and follow written Standard Operating Procedures (SOPs) for sanitation to reduce the likelihood that harmful bacteria will contaminate the finished product.

FSIS expects this combination of HACCP-based process control, microbial testing, pathogen reduction performance standards, and sanitation SOPs to significantly reduce contamination of meat and poultry with harmful bacteria and thereby diminish the risk of food-borne illness. FSIS further considers that this food safety system enables USDA to modernise its inspection program by focusing attention on the most significant food safety hazards and on ensuring that all plants have systems in place that effectively prevent food safety problems.

1.1.3 Hazard Analysis and Critical Control Points (HACCP)

The US Megareg requires all federally inspected meat and poultry plants to develop, adopt and implement HACCP systems to ensure that they have in place science-based process controls to prevent and reduce the significant food safety hazards that may arise in their particular processes and products. Each meat or poultry product must be covered by a HACCP plan based on the seven HACCP principles. FSIS believes that HACCP-based process control, combined with appropriate food safety performance standards, is the most effective means available for ensuring the safety of food, including controlling and reducing harmful bacteria on raw meat and poultry products. HACCP also provides a framework for better targeting of FSIS inspection on the most significant food safety hazards and their control, and more efficiently using inspection resources. Furthermore, implementation of HACCP helps in clarifying the responsibility of industry and FSIS to produce safe meat and poultry products. The role of FSIS is to set appropriate food safety standards and maintain vigorous supervision through inspection to ensure that those standards are met.

Plants are required to validate their own HACCP plans, i.e., ensure that they do what they were designed for. FSIS does not approve HACCP plans in advance but reviews them for compliance with the HACCP regulations.

Verification is a responsibility of both industry and FSIS. Industry must monitor and verify the performance of the controls in their HACCP plans and maintain records of this monitoring and verification. FSIS evaluates the adequacy of the HACCP plans and their successful operation as part of the inspection process. HACCP plans found by FSIS to be inadequate will have to be corrected, or the plant will face appropriate regulatory action.

1.1.4 Pathogen reduction and microbial testing

To be effective, FSIS considers that HACCP-based process control must be combined with objective means of verifying that meat and poultry plants are achieving

acceptable levels of food safety performance. Before the implementation of the Megareg, microbiological performance criteria or standards for raw products, with the exception of *E. coli* O157:H7 in ground beef, did not exist.

FSIS believes it is essential to the reduction of food-borne pathogens that slaughter establishments control their operations to prevent faecal contamination and that all plants producing raw meat and poultry products institute process controls to reduce the prevalence of *Salmonella*. These requirements provide an objective means of verifying process control in slaughter plants both with respect to faecal contamination and pathogen reduction performance. The measures will reduce the exposure of consumers to *Salmonella* spp., the most common cause of food-borne illness.

1.1.5 Generic *E. coli* testing for process control

FSIS requires all slaughter plants to conduct microbial testing for generic *E. coli*. This organism is considered an excellent indicator of faecal contamination, which is the primary source for contamination of meat and poultry with food-borne pathogens such as *E. coli* O157:H7, and *Salmonella* and *Campylobacter* spp. The testing requirement is believed to assist plants in maintaining adequate control of faecal contamination.

For verification purposes, FSIS has established **performance criteria** for each animal species that reflect the prevalence and levels of carcass contamination with *E. coli*, as determined by FSIS base-line surveys. FSIS is using the term «criteria» because they are guidelines, not regulatory standards. FSIS will not use the test results alone to take any regulatory action, but will consider them in conjunction with other information to determine whether a problem requiring regulatory action exists.

The required frequency of *E. coli* testing is based on production volume. Slaughter plants will be able to adopt alternative testing frequencies if the alternative is equally or more effective for verifying control of faecal contamination. FSIS intends to update the *E. coli* criteria periodically, based on future surveys and data generated by the testing, to ensure that the criteria adequately reflect an appropriate and adequate level of performance.

FSIS believes *E. coli* test results will help plants find and correct process control problems at this most important stage in meat production. The results will also support more objective assessments by inspectors as to whether plants are meeting current statutory requirements for sanitation and the prevention of adulteration. They will also play an integral role in the successful implementation of HACCP in slaughter plants.

1.1.6 Performance standards for *Salmonella* spp. and FSIS testing

FSIS has established pathogen reduction **performance standards** for *Salmonella* that must be met by slaughter plants and plants that produce raw ground products to verify that their HACCP systems are effective in reducing *Salmonella* contamination. The standards are thought to provide incentives for innovation to improve food safety.

FSIS believes that the production of raw meat and poultry with a *Salmonella* prevalence below the current national level is readily achievable with available technology and production methods. *Salmonella* was selected as the target pathogen because it is the leading cause of food-borne illness, is present at varying frequencies

on all types of raw meat and poultry products in the US, and can easily be detected in a variety of products. Furthermore, improvements in process control that result in reductions in *Salmonella* are expected to result in corresponding reductions in other pathogens found in the intestines of animals.

The microbiological performance standards that FSIS has adopted are part of a fundamental shift in FSIS regulatory philosophy and strategy. FSIS is moving away from a reliance on command and control regulations, which generally prescribe how desired objectives are to be achieved, to much greater emphasis on performance standards, which generally express the objective but do not specify the means for achieving it. FSIS believes that its food safety and consumer protection goals can, in most cases, be achieved most effectively by establishing clear objectives in terms of performance standards, while providing industry with flexibility to devise the best means of achieving the objective, and then verifying through inspection and other forms of supervision that companies are meeting the established standard.

FSIS believes that the performance standard for *Salmonella* and the *E. coli* performance criterion complement one another. While *E. coli* testing is a good indicator of faecal contamination, it does not correlate directly with *Salmonella* contamination, which is also affected by other factors, including the condition of incoming animals. The *Salmonella* standard will force plants not currently meeting the standard to take steps to reduce pathogen contamination.

Plants are required to achieve a prevalence of *Salmonella* contamination that is below the national base-line prevalence for each raw product. These are regulatory standards that FSIS will require the plant to meet consistently over time as a condition to maintaining inspection.

FSIS, rather than the company, is conducting *Salmonella* testing to verify compliance with the standard. Prior to the implementation dates, FSIS conducted *Salmonella* testing to provide plants with information on their level of performance relative to the standard. The frequency and intensity of testing is based on past plant performance and other factors.

FSIS believes that the *Salmonella* enforcement strategy represents an objective, uniform approach that will be administered and applied in a fair, equitable, and common-sense manner. FSIS plans to repeat its base-line surveys and collect substantial data through other means and, on that basis, will adjust the *Salmonella* targets and possibly set targets for additional pathogens, as appropriate.

1.1.7 Standard operating procedures (SOPs) for sanitation

All plants are required to prepare, implement and follow written plant-specific standard operating procedures (SOPs) for sanitation to ensure that they are meeting their responsibility to keep facilities and equipment clean. The written sanitation SOPs must describe the specific activities that plant management has determined is necessary to maintain good sanitation and prevent direct product contamination. Each SOP must specify the persons responsible for carrying out these activities. Daily records must be kept showing when procedures are accomplished and when corrective actions are taken.

It is assumed that sanitation SOPs will clarify the view that sanitation is industry's responsibility. Furthermore, they should make it easier for FSIS inspectors to perform their role of verifying that the plant is carrying out its sanitation procedures properly and allow FSIS to focus on the prevention and correction of direct risks of product contamination.

1.1.8 Requirements for foreign establishments

Foreign countries exporting to the United States must establish inspection systems that are «*equivalent to*» U.S. requirements. Thus, all foreign meat and poultry plants that export to the United States must operate "equivalent" HACCP-type process control systems and performance standards.

1.1.9 Food safety from farm to table

The new regulatory requirements - mandatory HACCP, pathogen reduction performance standards and testing procedures, and SOPs for sanitation- address hazards within slaughter and processing plants. FSIS recognises, however, that these measures must be part of a comprehensive food safety strategy that addresses hazards at other points in the farm-to-table chain. The FSIS has pointed out that the new measures are designed to reduce contamination of meat and poultry products with harmful bacteria when they leave the meat or poultry slaughter or processing plant. Distributors, employees in retail stores and restaurants, and consumers, however, must continue to store, handle, and prepare meat and poultry products carefully to keep food safe.

To improve food safety at the animal production and intermediate stages before the slaughter plant, FSIS is working with industry, academia, and other government agencies. The intention is to develop and foster measures that can be taken on the farm and during transport and marketing of animals to reduce food safety hazards associated with animals presented for slaughter. FSIS does not presently intend to mandate production practices for these stages, but believes that the voluntary application of food safety assurance programs based on HACCP principles can be useful in establishing the necessary risk reduction practices. FSIS believes that continued public concern about food-borne pathogens and the adoption of HACCP and performance standards in the slaughter house will increase incentives for producers to adopt similar practices at the animal production and handling level.

2 - DETAILED CONSIDERATION OF THE "US MEGAREG" - FINAL RULE AND COMMENTS

2.1 - Sanitation Standard Operating Procedures (SSOPs)

2.1.1 - The US final rule

Ref:

- Federal Register 9 CFR part 304 et seq., Chapt. III, Sanitation SOPs, pp. 38829-38835.

- Part 416, Sanitation, pp. 38868 - 38869.

- Appendix A, Guidelines for developing a standard operation procedure for sanitation in federally inspected meat and poultry establishments, pp. 38871 - 38872.

- *Appendix B, Model of a standard operation procedure for sanitation, pp. 38872 - 38875.*

- *All establishments shall develop, implement and maintain written sanitation SOPs. The sanitation SOPs shall describe all procedures that an establishment conducts daily to prevent direct contamination or adulteration of products.*

Such SSOPs should include pre-operational procedures, all other procedures at the frequency specified, daily monitoring of the implementation of these procedures.

Each establishment should identify an official who would monitor sanitation activities, evaluate whether sanitation SOPs are effective and take appropriate corrective actions when needed.

In addition, each establishment shall maintain daily records sufficient to document the implementation and monitoring of the SSOPs and any corrective action taken.

- *FSIS considers that responsibility for identifying and conducting procedures needed to maintain sanitary conditions rests with the establishment.*

Each establishment must determine for itself what procedures are necessary to prevent insanitary conditions that will cause direct product contamination or adulteration.

- *Sanitation SOPs are a "pre-requisite" for HACCP.*

- *FSIS will not provide a single format for individual sanitation SOPs nor mandate Good Manufacturing Practice (GMP), as it believes that detailed regulations are not feasible because of the difficulty of making them specific enough to be useful and resultant loss of flexibility.*

It would be the responsibility of each establishment to consider existing regulations and guidelines, evaluate its facilities, processes and sanitation conditions, determine those sanitation procedures that must be implemented to prevent direct product contamination or adulteration and describe these procedures in sanitation SOPs.

2.1.2 - Comments

- It is agreed that effective implementation of Good Manufacturing Practice (GMP) and the principles of good hygiene that they contain (Good Hygiene Practice – GHP), together with appropriate sanitation procedures, are an essential basis for food safety and wholesomeness. They should always be applied; they constitute a pre-requisite for the successful implementation of HACCP.

- It is also agreed that the responsibility for identifying and conducting procedures needed to maintain sanitary conditions rests primarily with the establishment in question. In this context, the role of inspectors is to verify that appropriate Good Hygienic Practice and sanitation procedures are being implemented.

The new US regulation mandates that the establishment has sanitation *procedures written and monitored*; keeps *records* documenting implementation, *monitoring* activities and *corrective actions* that are taken when needed. It prescribes also that each establishment should identify an *official responsible*.

Requirements for written procedures and identification of an official responsible are not at present included in the European regulations.

In practice, documentation of GHP and sanitation procedures, keeping records and identification of an official responsible are effective means for enhancing an operator's awareness of sanitation activities. Documentation reflects the commitment of the management to apply the control measures and procedures consistently. Documentation also demonstrates to third parties that the persons responsible for the establishment know and understand their operations and how to maintain sanitary conditions on a day-to-day basis. Therefore documentation of the implementation of GHP and sanitation procedures and record maintenance should be mandatory. However, mandating a single format for GMP, GHP and sanitation procedures is not appropriate, as they need to be specific to be effective, but flexible enough to incorporate technological improvements. For these reasons, guidance should be provided to food operators and inspectors. Guides to Good Hygienic Practice can serve this purpose and their development and use should be encouraged.

Regarding the regulation, Sanitation SOPs should be incorporated in the HACCP plan and therefore subjected to the same strategy for monitoring and control. At present, there is no clear measure of the effectiveness of the Sanitation SOPs in relation to the overall control of faecal contamination and criteria for *E. coli*. It is possible for *E. coli* to multiply in the slaughterhouse and therefore contamination of carcasses with this organism could be partly due to a failure in the Sanitation SOPs.

2.2 - HACCP

2.2.1 - The US final rule

Ref.:

- *Federal register 9 CFR part 304 et seq. chapt II, Hazard Analysis and Critical Control Point System, pp. 38814 - 38829.*

- *Part 417, HACCP systems, pp. 38869 - 38871.*

- *Appendix C, Guidebook for the preparation of HACCP plans, pp. 38875 - 38904.*

- *Appendix D, Hazards and preventive measures guide, pp. 38904 - 38917.*

- *All establishments shall implement HACCP systems to address hazards that are likely to occur in their operations.*

A list of processes for which HACCP plans must be developed is proposed and includes:

slaughter for all species;

raw ground meat or poultry products;

raw products not ground (e.g. meat cuts or cup-up birds);

shelf-stable untreated products (e.g. jerky);

shelf-stable, heat-treated products (e.g. edible fats);

thermally processed/commercially sterile products (e.g. canned soups);

fully cooked, non-shelf-stable products (e.g. canned hams that must be refrigerated);

partially cooked/heat-treated products (e.g. char-marked beef patties);

non-shelf-stable products with secondary inhibitors (e.g. fermented sausage).

- *Establishments are required to develop HACCP plans based on seven principles:*

(i) hazard analysis;

(ii) CCP identification;

(iii) establishment of critical limits;

(iv) monitoring procedures;

- (v) *corrective action;*
- (vi) *record keeping;*
- (vii) *verification procedures.*

In Appendix C (pp. 38903), a checklist is proposed to ensure that the HACCP plan adequately addresses all seven HACCP principles.

- FSIS will carry out various activities to ensure that industry HACCP systems are functioning appropriately:

- (i) general review of an establishment HACCP to determine compliance with the seven principles;*
- (ii) in depth review, on a regular basis, of the current HACCP plan to check its scientific validity and on-going adequacy for preventing food safety hazards,*
- (iii) following revision and amendment of the HACCP plan, review of the new plan to determine its compliance with regulatory requirements.*

A verification programme might include:

- (i) review of all establishment monitoring;*
- (ii) review of process records;*
- (iii) review of records for a production lot;*
- (iv) direct observation of CCP controls as conducted by establishment employees;*
- (v) collecting of samples for FSIS laboratory analysis;*
- (vi) checking establishment verification activities for a particular process.*

- Specific consideration is given to validation, verification and reassessment procedures (§ 417-4, p. 38870):

- (i) every establishment should validate the HACCP plan;*
- (ii) initial validation is intended to demonstrate that particular process control measures can adequately control the food safety hazards identified during the hazard analysis and that the process control measures, as written in the HACCP plan, can be operated in a given establishment to achieve the intended food safety objective.*
- (iii) ongoing verification activities include, but are not limited to, calibration of process monitoring instruments, direct observation of monitoring activities and corrective actions, review of records.*
- (iv) every establishment should measure the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan.*

2.2.2 - Comments

*- Food safety is promoted by the combined use of GHP, sanitation procedures **and** HACCP. In the framework of implementation of good practice (GMP – GHP), HACCP plans need only be commensurate with the risk involved. However, proper control of food safety requires taking steps throughout all phases of food production, from the farm to the consumer. In this regard, good practice and HACCP plans should be developed by the primary producers (i.e. at the farm), the slaughterers, the processors, the transporters, the retailers, the food service operators and restaurants to control all food safety risks. In addition, consumer education should be strengthened. This US regulation does not mandate any requirement at the farm level. At present, European regulations do not mandate HACCP in either the primary production sector or the slaughterhouse.*

Therefore, appropriate measures, including regulatory measures, should be considered to establish control practice (GHP and appropriate HACCP plans) on the farm and at the slaughterhouse, as well as at other stages of the food chain. Nevertheless, it has to be recognised that this approach is, at present, in its infancy.

- The US final rule mandates that HACCP plans should address all seven principles, as identified by the Codex Committee on Food Hygiene. However, European Directive 93/43/EEC does not mandate record keeping. For maximum effectiveness HACCP plans should address all seven principles identified by Codex. In particular, documentation and record keeping should be systematically developed and maintained, because they are essential for successful functioning of HACCP systems.

- The Committee endorses the notion that each establishment must carry out primary validation of HACCP plans upon completion, as well as ongoing verification and reassessment. Establishments should provide evidence of such validation, verification and reassessment to the inspectors. On the other hand, verifying the effectiveness of process controls designed to ensure food safety, e.g. HACCP systems, is a prerogative of public authorities. To facilitate inspection, appropriate procedures for official verification of HACCP plans should be elaborated, preferably on an international basis.

- The US final rule puts a strong emphasis on the implementation of HACCP for the slaughter process used for all animals.

Some limitations in applying HACCP at the slaughterhouse should be acknowledged. These are attributable to:

- (i) limited knowledge on the prevalence of specific pathogens in cattle and birds;
- (ii) limited knowledge on the distribution of pathogens on carcasses;
- (iii) the technology of the process and its adaptation to the anatomy of the animal;
- (iv) the limited availability of valid parameters relevant to on-line monitoring of contamination by pathogens;
- (v) the absence of any critical point with the capability to eliminate pathogens on raw meat and poultry products.

In this regard, the hygienic preparation of meat and poultry depends primarily on the implementation of GMP, GHP and sanitation procedures for the application of which all operators should be made accountable. In this framework, HACCP is an aid -(i) to assessing the sources of hazards, the procedures involved, the transfer and redistribution of hazards during the slaughter and dressing processes, and -(ii) for the identification of areas that require specific process control (the CCPs).

As implemented in a slaughterhouse, HACCP is a means of minimising the opportunities for microbiological contamination and of providing enhanced assurance of control. It is essential to recognise that HACCP, as applied at this stage of the production chain, cannot be regarded as a means of ensuring the absence or elimination of hazards.

In general, the Committee felt that the US regulation was being implemented without any information being available on its effectiveness or on the scientific basis for the linkage between HACCP and end-product testing, which is not a measure of the efficacy of HACCP. Also, the practical objective of the control strategy seems to have become obscure and could be either reduction of pathogen contamination, prevention of faecal contamination or control of *E. coli*. In practice, testing for *E. coli* should be

part of the HACCP validation and not used to indicate a presumed absence of pathogens.

Other details that are lacking include possible measures to prevent or reduce cross-contamination in the slaughterhouse and requirements for control of personal hygiene for operatives. Furthermore, the relative responsibility of FSIS inspectors and plant management in the operation of the HACCP system need to be clarified.

The responsibility of regulatory agencies is to define food safety objectives, which should be achieved by the companies using HACCP. The responsibility of designing and implementing a HACCP plan lies with the company concerned. Using Command-and-Control regulatory tools to enforce implementation of preventive and control measures within the framework of a given HACCP plan should therefore be avoided.

It is stated that *performance standards* measure whether HACCP systems are working effectively to address food safety hazards.

How can the salmonella results measure the success of HACCP as the salmonella prevalence in the plant mainly is a result of the status of the animals presented for slaughter? Furthermore, the salmonella prevalence is not directly related to any critical control point apart from the general effort of preventing faecal contamination.

The Megareg gives the impression of being an advocate for the Farm-to-table strategy. However, the Megareg itself only addresses a part of the farm-to-table continuum, namely the activities within the slaughter plants. It does not cover the animal production and the status of the animals presented for slaughter (FSIS is not authorised to mandate production practices). Most scientists agree that if trying to reduce the occurrence of pathogens on meat and poultry, it is of uttermost importance to reduce the proportion of animals being carriers of the specific pathogens.

2.3 - Concepts of "microbiological performance criteria and standards"

The following discussion considers the concept only, regardless of other requirements for testing, as laid down in the US final rule, or the microorganisms chosen as targets. These latter issues will be considered in subsequent sections.

2.3.1 - The US final rule

Ref.:

- *Federal Register 9 CFR part 304 et seq, chapt. IV, microbiological performance criteria and standards, pp. 38835 - 38854.*

- *FSIS introduces, probably for the first time in any food safety regulation, the concept of "microbiological performance criteria and standards" aimed at gauging whether HACCP systems are working effectively to address food safety hazards.*

The rationale is that, to be successful in addressing and ensuring food safety, HACCP should be coupled with "reference values" or "targets" against which the effectiveness of controls developed by each establishment could be validated and verified. Without such "reference values" there could be no objective basis for determining whether a particular HACCP plan is adequate for its food safety purpose.

- *"Performance criteria and standards" are seen as objective means of verifying the effectiveness of process controls and that meat and poultry establishments are achieving acceptable level of performance with regard to food safety requirements.*

- *As a gauge to evaluate a level of control, "Performance criteria and standards" will not serve for determining whether a particular lot of raw products could be released into commerce.*

2.3.2 - Comments

- The concept of microbiological targets to be used in conjunction with HACCP is novel in the present context. However, microbiological targets are essential for the appropriate design of HACCP plans and have multiple functions:

(i) they provide a reference to determine the extent of the program, which should be limited to that needed to meet the chosen targets (i.e. whether an in depth HACCP plan is necessary or not, due to the identification of a high risk process or to the need to substantially improve food safety performance);

(ii) they aid in determining, during the hazard analysis phase of HACCP, what is an acceptable situation and what is not;

(iii) they provide guidance to decide whether it is necessary to eliminate hazardous conditions that may exist in the process and / or to determine the stringency of control measures that need to be applied to meet targets;

(iv) supporting the establishment of CCPs, they provide a reference for the determination of critical limits;

(v) they provide objective reference for the primary validation of new HACCP plans, their subsequent verification and reassessment;

(vi) they allow for comparison of systems where different control measures have been set in place.

In addition, from a judicial point of view, they may serve as support or reference to assess the achievement of "due diligence" expected from any food operator.

- Components of such targets should include the type of food, the microbiological hazard(s) or relevant indicator(s), the level of hazard or indicator in food that is appropriate.

To allow for realistic implementation, such targets should be technologically feasible and achievable through implementation of GMP, GHP and HACCP. To be meaningful with regard to food safety, their establishment should take into consideration an assessment of the risk appropriate to the circumstances.

- Thus, there are good reasons for supporting the introduction of microbiological "targets" aimed at validating and verifying the level of process-control performance in HACCP plans. These should be considered in the process of assessing and revising the EU regulations. Also, public bodies have the authority to determine microbiological targets. However, for the sake of efficiency, the establishment of such targets should involve not only regulatory authorities but scientific experts, the affected industry and other interested parties, including consumers as has been the case in the USA. Microbiological targets are already used by public authorities as a basis for the assessment of HACCP systems. Equally, they are used by establishments to validate their own HACCP plans upon completion and to determine whether, on a

day-to-day basis, the system will maintain the required level of control. In particular, they serve to determine the operational parameters necessary for appropriate control.

- It should be emphasised that microbiological “targets” refer only to the performance of HACCP systems. When they are exceeded, corrective action and possible revision of HACCP plans should be undertaken by the establishment, under official supervision, where necessary.

Determining the acceptability of products placed on the market on the basis of their microbiological quality is different and should not be confused conceptually with the assessment of HACCP systems. Apart from taking into account the level of process control during production or manufacture as one element of judgement, determining the acceptability of a lot is based mainly on microbiological analysis of samples of the product, involving definition of appropriate sampling plans and end-product criteria.

- In the US regulation, the use of a *Salmonella* Performance Standard is not actually a measure of the effectiveness of the HACCP programme. The presence of *Salmonella* largely reflects the prevalence of the organism in the in-coming animals. Testing for *E. coli* may also be misleading, because the results have no bearing on whether *Salmonella* would be present or absent and the same would be true for other enteric pathogens; these would need to be tested for individually. Equally, no relationship has been established between levels of *E. coli* and the degree of faecal contamination on the product. In addition, the testing strategy would not distinguish between relatively uniform faecal contamination among a particular batch of carcasses and higher contamination as a result of a few, more heavily soiled individuals. The test for *E. coli* would be more meaningful if it was applied at all CCPs and not just on the final product. It would then be possible to determine whereabouts in the process any loss of control had occurred.

- Establishment and implementation of microbiological targets may raise specific concerns, as they focus on the outcome rather than on the steps taken to achieve the outcome. Achievement of targets should take into consideration the influence of each stage of the food chain on the microbiological load and be coupled with implementation of GHP and HACCP at all stages. In particular, targets would not justify reliance on one single reduction step such as the use of antimicrobial treatment in a system of production which is not otherwise well organised and controlled at all stages, with the aim of minimising the prevalence of pathogens in the food. It is recognised that targets allow for flexibility in identification of control measures and that they may facilitate the introduction of innovative technologies. However, their application should not encourage the use of objectionable or unsustainable treatments in an attempt to comply with the targets. Appropriate safeguards should be taken and unambiguous statements made to avoid misuse of targets when their introduction into a specific regulation is being considered.

2.4 - Routine testing and testing frequency of end -products for verification of compliance with "performance criteria"

This section considers the requirement for *routine* testing for process control verification only. The indicator chosen and method of analysis are addressed in the next section.

2.4.1 - The US final rule

Ref.:

- *Federal Register 9 CFR, part 304 et seq. :*
- *chapt.IV, Microbiological performance criteria and standards, pp. 38835 - 38854.*
- *Part 310, Post mortem inspection, § 310 - 25, Contamination with microorganisms; pathogen reduction standards for Salmonella, pp. 38864 - 38866.*
- *Part 381, Poultry products inspection regulations, subpart K, § 381 - 94, Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards, pp. 38866 - 38868.*
- *Appendix F, Guidelines for E. coli testing for process control verification in cattle and swine slaughter establishments, pp. 38929 6 38938.*
- *Appendix G, Guidelines for E. coli testing for process control verification in poultry slaughter establishments, pp. 38939 - 38944.*

- *FSIS requires establishments slaughtering livestock and poultry to conduct routine testing for generic E. coli as an on-going process control verification. FSIS considers the testing to be essential in meeting current statutory requirements for sanitation and the prevention of adulteration.*

- *FSIS recognises that there is no single method for determining the frequency of testing and that this is ideally determined on an establishment basis, taking into account a number of variables, including differences in sources of raw material, the type and nature of the process and the consistency of microbiological test results over time. However, FSIS considers it necessary to require a minimum frequency of testing.*

- *The frequency of testing mandated takes into account the volume of production, based on data characterising the US situation (FY 1993 and FY 1996, p. 38841) :*

A - Highest volume establishments, at least one test window (13 carcass samples) per day, with 1 test per 300 for cattle, per 1000 for swine, per 22000 for chicken, per 3000 for turkeys.

B - The above frequency notwithstanding, all establishments must conduct sampling at a frequency of at least once a week to provide "an adequate basis for process control verification".

C - Establishments with very low volumes (less than 6000 cattle, 20000 swine, 440000 chicken, 60000 turkey per year) are required to sample once per week only until a sampling window that verifies process control has been completed and the results indicate that the slaughter process is under control. Once these criteria have been met, these establishments will be required to complete a new sampling window only once a year, in the 3 month period of June through August or when a change has been made in the slaughter process or personnel.

- *Slaughter establishments under HACCP control may use a sampling frequency other than that provided for in the regulation, if the alternative frequency is an integral part of the establishment's HACCP verification procedures and provided that FSIS does not determine that the alternative frequency is inadequate to verify the effectiveness of the control system. Also, establishments which are not yet under a HACCP plan will have to test at the frequency specified in the regulation unless they have been made an exception by FSIS on a case-by-case basis.*

2.4.2 - Comments

Microbiological product testing can be used for several purposes, such as acceptance of lots, verification of the effectiveness of a control plan or overall surveillance. These different aims should be kept separate and the aim has to be very clear when testing is used as part of a regulatory measure. It is generally agreed that end-product testing is not an optimal procedure to ensure food safety. However, microbiological testing is a useful and practical tool in surveillance plans to ascertain whether a food system provides food of acceptable hygienic quality. This requires an appropriate sampling strategy relating the sample size to the target prevalence (for example absence in a sample size of 300 will assure a prevalence below 1% with 95% probability). The FSIS performance standards can serve this purpose, but routine end product testing for HACCP verification in individual slaughter plants is questionable.

It is widely recognised by the scientific community that, once a HACCP system has been properly validated and effective monitoring is being carried out, regular, systematic end-product testing is of little value. Nevertheless, sporadic verification is always necessary to ensure that no drift is occurring. For that purpose, microbiological end-product testing is only one of the techniques that may be used (always hampered by the inherent lack of sensitivity to detect low levels of defective products) besides, for instance, additional tests at CCPs (ICMSF, 1988), direct observation of monitoring activities and corrective action, and review of record keeping and maintenance.

- With regard to the above, there is a need for initial validation of HACCP plans (including validation of control measures, process controls and monitoring activities) aimed at reducing the potential for a production process to overrun its targets and for sporadic verification aimed at ensuring that no drift occurs. These are essential for HACCP plans to be effective. The responsible establishment should be able to provide evidence that such activities have been carried out.

- End-product testing may be of value as one of the possible criteria in the validation phase and for sporadic verification that no drift is occurring. However, due to the low probability of identifying an accidental event that results in an occasional low level of non-conforming products which simply is not detectable by any practicable sampling plan, systematic end-product testing (repeated, for instance, on a daily or weekly basis as mandated in the US final rule) will add nothing to HACCP systems. These systems may have been otherwise well conceived, appropriately validated, effectively monitored and rationally verified to be meeting the relevant process control targets.

It is of interest to note that FSIS (Federal Register, p. 38853, Methodology for meeting targets), recognised that moving sum procedures and control charts are useful to verify that a state of control exists. However FSIS admits that it "did not claim that the procedure would be useful for attaining and maintaining control. That requires more timely and probably more intense monitoring of process parameters at CCPs".

- The US final rule recognises that there is no one single method for determining the frequency of verification activities (including microbiological end-product testing when used for that purpose) and that ideally such verification frequency should be determined on an establishment by establishment basis.

Verification frequency may vary greatly, depending on the fluctuation of microbiological condition of the in-coming animals, the opportunities to reduce such variability, the types of process involved in production and their ability to maintain operational criteria, the volume of products and the recurrent rate of non-conformance, the results of previous verification activities, the consistency of conformance, how deviations are handled, and, finally, the results of the verification activity itself.

Estimating the 'risk' that a HACCP system should fail or deviate is part of the *validation* process and should determine the level of process control necessary and the frequency and stringency of monitoring activities which, in turn, determine the types of tests to be used for verification and the frequency of verification activities. Determining in advance the frequency for verification activities is contradictory to the HACCP logic and the wrong approach to creating incentives for better and more effective HACCP plans.

Validating HACCP plans and determining how they should be verified are integral parts of the HACCP approach and of the responsibility of establishments, which should be made accountable for doing so.

Nevertheless, public authorities should retain the possibility to challenge operators on the effectiveness of their verification activities, while having regard for the above mentioned factors that determine it. Guidance to both food operators and inspectors should be provided and preferably harmonised on an international basis.

2.5 - Testing for generic *Escherichia coli* to verify process control

This section should be read in relation with Section 2.4 and comments referring to the value of routine testing of end-products as a means for process control verification.

2.5.1 - The US final rule

Ref: as for Section 2.4

- Establishments that slaughter livestock and poultry currently have an obligation to control their slaughter and dressing process so that contamination with faecal material and other intestinal contents is prevented. The present FSIS verification activity to demonstrate that this has been accomplished is organoleptic inspection. FSIS inspectors apply a zero tolerance performance standard for visible faeces and ingesta on dressed carcasses.

- FSIS is requiring generic E. coli (biotype 1) testing in slaughter establishments. "This microbiological testing is designed to verify, for the establishment and FSIS, that the establishment has controlled its slaughter process with respect to prevention and removal of faecal material and ingesta and associated bacteria" (Federal Register, vol. 9 n° 144, p. 38838).

"E. coli..(is a) means of verifying that a slaughter facility's process is in control with regard to prevention of fecal contamination of the carcasses being produced. In other words, it becomes a marker for verifying a slaughter establishment's adherence to the zero tolerance for fecal contamination" (p. 38850).

- FSIS is not requiring E. coli testing of processed products (p. 38851).

- The rationale for using *E. coli* as an indicator is that there is wide acceptance in the international scientific community of its use as an indicator of the potential presence of enteric pathogens; that there is a strong association of *E. coli* with the presence of enteric pathogens and, in the case of slaughtering, the presence of faecal contamination; that *E. coli* has survival and growth characteristics similar to enteric pathogens such as *E. coli* O157:H7 and *Salmonella* (p. 38839).

- *E. coli* performance criteria have been established on the basis of FSIS's Nation-wide Microbiological Baseline Data Collection Programs results.

- *E. coli* performance criteria are expressed in terms of a three class attributes sampling plan which specifies cut-offs (*m* and *M*) for *E. coli* levels so as to define three classes of results: acceptable (< or = *m*), marginal (>*m* and < or =*M*), unacceptable (>*M*).

As the starting point for establishing the cut-off for *m*, FSIS has used the 80th percentile of current industry-wide performance in terms of *E. coli* levels for each slaughtering class. The starting point for establishing *M* is the 98th percentile of industry performance.

Marginal results (> *m* and < or = *M*) would be within the worst 20% of overall industry performance in terms of *E. coli* counts. Results worse than *M* are within the worst 2% of overall industry performance.

Specific values are as follows:

<i>slaughter class</i>	<i>m</i>	<i>M</i>
<i>steer / heifer</i>	<i>Negative</i>	<i>100</i>
<i>cow / bull</i>	<i>Negative</i>	<i>100</i>
<i>Broiler</i>	<i>100</i>	<i>1000</i>
<i>Hog</i>	<i>10</i>	<i>10000</i>

- FSIS has chosen the "moving window" statistical approach, as opposed to sampling of specific lots of products for contaminants, "to provide a continuous feature of establishment performance". Establishments that are operating at the acceptable performance level reflected by *m* will have, with an 80% probability, three or fewer results above *m* (denoted as *c*) within every 13 samples tested (denoted as *n*).

- The testing frequency has been determined on the basis of the volume of production according to national data, so that in the subgroup of establishments accounting for 99% of total production for each species, the 5% of establishments with the highest production volume would have to conduct a minimum of 13 *E. coli* tests or at least one complete test window each day. In addition, with this frequency, 90% of all cattle, 94% of all swine, 99% of all chicken and 99% of all turkeys will be slaughtered in establishments conducting a minimum of one *E. coli* test per day (see Section 2.4).

- Detailed guidelines for sampling are provided in annex F (cattle and swine) and in annex G (poultry). Cattle and swine carcasses must be sampled at the end of the slaughter process in the cooler 12 hours or more after slaughter. Sampling locations are identified (flank, brisket and rump for cattle; belly, ham, jaws for swine). The sampling involves using a sponge to sample all three sites on the carcass, using a template to delineate the area required. Poultry carcasses must be sampled after the

chill tank at the end of the dip line or last readily accessible point prior to packing / cut-up, using the whole chicken carcass rinse sampling procedure.

- FSIS is requiring the use of an analytic method approved by the Association of Official Analytical Chemists (AOAC) or any method validated by a scientific body in collaborative trials against the three tube Most Probable Number (MPN) method and agreeing with the 95% upper and lower confidence limit of the appropriate MPN index.

2.5.2 - Comments

- *E. coli* can be considered as an indicator of faecal contamination, *exclusively on raw products*. The organism is often absent or in low numbers on red-meat carcasses of good microbiological quality. The presence of high numbers of *E. coli* on carcasses indicates that hygiene rules have not been followed (contamination by faecal matter; contamination from the dirty hide; spread of contamination resulting from sloppy slaughtering and dressing practices).

- No single set of test results can demonstrate conclusively that adequate process control for faecal contamination is or is not being maintained in a slaughtering process and that any single carcass would be free from faecal contamination. However, certain measures are particularly appropriate to ensure that, on a day-to-day basis, effective controls of faecal contamination is being achieved. These include definition and appropriate assessment of the implementation of hygienic slaughtering and dressing practices, demonstration and evaluation of the validation of HACCP plans and the process controls they include, demonstration and assessment of the effectiveness of monitoring activities.

Nevertheless, this does not negate the possible use of regular *testing* associated with other types of verification activity *to determine whether there is a drift away from the validated HACCP plan* that needs to be corrected.

- Generic *E. coli* testing "does not address legitimate public health concerns about pathogenic bacteria in and on raw product. *E. coli* (except for certain pathogenic subgroups) is not itself a cause of food-borne disease. It is an indicator of faecal contamination which in turn is a source of many pathogens that may contaminate products. Faecal contamination however does not always correlate with the presence of pathogens: high levels of *E. coli* may be present without pathogens and pathogens may be present without high *E. coli* levels".

Effective pathogen reduction can therefore only be achieved by the combination of good practice and HACCP plans adequately validated with regard to all pathogens of concern both at the pre-harvest and slaughtering stages.

- Numerical values for *E. coli* performance criteria (m and M values) and the frequency of testing are based on prevalence estimates and establishment performance data obtained through US base-line studies. The M values for hogs are remarkably high in comparison with European experience.

It would appear that Europe should take appropriate measures to develop its own microbiological base-line data collection programs and its own benchmarks. This would facilitate the establishment of realistic "microbiological targets" for HACCP systems and therefore process control performance criteria. Thus the efficacy of

European control and inspection programs could be objectively demonstrated (or the need for improvement, where necessary) and a comparison with the US situation would be possible.

- Analytical methods required by FSIS should be approved by AOAC or should be validated by a scientific body in collaborative trials against the three tube MPN method. As they benefit from international recognition, methods developed under the aegis of the International Standardisation Organisation (ISO) should also be put forward and their use promoted.

In addition, there is a need for Europe to take appropriate measures, or to strengthen the initiatives already taken in this field, for comparison of existing methods of testing through comparative trials, conducted in accordance with internationally recognised protocols.

- There are two conceptual changes in the US final rule. The first is from systematic testing for *E. coli* as a marker for verification of the control of faecal contamination towards a more general process-control technique. This is unsatisfactory, because effective process controls need to address all contaminants of concern, whether they be biological (e.g. parasites, other microorganisms), chemical (e.g. residues) or physical (e.g. broken needles) in nature. The second drift is from the concept of verification of process control under HACCP plans towards an inspection activity aimed at determining the acceptability of products with regard to zero tolerance for faecal contamination. This is unnecessary because of surveillance by inspectors of the hygiene conditions that should prevail in a slaughterhouse and appropriate validation of HACCP plans by the establishment. There is also the impression that the requirement for establishments to systematically test for *E. coli* is a means of obviating some of the difficulties of official inspection, while providing assurance to the public at large which is in favour of more end product testing. This is illustrated by many of the comments from public hearings reported in the Federal Register.

- This US regulation requires that establishments failing to meet the *E. coli* performance criteria would have a testing programme for *E. coli* O157:H7. Why these establishments only?

This pathogen, which has a very low infectious dose, may be present even though the *E. coli* level is within the critical limits.

2.6 - Pathogen reduction performance standards for *Salmonella*

2.6.1 - The US final rule

Ref.:

- *Federal Register, 9 CFR, part 304 et seq., chapt. IV, Microbiological performance and standards, pp. 38846 - 38854.*

- *Appendix E, FSIS sample collection guidelines and procedures for isolation and identification of Salmonella from raw meat and poultry, pp. 38917 - 38928.*

- *FSIS is establishing pathogen reduction standards for Salmonella that will require all slaughter establishments to reduce the prevalence of Salmonella contamination on finished meat and poultry carcasses to below the national base-line prevalence.*

Establishments will not be required to test for Salmonella themselves. FSIS will conduct Salmonella testing in slaughter establishments to determine whether they are meeting the pathogen reduction performance standards and will require corrective action; otherwise, appropriate regulatory action will be taken.

The Salmonella pathogen reduction performance standards are not lot-release standards and the detection of Salmonella in a specific lot of raw product will not, by itself, result in condemnation of the lot.

- All establishments must achieve at least the current US base-line level of performance with respect to Salmonella for the product classes they produce:

<i>steer / heifers</i>	<i>1 % positive</i>
<i>cows / bulls</i>	<i>2.7</i>
<i>ground beef</i>	<i>7.5</i>
<i>hogs</i>	<i>8.7</i>
<i>broilers</i>	<i>20</i>
<i>ground chicken</i>	<i>44.6</i>
<i>ground turkey</i>	<i>49.9</i>

"This policy is based on the public health judgement that reducing the percentage of carcasses with Salmonella will reduce the risk of food-borne illness, and on the regulatory policy judgement that establishing for the first time a clear standard for Salmonella , in conjunction with the implementation of HACCP, will lead to significant reduction in contamination rates. This policy is not based on a quantitative assessment of the risk posed by any particular incidence of Salmonella contamination or the determination of a 'safe' prevalence or level. There is not currently a scientific basis for making such assessment or determinations".

- FSIS intends to revise its Salmonella performance standards periodically, as new base-line prevalence data become available, to further the agency's goal of reducing the risk of food-borne illness. The testing by FSIS in each establishment will be carried out in a manner designed to provide a reliable indication of the establishment's performance throughout a 12-month period. It is anticipated that FSIS will take approximately 250 samples per establishment over a one year period.

- "Slaughter establishments concerned that they might not meet the pathogen reduction performance standard have available a wide range of technologies shown to reduce the levels of pathogens that may be on the surface of carcasses and antimicrobial treatments are discussed in some detail in the proposed rule. Establishments producing raw ground products from meat and poultry cannot use technologies for reducing pathogens that are designed for use on the surfaces of whole carcasses at the time of slaughter. Such establishments may require more control over incoming raw product ... as well as careful adherence to their sanitation SOPs and HACCP plan".

2.6.2 - Comments

- Pathogen reduction programs should not consider Salmonella alone but should address other pathogens that are relevant to the classes of animal slaughtered and

associated raw products (e.g. *Campylobacter*, *E. coli* O157 H7, *Listeria monocytogenes*, *Staphylococcus aureus*).

- In the US final rule, performance standards for *Salmonella* have been established on the basis of prevalence estimates obtained through US base-line studies. In some European countries, these standards would not be acceptable, because they are too lax. This raises the question of "equivalency" in relation to US standards and whether a very low prevalence of *Salmonella* contamination achieved in Scandinavia by quite different control strategies would, on its own, meet US requirements. In such circumstances, the need for *Salmonella* testing is debatable.

It is recommended that appropriate data collecting programs should be developed in Europe to facilitate international comparisons. Such data should also serve to assess and/or demonstrate the effectiveness of particular interventions or to identify weak points and the need for improvement, as the case may be.

- There is clear merit in the concept of "targets" or "food safety objectives" similar to that of "pathogen reduction standards" in the US final rule (see Section 2.3 for specific comments). It is recommended that this concept should be introduced into the European regulatory framework.

- "Pathogen reduction standards" should be technologically feasible through the implementation of GMP, GHP and HACCP. In this regard account should be taken of the base-line levels of performance at establishments producing different classes of product. However, the "current" base-line in each case may or may not be acceptable and it would be more reasonable to take as a starting point the levels that are achievable in establishments operating under approved, best practice standards.

- To be meaningful from a public health point of view, "pathogen reduction standards" should also take into consideration the risk posed by any particular prevalence of specific pathogens in the product class under consideration. It could be difficult to determine an acceptable level of risk and a "safe" prevalence or level. Rather "targets" and related interventions should be evaluated by assessing their impact on risk reduction while having regard to other considerations such as technical feasibility, efficacy and cost.

It is recommended that targeted data collection systems and appropriate risk assessment simulations should be developed in Europe as soon as possible to assist in establishing meaningful food safety objectives that, so far, have not been identified.

2.7 - Other issues and initiatives

2.7.1 - The US final rule

Ref.:

- *Federal Register*, 9 CFR, part 304 et seq., chapt. V, *Other Issues and Initiatives*, pp. 38854 - 38858.

This relates to antimicrobial treatments and to international trade

2.7.2 - Comments

Antimicrobial treatments

- It is necessary to reduce contamination of foods with pathogens to alleviate the burden of food-borne disease. However, **the only effective approach would be a farm to table strategy involving an integrated system at all stages of the food chain**. Appropriate control measures are necessary at each stage and, where raw products are concerned, the most effective measures are those applied closest to the original source, i.e. before the slaughterhouse. Improved hygiene at the slaughterhouse can only minimise opportunities for secondary contamination of carcasses and spread of micro-organisms. Due to their limited efficacy, antimicrobial treatments cannot be considered as a panacea and will effectively contribute to pathogen reduction only when the system of production including pre- and post-harvest stages is otherwise well controlled. Therefore, pathogen reduction measures at the slaughterhouse level are only part of the necessary intervention strategy required and excessive reliance on this aspect, as it appears from the US final rule, may be misleading. It is clear that interventions for pathogen reduction, including regulatory interventions, should be aimed at introducing appropriate control measures at all stages including the primary production level.

It is positive that FSIS did not mandate the use of antimicrobial treatments. Nevertheless, FSIS believes «antimicrobial treatments could play an important role in reducing contamination with pathogenic microorganisms in slaughter establishments» (p. 38854). The Committee agrees with many of the commenters that argued that mandating the use of antimicrobial treatments would not be consistent with the HACCP philosophy. Furthermore, the use of such treatments may not give enough stimulation to activities aimed at reducing the level of pathogens at the pre-harvest level or at the slaughterline. As some commenters argued: «their use would allow for correction of sloppy carcass dressing procedures» (p. 38855).

International trade

The US Megareg “requires that meat and poultry products imported into the US be produced under an inspection system equivalent to the US inspection system”.

There are several other ways, which in some cases are more appropriate from a scientific point of view, to achieve the same or even better results.

CONCLUSIONS

The US Megareg is a new approach to the control of food-borne pathogens in slaughterhouses and is a first step in the reorientation of meat inspection systems towards reducing contamination of meat with food-borne pathogens.

Although the US Megareg cites the principle of ‘farm to table’, it only addresses a part of the farm to table continuum, namely the activities within the slaughterhouses. It does not cover the animal production and the status of the animals presented for slaughter (FSIS is not authorised to mandate production practices). The application of a HACCP system in slaughterhouses is a useful step but primary concern must be the control of pathogens at the farm level.

There is clear merit in the concept of ‘targets’ or ‘food safety objectives’ similar to the standards laid down in the Megareg. It is, from a scientific point of view, recommended that this concept should be considered within the European regulatory framework. It is suggested that targeted data collection systems and appropriate risk assessment simulations could be developed in Europe to assist in establishing meaningful food safety objectives.

HACCP has been mandated by FSIS as the tool to control operating conditions in slaughterhouse operations, that will assure hygienic products. The role of FSIS in validation and verification of HACCP is still unclear and the judgement of the efficacy of HACCP seems to be based solely on performance criteria and standards measured by microbiological testing. The validity of this association has yet to be established.

The US Megareg uses performance standards and microbiological testing for *Salmonella* to measure whether HACCP systems are working effectively to address food safety hazards. There seems to be no scientific basis for the linkage between HACCP and end-product testing. Although microbiological testing and standards such as the FSIS performance standards can serve as useful tools to ascertain whether a food system provides food of acceptable hygienic quality, it is questionable whether FSIS performance standards can be used as a verification criterion for HACCP in individual slaughter plants.

In some European countries the US performance standards for *Salmonella* would be considered too lax. If low prevalence levels for *Salmonella* are achieved through different control strategies, the need for testing such products, when exported to the US is not scientifically founded. On the other hand the question of US export into countries with a documented significantly lower prevalence of *Salmonella* could also be debated.

The Megareg does not mandate the use of antimicrobial treatments. Nevertheless, FSIS believes “antimicrobial treatments could play an important role in reducing contamination with pathogenic microorganisms in slaughter establishments”. Mandating the use of antimicrobial treatments would not be consistent with the HACCP philosophy. Furthermore, the use of such treatments may not give enough stimulation to activities aimed at reducing the level of pathogens at the pre-harvest level or at the slaughterline.

In practice it is clear that the option to use a decontamination treatment will only be successful if combined with good practices for hygiene control, as provided in the context of HACCP.

The US Megareg “requires that meat and poultry products imported into the US be produced under an inspection system equivalent to the US inspection system”.

The Committee recognises the intention of the US Megareg, a new approach, to reduce the occurrence and numbers of pathogenic micro-organisms on meat and poultry products and to reduce the incidence of food-borne illness associated with the consumption of these products.

However, the Committee considers that there are several other ways, which in some cases are more appropriate from a scientific point of view, to achieve the same or even better results.