codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 (b)

CX/MPH 03/06
November 2002

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON MEAT AND POULTRY HYGIENE

Ninth Session

Wellington, New Zealand, 17-21 February 2003

APPENDICES AND ADDITIONAL PROVISIONS TO THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR FRESH MEAT

PRINCIPLES AND GUIDELINES IN SYSTEMS FOR MICROBIOLOGICAL PROCESS CONTROL FOR MEAT, INCLUDING ESTABLISHMENT OF PERFORMANCE PARAMETERS FOR OUTCOMES OF PROCESS CONTROL AND IMPLEMENTATION OF NATIONAL MICROBIOLOGICAL DATABASES

(prepared by New Zealand)

Governments and interested international organisations are invited to comment on the attached Annex 1 to the Proposed Draft Code of Hygiene Practice for Fresh Meat. Comments should be sent to:

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with a copy to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Fax +39 06 570 54593; e-mail: codex@fao.org) **not later than 11 January 2003.**

BACKGROUND

The 8th Session of the Codex Committee on Meat and Poultry Hygiene noted the offer of New Zealand, with the assistance of the Codex Secretariat, to prepare two separate discussion papers[1] for consideration at its next session on the possible addition of Annexes to the proposed draft Code of Hygienic Practice for Fresh Meat. In this regard the Committee, noted that the proposal would be subject to approval as new work by the 50th Executive Committee (ALINORM 03/16, paras. 78-79).

The 50th Session of the Executive Committee noted that although the addition of appendices to a code under development did not generally require approval as new work, the Committee on Meat and Poultry Hygiene had sought such approval in view of the substantial work involved and to expedite the elaboration process in the Committee. The Executive Committee therefore approved as new work the elaboration of the two appendices to be included in the Code (ALINORM 03/3A, para. 84).

[1] "Principles and Guidelines for establishing risk-based and ante- and post-mortem inspections systems for particular slaughter population"; and "Principles and Guidelines on systems for microbiological process control for meat, including establishment of performance parameters for outcomes of process control and implementation of national microbiological databases"

Annex I to the Proposed Draft Code of Hygienic Practice for Fresh Meat

MICROBIOLOGICAL MONITORING FOR PROCESS CONTROL OF FRESH MEAT

1. INTRODUCTION

1. Microbiological monitoring at specific points in the food chain is increasing in importance as a tool for ensuring a risk-based approach to food safety. Specification of food safety microbiological outcomes assures that appropriate levels of consumer protection are achieved, while providing maximum flexibility to industry in terms of the detailed process control systems that are employed.

2. The General Principles of Food Hygiene[2] state that "in deciding whether a [food control] requirement is necessary or appropriate, an assessment of the risk should be made, preferably within the framework of the HACCP approach", and any microbiological specifications "should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and action limits"[3]. Process control is defined as "all conditions and measures applied during the production process that are necessary to achieve safety and suitability of meat"[4].

3. As described in this Annex, microbiological performance parameters for monitoring of fresh meat[5] are different to microbiological criteria for judging the acceptability of a process, product or food lot[6]. Although not included in the scope of this Annex, microbiological monitoring of fresh meat may also be used to ensure suitability.

2. OBJECTIVES OF MICROBIOLOGICAL MONITORING OF PROCESS CONTROL FOR FRESH MEAT

4. A preventative, HACCP-based approach should be regarded as the most effective means of ensuring microbiological process control requirements. Once a HACCP plan has been properly validated, microbiological monitoring should be limited to that level necessary to verify that required food safety outcomes are being met on an on-going basis.

5. Microbiological monitoring of process control of fresh meat provides a tool for:

- Verification by the competent authority of the adequacy of establishment process control in relation to faecal and other contamination;
- Assurance of the level of control of specified hazards of public health importance;
- Facilitating development of process parameters at a specified step or combination of steps that achieve microbiological performance parameters;
- Review and redesign of HACCP plans;
- Objective comparison of the outcome of different process control systems in different situations;
- Provision of export assurances by competent authorities.

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[2] General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 3 (1997)

[3] Specifications for microbiological monitoring of the outcome of SSOPs are not regarded as performance parameters for process control

[4] Proposed Draft Code of Hygienic Practice for Fresh Meat (CX/MPH 3/4)

[5] The Proposed Draft Code of Hygienic Practice for Fresh Meat (CX/MPH 3/4) defines a performance parameter as "An expression of the required level of hazard control at a specified step that is considered necessary to achieve the appropriate level of protection"

[6] Principles for the Establishment and Application of Microbiological Criteria for Foods. CAC/RCP 1-1969, Rev. 3 (1997)

3. GENERAL PRINCIPLES FOR MICROBIOLOGICAL MONITORING OF FRESH MEAT

i. Microbiological monitoring for process control purposes should only be implemented where meaningful in terms of consumer protection.

ii. Microbiological monitoring should be based on scientific analysis and advice, and, where sufficient data are available, on microbiological performance parameters developed from risk analysis.

iii. Establishment of microbiological performance parameters should take into account all information available throughout the food chain, including the health status of animals at the production level.

iv. Microbiological monitoring should be product specific, and should be applied only at those points in the food chain specified.

v. Microbiological monitoring should be reasonably achievable.

vi. Establishment of microbiological performance parameters is the responsibility of competent authorities, in consultation with relevant interested parties, and may consist of guidelines or mandatory regulatory standards.

vii. Microbiological performance parameters that are established for the purposes of statistical process control should be based on micro-organisms that are indicative in the food specified of the presence of hazards to human health.

viii. Microbiological performance parameters that are established as regulatory standards should monitor specific hazards.

ix. The competent authority should verify compliance with microbiological performance parameters that are regulatory guidelines or standards e.g., microbiological statistical process control requirements, standards for *Salmonella* spp.

4. GUIDELINES FOR THE IMPLEMENTATION OF MICROBIOLOGICAL MONITORING FOR PROCESS CONTROL OF FRESH MEAT

4.1. TYPES OF MICROBIOLOGICAL PERFORMANCE PARAMETERS

6. Microbiological performance parameters can take the form of regulatory guidelines or standards. Guidelines that indicate the hygienic adequacy of process control implemented by the establishment will most likely be formulated in terms of indicator microorganisms. Regulatory standards should specify mandatory levels of control of particular hazards.

4.2. DEVELOPMENT OF MICROBIOLOGICAL PERFORMANCE PARAMETERS

7. Where possible, microbiological performance parameters should objectively express the level of hazard control as derived from the application of risk analysis principles. This entails knowledge of the level of control of hazards that is attained in the fresh meat relative to the appropriate level of consumer protection (ALOP).

8. In the absence of sufficient knowledge of risks to human health, microbiological performance parameters can initially be established from baseline surveys of current industry performance, and can subsequently be modified as appropriate to reflect public health goals. Sampling plans for baseline surveys should be representative of the slaughter population, and cater for known biological variation in respect of hazards in the raw material supply e.g. influence of geographical region, farming type and season.

9. A microbiological performance parameter can be established at any step in the food chain, provided that there is an established link between the required level of control of hazards at that step and the ALOP. For the purposes of the CCMH, a performance parameter is defined as “an expression of the required level of hazard control at a specified step that is considered necessary to achieve the appropriate level of protection”.

10. Microbiological performance parameters for fresh meat are unlikely to be of a nature that they can be verified on an on-going basis as part of a HACCP plan. In most situations, process parameters that are validated as achieving microbiological performance parameters at a particular step in the food chain will be used. These process parameters should be measurable in real time, and will most likely constitute critical limits at critical control points in HACCP plans.

11. For the purposes of the CCMH, a food safety objective (FSO) is defined as "a performance parameter at the point of consumption". It is unlikely that microbiological FSOs will be established that are subject to verification as part of a risk-based meat hygiene programme. However, microbiological performance (and process) parameters that meet the FSO can be established at other steps in the food chain.

4.3. SPECIFICATION OF MICROBIOLOGICAL PERFORMANCE PARAMETERS

12. A microbiological performance parameter should be specified in terms of type of microorganism, product and process being monitored, monitoring methodology, and regulatory response to non-compliance. Microbiological limits should take account the likelihood of uneven distribution of microorganisms in the sampled unit and the inherent variability of the analytical procedure.

13. In the case of indicator microorganisms e.g. generic *Escherichia coli*, Enterobacteriaciae and total viable counts (aerobic plate counts), the detection rate should generally be reflective of the level of process control. In the case of specific hazards (e.g. *Salmonella* spp.) and appropriate process control, the detection rate will generally be reflective of hazards arising pre-slaughter. In the latter case, there is limited availability of valid HACCP parameters that are relevant to on-line control of the level of contamination with specific pathogens.

14. A standardised random sampling plan should be developed, including specification of the process step, size and type of sample, collection methods and transport. Sampling may take place at single or multiple steps in the food chain e.g. carcasses on the slaughter floor, carcasses post-chill, meat cuts or trim at packing. Use of multiple steps in the food chain may provide greater information on process control and allows for a more targeted response to non-compliance by the establishment and the competent authority.

15. Sampling of tissue may be destructive e.g. by excision, or non-destructive e.g. by swabbing or sponging. As only a proportion of the total flora present will be removed by non-destructive sampling, performance parameters specified in this manner should be established in relation to destructive sampling. Pooling of samples provides reductions in cost but has some disadvantages in terms of knowledge obtained from monitoring.

16. The competent authority should provide flexibility in regulation so that the most effective monitoring systems can be established at the establishment level e.g. provision for alternative carcass sampling sites if an establishment can identify that they are likely to bear more contamination than those specified.

17. Alternative monitoring parameters to microbiological testing that are properly validated e.g. serological testing of meat juice, should be established where they offer practical advantages.

4.4. FREQUENCY OF MONITORING

18. There is no single method for determining the frequency of sampling. Frequency may be "process-based" or "throughput-based", and low-throughput establishments may require special consideration in terms of sample numbers. In addition to ensuring randomness, variables to be taken into account at the establishment level include: source of raw materials, type and nature of the fresh meat process, and volume of production.

19. Sampling frequency may be modified according to performance. Once a particular level of process control has been established according to standardised criteria, the frequency of subsequent microbiological monitoring may be decreased.

4.5. LABORATORY ANALYSIS

20. Methods for detection and enumeration should be practical and effective. Only methods for which the reliability has been established (accuracy, reproducibility, inter-laboratory variation) should be used. Compulsory inter-laboratory testing should be a feature of a microbiological monitoring programme. New rapid methods may assist microbiological monitoring for indicator organisms e.g. fluorescence spectroscopic methods for detecting faecal material may provide the trigger for subsequent on-line microbiological sampling.

4.6. MICROBIOLOGICAL FOOD SAFETY OUTCOMES

21. Required regulatory outcomes for microbiological monitoring may be specified in several ways. For indicator organisms, two or three class attribute sampling plans that specify cut-offs for numbers of microorganisms (m and M) are useful. Where microbiological performance parameters are set according to

current industry performance, percentile values may be used e.g. 80th percentile for m and 98th percentile for M. A variety of statistical approaches can be used e.g. “moving windows”, or sampling of specific lots.

22. Recording and analysis of results should be subject to regulatory specification. Effective systems should be in place for feedback of monitoring information from the establishment to all interested parties, so as to maintain and improve process control of fresh meat.

23. The competent authority should regularly analyse results at both the establishment and national level, and provide appropriate feedback to establishments and other interested parties.

24. Additional to monitoring of process control, the results of microbiological monitoring may be used to establish on-farm regulatory controls e.g. intensive measures to reduce the prevalence of *Salmonella* spp. in fattening pigs.

4.7. REGULATORY ACTION

25. In situations of non-compliance with microbiological performance parameters, regulatory actions should be specified. Regulatory responses should be graded according to different microbiological outcomes. Where detailed information on the health status of slaughtered animals is available from the place of production e.g. in the case of *Salmonella* spp. in fattening pigs and broiler chickens in some intensive production systems, regulatory responses in relation to process control may include consideration of pre-slaughter levels of hazards.

26. The competent authority should consider microbiological results in conjunction with all other information when taking regulatory action. Regulatory intervention and/or sanctions will be necessary when the establishment consistently fails to meet process control requirements.

27. In cases of repeated non-compliance and in addition to other actions, the competent authority may specify an increased sampling frequency until the required level of process control is restored.