NEW ZEALAND EMBASSY

TE AKA AORERE

WASHINGTON

(8)

Ref: 40/4

00-014N
00-014N-8
Dr. WT Jolly

19 July 2000

USDA FSIS Docket Room
Docket Number 00-014N
Room 102 Cotton Annex
300 12th St, SW
Washington DC 20250-3700

To whom it may concern

Please find attached the New Zealand Ministry of Agriculture and Forestry's comments on aspects of Docket No. 00-014N, published in the Federal Register on May 15 2000.

Yours sincerely

For : Dr WT Jolly
Counsellor (Veterinary Services)

37 OBSERVATORY CIRCLE, NW WASHINGTON, DC 20008 UNITED STATES OF AMERICA
TELEPHONE (202) 328 4800 FACSIMILE (202) 667 5227
E-MAIL nz@nzemb.org INTERNET www.nzemb.org

New Zealand submission to USDA in response to Federal Register Notice in Volume 65, No. 94. Monday May15, 2000.

Preamble

New Zealand acknowledges the importance of the Codex Alimentarius Commission's (CAC) "*Hazard Analysis And Critical Control Point (HACCP) System And Guidelines For Its Application*" with regard to the World Trade Organisation Sanitary and Phytosanitary Agreement (WTO SPS), and in relation to the application of HACCP principles by any member nation. This CAC document therefore has been duly considered along with New Zealand's approach to application of the HACCP principles, when answering the questions raised in the Notice.

Question 1: The industry petition relies mainly on the NACMCF document and does not provide any data or examples to support its request. Is there any information that would support taking any of the actions requested in the petition?

New Zealand believes that there is information/experience available internationally to assist USDA in responding to requests in the petition.

Question 2: Would amending 9 CFR 417.2(a) in the manner suggested in the petition result in regulations that provide the level of public health protection required by the Federal Meat Inspection Act and the Poultry Products Inspection Act?

New Zealand agrees in principle with the changes recommended in the petition but also would like to add further suggestions to assist in clarifying application of HACCP principles. These suggestions are:

Hazard

New Zealand suggests that the definition of "food safety hazard" be aligned with that of Codex, namely "A biological, chemical or physical agent in, or condition of food with the potential to cause an adverse health effect". This definition equates well with the current USDA definition of food safety hazard and would be readily recognised by international trading partners. The suggested replacement definition in the **Notice** is restrictive in that it is limiting "hazards" to those that have to be controlled, presumably within the establishment. The hazard definition should not be constrained by consideration of control. That consideration comes later with the analysis of hazards and the determination of critical control points.

Hazard analysis

The current USDA hazard analysis definition intimates that all hazards reasonably likely to occur, require control at the establishment. Practically this definition must pose problems when trying to apply and implement HACCP principles, particularly in a fresh meat processing environment because there are hazards that cannot be controlled in that part of the food chain. An example is *Toxoplasma gondii* in fresh meat (no technology available) and *Campylobacter* on fresh poultry (only limited ability of technology to remove). The suggested change to this definition more closely aligns with that given in the CAC HACCP guide. However to use the word "must" rather than "should" also will pose problems to the HACCP application for the same reasons given

above. Hazards identified as significant may not be able to be controlled adequately under current processing knowledge and technology. *Campylobacter* is such a hazard in association with raw chicken production. "Should" means that every endeavour must be made to control such significant hazards to acceptable levels but it is accepted that there may be some instances where this is not possible.

Severity

New Zealand does not support the proposed change. Severity as proposed in the petition, relates to adverse health effects rather than hazards in the context of HACCP and risk analysis. The Codex definition of "risk" supports this, being "A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food". New Zealand believes that in most cases of HACCP application, particularly in relation to fresh meat production, information on severity is currently lacking and will only be rectified by further risk analysis studies. Therefore "severity" should be used in context with introduction of risk analysis alongside HACCP as applicable.

Food safety objectives

Use of food safety objectives as providing "targets" for the control of hazards resulting from application of a HACCP plan, is a more realistic approach to take. Wherever possible, the target should relate to the level of consumer protection that is required. In many cases however, the target will only be a qualitative link based on available scientific information rather than a quantitative link based on a quantitative risk assessment. However, the objectives can provide an expression of the level of the hazard as a maximum tolerable concentration and/or frequency and this is of considerable value when validating HACCP plans as being effective in meeting stated food safety goals.

"Shipped"

New Zealand agrees with "shipped" as being when product goes out of the control of [the HACCP plan or plans belonging to] one owner or company, into the control of another owner or company. This definition will help make it much clearer as to when HACCP plan inadequacies must be addressed.

HACCP plan inadequacies

New Zealand agrees that when a HACCP plan is implemented, establishments must be given the freedom to take corrective action themselves prior to regulatory intervention and application of sanctions. Repetitive inadequacies of a similar nature (except for instances of identifiable danger to human health) also must be dealt with in an escalating manner by establishments before regulatory intervention is necessary.

Question 3: Should FSIS consider regulatory modifications that would acknowledge the prerequisite programmes concept of NACMCF?

Yes. Note that CAC's HACCP guide refers to operations prior to application of HACCP, being based on the general principles of food hygiene, appropriate Codex Codes of Practice and appropriate food safety legislation. Inherent in this reference is the assumption that some food safety hazards will be controlled by such operations. HACCP application then focuses on the process itself.

New Zealand takes a similar view and defines prerequisite programmes as "documented programmes covering good manufacturing practice (GMP)-based food hygiene activities that may interact at a number of process steps within and across various processes in a food premises, and that have the potential to influence the hygiene status of the product". These documented prerequisite programmes are expected to be in place and operating substantially in compliance before HACCP is implemented. The programmes do not necessarily reduce the list of hazards to control, but they are often adequate to reduce many hazards to acceptable levels. Consideration of prerequisite programmes in this way focuses the HACCP plan on CCPs for hazards that are not controlled to an acceptable level by GMP-based food hygiene activities.

Question 4: Do FDA regulations, such as the GMP regulations, offer an approach that FSIS should consider? How would such an approach fit within the HACCP concept? How would FSIS implement such an approach?

New Zealand suggests that consideration of other regulatory agencies' approaches, particularly within the same country, would be essential when developing and reviewing food safety principles. This also assists in harmonisation of approach between agencies.

Question 5: What will be the effects of making FSIS and FDA HACCP regulatory requirements dissimilar?

This is an internal matter that needs to be considered between the two agencies. However, both agencies state in strategy documents that they want farm-to-plate control systems so as to optimise food safety. A "seamless / harmonised regulatory environment is essential for this purpose.

Question 6: Should the changes suggested in the industry petition be considered in light of the views expressed on HACCP by Codex and by other countries?

Yes, New Zealand fully supports this consideration in light of international work by Codex and member countries, including risk analysis principles and the current work on the proposed framework for determining the equivalence of sanitary measures associated with food inspection and certification systems. Further, international work on verification of HACCP plans (including validation) is leading to recognition of the essential nature of this function if HACCP plans are to be demonstrated as being effective.

Other comments relevant to the submission:

Performance-based verification

New Zealand believes that the concept of performance-based verification should be considered in light of verification activities implemented by the establishment for HACCP plans. This would be particularly relevant to ongoing review of HACCP plan monitoring and corrective action records prior to shipping. Based on an individual establishment's performance record, flexibility should be available to adjust the frequency of ongoing review. The concept can be applied across all aspects of verification.

CCP determination

New Zealand fully supports the customisation of application of HACCP principles at each establishment and believes that CCPs should be identified and scientifically justified by these individual establishments on a step-by-step basis. This customisation of application may be restricted by the mandatory requirement of one or more CCPs.

CCPs are deemed to be necessary where both of the following criteria are met:

- Unacceptable levels of hazards are likely to be present, in relation to objectives or outcomes to be achieved by the HACCP plan, and
- Control measures are able to be applied at the step under consideration.

If any hazard is already controlled to an acceptable level by an effective prerequisite programme, then the hazard itself may not feature in the hazard analysis applied to an on-line process. Alternatively, the hazard may feature in relation to the process but already be at a level that is acceptable, given the desired food safety outcomes.