Technews

National Dairy Development Board

For Efficient Dairy Plant Operation

September-October 2005 **No.58**

NEW FOOD SAFETY CONCEPT: FOOD SAFETY OBJECTIVE

This bulletin includes technical information based on latest developments on products, systems, techniques etc. reported in journals, companies' leaflets and books and based on studies and experience. The technical information in different issues is on different areas of plant operation. It is hoped that the information contained herein will be useful to readers.

The theme of information in this issue is **New Food Safety Concept: Food Safety Objective**. It may be understood that the information given here is by no means complete.

In this issue:

1. INTRODUCTION

In the recent years, there has been greater consumer awareness of the issue of food safety for several reasons. Both raw and processed foods now travel large distances. Demand for processed food is increasing. Further, the globalization of the food trade, as a result of liberalized trade policies advocated in World Trade Organization (WTO) Agreements, has increased the risk of cross-border transmission of infection and toxin agents. This has created an environment in which both known and new food-borne diseases can become prevalent. At the same time, there have been incidents of food-borne disease outbreaks. Crores of people fall ill and many die as a result of eating unsafe food. Food safety therefore has assumed great importance the world over. Producing safe food, including dairy products, is now not a matter of choice, it is a necessity.

To ensure that the food in international trade is safe, the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (WTO/SPS Agreement) has elaborated the concept of appropriate level of protection (ALOP) and states that foods can be freely imported if they would not endanger the country's appropriate level of consumer protection.

To meet the requirement of ALOP, the Codex Alimentarius Commission (CAC) has been developing approaches to enhance the safety of food production, such as Recommended International Code of Practice: General Principles of Food Hygiene, which includes Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, with its extension code specific to milk and milk products, namely, Code of Hygienic Practice for Milk and Milk Products, and maximum residue levels for chemical contaminants in milk and milk products. The current food safety systems, particularly those related to safety from microbiological hazard, however do not directly relate to

achieving ALOP.

A need was therefore felt to develop a more stringent and exact approach for microbiological safety management to achieve the ALOP. Thus, the introduction of Food Safety Objective (FSO), Performance Objective (PO) and Performance Criteria (PC) concepts in the food safety management has already been accepted by Codex. This means setting a microbiological standard for identified pathogens in the end product at consumer level (FSO) and microbiological standards for those pathogens at the intermediate stages of the food chain (POs), and determining and employing PCs between two consecutive POs. The system is complex, needs considerable technical analysis for each product-line by each manufacturer and would require a lot of documentation. The system is considered to assure production of safe food.

Codex has already endorsed the definitions of FSO, PO and PC. It is now developing this new food safety system. This issue of *Technews* provides the details of this new concept of food safety system as being considered in Codex.

2. APPROPRIATE LEVEL OF PROTECTION

According to SPS Agreement the ALOP is the level of protection deemed appropriate by the country establishing a sanitary measure(s) to protect human health within its territory (Table 1).

The Agreement also specifies that the measures employed in achieving ALOP should be based on risk assessment. Determining the ALOP is the responsibility of countries and is the reflection of a particular country's expressed public health tolerance for a food safety risk.

Table 1: Definitions of the terms used in the new food safety concept

Term	Definition
Appropriate Level of SPS Protection (ALOP)	The level of protection deemed appropriate by the Member establishing a sanitary or phytosantary measure to protect human, animal or plant life or health within its territory.[1]
Food Safety Objective (FSO)	The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).[2]
Performance Objective (PO)	The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable.[2]
Performance Criterion (PC)	The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.[2]

[1] WTO Agreement on the Application of SPS Measures
[2] Codex Alimentarius Commission: Procedural Manual, 14th Edition

An ALOP could be qualitative, such as 'reasonable certainty of no harm', or quantitative, such as a 'number of illnesses in a population per year'. However to be able to meet the ALOP, it needs to be translated in to a measurable hazard(s) in food(s). This is the basis of the FSO concept.

3. FOOD SAFETY OBJECTIVE

The Food Safety Objective (FSO) is the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the ALOP (Table 1). As FSOs are linked with ALOP, they are to be established by competent national authorities. Codex can help in establishing FSOs, for instance through recommendations based on national or international microbiological risk assessment.

There are two approaches to establishing an FSO:

- One is based on an observation of the public health status, mainly with the help of epidemiological surveys; and

- The other is based on experimental or other scientific evidence to develop a risk characterization curve linking hazard levels to disease incidence (Fig 1). If such a curve is available for a given hazard, it can be a helpful basis to relate the FSO to the ALOP**.**

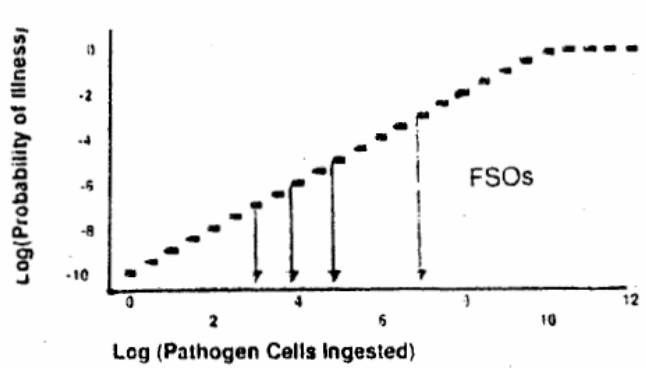

Figure 1: Relationship between ALOP and FSOs

In countries, FSOs can be used:

- to express the ALOP (whether explicit or implicit) as a more useful parameter for the industry and other interested parties;
- to encourage change in industry food safety control systems, or in the behaviour of consumers, in order to enhance the safety of certain products;
- for communication to parties involved in food trade; and
- as a performance target for entire food chains to enable industry to design its operational food safety control systems.

Conceptually the impact of the different elements in the food chain on the FSO can be expressed by the following equation:

$$H_0 - \sum R + \sum I \leq FSO$$

Where H_0 = initial level of the hazard,
$\sum R$= the sum of the hazard reductions,
$\sum I$ = the sum of any increase (growth or contamination).
FSO, H_0, $\sum R$ and $\sum I$ are expressed in $\log_{10}$ units.

It may be noted that FSO, may not be universally common and may take into account regional differences.

To ensure the achievement of ALOP, the FSO must specify the maximum level or frequency in all foods. The FSO applicable to a particular hazard / commodity combination will only contribute to the ALOP, not achieve it, as the FSO would then not address all food-borne sources of the hazard. Since the concept is new, no international or national authorities have established FSOs yet.

Some hypothetical examples of FSOs could be:

- An amount of staphylococcal enterotoxin in ready-to-eat food (or cheese) not exceeding 1 µg/100 kg;
- A concentration of salmonellae in powdered milk below 1 cfu per 100 g or in reconstituted milk powder below 1 cfu per kg;
- Aflatoxin M_1 in drinking milk: maximum 0.5 µg/kg;
- *Listeria monocytogenes* in ready-to-eat food: maximum 100 cfu per g.

Since setting FSOs is the responsibility of the governments, prioritization of which pathogen(s) to be addressed is in their hands. It is reasonable to consider that they will decide not to set up standards for pathogens that are considered a low risk for public health. Limited resource availability may prompt authorities to set FSOs first for higher-risk pathogens. An FSO may need to be established for a special population exhibiting a particular level of concern or need for protection. In such cases, either a more stringent FSO is set that must be followed for the entire population or a more lenient FSO is set for the entire population with additional measures to protect the safety of sub-population.

While deciding on the appropriate FSO, the specified ALOP as well as issues such as the following will be considered:

- The expected efficiency of microbiological risk management options to deliver the FSO;
- Insight in to the question of risk, such as the uncertainty and variability in exposure assessment and hazard characterization;
- The technical capabilities of the affected supply chains and compliance measures;
- Enforcement and monitoring aspects;
- Short term and long term risk reduction policy.

FSOs are seldom verifiable as regulatory standards as they apply at the time of consumption. They should, therefore, be given effect by actions at earlier stages in the food chain by the competent

authorities or by an individual food business operators (for example food manufacturer) setting POs and PCs as appropriate.

4. PERFORMANCE OBJECTIVE

The Performance Objective (PO) is the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable (Table 1). Thus the FSO can be regarded as a PO that applies at the end of the food chain i.e., at the time of consumption. This is illustrated through a simple block diagram in Figure 2.

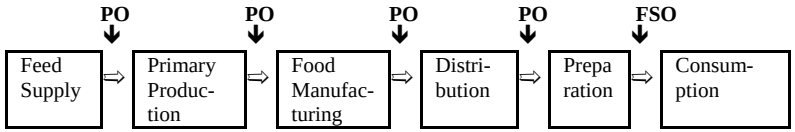

Figure 2: Location of POs and FSO in food chain

The frequency and/or concentration of a hazard at individual steps throughout the food chain can differ substantially from the FSO. Therefore, the following generic guidelines should apply:

- If the food is likely to support the growth of a microbial hazard between the point of the PO and consumption, then the PO will necessarily have to be more stringent than the FSO. The difference in stringency will depend on the magnitude of the increase in levels expected;
- If it can be demonstrated and validated that the level of the hazard will decrease after the point of the PO (e.g. cooking by the final consumer), the PO may be less stringent than the FSO. By basing a PO on the FSO, the frequency of cross-contamination could also be factored into the control strategy;

- If the frequency and/or concentration of the hazard is not likely to increase or decrease between the point of the PO and consumption, then the PO and the FSO would be the same. An MRA can assist in determining such relationships.

The risk manager can also learn about the hazard levels possibly occurring at specific steps in the chain and the issues regarding the feasibility in practice to comply with a proposed PO/FSO from a microbiological risk assessment. The individual food operator should consider its capability to consistently meet the required standards, including the safety margin, while designing its food safety control system to meet the PO (set by government or the individual food operator) and the FSO (set by government).

The individual food business may find it beneficial to establish its own POs. The POs established at the various steps in the same food chain must be mutually connected and coherent with the corresponding FSO. Therefore, exchange of information between he food businesses involved, both up - and down-stream in the food chain, must be ensured. The POs would normally not be universally common and should take into account the position of the business within the food chain, the various conditions at the subsequent steps in the food chain (probability and extent of pathogen growth under specified storage and transport conditions, shelf-life etc.) and the intended use of the end products. Although POs are generally not intended to be verified by analytical means, compliance with POs may need to be verified by other means, such as:

- establishment of a statistically-based MC for end products;
- monitoring and recording of pertinent validated control measures;
- surveillance or screening programmes on the prevalence of a microbial hazard in a food (especially relevant for POs established by competent authorities).

5. PERFORMANCE CRITERIA

The Performance Criteria (PC) is the effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO (Table 1). PCs are generally set by individual business. However, this may be set by national governments for specific control measures where its application by industry is generally uniform and/or as advice to food businesses that are not capable of establishing PCs themselves.

The PC can be expressed in terms of a desired reduction, or acceptable increase in the concentration and/or frequency of a hazard in the course of a particular control measure. Thus it is the result of a particular treatment.

Normally PC relates to a control measure with a microbiocidal and/or microbiostatic effect. A PC for a microbiocidal control measure, for example heat treatment, expresses the desired reduction of the bacterial population during the application of the control measure. A PC for a microbiostatic control measure, for example chilling, expresses the maximum increase in the microbial population that is acceptable under the various conditions during which the measure is applied.

PCs are often translated by industry or some times by competent authorities, into process criteria or product criteria (Table 2 provides their definitions as suggested in the *Codex draft principles and guidelines for the conduct of the microbiological risk management*). For example, if a PC indicated that a heat treatment should provide a 5-log reduction of a hazard, then the corresponding process criterion would stipulate for example the specific time and temperature combination(s) that would be needed to achieve the PC. Likewise, if a PC required that an acidification treatment of a food reduces the rate of growth of a

hazard to lesser than 1-log in two weeks, then the product criterion would be the specific acid concentration and pH that would be needed to achieve the PC.

Table 2: Definitions of process criteria and product criteria

Term	Definition
Process criteria	Parameters of a control measure that if properly applied have been established as meeting, either alone or in combination with other control measures, a performance criterion
Product criteria	A physical or chemical attribute to a product that if properly applied as a control measure has been established as meeting, either alone or in combination with other control measures, a performance criterion

6. SUMMARY

A new food safety system based on the concepts of FSO, PO and PC is being evolved to achieve a specified ALOP. The new system is quite rigorous and based on risk analysis. While Codex has already defined these concepts and the terms involved, it is still working on the details of the system and is likely to finalize it in the near future. It would therefore be very useful for the Indian cooperative dairy industry to be adequately informed on this new system and prepare to implement it when possible. This will provide them an important competitive edge over their competitors in both domestic and international market.

REFERENCES

1. Codex Committee on Food Hygiene (2005). Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM). Appendix III of the Report of the 37th Session of the CCFH, March 2005.

2. Food and Agricultural Organization / World Health Organization (FAO / WHO) (2002). Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts. Report of a Joint FAO / WHO Consultation, Kiel, Germany, March 2002, FAO, Rome and WHO, Geneva.

3. International Dairy Federation (2004). Food Safety Objective (FSO) & Performance Objective (PO). Bulletin of the IDF, No.392, 2004.

4. Stringer, Mike (2004). Food Safety Objective – Role in Microbiological Food Safety Management. Summary Report of a workshop, Marseille, France, April 2003, International Life Sciences Institute, Europe, March 2004.

I find this bulletin:

Useful	☐	Informative	☐
Only entertaining	☐	Boring	☐

I think the format of this bulletin needs/does not need change.

I would like information in any subsequent issue on _____

_____

Please send your letters to:

Dr. N.N. Varshney
National Dairy Development Board
PB No.40
Anand 388001
Gujarat

Fax No. (02692) 260157
Email : nnv@nddb.coop