Towards an FSO/ALOP based food safety policy

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Abstract

To gain more insight in the possible process of setting a food safety objective (FSO), a concept developed by Codex Alimentarius for microbial hazards, in national food safety policy, a study was executed in the Netherlands. This Dutch study consisted of a case study regarding the process of setting a FSO for a chemical and for a microbiological hazard as well as of a theoretical study concerning the possible development of new decision-making tools. The study resulted in a model for a decision-making process that integrates life sciences, socio-economical studies and technology assessment. It also features close interaction between policymakers and researchers. As a result of the study, it is advised to install an independent advisory committee that helps government in deciding on appropriate levels of protection of the population and setting FSOs.

Keywords: Food safety objectives; Public policy; Consumer protection

1. Introduction

At national as well as international level, efforts are made to define the concept of food safety objective (FSO). FSOs are proposed to be a metric that gives guidance to food production and preparation professionals concerning the expected compliance of foods to consumer protection policy with regard to a possibly associated hazard. FSOs should be arrived at in an objective and transparent way. Within the Codex Alimentarius Food Hygiene Committee (CCFH), the following working definition of a food safety objective is currently discussed: “The maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection” (ALOP) (CAC, 2003). While Codex considers FSOs only for microbial hazards, in principle, the concept could apply to other types of hazards as well.

The concept of ALOP was introduced in the WTO Agreement on the application of sanitary and phytosanitary measures (the SPS Agreement) in 1995 (WTO, 1995). An ALOP is defined in the SPS agreement as: “The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory”. The purpose of the SPS-agreement was to increase the transparency of SPS-measures. It is the prerogative of individual Member states to determine what constitutes an ALOP that is appropriate for its population. Discussion is actively ongoing whether in addition to scientific insights, other factors can be considered in the decision on an ALOP. Such other factors could be for instance technological and economical (Table 1).

An ALOP can be expressed in a range of terms, for instance from broad public health goals to a quantitative expression of the probability of an adverse public health consequence or an incidence of disease.

By formulating an FSO, governments communicate to interested private and public parties a more practical
form of food safety guidance than the rather abstract ALOP. In particular guidance is given to food industry (e.g. primary producers, food processors, catering, distribution and retailers) involved in the production of the particular food as to the required level of control over the hazard in the food such that consumers are duly protected. FSOs can then be translated into a set of quantitatively stated requirements that enable appropriate design of product, process and control measures (Jouve, 1999). In this context, the agro-food industry would use FSOs as a means to co-ordinate risk management in the production process throughout the farm-to-fork production chain.

Up to now, the international discussion has focused on the scientific development of FSOs and its use by governmental risk managers and the food industry. The implications and chances of implementing FSOs in the policy-making process have hitherto received not much attention. Since the scientific development of FSOs by organisations as the Codex Alimentarius, the International Commission on Microbiological Specifications for Food (ICMSF) and the International Life Sciences Institute (ILSI) progresses it is time to consider the first steps towards the implementation of FSOs in public policy.

### 2. Goal

The Netherlands Ministry of Agriculture, Nature Management and Fisheries wanted to gain more experience and insight in the process of establishing food safety objectives. To this end, the National Reference Centre for Agriculture, Nature Management and Fisheries, the RIKILT Food Safety Institute and the Agricultural Economics Research Institute were commissioned to execute a case study on FSOs based policy for a microbiological hazard (Campylobacter) and a chemical hazard (dioxins) as well as a theoretical study on the implementation of FSOs in policy processes.

The purpose of this research was to investigate whether the Codex Alimentarius concept of FSO could be of added value for policymakers in comparison to current food safety policy.

Important questions that needed to be answered for the implementation of FSO policy were:

- What information is needed to establish quantitative FSOs in an objective and transparent way?
- What procedures are to be followed?
- Who should be involved in the process of deciding on an FSO, when and to what extent, in order to arrive at a broadly supported FSO?

### 3. Microbiological hazards: the Campylobacter case

In policy processes, four separate phases can in general be distinguished: (1) the phase of recognition of the existence of a problem, (2) formulation and demarcation of the policy problem, (3) development of possible solutions and (4) implementation and maintenance of management.

The recognition phase for Campylobacter in the Netherlands was between 1992 and 1997 when incidents caused by Campylobacter, together with Salmonella incidents, became more and more a political issue. Since 1997 several plans have been launched to tackle the Campylobacter problem. However, the policy process seemed to go back and forth between the policy formulation and solution phases without making any significant progress. Up to this date possible solutions did not lead to a decrease in Campylobacter incidence or to a clear management of the problem. The microbiological case also showed that the present food safety policy for Campylobacter was not very transparent. Although scientific, socio-economical and technical considerations were indeed part of the risk management process, it was not clear on which grounds decisions were made and what weight was given to the different arguments. Responsibilities and targets for the stakeholders involved were not clearly defined. Notably, policy objectives were not made explicit, due to which goals and means to achieve remained a matter of debate and opinion. It was expected that the introduction of an ALOP based on the life-sciences, socio-economical data and current technical possibilities would set a clearer political goal in reducing food-borne Campylobacter infec-

<table>
<thead>
<tr>
<th>Scientific and production factors</th>
<th>Economical factors</th>
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<tbody>
<tr>
<td>• All available scientific evidence;</td>
<td>• The potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease;</td>
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<tr>
<td>• Relevant processes and production methods;</td>
<td>• The costs of control or eradication in the territory of the importing member;</td>
</tr>
<tr>
<td>• Relevant inspection, sampling and testing methods;</td>
<td>• The relative cost-effectiveness of alternative approaches to limiting risks.</td>
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<td>• Prevalence of specific diseases or pests;</td>
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<td>• Existence of pest—or disease—free areas;</td>
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<tr>
<td>• Relevant ecological and environmental conditions;</td>
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<td>• Quarantine or other treatment.</td>
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4. Chemical hazards: the dioxins case

The application of risk analysis to chemical hazards has a longstanding tradition. Risks are interpreted on generally the basis of experimental studies and acceptable daily intakes (ADIs) are set for individual chemicals that represent principally safe levels of intake. Public management of chemical hazards is clearly based on either physiological, scientific evidence or on ALARA principles. Although dispute about specified ADIs and the scientific means of calculating them is probably inevitable, there is no debate on the principles of the ADI concept.

However, for chemical hazards it is more difficult to set a meaningful ALOP as compared to ALOPs for microbiological hazards. With chemical hazard, often there is no proof of causality between a chemical hazard and an individual case of a food-borne disease because impacts of chemical hazards may be more chronic in nature. A second complication regarding ALOPs for chemicals is that most chemical hazards can be found in a variety of products, both food and non-food, and in our direct living environment. On the other hand the ADI concept is based on scientific considerations, which certainly can be taken into account in the ALOP/FSO approach.

5. Discussion

One of the advantages of an ALOP/FSO based policy is that information from life sciences, socio-economical studies and agro-technology/agro-logistics can explicitly be taken into consideration when deciding on an ALOP and on subsequent FSOs. These different scientific fields should closely interact with each other. Policy makers, food industry, consumers and other stakeholders should likewise interact closely to achieve effective development of FSOs and ALOPs. Since food safety on an operational level is primarily the responsibility of the food industry, the food industry is responsible for meeting ALOPs and FSOs. The national authorities however are responsible for controlling the process of setting, achieving and evaluating ALOPs and FSOs. The implementation of an FSO policy could result in less governmental involvement in detailed measures concerning food safety, leaving the food industry more freedom and flexibility to organise their quality management tools (HACCP, GMP, etc.).

The development of ALOPs and FSOs is an iterative process, periodically starting a new cycle. This means that the FSO/ALOP-system should in principle be flexible, allowing for policy adaptations due to new scientific insights and shifts in societal and political priorities. A system of checks and balances ensures the effectiveness of measures and that public health goals remain up to date (see Fig. 1).

Overall, the FSO/ALOP-system could be divided in four major phases:

1. Risk assessment,
2. Setting ALOPs and FSOs,
3. Translating risk management to process management,
4. Feedback on risk assessment and risk management, starting a new cycle or consolidation.

Based on a risk profile, the initial inventory of a food safety problem that is compiled by the governmental risk managers within the framework of risk analysis, a hazard can be examined from different viewpoints, as discussed in CCFH (CAC, 2003). Risk assessors are then briefed regarding the risk management question they are asked to address in the risk assessment phase. Current risk assessment is usually an assessment of the characteristics of a microbiological or biochemical hazard, taking into account an estimate of the occurrence of such a hazard in foods and the actual exposure of consumers. In order to implement effective risk management, other factors such as socio-economic factors and technological possibilities should be taken into account as well. Before an ALOP can be set, different outcomes of risk management options should be evaluated by developing different scenarios for intervention strategies as well as the resulting public health impact, socio-economic consequences and technological development. A decision then has to be made on an appropriate ALOP and FSO, considering the outcomes of the different scenarios and the risk management options available. The FSO can be implemented, using food safety management metrics such as performance criteria. Obviously, it is important to establish methods to assess whether the FSO is met. Also, a periodical evaluation of the FSO is needed to ensure that it still meets the food safety policy. When a new ALOP has been decided on, there may be a need to adapt the FSO.

This management model can be made operational within the current public machinery of most countries. Because ALOPs are set at population level and FSOs—where possible—at consumer level, less governmental involvement and concomitant greater responsibility for the food industry can be effectuated without compromising public consumer protection.
In support of setting new FSOs and ALOPs, the Dutch government commissions research institutes to perform risk assessments, socio-economic impact studies and technological analysis. It is crucial that research institutes of all fields involved will closely co-operate and take into account available knowledge of the food industry. The research institutes should develop different scenarios based on life sciences, socio-economic research and technical analysis. However, it is proposed (de Swarte et al., 2002) that it should not be these research institutes who ultimately recommend ALOPs or FSOs to the government. Instead, an independent ALOP/FSO advisory committee should be installed to review the different scientific scenarios, weigh the arguments of stakeholders and thus in the end come to an independent advice for ALOPs and FSOs. Independent representatives of the scientific community, the agro-food industry and consumer organisations could participate in such an advisory committee. It is of course the government who is finally responsible for setting ALOPs and FSOs and for enforcing measures that warrant that food industry complies to the ALOPs and FSOs.

Most governments have advisory scientific bodies on food safety and these could be capable of evaluating scenario’s and advising risk managers responsible for setting ALOPs and FSOs. A specific and independent ALOP/FSO advisory committee will be a novelty for most. However, it is felt that such a committee in best placed to assess the consequences of different risk management options and, based on the information accumulated in considering different scenarios, to give advice to the government on appropriate ALOPs and FSOs. Evi-
dently, the proposed integration of scientific/technical expertise with socio-economical and consumer level thinking should be within the scope of such a committee. Committee members also need to have a good appreciation of the risk analysis framework and its different elements in order to adequately fulfill their role.

Choosing an appropriate ALOP is very much a political decision. Setting an FSO is less political, and will be based more on scientific, technical and socio-economical factors. Setting an FSO will divide and prioritize the ALOP among different food groups and needs to take into account the prevailing technical capabilities in and the current food safety performance of the relevant food chains. However, FSOs could be set and adapted without changing the political goals of an ALOP. Once an FSO is set, the food industry is responsible for setting up management systems that deliver a level of food safety in compliance to the FSO. Performance criteria and other metrics on the operational level can be derived by food industry from FSOs by chain-reversal, in effect articulating appropriate food safety standards for individual links in the chain. Such standards as well as particular control measures that government may choose to mandate should be enforced and inspected by (private and public) certification and inspection systems.

Some improvements of the existing approaches to risk assessment, management and risk communication are needed in order to make the integrated ALOP/FSO model work more smoothly.

**Improvements relating to risk assessment**
- Current risk assessment focuses mainly on life sciences. ALOP/FSO methodology must also take into account socio-economic and technological consequences of risk management. Consequently, in the future, life sciences, social sciences and engineering need to co-operate more closely to develop integrated scenario's for assessing risk management options.
- In order to set meaningful ALOPs and consequent FSOs a better knowledge of the impact of a food safety hazard is needed. Epidemiological data can help gain more insight on the impact and to develop models on major sources of infection and public health impact of food-borne illnesses. Epidemiological data for food-borne illnesses can be quite scarce, depending on the pathogen and the country or region considered. Often, epidemiological data are not accumulated in a way that it is directly usable in risk assessment. There is clear room for improvement in that respect.

**Improvements relating to risk management**
- If FSOs are indeed set at the time of consumption, as proposed in the working definition of CCFH, a better knowledge of consumer behaviour and insight in key aspects of the capabilities and food safety performance of the agro-food business is necessary in order to set appropriate FSOs. In part, such insight is brought to bare by a close involvement of the private sector as a particular stakeholder in the risk management process. Also other parties can contribute significantly here, including academia specialized in consumer behaviour as well as consumers themselves or their representatives.
- Performance criteria and other food safety management measures are governed by private law; they should be an agreement between two or more links in the chain of a food supply chain. These private performance criteria must lead to the achievement of FSOs, which are subject to public law. It is not clear yet what legal implications this may have. One of the advantages of the ALOP/FSO methodology is that food safety measures are directly linked to public health goals. In order to evaluate the effectiveness of ALOP/FSO-food safety policy, more knowledge is needed on public health figures of food-borne illnesses and patterns of food consumption.

**Improvements relating to risk communication**
- By explicitly stating a level of safety by setting an ALOP, implicitly one sets a level of unsafety. Society, consumers and politicians will have difficulty accepting a certain level of unsafety. In order to successfully implement an ALOP/FSO based policy it is important new risk communication tools are developed to overcome this problem.

6. Conclusion

FSOs can be powerful tools in risk management. FSOs assist governments in conveying health goals throughout the food chain. FSOs actually help translate health goals into appropriate food safety measures. An ALOP/FSO based policy requires more than a better understanding of risk assessment or better process management at individual businesses. It requires an integrated approach of risk assessment, risk management, process management and above all, risk communication. This means a new challenge in the way scientists, politicians, policymakers and food operators interact.

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References


