Determining a Science-based Food Safety Objective/Appropriate Level of Protection for Application in Developing Countries

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Abstract

When determining the Appropriate Level of Protection (ALOP) in food safety law, developed countries rely on the Food Safety Objective (FSO) to meet the requirements of World Trade Organization (WTO) law and to provide a high level of protection based on insights from food safety science. Implementing an FSO/ALOP is resource-intensive and costly. Developing countries who would like to provide similar levels of protection are restricted by limited resources and often face difficulties implementing such an FSO-based ALOP. As a consequence, developing countries may base their ALOP on other legally acceptable reasons, which are non-scientific and less effective. We illustrate a less resource-intensive way to implement the FSO in the ALOP, which enables developing countries to design an ALOP that is based on food safety science. Depending on the resources available in the respective country, we map different possibilities to determine a science-based FSO/ALOP concept for developing countries, which also takes into account the requirements of WTO law.

I. Introduction

Food safety ensures that food will not cause harm to consumers when it is prepared and/or eaten according to its intended use.[1] The World Health Organization (WHO) stipulates food safety as a priority for public health, as every year 1 in 10 people fall ill and 125,000 children under the age of 5 years old die because of unsafe food consumption.[2] Recent cases of food contamination have called for more effective food safety management systems (FSMS).[3] In addition, the constant increase in global food trade widens the

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[1] CAC, "General Principles of Food Hygiene", CAC/RCP 1-1969 (2003), available at <http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BRCP%2B1-1969%252FCXP_001e.pdf> p 4 (accessed 30 March 2017).

[2] WHO, "Food Safety" (2016), available at <http://www.who.int/topics/food_safety/en/> (accessed 30 March 2017).

[3] LG Gorris, "Food safety objective: an integral part of food chain management" (2005) 16(9) *Food Control* 801 et sqq.

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international penetration of foodborne hazards.[4] For this reason, solutions for food safety problems increasingly need to be found at the global level rather than at regional or national level.[5] To be relatively safe to be in compliance with WTO law, there are at least two options for a country to develop its FSMS: complying with international standards (e.g. Codex standards) or providing risk assessment if it deviates from international standards.[6] Life is certainly simpler for regulators if a country complies with international standards, not only to determine SPS measures, but also when developing an ALOP.[7] Unfortunately, not all food safety issues are covered by international standards. In such a situation, which this paper covers, developed countries have a comparative advantage over developing countries. Developing and conducting scientifically-rigorous risk assessments, such as the FSO, to implement strict and tailor-made standards for the peoples of a designated country is possible for developed countries because of their access to adequate resources. In contrast, developing countries face difficulties meeting these expectations, particularly in the health sector, as the data required to develop a scientific risk assessment are rarely available or there are insufficient resources to gather data. Developing countries do not need to perceive determining a scientifically robust ALOP as a barrier, but rather as an opportunity to increase food safety for their citizens and for designing food safety standards to be, at the safety level, comparable with developed countries.[8] Doing this increases not only the life and health of their citizens, but also their chances to participate in the global market, enabling them to trade surpluses, and benefit from comparative advantages.[9]

In this paper, we suggest a solution to the problem of how to develop an ALOP in line with the FSO standards of developed countries, given the constraints faced by developing countries. We propose a differentiated approach for developing countries, which allows them to develop an FSO/ALOP that meets the requirements of WTO law, food safety science and responds to the specific constraints of developing countries:

1. To meet WTO legal requirements, developing countries base their ALOP on the concept of FSO.
2. Developing countries with an effective food inspection and laboratory system can develop an FSO/ALOP based on data on the frequency of a hazard at the retail level, as an alternative for robust epidemiological data.
3. Where an effective food inspection and laboratory system is absent, developing countries may resort to epidemiological data available at international level and extrapolate the data to the population of their own countries.

[4] T Van de Venter, "Emerging food-borne diseases: a global responsibility" (*FAO*, 2000) <http://www.fao.org/3/a-x7133m/x7133m01.pdf> (accessed 18 April 2017) p 26.

[5] B Van der Meulen, "The Global Arena of Food Law: Emerging Contours of a Meta-framework" (2010) 3(4) *Erasmus Law Review* 217.

[6] WTO-Apppellate Body, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (Report of the Appellate Body, 2008).

[7] J Atik, *On the Efficiency of Health Measures and the "Appropriate Level of Protection*" (Edward Elgar 2011) 1.

[8] L Unnevehr, "Food safety in developing countries: Moving beyond exports" (2015) 4 *Global Food Security* 24.

[9] See, for the pros and cons of these effects, D Sinopoli and K Purnhagen, "When Life Gives You Lemons: The Dispute on the Correct Interpretation of Data on the Citrus Black Spot Disease between the European Union and South Africa according to the SPS Agreement" (2017, forthcoming) *Trade, Law and Development*.

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4. Regardless of which FSO/ALOP system is implemented, a lack of resources makes it more effective for developing countries to approve and verify a risk management plan (RMP) of a company, rather than rely only on costly on-site inspection and end-product testing. The RMP defines how risk related to the product is identified, analysed and managed by the food manufacturer, which is the most important actor in ensuring the safety of a product.[10]

We will proceed as follows. As any WTO Member developing an ALOP is framed in the legal context of WTO obligations, we will first map these obligations as determined by WTO law (Section II). Subsequently, we will demonstrate how food safety science has determined the FSO concept to fill the gaps left by WTO law (Section III). We will then proceed to discuss how these concepts can be applied in the specific context of developing countries (Section IV). We will close with the conclusion of the findings (Section V).

II. Member's right to determine its ALOP and the need for quantitative criteria in the SPS Agreement

This section illustrates the WTO legal framework with regard to the law of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)[11] as a context condition for the development of an FSO-based ALOP for developing countries.[12] The concept of ALOP[13] is specified in the Agreement on the Application of Sanitary and Phytosanitary Measures, Annex A, paragraph 5. WTO law and jurisprudence have, meanwhile, put some flesh on the bones of this definition.[14] As a general rule, WTO members are obliged to determine ALOP *ex-ante* of subsequent SPS measures.[15] This ex-ante obligation implies that WTO members have to actively determine an ALOP.[16] Regarding the content of an ALOP, WTO Members, however, have the right to determine which level is "appropriate" according to their national demands,[17] reflecting different levels of tolerance for risk.[18] This ultimately leads to different levels of ALOP in different Member States.[19] What is "appropriate" may indeed vary around the world according to different socio-economic settings of food

[10] CDC, "Risk Management Plan" (2006) available at <http://www2a.cdc.gov/cdcup/library/templates/CDC_UP_Risk_Management_Plan_Template.doc> (accessed 30 March 2017).

[11] WTO, "Agreement on the Application of Sanitary and Phytosanitary Measures" (1995) <https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm> (accessed 18 April 2017).

[12] See, for a more elaborate assessment, MM Du, "Autonomy in Setting Appropriate Level of Protection under the WTO law: Rhetoric or Reality?" (2010) 13 *Journal of International Economic Law* 1 et sqq; Atik, supra note 7.

[13] Paragraph 5 of Annex A of the SPS Agreement defines ALOP as "the level of protection deemed appropriate by Member establishing a sanitary or phytosanitary measure to protect human, animal or plant health within its territory".

[14] On the risks of and reasons for extrapolating from WTO case law to general WTO law, see D Sinopoli and KP Purnhagen, "Reversed Harmonization or Horizontalization of EU Standards?: Does WTO Law Facilitate or Constrain the Brussels Effect?" (2016) 34 *Wisconsin International Law Journal* 97; C Downes, *The Impact of WTO SPS Law on EU Food Regulations* vol 2 (Springer Science & Business Media 2014) 110–111.

[15] WTO Appellate Body, *Australia – Measures Affecting Importation of Salmon* (Report of the Appellate Body, 1998) para 205.

[16] ibid.

[17] ibid.

[18] E Reid, "Risk Assessment, Science and Deliberation: Managing Regulatory Diversity under the SPS Agreement?" (2012) 3(4) *EJRR* 535.

[19] Du, supra note 12.

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trade and consumption, particularly in developing and developed countries; hence the determination of ALOP is indispensable for ensuring local economic growth and the maintenance of national identities and cultures. Robert Howse has termed this the determination of "citizen's preference about risk" in opposition to risk itself.[20] As a consequence, Members have a wide margin within which they can set their level of appropriate risk: they can choose zero risk or a level higher than international standards.[21] This Member's "right" to develop its own ALOP is framed by WTO rules, which "provide for disciplines that a WTO Member must respect when it selects regulatory measures to fulfil its ALOP".[22] As a general principle, according to Article 5.4 of the SPS Agreement, an ALOP needs to be designed to minimise negative trade effects. This means in particular that according to Article 5.5. of the SPS Agreement, a WTO Member must avoid arbitrary or unjustifiable differences in the levels it considers to be appropriate in different situations. This does not mean, however, that an ALOP needs to be expressed in quantitative terms.[23] Arguably, it might not even have to be based on science. However, "a more explicit and in particular a quantitative expression of a Member's ALOP would greatly facilitate the consideration of compliance with the SPS Agreement."[24]

In summary, WTO Members have discretion to determine their ALOP. This "right" is important, as socio-economic differences and differences in the ability to conduct studies require such a differentiated approach. Although the "right" to develop their own ALOP allows WTO Members to adjust food safety standards to their citizens' needs, developing countries often lack the resources to determine the level of protection that is required by their population. Resources for the collection of epidemiological data at the population level are often limited, and available data are not robust.[25] Developing countries, hence, cannot realise the right granted by WTO law to develop their own ALOP effectively, nor are they able to present a quantitative ALOP in a meaningful way.[26] Consequently, the risk exists that developing countries determine an ALOP that is in compliance with WTO law, but neither effectively protects its citizens at the desired level, nor does it enable products to become tradable on the international market.

III. Quantifying an ALOP through the FSO in the Food Safety Realm

Research has responded to the WTO Panel's request for "a more explicit and in particular a quantitative expression of a Member's ALOP"[27] by integrating insights from FSMS

[20] R Howse, "Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization" (2000) 98 *Michigan Law Review* 2329.

[21] WTO, "European Communities – EC Measures Concerning Meat and Meat Products (Hormones) – AB-1997-4-Report of the Appellate Body" (1998), para 172. See supra note 15, para 125; Reid, supra note 18.

[22] Du, supra note 12.

[23] ibid.

[24] WTO Panel, *Australia – Measures Affecting Importation of Salmon – Recourse to Article 21.5 by Canada* (Panel Report 2000) para 129.

[25] Government of Malaysia, "Foodborne disease monitoring and surveillance systems" (FAO/WHO 2004), available at <ftp://ftp.fao.org/docrep/fao/meeting/006/J2381E.pdf> (accessed 30 March 2017).

[26] See Atik, supra note 7, who stipulates that in practice of dispute settlement Members "promulgate idiosyncratic measures and then ex-post seek to justify them by telling a story of careful legislative deliberation (which likely never happened)".

[27] See WTO Panel Report, supra note 24, para. 129.

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into ALOP.[28] While there is no legal obligation under WTO law to base a country's ALOP on scientific criteria, good practice of food control requires exactly this: "Whilst a country has the sovereign right to decide on the degree of protection it wishes of its citizens, it must provide, if required, the scientific evidence on which this level of protection rests".[29] In this context, the International Commission on Microbiological Specifications for Foods (ICMSF) developed the concept of the FSO to link the broad legal ALOP requirement to tangible, science-based criteria that can be applied by actors in the food chain.[30] ICMSF defines FSO as "the maximum frequency and/or concentration of a hazard in food at the time of consumption that provides or contributes to the appropriate level of protection".[31] In other words, FSO is recognised as a level of a hazard in food at the time of consumption that may cause a certain tolerable number of food-borne diseases per population per year.

$$H = Ho + \Sigma I - \Sigma R \leq FSO,$$

where H is the level of the hazard, Ho is the initial level of the hazard, ΣI is the total (cumulative) increase in the hazard and ΣR is the total (cumulative) reduction in the hazard. FSO, Ho, R and I are expressed in μg kg^{-1} for mycotoxins and log CFU g^{-1} for microbial contaminants. In this way, the ICMSF introduced a quantitative ALOP that is relevant to achieve the public health goal, but leaves the exact method of calculation open.

In practice, this may work as follows. Regardless of whether the calculation is based on epidemiological data or food supply chain data, the current state of disease X is 5 cases per 100,000 people per year and if the government agency of the Member State desires to reduce the number of cases to 2.5 cases per 100,000 people per year, then that latter number will serve as the ALOP.

IV. Quantifying ALOP through the FSO in developing countries

For developing countries, it will take a longer time frame to comply with SPS measures to meet the ALOP.[32] Experience has shown, however, that due to a lack of available resources and data, developing countries often do not have the means to design an FSO/ALOP in the same way as developed countries.[33] Nevertheless, the FSO/ALOP concept remains a useful way for developing countries to design food safety goals tailored to their actual food safety problems and to ensure that the WTO legal requirement on ALOP is

[28] AH Havelaar, MJ Nauta and JT Jansen, "Fine-tuning food safety objectives and risk assessment" (2004) 93(1) *International Journal of Food Microbiology* 11 et sqq; E Rieu and others, "Food safety objectives should integrate the variability of the concentration of pathogen" (2007) 27(2) *Risk Analysis* 373.

[29] ICMSF, "A Simplified Guide to Understanding and Using Food Safety Objectives and Performance Objectives" (2006), available at <http://www.icmsf.org/pdf/FSO%20Ojectives/GuiaSimplificadoEnglish.pdf> p 5 (accessed 30 March 2017).

[30] E Gkogka and others,"The application of the Appropriate Level of Protection (ALOP) and Food Safety Objective (FSO) concepts in food safety management: using Listeria monocytogenes in deli meats as a case study" (2013) 29(2) *Food Control* 382.

[31] ibid.

[32] Art. 10 of the SPS Agreement.

[33] WHO, 'Access to Data in Health Information Systems' (*Bulletin of the World Health Organization*, 2005) <http://www.who.int/bulletin/volumes/83/8/editorial20805html/en/> (accessed 18 April 2017).

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applied in a non-arbitrary manner. In order to benefit from applying an FSO/ALOP given the limited resources available, developing countries need to use a workable FSO/ALOP that is fit to their setting.

To design a workable FSO/ALOP we propose that governments of developing countries regulate in three steps. First an FSO/ALOP is determined at government level according to WTO requirements. The FSO/ALOP establishes an effective risk management system that accounts for food safety science and the available resources. Second, in order to ensure enforcement, technical guidelines are created, which contain detailed steps to show food manufacturers how to apply the FSO/ALOP. Finally, governments establish an effective public enforcement system, mainly by evaluating the application of the FSO/ALOP system by food manufacturers. These three steps are explained in detail in the following sections.

1. FSO/ALOP as effective risk assessment system in developing countries

Countries need to design an effective risk assessment system as a prerequisite of both WTO law and FSO/ALOP.[34] This requires a ranking of possible risks according to the needs of a country to achieve its public health goal.[35] The ranking of risks as an expression of a country's public health goal is a political decision, which precedes the (scientific) determination of an FSO.[36] However, in order to ensure that countries obtain the most benefit from WTO law and design their ALOP effectively, the ALOP should also be informed by a quantifying approach.[37]

Food safety science has developed two approaches to quantify ALOP and FSO: the "top down" and "bottom up" approach. The "top down" approach requires the availability of robust epidemiological data for a country. This approach provides the most accurate formulation for a public health policy goal, because it uses the actual level of the targeted disease in the relevant population. However, the feasibility of this approach relies on a sensitive and effective surveillance system, which is a great challenge in developing countries.[38] Surveillance data is likely to be limited or even non-existent in developing countries because of a lack of resources.

As a consequence, the "bottom up" approach may be a better alternative to meet the science-based requirement given the limited resources available. In the "bottom up" approach, the ALOP is based on available clinical information (e.g. the number of stool samples that contain a targeted microbial hazard). This information is combined with microbiological surveys, which provide the concentration of certain microbiological hazards in food at the

[34] E Gkogka and others, "Risk assessment strategies as a tool in the application of the Appropriate Level of Protection (ALOP) and Food Safety Objective (FSO) by risk managers" (2013) 167(1) *International Journal of Food Microbiology* 8.

[35] RJ Lake and others, "Risk ranking for foodborne microbial hazards in New Zealand: burden of disease estimates" (2010) 30(5) *Risk Analysis* 743; S Hoffmann, "Ensuring Food Safety around the Globe: The many roles of risk analysis from risk ranking to Microbial risk assessment" (2010) 30(5) *Risk Analysis* 711; FJ Angulo and others, "World Health Organization ranking of antimicrobials according to their importance in human medicine: a critical step for developing risk management strategies for the use of antimicrobials in food production animals" (2009) 49(1) *Clinical Infectious Diseases* 132.

[36] C De Swarte and R Donker, "Towards an FSO/ALOP based food safety policy" (2005) 16 *Food Control* 825.

[37] Gkogka and others, supra note 34.

[38] ICMSF, supra note 29.

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retail level.[39] In a "bottom up" approach, gathering data relies on inspection and laboratory capacity; this is generally more available in developing countries than an all-encompassing and costly surveillance system. However, although some developing countries have a well-established inspection and laboratory system in place, some do not. For developing countries without the required inspection and laboratory capacity, the ALOP could be determined by extrapolating from available international data, particularly epidemiological data from other countries with similar cultures. However, this approach should be applied with care and only in a temporary fashion, while efforts are made to establish systems to gather original data for the preferred approach. Either way, such data can only form the basis for the political determination of a public health goal. Other factors, such as economic prerequisites and production factors, need to be considered as well.[40]

To be meaningful, the risk ranking performed by governments needs to be translated into parameters that can be assessed by government agencies and used by food manufacturers. This is done by translating the political ALOP into an FSO in the next step. The approach used for this purpose resembles the approach used to quantify the ALOP, however, this time in terms of food safety science.[41] To ensure that the FSO is accessible to government officials and food manufacturers, it should be an officially published standard or a publicly available regulation. In this way, businesses have flexibility to apply any available food control process in their production or distribution facilities, as long as the concentration of a hazard in their products does not exceed the FSO value.

2. Guideline: who should determine the FSO/ALOP? And how?

The ALOP proposed here should only be established if there is proof of a significant impact on public health. Thus, an effective establishment of FSO/ALOP requires careful consideration of which foods have an impact on public health.[42] In order to achieve this, an integrated approach in the food supply chain is indispensable. First, extrapolating from the experience with EU food law,[43] food manufacturers should have prime responsibility to assess the risk in their supply chain, from post-harvesting of the food, through to production, storage, distribution and finally its preparation for consumption. The food manufacturer therefore carries the burden to gather and assess information about any possible risks related to its product and to eliminate or reduce these risks to an acceptable level. This significantly reduces the information burden on the food safety authority and produces a more accurate risk assessment profile, because it is conducted by the actor with the best knowledge of the risks related to a product. The authority's role in this step is to supervise and verify the risk assessment.

Second, based on the risk assessment from the food manufacturer, ALOP should be determined by the authority responsible for food safety control, in cooperation with an

[39] ibid.

[40] De Swarte and Donker, supra note 36.

[41] Gkogka and others, supra note 34.

[42] ICMSF, supra note 29.

[43] Art. 17(1) of Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L31, p1, 1/02/2002.

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independent scientific advisory body. This ensures that the determination of ALOP is based on science and less influenced by political institutions. For this approach to work in practice, the authority needs to translate the desired ALOP into the language of the FSO. However, because the FSO is a level of a hazard at the point of food consumption, the level is not verifiable because it includes the variability and uncertainty of food handling before consumption. Food manufacturers must establish an intermediate target to apply and verify FSO: the Performance Objective (PO). PO is defined as "the maximum frequency and/or concentration of a hazard in a food at a specific step of the food production chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable".[44] From the point of view of Hazard Analysis and Critical Control Points (HACCP), this PO can be regarded as a critical limit, which contributes directly to the FSO as the acceptable level.[45] The food manufacturer needs to determine the value of the PO at each Critical Control Point (e.g. receiving raw material from primary production, during the production process and at retail level). In order to meet the PO value, the manufacturer must ensure that primary production follows Good Agricultural Practice (GAP), apply suitable control measures (e.g. Good Hygiene Practice (GHP), Good Manufacturing Practice (GMP) or HACCP) in its production processes and ensure that the retail level applies Good Retail Practice (GRP). By translating the desired ALOP into the FSO, the authority can use the FSO/PO to communicate the ALOP to the food manufacturer. Close cooperation between the authority and food manufacturer is needed to achieve the ALOP.

3. Effective enforcement of FSO/ALOP regulation

Successful implementation of the proposed FSO/ALOP concept in developing countries requires enforcement. Enforcement is a challenge in developing countries as economic and intellectual resources are often not available. Despite this, food safety controls often rely heavily on on-site inspection of food facilities and end-product testing. These result in a costly inspection system, which in turn often leads to low enforcement of food safety standards. We propose a novel approach to enforcement to overcome this problem.

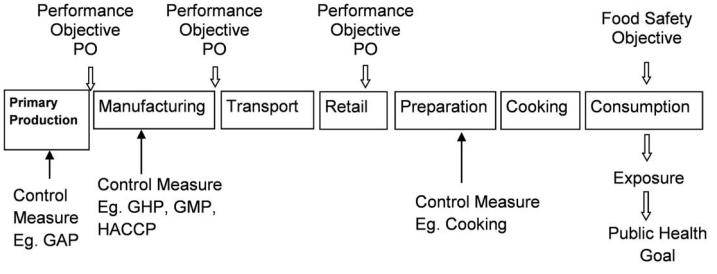


Figure 1. Model of FSO/PO system in the supply chain.[46]

[44] ICMSF, *Microorganisms in Foods: Microbiological Testing in Food Safety Management* (Springer US 2002) 290.

[45] FAO, "Within the Concept of HACCP, Critical Limit is Defined as A criterion which Separates Acceptability from Unacceptability" (1997), available at <http://www.fao.org/docrep/005/y1579e/y1579e03.htm> (accessed 30 March 2017).

[46] See ICMSF, supra note 29, 9.

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In this novel approach, costly on-site inspection plays only a minor role. Instead, enforcement switches to a co-regulation framework. Food manufacturers are obligated to draw up a RMP that integrates the FSO/ALOP concept within the inspection system. [47] The RMP contains the following steps:

a. The food manufacturer registers with the authority to participate in the RMP.

b. The authority then verifies the eligibility of the food manufacturer based on its history of food safety control system from the authority's on-site inspection database. If it is eligible, then the food manufacturer must prepare the following RMP documents: current implementation of GMP, HACCP and other food safety control systems in its facilities, and implementation of internal audits. However, if it is not eligible, the authority will inform the food manufacturer to do the Corrective and Preventive Action (CAPA) on the current food safety control system and afterward, the food manufacturer should update its RMP documents.

c. The authority then makes an on-site inspection to verify the RMP documents of the food manufacturer. Based on this verification, the authority determines the current risk profile and classifies the food manufacturer into a risk zone. The risk zone determines the frequency of future on-site inspections, which are conducted by the authority.

The evaluation of a RMP by the authority can use two different concepts: a benchmark method developed by ICMSF or the margin of safety (MOS) of the accounting tool. The benchmark method developed by the ICMSF is as follows:[48]

$$H = Ho + \Sigma I - \Sigma R \leq FSO \tag{1}$$

$$FSO - H \geq 0 \tag{2}$$

FSO, which is derived from the ALOP, provides an explicit level of a hazard at the point of food consumption and should be regarded as an intermediate objective. The stringency of FSMS, such as HACCP or good practices (GHPs and GMPs), should be based on the PO and Performance Criteria PC set by the food manufacturer.

National Government determine an ALOP and translate it to FSO and put it in food safety regulation. Food supply chain actors then determine PO based on regulated FSO. Each of food supply chain actors must arrange food safety control programs, which meet the PCs to further contribute to PO. Government must continuously evaluate ALOP and FSO based on the latest scientific and socio-economic development.

The MOS of the accounting tool is an alternative method to measure whether the manufacturer has sufficiently integrated the FSO/ALOP concept into its RMP.[49]

[47] RMP is an Information Communication Technology (ICT) base program. The program uses web-based software. The participant (food manufacturer) can upload RMP documents and the documents are saved in a database. The authority can verify the documents and provide a real time progress of the process online. Indonesia has been implementing this system since 2015. NADFC, "Risk Management Program" (2016), available at <http://pmr.pom.go.id/index.php> (accessed 30 March 2017).

[48] M Cole, "Food Safety Objectives – Concept and Current Status" [ICMSF] 36th Symposium of the Swiss Society of Food Hygiene 13.

[49] JJ Weygandt, PD Kimmel and DE Kieso, *Managerial Accounting: Tools for Business Decision Making* (John Wiley & Sons 2009) 220.

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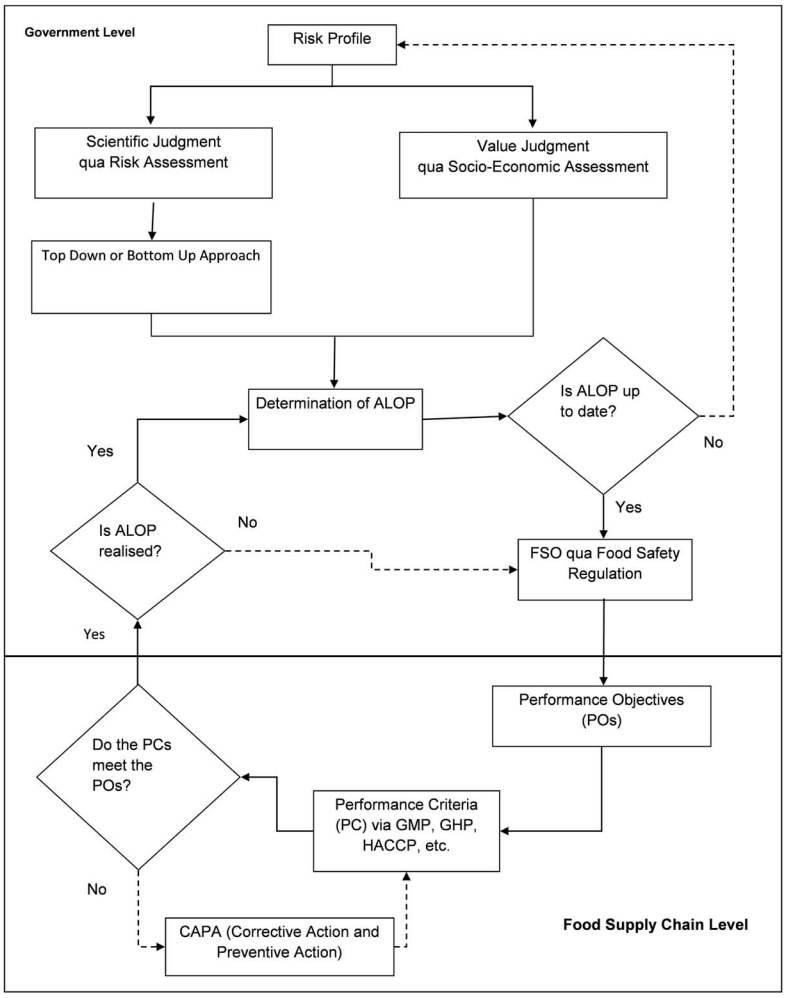


Figure 2. Management model for the application of FSO/ALOP.

The government agency may use the MOS equation, which is derived from Equation 2, for the evaluation:

$$MOS = FSO - H \tag{3}$$

$$MOS\ Ratio\ (\%) = \frac{MOS}{FSO} \times 100 \tag{4}$$

The MOS must be positive to ensure that the level of hazard (H) as the result of the FSMS complies with the expected level of hazard at the point of consumption (FSO). If the MOS is negative, then the food manufacturer must apply more stringent PO in its production processes. Moreover, a food manufacturer can use the MOS ratio to evaluate the performance of current food safety controls. A low MOS ratio alerts the food manufacturer that it needs to start finding a new combination of food safety controls before the level of hazard exceeds the FSO or PO.

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We propose that developing countries change their costly on-site inspections and end-product testing to a more cost-effective RMP approach. In this approach, the authority checks whether a food manufacturer meets the requirement of FSO/ALOP through its RMP document and internal audit, which acts as a baseline for the existing food safety risk management of the food manufacturer. Under the RMP scheme, the manufacturers must periodically carry out an internal audit to measure the current level of food safety risk management. Furthermore, the authority should register the RMP document and internal audit document in a database that records past performance. This allows the authority to black- or whitelist certain manufacturers, which then determines the frequency of on-site inspection and can eventually be used to evaluate the implementation of FSO/ALOP.

As previously mentioned, an ALOP should only be established for foods that have a significant impact on public health. The approach should thus only be applied for high-risk food, such as infant food, canned food and frozen food. This will ensure that the resources of both the authority and food manufacturers are more effectively allocated.

V. Conclusion

The position of developing countries in the WTO is special.[50] However, this special position does not lift the burden of developing countries to implement the obligations enshrined in the WTO legal framework that relate to food safety, the SPS Agreement. Within this agreement, there are two strongly related components in the establishment of food safety standards: ALOP and SPS measures. ALOP acts as the objective and SPS measures are the tool to achieve the objective. Developing countries lack resources to establish appropriate food safety standards that meet the needs of their population. A differentiated approach is urgently needed to fill this gap. We proposed the FSO/ALOP concept to help developing countries establish food safety standards that meet the requirements of WTO law, food safety science and the specific challenges faced by developing countries:

1. Given that available resources limit the opportunities to develop a tailor-made FSO/ALOP system, determining ALOP based on FSO may form a preferred option for developing countries.
2. FSO/PO system is the key for a government to communicate the ALOP to a food manufacturer.
3. Successful implementation of the FSO/ALOP concept in developing countries requires enforcement. An ICT-based program of RMP is one option for developing countries to ensure food manufacturers' compliance with existing food safety standards and to reduce the cost of inspection and compliance.

The proposed FSO/ALOP concept provides an approach for developing countries that is particularly relevant in two situations: when international standards are absent or when developed countries apply very strict food safety standards to the exports of developing countries.

[50] This is recognised in numerous provisions in WTO law, most prominently in GATT, Part IV on Trade and Development.

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