

Guidance for Writing SOPs

(A Generic Model)

Introduction

The purpose of the present document is to describe a protocol to follow while prescribing Standard Operating Procedures (SOPs). It outlines elements indicating actions and decisions that need to be considered in writing SOPs.

Executive Summary

Providing for food safety is complicated. It is bound by regulations, the food safety policy of the organisation in question and good practice in food production – processing – distribution. To achieve and maintain it, certain protocols have to be followed, regardless of changes in personnel or other parameters in the food chain. One of the ways to ensure that the required conditions are met, is to formulate and follow SOPs. Standard Operating Procedures are just that: the “procedures” and processes that are used and “operated”, under what have been “standardised”, to ensure that we do them the same way each time. An SOP is nothing more than a clearly written description of how a particular task is to be performed. SOPs are critical tools in successful business operations in general, including all those in the food industry, involved in achieving food safety. They are particularly important in relation to tasks pertaining to food safety. The present document is Food Safety Management System (FSMS) oriented. SOPs are essential for standardising processes for ensuring that regulatory and organisational policy requirements are met and, also, for training new personnel and managing workload.

Every good quality system is based on its SOPs. It is therefore a must that all people and sites involved in food safety have appropriate SOPs in place, in order to credibly be in a position to prove the level of their operations, as a substantial part of the whole FSMS.

Additionally, the presence of these quality documents is essential when inspection takes place, since one of the most frequently reported deficiency, during inspections are the lack of written SOPs and/or the failure to adhere to them. The risk of non-compliance is higher in organisations with poor SOPs and/or also poor availability and implementation.

It therefore becomes very important for the personnel to be trained on the SOPs of concern to them, so that actually are aware why and how SOPs can play their significant role, in fulfilling their expected functions in implementing regulatory and/or FSMS requirements.

The production of safe food products requires that the HACCP system to be build on a solid foundation of prerequisite programs. To be successful, a HACCP plan, must be implemented in a hygienic environment, and processing must be conducted in a manner preventing contamination of the ingredients or product and minimise growth of microorganisms. Prerequisite programs provide the basic sanitary environment and operating conditions that are necessary for the production of safe, wholesome food. ISO 22000:2005 standard recognises this principle and especially includes the prerequisite programs as an integrated part of a properly functioning FSMS.

Prerequisites are broad in scope encompassing both quality and safety. They include Good Manufacturing Practice (GMP), pest control, facilities and equipment design, maintenance, cleaning and sanitation, training and education, process control, quality control, receiving raw materials, storage and shipping of final products, and traceability and recall. All these could be considered as falling under the GMP umbrella, but are normally separated for emphasis, easier control and implementation as Good Hygiene Practice (GHP), directly related to food safety.

Standard Operating Procedures (SOPs) are guides expected to follow in operating these particular tasks in an organisation. Concerning food safety and hygiene, sometimes the expression Sanitary Standard Operating Procedures (SSOP) is used. In that case, further, Pre-Operational and Operational SSOPs can be distinguished. Pre-Operational (S)SOPs are related to activities, which have to be fulfilled before starting the operations of the day. Operational are the SOPs, which have to be implemented during the operation.

The primary purpose of an SOP is to standardise working procedures in order to ensure food safety. It is therefore crucial that personnel read and follow the SOPs. If this is not the case, not only will the SOPs fail in fulfilling their goal, but will also lull staff and management into a sense of false security. The following list shows why personnel might resist using SOPs:

- The SOP is written in a language difficult to follow.
- Instructions and general information are mixed.
- The procedure is described in an unfamiliar way.
- The user knows another (better fitting to him/her) method.
- Middle management fails to monitor SOPs implementation, on the assumption that SOPs diminish their authority (insecurity feelings).

Finally, it should be understood that SOPs are not a silver bullet. They are one of the tools used for a proper implementation of a FSMS. They will help substantially in improving the performance of an organisation. However, they need continual review and development, to ensure that they integrate new aspects. These aspects are related to changing regulatory, technical or organisational requirements and the functioning of the whole organisation, while remaining relevant and useful to the employees. Regular analysis of comments on the experience gained after implementation is vital.

Advantages and Disadvantages of SOPs

As potential advantages of SOPs the following are noted:

- Standardise the activities of personnel within an organisation to specific procedures, while improving the quality and speed of decision making.
- Provide a valuable structure for internal communication with a key role, within the organisation, in creating a knowledge management base.
- Act as a vehicle for disseminating best practices within the organisation, while updated as conditions and regulatory aspects may require.
- Serve to speed the integration of an individual into the organisation during the introductory training phase, by making available a library of organisation wide best practice and organisation operating procedures.
- Improve transparency within the organisation, by enabling all employees to see how specific activities are performed in a standard and clear fashion.
- Provide a clear audit trail in cases of dispute or external investigation by showing the procedures followed and records maintained.
- Provide a check list which is action and implementation oriented.
- Provide highly cost effective maintenance training.
- Provide valuable background information to change management policies, by embedding new best practice.

As potential disadvantages of the use of SOPs are mentioned:

- SOPs can become more and more restrictive and more and more detailed, reducing individual liberty and individual approaches to work.
- SOPs can become very time consuming involving the completion of excessive paperwork.
- SOPs can be extended to cover even the most minor aspects of work, creating a complete controlled environment – ideal for bureaucratic management style.
- Unless updated with new regulatory requirements and best practices they will rapidly fall into disrepute.
- Unless they are used by all they will also seen as part of a system put in place to mollify employees rather than as a key universal management tool.

Characteristics of a good SOP:

- Can be shown to have benefits to the employees in improving and simplifying job performance.
- It is easily and rapidly accessible to employees.
- Its role and importance can be easily and clearly demonstrated in an accompanying explanation.
- Leads to specific and ideally simple action which can be rapidly documented.

How to write an SOP

General considerations

In writing an SOP follow the ISO circle (ISO, Understanding the basics) **Plan – Do – Check - Act** and consider it as an operating principle:

- **Plan** → establish objectives and make plans (analyse the situation of the organisation, establish the overall objectives and set the interim targets, develop plans to achieve them).
- **Do** → implement the plans (do what it is planned to do).
- **Check** → measure the results (measure/monitor how far the actual achievements meet the planned objectives).
- **Act** → correct and improve plans and how you put them into practice (correct and learn from mistakes to improve plans in order to achieve better results next time).

SOPs are produced for core practices and when it is necessary to communicate and/or standardise administrative or technical tasks. Overall responsibility for deciding the requirements for an SOP and its planning and description is the responsibility of the plant manager who for this reason is cooperating with the manager responsible for the FSMS. Describe the principle behind or the purpose of the operation. Express what will be accomplished by performing the task. Summarise the methodology.

The identity number of an SOP, the arrangement of material in it and the level of detail depends entirely on the organisation particularities. It also depends on the requirements and the role of the staff members executing their work. SOPs should cover:

- A descriptive title and indication of the SOP's position in the total collection of FSMS documentation.
- Date, when the SOP became operative.
- The edition number and a relevant statement if the SOP edition replaces an earlier one.

- Periodicity of review.
- The exact distribution list of the SOP.
- The signature and the name of the person responsible for writing the SOP.
- The signature and the name of the person responsible for authorising the SOP.
- The purpose of the SOP.
- Intent of the SOP.
- Scope, including functions performed, equipment necessary, types of products to be used
- Numbered steps
- Clear definition of:
 - A description of procedures.
 - Those in the organisation to be involved.
 - Responsibilities.
 - Procedures for internal and external communication.

The title should contain sufficient information about the SOP's content and be placed prominently on the front page, to allow the user to identify and find it easily.

The distribution list directs the SOP to persons, which will use it. It should be distributed to all related persons of its function. A strict check should be kept for numbers of SOP issued and distributed at each working area.

The signature of the person responsible for writing the SOP shows that the SOP is complete and correct. Should an auditor or, for the matter, anyone else have a query about the content of an SOP, this would be the person to contact, through the FSMS manager. The signature of the person responsible for authorising the SOP shows that the SOP is operative.

The plant manager and/or the FSMS manager (depending on the size of the organisation and the assigned responsibilities) signs and dates the SOP. The time for filing and keeping the monitoring or other records pertaining to the implementation of the SOP are clearly stated, as well as the person responsible. All documentation should be available at the request of appropriate persons.

Attachments to the SOP description should include copies of all worksheets, logs or forms required for the procedure. Provide examples of how to complete the attachments.

In writing an SOP the following aspects should be considered:

- Questions to ask yourself.
- Tools to consider.
- Why do it.
- Practical implementation tips.
- Write down what you do, do what is written down and document what you do.
- Why is it important?
 - What are useful background concepts?
 - What is best practice, in relation to current research findings?
 - What are the regulatory or food safety policy requirements of the organisation, linked to a certain SOP and leading to relevant documentation?
 - What is the specific activity designed to achieve?
 - What resources are needed to carry it out and are they in place?
 - What tools are needed to implement and measure its achievement?
 - Who will be involved?
 - What kind of documentation support should be designed?

Particular reference is made to the actual legal or other regulatory texts, which have to be implemented, binding the organisation. External communication aspects should be addressed in this respect.

Write the instruction in the right order, so that the operator knows when to perform the appropriate steps. Separate the instructions from general explanatory information, either typographically or by using footnotes. Nevertheless, SOPs do not have to “fit into a box”. Formats can vary. Presentation techniques, such as flow charts, diagrams, narratives, tables and bulleted lists should be considered in addition to the traditional text and paragraph formats. Presentation might vary, and should address conditions pertinent to the individual environment. Procedures should be presented in a format that will work for the organisation and address specific needs in various ways. The goal is to have an easily understood procedure that the personnel operating on the floor will clearly understand and utilise.

The SOP must communicate its message effectively. Must be crystal clear on who is doing what. This almost seems obvious to write, but many SOPs are difficult to read and understand. Sort of rule of thumb for writing is:

- Use short active sentences.

- Use simple words and simplified terms where possible.
- Write the sentences as instructions, that is “do this, do that”.
- Limit the amount of information per-page to maximum of ten different actions.
- Use diagrams where appropriate.
- Give sources and references at the end.

Who writes SOPs

The SOP must convey a clear instruction. Not only must the user understand the instruction, he/she also must be prepared to carry it out. The logical step is to let the user, as far as possible, write a draft of the SOP, in cooperation with the FSMS manager.

The user author practice prevents the working procedure appearing to the reader unfamiliar or awkward. If it is not, is likely that the user would resist using it on the grounds that “he could do his/her job in his sleep”. It is much likely that the user-author practice will result in an improved sense of responsibility for the obligation to use and comply with the SOP.

Objectives

The author of an SOP should be very clear on its objectives while writing it. They can broadly be described as follows:

- Define the expected results of implementation, regulatory or organisational.
- Understand why an SOP needed, who and how will use it.
- Determine SOP needs and assign local responsibility for management and review.
- Distinguish between SOPs, guidelines, policy statements and work instructions and learn how each may work for area of responsibility in a concerted integrated way.
- Implement appropriate SOP training programs.
- Integrate SOPs into comprehensive documented actions, operating within the FSMS.
- Implement review and control system.
- Understand the role of food safety assurance in SOP systems.

Implementation and maintenance

Implementing and maintaining an SOP involves:

- Daily monitoring of pre-operational and operational SOP.
- Recording the findings of monitoring.

- Performing corrective actions as it may be needed.
- Documenting all activities as prescribed, including corrective actions.
- Revising the SOP as needed.

Monitoring

In monitoring, Pre-Operational SOPs are expected to be completed before processing starts, or rather at the end of the shift to prepare the facility for the next. In particular any surface in contact with the product (e.g. packaging boards) is included in this category. Parameters to observe and documentation to provide evidence of monitoring are determined.

In implementing Pre-Operational SOPs, the plant manager is expected to inspect equipment and other food-contact surfaces before starting production each workday to monitor the effectiveness of cleaning and sanitising. He/She relies on documented results of measurement (e.g. ATP measurement), appearance, odour and feel of food contact surfaces (a "sensorial inspection"). This procedure is clearly described including performance of any necessary corrective actions, which have to be documented in the Corrective Action Log. The corrective action must prevent direct product contamination. Changes in the procedure should be signed and dated appropriately.

The inspection results are recorded on the SOP Inspection Form. The inspection Form should be an easy completing check list. All inspected areas, programs or equipment are notified on the board. A deviation is recorded with a different symbol, the problem is briefly described and corrective actions follow, recording on the Corrective Action Log. Signing and dating is important. Therefore appropriate part in the form should be included. Possible corrective actions should be described including the option of re-training responsible personnel, changes of procedures, and/or repeating existing procedure with greater care and re-inspecting.

Outsourcing

Certain actions may be performed by third parties, as a hired outsourced service. Examples are the pesticide and insecticide activities, cleaning and disinfecting the establishment, water supply hygiene, due to reasons such as structural (water supply by third parties), legal or cost efficiency. Also, laboratory support, complete or partial, depending on the laboratory adequacy of the organisation. In these cases, SOPs should be written in cooperation with those providing the hired service, paying specific attention to responsibilities of monitoring and control.

Corrections – Corrective actions

If deviation from the implementation of an SOP occurs, this can be either the result of unacceptable implementation by the responsible personnel or it might be the SOP itself that is at fault. Perhaps the user found a much superior way of doing the job, from the one described in the SOP. If the cause lies with the SOP this is a signal for the SOP to be updated, since continuous deviation in implementation is not acceptable.

Verification

EU legislation and ISO 22000 implementation of prerequisite programs, at a significant extend, are supported by (S)SOPs. These should be established for each plant and are inspected by either or both regulatory authorities or certifying organisations. The objective is to prevent food contamination due to handling by personnel, or processing procedures. Relevant rules have to be put together in order that food is effectively protected from contamination. Rules for personal hygiene, equipment and tool sanitation during and after processing considered as appropriate.

Validation

Procedures for SOP validation within the FSMS functioning include, among others:

- Process for collection and documentation of necessary information.
- Creating meaningful risk/hazard analysis documents.
- Laboratory confirmation of final product safety.

Auditing

In planning SOPs, having in mind the possibility for eventual positive audit, as it case might be, the following should be addressed

- The overall flow of the design is clearly defined in chapters and paragraphs.
- If resources and competencies are required and provided.
- What part of the implementation will be outsourced.
- Responsibilities and authorisations are defined and properly allocated.
- Interfaces with internal and external groups are identified.
- Implementation and effectiveness of the SOP is monitored.
- Verification, validation and review are defined.
- Updating and proper communication to all relevant points in the organisation as necessary are foreseen.

Documentation

An establishment must maintain daily records, sufficient to prove the SOP is being implemented and monitored and that it documents all corrective actions taken. Make sure the records:

- Contain all the procedures the establishment is conducting daily pre- and operatively.

- Specify the frequency of each procedure.
- Identify employees or positions responsible to implement the procedures.
- Are signed and dated by the person with overall authority on-site.

Daily record keeping is critical to make the SOPs effective. Corrective actions must be recorded by the beginning of the same shift the following day. Records may be maintained in computers provided appropriate controls are implemented to ensure the integrity of the data. Time of documents preservation must be specified and their availability to be at request.

SOP review

Use the monitoring results for informed changes of the SOP. Follow it with compliance documentation. Make sure to sign and date all procedure modifications. More specifically, when monitoring reveals product contamination, prescribe actions and corrective actions, such as:

- Dispose of contaminated product.
- Restore sanitary conditions.
- Prevent recurrence.
- Document both contamination and corrective actions.

When changes are made in facilities, equipment, utensils, operations or personnel, the SOP may need to be updated to take in account these changes. It is incumbent on the establishment to routinely evaluate the effectiveness of its SOPs and proceed to appropriate changes accordingly. Setting up a regular timetable for reviewing SOPs is strongly advised.

Further, Standard Operating Procedures should be regularly reviewed and updated to ensure that they encourage efficient working practice, that comply with the ever increasing requirements, improvements and government regulatory framework changes. If no changes are necessary this decision should also be recorded and reflected in the number of the SOP version.

References

List of standards, regulations, guidance documents used as authorities for the procedure of writing and implementing an SOP should be displayed at the end. List of sources for further reading on the subject of an SOP is provided, as well as relevant external training opportunities.

Second or third party quality assurance

Understanding what is required for a successful inspection and auditing helps for a proper design and implementation of an SOP. Before any inspection or auditing, the person responsible for it must read and understand the SOP. During inspection the inspector sees if:

- Appropriate SOPs are available.
- Edition numbering is correct and all obsolete editions have been withdrawn from circulation.
- Distribution lists are correct and updated.
- SOPs are effective, reasonably covering all necessary procedures.
- If the process described in the SOP is adequate for performing the task intended to.
- Relevant responsible personnel:
 - Is well briefed for implementing the SOP.
 - Is familiar with the SOP content.
 - Has been trained and training is documented in the personnel training records.
- If SOP requirements are enforced.

The following are negative indications:

- Unauthorised copies in use.
- Unauthorised or SOP drafts in use.
- Deviations in implementing the SOP.
- Inadequate SOP training records for personnel.

The inspectors or auditors take a note of such findings and try to establish whether they affect a failure, perhaps in training, understanding the purpose of SOP, management commitment. The findings should be used to optimise the effectiveness of an SOP.

Steps for SOP production

Step 1 – Charting the SOP

Charting is a procedure of laying out all steps and analysing the process with the goal of making it more efficient and easier to follow. It involves taking each step in the process and

placing it into a process chart. All people involved in performing relevant tasks should participate in charting the process, following free, exhaustive and open discussions.

Step 2 – Writing the SOP

Use suggestions as above in chapter “How to write an SOP”.

Step 3 - Editorial responsibilities

It is advantageous to give editorial responsibilities to a person within an organisation. The FSMS manager decides on whether an SOP is needed and he/she also could act as the editorial personnel. The editorial duty for a new SOP is to scrutinise it for:

- Style and format.
- The edition number.
- Consistency of content in context with other relevant SOPs.
- Compliance with the organisations food safety policy and regulatory requirements.

Step 4 - Authorising the SOPs

No SOP is an SOP unless it is properly authorised. With authorisation concurrence for implementation of an appropriate method for a given procedure, standardise performance of a particular activity and communicating the SOP to all involved is revealed.

It is the responsibility of the top management to possibly delegate the responsibility for authorisation to a manager above the FSMS manager, as the case might be.

Step 5 – Distribution and filing the SOPs

The FSMS manager is responsible for distribution and withdrawal of SOPs. When the required number of SOP copies from the original is produced, they are stamped “DO NOT COPY” and “CONTROLLED COPY”, in colour or some other technique to distinguish between the original from the photocopied versions. The original is kept secured by the FSMS manager in the master file of the FSMS.

The historical or expired SOPs, whose new versions have been issued, should be properly filed with “FILED” stamp on the original SOP. This is kept in a designated (historical) file under the responsibility of the FSMS manager. All copies of expired SOPs must be destroyed immediately after its new version comes in effect. This is to reduce the confusion for the personnel working on the floor by existence of two different methods floating simultaneously.

Step 6 - Training on the SOPs

SOPs are training tools. At first level this is associated with understanding the way of implementing certain tasks, while at a second level is a reference for knowledge updating, as it may be needed.

Training on SOPs is often neglected. It is frequently the case that, personnel does not receive adequate training on the SOPs implementation. The purpose of the SOPs thus remains unfulfilled.

The FSMS manager should see that there is continues training of personnel on SOPs. The training should be properly documented. Generally, the effective date for SOP training must be 2-3 days after it is authorised. This is to give sufficient time for staff to read and understand the SOP before it is actually implemented in the system.

Formal and continuous training sessions should be delivered by the FSMS manager. Thus awareness among the staff will increase and, also, it will contribute to the continuous review for improving the SOP.

Step 7 – Changes in SOPs

When a mistake in an SOP is found, it is tempting to change the text by hand. It is especially tempting when the SOP is newly issued or if the change is only for example in the distribution list. Such alterations are dangerous as no one knows whether the comments appear in all SOP's copies of a certain edition, how long have existed there, whether any one has modified their working routine as a result, or whether data has been compromised. The detection of such actions must prompt inquiry, and if changes are necessary the SOP will need updating and the procedure should be followed as prescribed for review of documents in the FSMS.

Step 8 – Review of SOPs

Review SOPs regularly and occasionally, for keeping them updated, as the case might be, as described above in the chapter "SOP review".

Glossary

Standard Operating Procedure (SOP): "detailed, written instructions to achieve uniformity of the performance of a specific function" (ICH*).

Generic: "a standard that can be applied to any organisation, large or small, whatever its product or service, in any sector of activity, and whether it is a business enterprise, a public administration, or a government department" (ISO, Understand the basics).

Management system: "what the organisation does to manage its processes, or activities, so that its products or services meet the objectives it has set itself" (ISO, Understand the basics).

* *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceutical Products for Human Use.*

Management system standards: “Provide a **model to follow** in setting up and operating a management system” (ISO, Understand the basics).

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