

Risk-based controls & the MANCP: approach of the Belgian Federal Agency for the Safety of the Food Chain

1. Introduction

In Belgium, the Federal Agency for the Safety of the Food Chain (FASFC) is the competent authority for official controls of the safety of the entire food chain, including animal health, plant health and animal welfare. These controls include analyses of products to check their quality and safety, and inspections of establishments, documents and products at all stages of the food chain.

The FASFC being in charge of the control policy of most of the official controls with regard to Regulation (EC) No 882/2004, it also draws up the Belgian MANCP.

Two main features must be taken into account to comprehend the most important operational aspects of the MANCP:

- the duration of the MANCP is the same as that of the business plan of the Chief Executive Officer (CEO) of the FASFC. This way the strategic and operational objectives of the FASFC are linked to those of the MANCP;
- the core process of the FASFC.

This document is a concise description of the risk-based programming, planning, and implementation of official controls carried out by the FASFC, and their link with the MANCP.

2. The strategic and operational objectives

The strategic and operational objectives of the MANCP originate from the business plan of the CEO of the FASFC¹. The current business plan (2009-2011) was approved by the Minister in charge of the FASFC (i.e. the Minister of Agriculture).

There are twelve strategic objectives in place for the period 2009-2011:

1. an ever safer food chain;
2. a FASFC accepted by the operators and recognized by society;
3. a transparent FASFC;
4. the promotion of self-checking;
5. simplification of administrative procedures;
6. a FASFC that is professional and exacting in terms of results;
7. optimal collaboration between public and private sectors;
8. constructive and efficient cooperation with other official authorities;
9. integrated management of information and data (ICT);
10. guarantees on the quality of services rendered;
11. sustainable development at the FASFC;
12. a significant role on an international scale.

These strategic objectives have been translated into operational objectives. The achievement of these operational objectives can be followed via the FASFC website.

¹ Available via the FASFC website: <http://www.favv-afsca.fgov.be/>

With regard to the programming of official controls, the strategic objectives 'an ever safer food chain' and 'the promotion of self-checking' are of particular importance. Actions associated with the objective 'an ever safer food chain' are for example, the increase of statistical knowledge of the experts of the FASFC who program official controls, the continuing evolution of the methodology for Pest Risk Assessment, and the execution of an exposure assessment for pesticides. The promotion of self-checking in companies, an objective pursued by the FASFC right from the start, remains an extremely important point. In addition to raising awareness and informing companies, several stimuli are in place to enhance the implementation and validation of self-checking systems. Food business operators (FBO) who have a validated/certified self-checking system receive a financial bonus on their annual levy (contribution). Also, these FBO will be less controlled by the FASFC since the presence of a validated self-checking system is a risk factor taken into account in the programming of inspections.

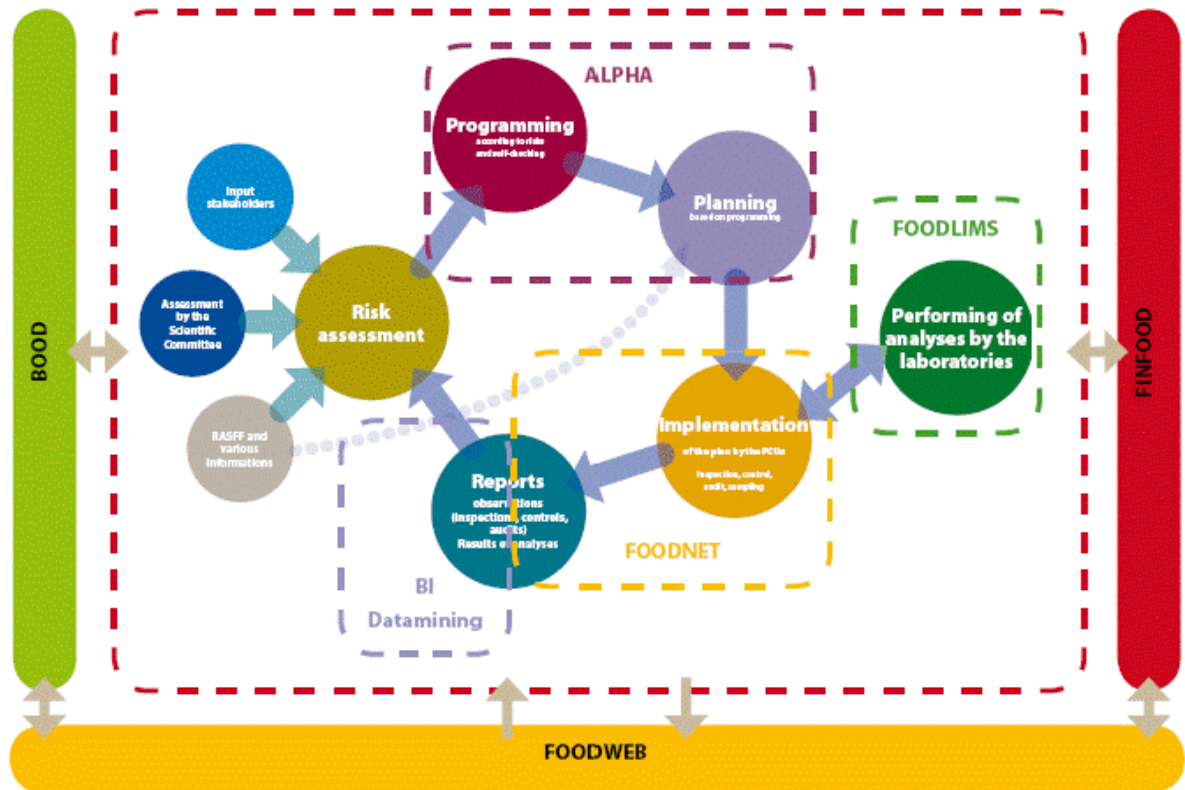
3. The core process of the FASFC

The core process of the FASFC is cyclical (the cycle covers one year) and consists of 3 stages (diagram 1):

- each year, the FASFC drafts a control program based upon risk assessment. This program is composed of 2 parts: sampling and inspection. The methodology developed and applied by the FASFC is based on risk evaluation, the use of statistical tools and current scientific knowledge. Other factors that are taken into account during programming are information received from businesses in relation to the obligatory notification and from the European Rapid Alert System (RASFF), and complaints from consumers;
- the control program is then translated into a planning of all control activities that sets the targets per province, sized to sector level, and takes into account the available resources;
- the staff members of the FASFC in the provincial control units (PCU) carry out the controls (inspection and sampling) and report their findings. The laboratories report the results of analyses.

Inspection reports and results of analyses are then used to make risk assessments and require a regular, sometimes immediate, adjustment of the program/plan to maximize hazard management. In this respect, the expertise of the Scientific Committee of the FASFC is of vital importance.

Diagram 1: the core process of the FASFC.



BOOD: database for registration of the FBO; ALPHA: tool for translating the control program into a control and analysis plan for the 11 Provincial Control Units (PCU); FOODNET: tool for recording the control missions and the respective findings; FOODLIMS: tool for recording analysis results; SANITRACE: tool for registration and traceability of farm animals; FOODWEB: tool for FBO by which they have access to the information on their business that is recorded in the FASFC database; DEBOHRA: human resource database; FINFOOD & ADMINLIGHT: tools for billing related to the funding of the FASFC; BUSINESS INTELLIGENCE or BI: use of the data of all databases.

3.1. Programming official controls²

3.1.1. Introduction

Official controls executed by the FASFC are either planned in the control program ('within scope', cfr. 3.1.1.1.) or initiated by other events such as RASFF notifications, complaints, actions by other authorities with assistance of the FASFC,... ('outside the scope', cfr. 3.1.1.2.).

² Also see: Maudoux et al. (2006). Food safety surveillance through a risk based control programme: approach employed by the Belgian Federal Agency for the Safety of the Food Chain. Veterinary Quarterly, 28(4): 140-154 (available via the FASFC website: <http://www.favv-afsc.fgov.be/about/>).

3.1.1.1. Official controls within the scope of the control program

The integrated control program, drawn up by experts of DG Control Policy of the FASFC is based upon a risk-based methodology. Moreover, during the process of risk assessment, the following factors are taken into account:

- national and international (mostly European) legislation and recommendations;
- results of the controls of previous years;
- results of food poisoning inquiries;
- information received by RASFF;
- results of epidemiological surveillance of animal diseases and zoonoses;
- contaminant features and behavior;
- advices of the Scientific Committees of the FASFC, the European Commission or other Member States;
- information received in international fora;
- consumption data;
- consumer complaints;
- results of research of independent institutes.

3.1.1.2. Official controls outside the scope of the control program

Unplanned controls include controls that are conducted following a positive or dubious test result, epidemiological inquiries (animal or plant disease, contaminants,...), interventions at the border inspection posts, controls following complaints, certification at the request of the person in charge (e.g. for export), and controls with regard to applications for approval by persons in charge.

Self-checking systems are audited and approved by either independent accreditation bodies or the FASFC. These audits are not part of the control program of the FASFC.

Inspections (ante mortem and post mortem) in the slaughter-houses are also not included in the FASFC control program because they are carried out 'on request'.

Inspections with regard to animal welfare are programmed by the Federal Public Service Public Health, Safety of the Food Chain and the Environment and handed over to the FASFC who incorporates them in the overall FASFC control program.

3.1.2. Control program – Analyses

A distinction is made between several situations, which determine how the number of analyses must be defined:

- the number of analyses is imposed by legislation;
- the number of analyses is determined by risk analysis;
- the number of analyses is linked to monitoring;
- the number of analyses is estimated beforehand.

3.1.2.1. *The number of analyses is imposed by legislation*

When regulations impose or recommend a certain frequency or number of controls, the programming team describes the criteria defined by the legislation and indicates how these will be implemented in order to achieve the goals set.

E.g.: detection of zoonoses, residues of veterinary medicinal products,...

3.1.2.2. *The number of analyses is determined by risk analysis*

This statistical approach is adopted only for programming controls which aim to detect, with a certain confidence level (CL), the contaminations exceeding a predefined prevalence level to be controlled (PLC). The confidence level and the predefined prevalence level to be controlled depend on the risk posed by the hazard that must be controlled.

There are three (risk) criteria that are taken into account (diagram 2); for each criterion, a score is attributed:

Criterion 1: degree of harmful effect of the hazard, the disease, the parameter related to toxicity, virulence or negative economic impact:

- score 1 (not harmful or negligibly harmful) to 4 (very harmful).

Criterion 2: prevalence of the contamination or disease within the population to be controlled:

- score 1 (very low prevalence; low analytical detection and standard not exceeded) to 4 (high probability of prevalence; frequent analytical detections and exceeding of standards).

Criterion 3: contribution of the population to the overall food chain contamination, to the spread or the impact of the disease:

- score 1 (limited contribution) to 4 (very substantial contribution).

The prevalence level to be controlled is defined as the contamination rate (infection rate) that has to be detected with a given confidence level. The absence of non-compliance suggests, with a certain confidence level, that the accepted PLC is not exceeded. The PLC is determined by criterion 1 (degree of harmful effect of the hazard). The more harmful a hazard is, the lower its accepted prevalence and hence the sooner it has to be detected.

The harmful effect associated with the two components of exposure, represented in the formula:

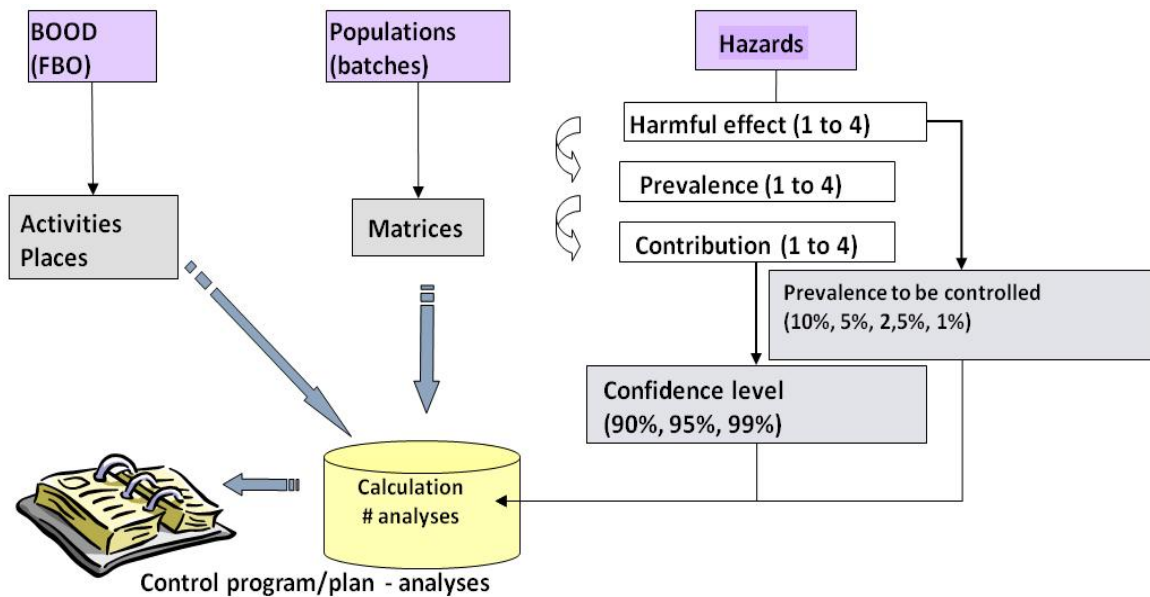
$$\text{harmful effect} + (\text{prevalence} \times \text{contribution}) = \text{score of criterion 1} + (\text{score of criterion 2} \times \text{score of criterion 3})$$

is the risk that makes it possible to determine the confidence level; the higher the total score, the higher the confidence level.

The number of analyses to be carried out in a population (group of products or matrices) is then calculated by means of a modified Cannon & Roe formula (binomial approach). The analyses are distributed between the sample matrices that constitute the population. Next, the sites of sampling are chosen.

E.g.: chemical and microbiological contaminants, residues,...

Diagram 2: synthesis risk analysis (control program FASFC).



BOOD: BOOD: database for registration of the FBO.

3.1.2.3. The number of analyses is linked to monitoring

In this case, the statistical approach is used only for programs with the purpose of estimating true prevalence within a population, with a certain accuracy and confidence level. The number of samples to be tested essentially depends on the accuracy and confidence level to be attained. Hence the higher the required accuracy of the true prevalence at a given confidence level, the higher the number of samples required.

E.g.: microbiological contaminants, plant diseases,...

3.1.2.4. The number of analyses is estimated beforehand

This approach is linked to the occurrence of a particular event and aims at detecting a contamination. The number of analyses to be performed depends on the frequency of controls and the prevalence of the event taken into account.

E.g. import controls, verification in case of symptoms,...

3.1.2.5. Adjustment of the number of analyses

The programmed number of analyses can be adjusted for the following reasons:

- control plans set up by the sector and approved by the Scientific Committee of the FASFC beforehand;
- political;

- economical;
- consumers lobby;
- media.

In this respect should be mentioned that each year, the control program for analyses for the following year, is presented to the Advisory Committee of the FASFC in which the sector and consumer organizations are represented. Remarks concerning the program are evaluated and if necessary, the program will be amended.

3.1.3. Control program – Inspections

For inspections the FASFC makes use of inspection frequencies. For that purpose, the entire food chain is divided into a series of fields of activity presenting a particular risk profile of the FBO. The risk profiles have been discussed with the sector organizations represented in the Advisory Committee. To each field of activity is attributed one of the following sensitivity levels: low sensibility (LS), medium sensibility (MS) and high sensibility (HS). The choice of the sensitivity level reflects the risk related to the activity of the FBO working in the fields of activity concerned. It takes into account the experience acquired and the existence of specific regulations for risk management, if any. The sensitivity level determines the ratio between the annual inspection frequency of a 'good' and a 'bad' operator within a certain field of activity (table 1).

The FASFC distinguishes three categories of inspection frequencies: reduced frequency, basic frequency and increased frequency. For each field of activity a basic inspection frequency corresponds to the number of inspections that should be carried out each year on an FBO considered as representative of a field of activity. Apart from primary production, the reduced and the increased frequencies are calculated for each field of activity taking into account the basic frequency and the sensitivity level. For plant, animal or mixed primary productions, the reduced and the increased frequencies respectively amount to $F_i/4$ and $2F_i$, with F_i being the basic frequency.

Table 1: calculation of inspection frequency, taking into account the sensitivity level of the field of activity.

Inspection frequency	Category	HS	MS	LS
Reduced (best)	1	$F_i/2$	$2F_{ii}/3$	$3F_{iii}/4$
Basic (normal)	2	F_i	F_{ii}	F_{iii}
Increased (worst)	3	$2F_i$	$2F_{ii}$	$3F_{iii}/2$

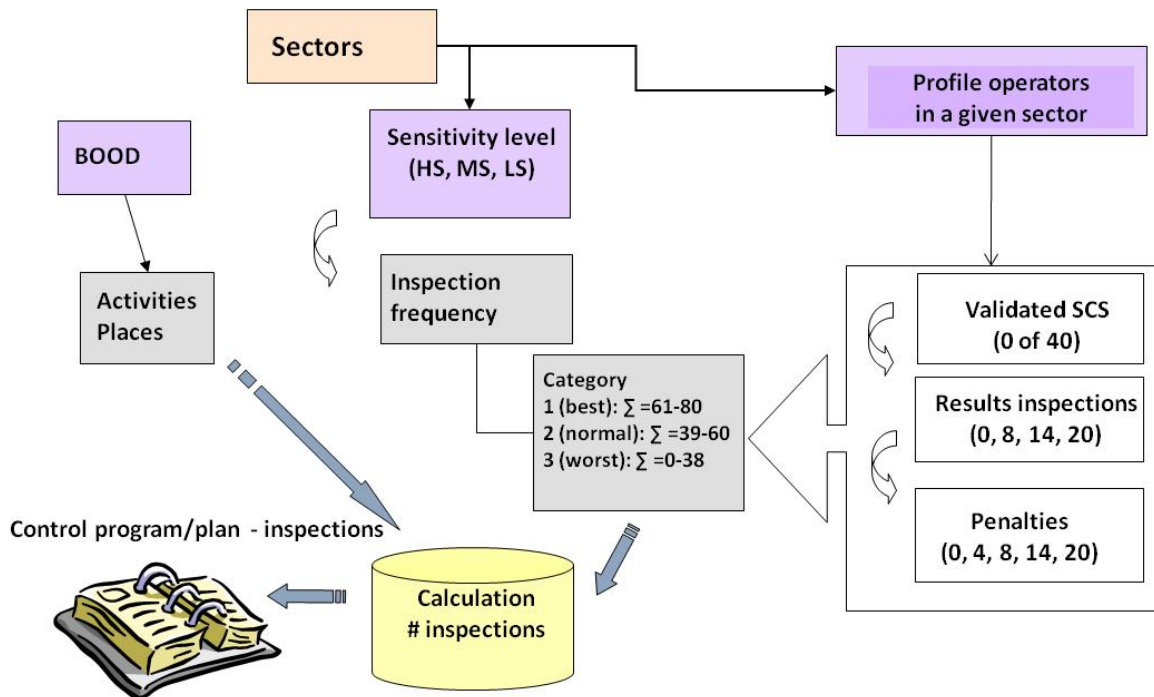
LS: low sensitivity, MS: medium sensitivity, HS: high sensitivity.

The average profile of the operators of a particular field of activity as well as the profile of a specific operator is derived from the sum of the scores attributed to the three following (risk) criteria (diagram 3):

- the presence (or absence) of a validated self-checking system;
- the results of inspections during a certain reference period;
- the number of penalties incurred over a certain reference period.

The final basic inspection frequency is determined taking into account available resources.

Diagram 3: synthesis calculation inspection frequencies.



BOOD: BOOD: database for registration of the FBO.

3.1.4. Role of the Scientific Committee of the FASFC

The risk-based methodology for programming the official controls of the FASFC has been assessed by Scientific Committee of the FASFC and will be reassessed every time a substantial change of methodology takes place.

Also, the scientific advice of this Committee is asked periodically (at least once in the duration period of the MANCP) on the risk assessment of the experts. This advice may concern:

- the list of hazards and harmful effects (scores) related to these hazards (cfr. criterion 1, paragraph 3.1.2.2.);
- the relevance of the chosen matrix/hazard combination and the number of analyses;
- the relevance of the chosen places in the food chain where samples are taken (distribution of the samples and the control efforts on the entire food chain);
- the control pressure with regard to the contamination for which programming official controls takes place.

3.1.5. Adjustment of the control program/plan

During a cycle (programming-planning-implementation of controls), the control program/plan can always be adjusted due to unforeseen circumstances (e.g. RASFF, crisis, outbreak of animal disease). This review is managed within a special structure: the Coordination Cell Control Program & External Reporting (CCER). This cell is composed of representatives of all DGs of the FASFC and assesses the impact of the proposed changes in the program.

3.1.6. Further planning and performing of controls

3.1.6.1. Analyses

Once the analysis program is approved by the hierarchy, it is sent from DG Control Policy to DG Laboratories where it is translated into a sampling program by means of a rationalisation process (recombining parameters and matrices). When rationalised, the sampling program is sent to DG Control which will draw up the final planning of samplings. To do so, the controls mentioned in the control program are distributed among the 11 PCUs and spread in time, taking into account certain parameters such as the seasonal nature of some controls, the geographic presence of operators exercising the activity that must be submitted to control, etc. For some specific controls, only the number of controls to be carried out per year is established without any specification as to the PCU where they must take place. For other specific controls the PCUs are given a year target without specifying the moment at which the controls must take place.

When the control program is converted into a control plan, the central administration of DG Control contacts the DG Control Policy when it discovers elements that are technically/operationally unfeasible. The control program is then adjusted. The PCUs are also given some time to look into the plan and give response which may also lead to amending it.

Scale effects are taken into account when controls are distributed among the different PCUs. Large PCUs are able, in relative terms, to carry out more controls than small PCUs because of their size since they are better able to cope with unexpected temporary absences of control officers. Samples are first distributed among the PCUs and then assigned to individual control officers.

3.1.6.2. Inspections

The inspection program is converted into an Access-/Excel data file made up of inspection lines. On each line are mentioned :

- the place, the activities, the product (BOOD data);
- the sector;
- the scope of the checklist;
- the person to be contacted;
- the inspection frequency;
- the % scope: in fact, the frequency at which a checklist of a certain scope must be used during missions;
- the checklist.

In practice, the planning of the control officers is made up in the PCUs under the responsibility of the sector head in charge.

3.1.6.3. Prioritisation of controls in the PCUs

At PCU level, the PCU head supervises and co-ordinates the three sectors (primary production, processing and distribution) each of which come under the authority of a sector head. Together, they are responsible for the correct communication on instructions, checklists, new legislation, etc. and for the guidance of control officers, independent veterinarians with special assignments included.

The priority list for tasks of the PCU is as follows:

- 1st priority:
 - o non compliant samples;
 - o complaints;
 - o RASFF;
- 2nd priority:
 - o non compliant inspections (re-controls);
- 3rd priority:
 - o control plan:

- inspection plan;
- carrying out samplings;
- o services rendered at the request of the operator, e.g. validation of the self-checking system, certification, inspection of meat and fish, etc.

The continuous follow-up of the carrying out of controls and comparing them with the targets set allow the PCU heads to assess the state of progress within their PCU and to take action, if need be, when deficiencies are found. The central services of DG Control follow up the statistics. The National Implementation and Co-ordination Unit of that DG which is in charge of the overall co-ordination of controls and audits on the spot plays an important part in that respect.

Reference of the document

Version	Date	Remark(s)
1.0	20/10/2011	The risk-based methodology as described in this document is valid in the period of validity of the current (2009-2011) business plan of the CEO of the FASFC, and therefore it is valid in the second MANCP (2009-2011) of Belgium. Within the scope of the new business plan of the CEO (and third MANCP), this methodology is currently under revision.