

*MANCP
Network*

RISK BASED PLANNING OF OFFICIAL CONTROLS

The Network of MANCP national experts have produced this non-binding reference document based on agreed good practices to provide guidance on possible approaches to risk based planning of official controls.

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Version 1

The Multi Annual National Control Programme (MANCP) Network

The MANCP network is a network of officials from national competent authorities, who have a coordinating role in the preparation and reporting on the Multi Annual National Control Programme (MANCP, provided for by articles 41 to 44 of Regulation (EC) No 882/2004¹. The networks meet regularly, under the chairmanship of, and facilitated by, the FVO to exchange experiences on preparation, implementing and reporting on national MANCPs. During the course of these exchanges; discussions, workshops etc. good principles and practices are identified and agreed by the network.

To enable dissemination of information the network, working in plenary session and through sub-groups, facilitated by the FVO, consolidate agreed principles and good practices on specific topics into documents. These documents may be used as reference documents, however, they do not constitute an audit standard and are not legally binding.

Risk-Based Planning of Controls

1. Background

The requirement for Member States to organise their official controls on a risk basis has been discussed during a series of meetings by experts from Member States responsible for co-ordinating MANCP activities and also by experts from national audit systems (NAS) over a number of their respective "network" meetings at the FVO offices in Grange.

The purpose of the discussions of both groups was to

- Provide ideas for criteria to be taken into account in risk-based planning – not to be read as a prescriptive guidance but rather as a "menu" of options;
- Help in designing and operating risk-based planning processes;
- Provide concepts and terminology for describing such processes in the context of MANCP and audits of competent authorities by the NAS;
- Explain the elements and complexities that need to be taken into account while describing and/or evaluating risk-based planning processes; and
- Share knowledge by disseminating examples of approaches already in place in some MS.

Discussion by the networks included presentations on systems applied in a selection of Member States and workshops to identify appropriate principles and good practices; the output from these discussions has been consolidated and analysed, and used as the basis for this report.

2. Benefits and Challenges of a risk based system

The group agreed that the benefits of implementing a system of risk-based controls extend beyond meeting the legal obligation of Regulation (EC) No. 882/2004. Risk-

¹ OJ L 191, 28.5.2004

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based controls are important in ensuring effective controls and efficient use of resources.

Benefits of Risk Based Controls

- To ensure effective controls with limited resources/staff, in other words – to allocate resources in areas which indicate high risk and where maximum impact can be expected.
- To provide reasonable assurances as to the level of compliance with feed and food law (AH, AW, PH), effectiveness of official controls – in other words: safety of food.
- To improve public confidence and to justify the allocation of resources – consumers have a legitimate expectation to have relatively high assurances on high risk areas and get good value for public spending
- To contribute to the management of legislative risk i.e. where legislation is in some respect ineffective, to indicate those deficiencies to the legislative process.

Notwithstanding the benefits of a risk-based approach to planning official controls, in practical terms the network members identified a number of challenges and constraints in designing, developing and implementing risk-based planning processes.

Constraints and Challenges

- Balance between consumer, political and economical risks
- Cost-effective way of providing reasonable assurances and increasing compliance by means of effective prioritisation
- Need to have sufficient knowledge of activities to be controlled
- To ensure adequate level of controls in low risk FBO/activities
 - Need to keep low risk operations under review to ensure no significant changes missed
 - New riskier product lines introduced without notification of authorities
- Relationship between central and local authorities
 - Co-operation & integration
 - Intelligence sharing with partners
- Flexibility
 - Determining the frequency of controls (other parameters as well)
 - Adjustment (long term, short term)
 - Suitability for all types of planning at all levels
- Distortion of risk categorisation by media/political/interest group intervention
 - Pressure to relax or to increase control activity on certain sectors or commodities in response to media coverage of issues or lobbying
- Certification requirements are sometimes not compatible with risk-based approach
 - International acceptance of risk-based controls

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While organisational and political risks are acknowledged to play a role in real-world situations, there was some uncertainty over the inclusion of these factors into risk-based planning (as defined by Article 3 of Regulation 882/2004). The same applies to public perception of risks which is an important driving force in the political and legislative processes and in many cases must be factored into risk-based planning. Although these factors may not be always be at the core of risk-based planning it was considered that their potential influence should be acknowledged.

3. Desirable Features of a risk-based system

Desirable features of a risk based system
<ul style="list-style-type: none">• Not too complex a system nor too costly, in terms of resources• Documented system – evidence of decision-making process• Relatively easy to understand for all stakeholders (transparency)• Continuous improvement process• Flexible and modular process

The group agreed that in addition to a clearly defined process for planning risk-based controls it is important that the system/processes are practicable and easily adaptable. They should neither be too complex nor too costly e.g. in terms of resources, nor detract from the overall aim of MS to perform effective official controls. The system should be easily understood by all stakeholders, especially those involved in risk-based planning and those who must assess these processes and it should be documented sufficiently to provide evidence of the decision-making process(es). This is also consistent with the principle of transparency. The principle of continuous improvement should also be a feature of the system/processes.

In considering the desirable features of a risk based system the groups took account of the fact that planning of official controls (including audits) takes place at various levels: national, regional, local and establishment level and that the implementation of these planning processes are up to the Member States to decide depending on their specific circumstances. Account was also taken of the fact that planning activities range from long term strategic and multi-annual programme planning through annual planning and specific programme planning down to planning of individual controls. It was noted that long term planning is usually at a higher corporate and strategic level whereas and shorter term planning usually relates to operational matters and mostly takes place at sectoral and local level.

4. Risk-model for official feed and food controls

In their discussions the group identified a complex matrix of different aspects of risk which the risk model needs to take into account. A risk model based solely on inherent product risk would not meet the legal requirements which require that and "risk" in the context of official controls and in the organisational, political and

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economic environment should be taken into consideration. The risks identified as relevant by the group are set out and defined in the following table.

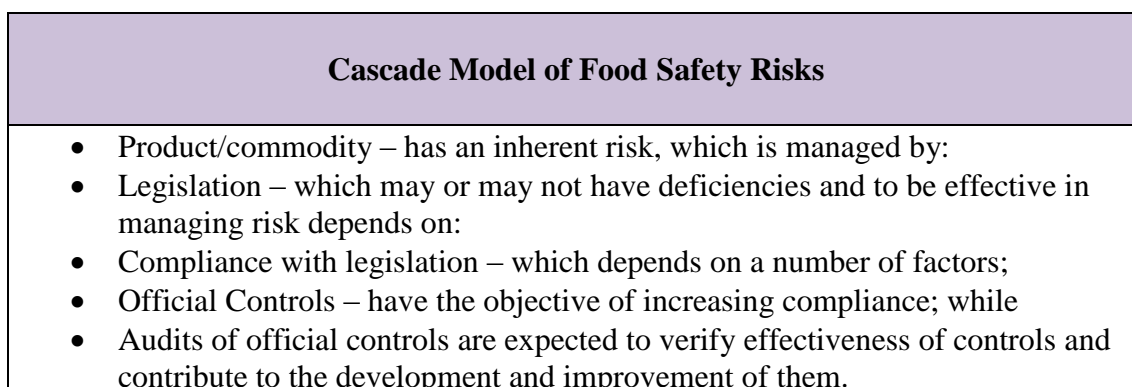
<i>Relevant Risk Types</i>
<p><i>Inherent Product Risk</i> is the probability of adverse effects being caused by a commodity (including live animals and plants) in the absence of any risk management measures – it does not contain the component of "severity of the adverse effect".</p>
<p><i>Legislative risk</i> is the probability of a commodity causing adverse effects provided that all relevant legal requirements are complied with.</p>
<p><i>Risk</i> in the context of official controls is the probability of failure to comply with requirements or detect non-compliance by those who are responsible for either complying with animal health, animal welfare, plant health, feed and food law or for verifying compliance. It can be divided into three components: Compliance Risk, Official Control Risk and Audit Risk.</p>
<p><i>Compliance Risk</i> is the probability of a Food Business or other Operator to comply with relevant legal requirements.</p>
<p><i>Official Control Risk</i> (and similarly, <i>Audit Risk</i>) is the probability of official controls not changing non-compliance into compliance during the course of controls. It is affected by factors such as existence of relevant legal powers, ability to detect non-compliance and effectiveness of follow-up including corrective actions and sanctions.</p>
<p><i>Detection Risk</i> is a component of Official Control Risk and Audit Risk – it refers to the probability of the controls not detecting non-compliance. (ISA 200)</p>
<p><i>Organisational risk</i> – the risks associated with environmental factors. It results from significant conditions, events, circumstances or actions that could reduce a organisation's ability to achieve its objectives and execute its strategies. (ISA 315, business risk)</p>
<p><i>Political risk</i> refers to the complications organisations may face as a result of what are commonly referred to as political decisions – or "any political change that alters the expected outcome and value of a given action by changing the probability of achieving the organisation's objectives.</p>
<p><i>Economical risk</i> is the probability and amount of financial consequences arising from non-compliance or failure to detect non-compliance – may or may not be associated with adverse effects to the consumer.</p>
<p><i>Consumer risk</i> is the residual probability remaining after official controls and audits and refers to the risks consumer faces with a given food safety system. A successful food safety system is able to deliver a consumer risk which is at or below acceptable level of protection.</p>

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Working from this point the group identified a hierarchy of risks that cascade from national to local level, right down to individual establishments. Not all categories of risk apply at every level or in every situation



From this analysis a model which views food safety risks as a cascade of five components is proposed:



Food safety – or as the case may be – animal health, plant health and animal welfare is a cumulative effect or product of all these components forming a serial process, where the net effect is largely determined by its weakest link(s). Managing the overall risk is most effective when the highest risk components can be identified and the most effective/appropriate measures implemented to reduce the risk. Risk based planning of official controls is a process which is trying to achieve this.

5. Components, mitigating and aggravating factors of the main types of risk

In addition to identifying the main components a series of mitigating and aggravating factors have also been identified for each category of risk. These lists are not exhaustive, but could be used as the basis for a checklist of factors that might be considered when determining risk. Again not all factors will be relevant for each level of risk assessment. Factors should be selected as appropriate

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1. Inherent Product Risk		
Components	Mitigating factors	Aggravating Factors
<ul style="list-style-type: none"> • Raw Material Risk: hazards associated, sourcing, suitability to act as a vehicle • Processing Risk: effect of normal processing, critical control points • Production Chain Risk: complexity and structure of the chain 	<ul style="list-style-type: none"> • Well known hazard(s) • Effective and easily implemented protective measures available • Low prevalence of hazard in the production environment • Availability of relatively safe raw materials • Safe sourcing of raw materials is feasible at low additional cost • Single or only few "points of entry" along the production chain • Easy to identify critical control point(s) • Effective risk management measures known and readily available 	<ul style="list-style-type: none"> • Hazard and/or risk mechanisms not well understood (new hazard) • Production process technically challenging, requires specific skills and competences • Complexity of process (PR) and complexity of food production chain (PCR) • Perishable raw materials and/or product associated with a number of potential hazards or hazard-groups • Raw material and/or product associated with multiple hazards
2. Legislative Risk		
Components	Mitigating factors	Aggravating Factors
<ul style="list-style-type: none"> • Protective Measure Risk: validity (effectiveness) of adopted legal measures • Enforcement Risk: 	<ul style="list-style-type: none"> • Extensive and effective requirements with a "multiplicative" effect • "Critical control points" addressed • Wide consultation 	<ul style="list-style-type: none"> • Out-dated requirements i.e. not reflecting real-world situation • Requirements adopted without sufficient prior consultation and

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<p>are requirements possible to enforce, clear designation of CA</p>	<p>of stakeholders leading into "ownership" and commitment to new legal requirements</p> <ul style="list-style-type: none"> • Simple to understand requirements, which are technically easy to comply with • Relatively low cost of complying as compared to non-compliance 	<p>communication</p> <ul style="list-style-type: none"> • Lack of training and/or information available on the practical interpretation of requirements • Scientific basis of requirements not obvious, rationale not communicated to FBO
3. Compliance Risk		
Components	Mitigating factors	Aggravating Factors
<ul style="list-style-type: none"> • Inherent Compliance Risk: (un)intentional non-compliance, cost, respect etc. • Own/Auto-control Risk: ability of own-controls to detect non-compliant product or process 	<ul style="list-style-type: none"> • Good knowledge of rules • Cost of compliance reasonable compared to benefits of non-compliance • Acceptance of rules • Respect for authority • "Social control" • Risk of being reported • Risk of inspection • Risk of detection (if inspected) • Selectivity of controls • Risk of sanction (if inspected) • Severity (dissuasiveness) of sanctions 	<ul style="list-style-type: none"> • History of non-compliance • No positive incentives to comply e.g. official control frequency remains the same no matter what • Lacking or deficient own controls and/or quality, accreditation or certification schemes • Lack of competences / knowledge • Difficult financial situation e.g. low margin of profit • Changes in management or ownership • Negative view of authorities/law

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4. Official Control Risk		
Components	Mitigating factors	Aggravating Factors
<ul style="list-style-type: none"> • Legal Powers Risk: powers to enter, collect evidence, take emergency measures • Targeting Risk: effectiveness in finding the most likely non-compliers • Analytical Procedures Risk: detection of non-compliances or non-effectiveness • Allowed Test-of-detail Risk: level of detail, sample-size • Sanction Risk: are sanctions applied when appropriate, effectiveness of sanctions 	<ul style="list-style-type: none"> • Risk-based controls resulting in efficient use of resources and effective targeting of controls • Effective control procedures • Good analytical procedures • Timely and effective corrective actions • Effective follow-up • Effective, proportionate and dissuasive sanctions combined with timely sanctions, as appropriate. • Accreditation and/or certification 	<ul style="list-style-type: none"> • Unclear designation of tasks and responsibilities • Lack of resources • Insufficient competences and lack of training system • Insufficient documentation of procedures • Lack of clear objectives • Ineffective planning • Overlaps and/or gaps
5. Audit Risk		
Components	Mitigating factors	Aggravating Factors
<ul style="list-style-type: none"> • Independence and Mandate Risk: clear mandate, access and independent, external view • Targeting Risk: random sampling vs. selective sampling – effectiveness of targeting • Analytical Procedures Risk: ability to test effectiveness and suitability 	<ul style="list-style-type: none"> • Good planning (risk based) • Effective audit techniques • Efficient use of resources • Systems approach and sound analytics • Accreditation and/or certification 	<ul style="list-style-type: none"> • Long term plan missing • Compliance focused techniques • Low degree of transparency • High turn-over rate of staff

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<ul style="list-style-type: none"> • Allowed Test-of-detail Risk: level of detail and extent of sampling • Follow-up Risk: effectiveness of follow-up, corrective actions by the auditee 		
<p>6. Consumer Risk = the residual risk consumer is exposed to after the previous layers.</p>		

6. Implementation of a risk based planning system

"In order to have a risk-based planning process in place, three elements need to be clearly identifiable: inputs, process and outputs."

Overall it was agreed that systems based on the Input – Process – Output principle represented "best practice" of the models considered.

The groups agreed that the same principles apply to both those the implementation of a risk based planning process and those who need to evaluate that process in the context of internal or external audits. However, although principles are shared and the framework is similar for NAS audits and other types of official controls, it is important to recognize that the inputs, process and outputs are somewhat different. Where applicable the differences in these elements, identified by the group are highlighted in the following sections which summarise the outcome of the discussion on the practical application of these principles.

6.1. Input

Input to the risk-based planning process is divided into four broad categories: entities for categorisation, features of those entities, control parameters and criteria (or rules) for categorising entities and assigning control parameters for the categories.

Entities for categorisation

One of the first steps in a risk-based planning process is to decide which entities to categorise. Although it is common practice to focus mainly on the categorisation of types of establishments/CA, the FBO/CA are not the only entities that could be assigned to various risk-categories if cost-effective controls are to be applied. The following list provides examples of entities, which could be the subject of a categorisation exercise:

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Possible entities for categorisation

- Commodities or groups of commodities;
- Hazards (largely a policy choice) or [Hazards matter of scientific evaluation not policy choice?];
- Various stages in the production chain;
- Types of establishments, activities or processes;
- Operators, Competent Authorities (organisations, individuals);
- Requirements of the AH, AW, PH, feed and food law

This list is not in any particular order of importance, nor does it imply that all of the entities need to be considered every year at every level.

The entities mostly considered for NAS audits are in most cases the Competent Authorities and/or their control processes. However, in order to implement a from-farm-to-fork approach and identify gaps/overlaps, it may be necessary to consider other entities as well e.g. production chains, legal requirements or hazards.

Features

In order to reach a meaningful categorisation, the process needs to choose and take into account a set of key features of the selected entities. In most cases those features would be mitigating/aggravating factors of risk components or alternatively, indicators closely related to them. Some typical features and/or sources of data are:

Possible Features and Data Sources

- Import/export data (Production Chain Risk)
- Trading patterns, structural data (Production Chain Risk)
- Volume of production vs. raw materials (Processing Risk)
- Market or other surveillance data (Compliance Risk, Official Control Risk)
- Rapid Alerts (Compliance Risk, Official Control Risk)
- Scientific evidence
- Pricing, advertising, labelling (Inherent Compliance Risk)
- FBO records (Auto-control Risk)
- quality of operators own-controls including, but not necessarily, accreditation and certification schemes
- Results of official audits of FBO HACCP systems
- Changes in management or ownership (of FBO or CA)
- Annual reports and associated critical assessment of controls
 - Importance of deadlines for reporting and alignment of reporting periods
 - Identify sectors with persistent non-compliance problems (Compliance Risk, Official Control Risk)

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Most of the time NAS focus on CA-specific features but from time to time other sources of information (e.g. RASFF, scientific evidence, and surveillance data) may give rise to the need of planning NAS audits that cover areas where two or more Competent Authorities are involved. Cross-cutting issues like coordination or training could then emerge as risk-factors instead of the features listed above.

Control Parameters

The third type of input is a set of control parameters to be used in the outputs of the process. These need to be chosen before the actual process of assigning parameters to entity categories can take place. Examples of control parameters:

Control Parameters
<ul style="list-style-type: none">• Control frequency or maximum time between two controls;• FTE used for each control, sector or type of operator/CA;• Scope of the control i.e. are all aspects of an operator/CA to be covered;• Control methods and techniques e.g. inspection, sampling, (desk?) audit etc.• Full control or a control based on a sample (of documents, processes etc.)• Legal requirements to be covered (all relevant rules or a sub-set)

These control parameters are equally applicable to NAS audits and other types of official controls.

Criteria for categorisation and setting control parameters

Finally, criteria (thresholds, sums or some sort of algorithm) are needed to process the set of features for each (instance of an) entity and place it in an appropriate risk category. Instead of having established a fixed set of risk-categories, an alternative approach could be the ranking of entities according to a scoring system and selecting some proportion of highest scoring entities for controls. Similarly, criteria/rules need to be established for assigning control parameters to risk categories.

These inputs should be documented at a level sufficient to an external (uninitiated) reader to understand the inputs and preferably providing some degree of justification or rationale behind the choices.

6.2. Process

Several processes may be needed, for example: at national, regional and local level. At national level a process may consider e.g. Inherent Product Risk, Legislative Risk and Inherent Compliance Risk while at regional and local level some components of Inherent Compliance Risk and local knowledge on Own/Auto-control Risk may be more relevant. The scope of planning may also vary between these levels i.e. which sectors are included in the planning process.

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As regards NAS audits, the legal requirement/obligation to have internal or external audits is at the level of the individual Competent Authority. However, there is a general requirement to coordinate between Competent Authorities and CD 2006/677/EC provides further advice: "where more than one audit programme is envisaged within a Member State, steps should be taken to ensure that such programmes are effectively coordinated, so as to ensure a seamless audit process across the relevant competent authorities". This implies that risk-based planning for audits should preferably have a national component/process – also in Member States with de-centralised NAS.

At all levels the process(es) need to have resources allocated (including working groups, task forces etc.), methods and procedures to be applied and all of these should be documented in order to demonstrate the existence of a process. The documentation should be sufficient to verify that the process is using inputs, it is implemented in a consistent way and it produces output(s) which feed into the control processes with some observable effect.

A wide variety of methods and procedures can be used depending on the resources, organisation of the Competent Authority, structure of industry and other local conditions. A commonly used simple implementation of the process is to use sector specific categorisation of Food Business (or other) Operators and assign a predefined control frequency for each category. The process in itself is less labour-intensive than more elaborate approaches but to some extent fails to use the full potential of saving resources by utilizing other control parameters such as control methods, scope and level of detail.

6.3. Output

The output is essentially a mapping between entities and a (set of) control parameter(s) or in other words: (1) targeting of controls and (2) applying the most appropriate methods/frequency to the target groups. At national level of planning this could take the form of allocating resources into certain control areas either in absolute FTE terms or in percentages or possibly some kind of principles and/or guidance to be applied locally. Output from this level would typically feed into another prioritisation process at a lower level. At a more local level the mapping may be between individual establishments and for example control methods and frequencies.

Control parameters are meant to steer the frequency, intensity, scope, methods, selection criteria or other factor having an effect on the probability of detecting non-compliance where its occurrence is most likely. The main objective is to minimise the Detection Risk Component. In most cases it is desirable to select the parameters with a view of optimising the use of resources as well as managing the Audit or Control Risk.

In order to be effective, the outputs should be unambiguous and practical enough to have the desired effect on the controls. Desired effect in this context means effective targeting and use of resources. Effective targeting means focusing control resources

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on high risk areas and operators/CA which are most likely to be either non-compliant or ineffective in their compliance while maintaining sufficient level of controls to provide reasonable assurances of compliance in lower risk areas.

The outputs of long-term planning tend to be more stable and differ from short-term priorities. It is therefore important that flexibility to adjust short-term priorities should be built in to the system adopted.