European Organic Certifiers Council

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EOCC Task Force Risk Assessment
Final report

Risk-assessment in organic certification:

A snapshot of the current implementation and further perspectives

A report by EOCC Task Force Risk Assessment composed of
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EXECUTIVE SUMMARY

This report was drafted by between June 2015 and January 2016 by a Task Force of the *European Organic Certifiers Council* (EOCC).

On the basis of an analysis of the existing legislative framework (Chapter II), a desk study (Chapter III), a survey (Chapter IV) and exchanges of experiences among the participants (Chapter V), the Task Force Risk Assessment identified common patterns and best practices and made recommendations, which are available in Chapter VI.

Risk-Assessment has been identified as a comprehensive approach, which requires the awareness of all actors involved, and especially operators, control bodies and inspectors, authorities and accreditation bodies. It is based on a systematic and comprehensive risk management by the operators participating in the control system. Attention of control bodies should be paid well beyond inputs (which are the – potential – risks, how to translate them into appropriate criteria, how are they identified and weighted?) to cover also outputs (what does a risk-classification mean for the frequency, nature and intensity of controls and other outputs, what are the appropriate tools to be put in place?). Authorities and accreditation bodies should also participate in this system with a risk-oriented surveillance approach well defined.

EOCC considers this report as a progress report. We would like to take the opportunity of the report's publication to initiate a debate with all stakeholders involved in the organic production chain. We therefore hope that you will enjoy the reading but, more importantly, that you will come back to us with thoughts on how to improve jointly risk assessment tools and methods.

Fabrizio Piva
EOCC President

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Co-ordinator of Task Force
Risk Assessment

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1 Introduction and origin of this work

After a decision by the General Assembly in April 2015, the EOCC Board adopted in May the proposal to launch a Task Force on Risk Assessment.

Following goals were assigned to this working body:

- **exchange experiences and lessons learned** among EOCC members in relation to the application of risk assessment in the different EU member states

- elaborate a **corresponding report containing recommendations for more effective and more harmonized application of intelligence** and development of available capacities at the level of EOCC members

- provide for a background information which serves as a solid **basis for EOCC involvement in policy work** in relation to risk assessment in the organic sector in the EU

The Task Force Risk Assessment was composed of following members:
- Jan Hoekman, co-ordinator, Skal Biocontrole
- Gerald Altena, Debio
- Jochen Neuendorff, GfRS
- Tom Nizet, Certisys
- Jérôme Viel, Ecocert France

The Task Force worked between June 2015 and January 2016 to produce this report to the attention of the Board and members of EOCC. Its members had the occasion to meet twice, on October 8 and 9 at Skal in Zwolle and on November 26 and 27 at Ecocert France in L'Isle Jourdain in order to exchange on the practices of their respective CBs and the orientations of the report. Further exchanges took place via e-mail and telephone conferences. The EOCC Board would like to thank the participants for their investment in this work as well as their employers for having made them available for this work and for having accepted to open in a very transparent way their risk assessment tools. Special thanks are reserved for the EOCC Representative for her all round support.

This report was endorsed by the Board on February 4, 2016.

2 Legislative frameworks: EU and national requirements

The European regulatory framework for the risk assessment by organic control bodies (CBs) and authorities (CAs) is defined by horizontal provisions on controls on the one hand (Regulation 882/2004) and specific requirements for the organic sector on the other hand (Regulation 834/2007 and Regulation 889/2008). The applicable articles of the relevant European Regulations are available in the annex.

The European Commission also adopted in 2011 guidelines on the implementation of these Regulations[1]. Although having no legal value in itself, the document helps understanding the European Commission's approach and expectations regarding controls in the organic sector. Amongst other elements, the Commission underlines or specifies following aspects of the Regulations:

- that the risk of non-compliance of each operator should be determined on the base of "objective methods";
- The minimum criteria to be included in the risk assessment are (1) "the results of previous controls", (2) the quantity of products concerned" and (3) the risk for exchange of products". A non-exhaustive list of other possible criteria/aspects to be taken into account is also available;
- that the result of the process should be "quantified", for example "translated into points". Operators above a certain level of points (and at least 10% of all operators in each Member State) should receive an additional control visit;
- that for operators receiving an additional inspection, the latest is expected to be targeted at high-risk areas;
- that the Commission expects the documentation by control bodies and authorities of their risk analysis and their implementation;
- finally, that the competent authorities are responsible for reviewing and monitoring the procedures and making sure that all the CBs operating in the same Member State have harmonized procedures.

In addition to these European provisions, additional requirements have been put in place at national level – or even regional level in some federal Member States. Examples of national rules control bodies have to comply with are detailed in Chapter IV. They might for instance set higher objectives for the number of operators to receive additional inspections or for samples to be taken (respectively 10% and 5% in the European legislation), or ask control bodies for a specific focus on some kind of operators/products.

3 Outcomes of the desk study

3.1 General principles

The following principles, written in 1976[2], are still very relevant:
(1) risk can never be completely eliminated
(2) care and effort can reduce risk, and
(3) efforts to reduce risk should achieve maximum possible benefits.

This is represented by this widespread formula of risk:

*risk = likelihood * consequence*

Risk-based inspections are used to prevent the occurrence of incidents. A control authority/control body (further CA/CB) shall be independent, unpredictable, strict, righteous and alert[3].

[1] Working document of the Commission services on official controls in the organic sector
[2] Practical Risk Analysis for Safety Management, 1976

3.2 What is a risk?

Beside the definition of a risk there are always risks that cannot be measured. Control bodies and authorities and operators have to deal with uncertainty (they know what would be the effect of a certain risk, but they do not know when and how it occurs), nescience (one cannot know what one does not know) and indeterminacy (causal relations between incidents are undetermined)[4]. It is therefore recommended to investigate and to adapt to the lessons learned, to exchange views with sector specific experts or to participate in research projects with specific links to the integrity of the organic products.

Four questions help defining a risk[5]:

1. What is the likelihood?
2. What is the consequence?
3. What is the expected development?
4. What is the political and social sensitivity?

In the organic production process, these risks can be evaluated at 3 different levels:

1. Operator
2. Control bodies and authorities
3. Inspectors

The organic Regulations use the terminology "the general evaluation of risk for non-compliance with the organic production rules (art. 65.4 of Reg 889/2008) and "the nature and frequency of the controls is determined on the basis of an assessment of the risk of occurrence of irregularities and infringements as regards the compliance with the production rules laid down in the organic regulation" (see Art. 27.3 of Reg. 834/200). In addition to the performance of annual verification of compliance for all operators, CBs organize additional controls to verify the integrity of organic products in critical point of the process. This is done by using different techniques and methodologies.

From the operator's point of view, being considered as an operator with a higher risk classification results in being subject to additional controls and other measures which are targeted to critical aspects.

3.3 Risk awareness of the operator

The Task Force members consider that operators should pay the utmost importance to the relevance of their own risk awareness. There is only little literature on the operators' declarations (Art 63.2 of Reg. 889/2008). Control bodies have to make their registered processors aware of the Organic Control Points (Art. 26 of Reg. (EC) No. 889/2008). The operator itself has to think and act on its specific risks. If an operator cannot show its specific risks, it is a risk in itself[6].

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[3] Goed Toezicht, Dick Ruimschotel

[4] Aan tafel: *Een onderzoek in opdracht van vno-ncw en mkb-Nederland naar publiek en privaat toezicht op bedrijven*

[5] Inspectie Sociale Zaken en Werkgelegenheid, The Netherlands

[6] Actieplan Aan tafel (LTO, VNONCW, MKB-Nederland)

While the European legislation sets a specific framework for processors in Art. 26.2 of Reg. 889/2008 ("*Operators producing processed feed or food shall establish and update appropriate procedures based on a systematic identification of critical processing steps*"), other operators are so far not covered by such provisions. The Task Force considers that it would be appropriate to extend this measures to all operators.

Operators producing processed feed or food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.

During a joint EOCC-IFOAM-EU workshop on September 2, 2015 in Brussels the need of an adequate risk awareness of the operator regarding the Organic Control Points was underlined by all participants.

3.4 Risk classification of an operator by the control body

If a CB defines the risk criteria, it can calculate the risk points of an operator. This calculation has to be done every year[7] for every operator. CBs should be aware of the possibility that more operators than expected can be part of the high-risk category. This means that their enforcement tools (unannounced inspections, crosscheck, sampling etc) must be used more than expected (relation with CB costs and manpower). The lack of inspection capacity in specific geographical areas or periods of the year should not intervene in the risk classification of an operator.

CB's have to evaluate their risk criteria (are the criteria used for the risk assessment still relevant) and the amount of points given to the specific criteria on a frequent way, based on previous years' experiences. CBs should check whether or not the outcomes of the calculated risk classification are in line with the expected outcome. EOCC recommends to check it with different operators in different risk categories.

The European Commission wrote down in its document from 2011[8]: In practice each operator should be assessed against pre-defined risk criteria. The result of the assessment needs to be quantified, e.g. translated into points. The scoring per each criterion can be for example as follows: 0 – no risk, 1 – low risk, 2 – medium risk, 3 – high risk. In the end, the total amount of points per operator is calculated. The operators with a total amount of points exceeding a certain amount are to receive an additional control visit. The control body or the control authority needs to define from which level of points they consider an operator to represent a higher risk.

3.5 Useful risk-criteria for control bodies in the organic sector

In the organic Regulation 889/2008, the following criteria are mandatory to determine the level of risk for non-compliance for operators:

[7] Risikobasierte Zertifizierung im ökologischen Landbau: Ableitung verbesserter Strategien auf der Grundlage der Daten großer deutscher Kontrollstellen

[8] Working document of the European Commission on official controls in the organic sector, Version 8 July 2011:http://ec.europa.eu/agriculture/organic/documents/control-bodies/controls-working-document-20110708_en.pdf

Article	Description
Art. 65.4	Non-conformities from earlier inspections
	Amount of organic products
	Only organic production or mixed production (conventional and organic)

In addition, in its working document addressing EU provisions on official controls in the organic sector[9], the European Commission indicates that depending on the characteristic of the organic market in a given region, it might be necessary to take other risk criteria into consideration. Possible additional criteria are listed:

"- type of operator (producer, processor, importer, distributor);
- structure of operator (stages of production, type of staff, number of premises);
- new operators;
- operators with mixed production / processing;
- type and value of products;
- rapid increase of production;
- complaints / denunciations received;
- suspicion of fraud;
- other criteria"

Based on input by several control bodies and authorities, other possible risk criteria were identified. Their impact should be carefully evaluated and validated in particular contexts before they are used. They cover for instance:

Operator's size /complexity	Parcels in conversion	Motivation of the management to confirm to (other) regulations
Amount of hectares	Cultivation of vegetables	Gut feelings of the inspector, related to the company
Risky animal productions	Financial health of the company	Type and value of the product
Operator type	Complaints and denunciations	Suspicion of fraud
A lot of new (unknown) suppliers	A strange ratio between price and quality of the product (low price for organic products)	A lack of a specific product in the market
Rapid increase of organic production	product in third countries (import outside EU)	Often parallel production
Failure to identify / register treatments on crops and animals	Use of GMO materials	Group certification
Contamination with cleaning / disinfection / pest control substances	Products whose labels / characteristics are easily changed	Processor is not producing under its own brand

[9] European Commission, Working document of the Commission services on official controls in the organic sector, Version 8 July 2011: http://ec.europa.eu/agriculture/organic/documents/control-bodies/controls-working-document-20110708_en.pdf

Complex or long production chain	Quality Assurance systems are not matching to each other	Many changes in the management team
Compliance management not applied (ISO 19600)	Risk management not applied (ISO 31000)	Does the operator have a sample taking plan?

In any case, **risk criteria should be determined on the base of objective criteria and need to be validated in practice prior to their application**. They should also be easily computerized. It is not useful to establish more and more complex matrices for risk-classification without a clear, objective proof that these factors have an influence on the risk level of an operator.

3.6 Risk management by inspectors during inspections

The risks in the organic production can be determined at several levels: strategic level (for instance boards, authorities), operational level ((management) team, choice of instruments…) and execution level (inspector). The inspector is the one who has a direct contact with the inspected operator. For him/her, the recognition/knowledge of risks related to organic production at the inspected operator is a crucial skill. Inspectors must focus during their inspections on the most relevant risks for organic integrity in a particular operation. They should use the operator declaration and – in case of processors – the preventive measures according to Article 26 of Reg. (EC) No. 889/2008 for this purpose. In particular in the event of identification of non-compliances, the inspector has to be able to assess the impact of the situation as a whole and initiate the adequate procedure to block or event downgrade the products affected by the non-compliances. Control bodies and authorities have to instruct and train inspectors regularly on these skills[10]. The Task Force considers that regular training and examinations combined with a witness audits are appropriate tools to increase the inspector's competence.

4 Outcomes of the EOCC survey

A survey conduct by EOCC in August and September 2015 among 8 of its member control authorities and control bodies allowed to gain a better insight of their risk assessment methodology.

The survey allowed to highlight following elements:

- 100% of the respondents apply risk-assessments on their operators;
- Respondents mentioned one to 10 parameters as criteria of their risk assessment tool. They cover the history of the operator (newly registered operators, history of non-compliances…), its nature (type of activity, mixed production, other certification schemes…), its structure (complexity of the enterprise, number of suppliers, size, turnover, number of products…), its

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management (quality of the management system, of the record keeping…), and subjective factors (motivation of the operator, auditor's intuition…)

- The survey showed three types of risk classifications following the risk-assessment:
  1. Most respondents have a division of their operators into risk categories (high/medium/low);
  2. Some respondents assign a score or note to each operator;
  3. Some outcomes directly assign a number of additional controls/sample takings to each operator

- Next to additional controls/sampling for high risk operators, some CBs mentioned visits by senior auditors as a result of their risk assessment.

- Most respondents mentions that the accreditation body has a yearly check of the risk assessment system, mostly during the surveillance audit.

5 Risk assessment at control body-level

5.1 Certisys

The risk-assessment of Certisys described below is applicable for Belgium and Luxembourg.

5.1.1 Concept of Certisys' risk assessment

The risk assessment is a method based on **objective criteria**, which takes into account the **specific requirements** of competent Authorities regarding additional controls in Belgium to determine the **number of additional inspections** to be conducted and a number of **samples** to be taken for each operator during one calendar year.

The risk assessment does **not influence the content and the nature of the annual verification of compliance**. Additional controls and sample takings, organized in the **context of suspicions or irregularities** are neither taken into account in the planning of additional controls and samples, nor in the reporting about the application of the risk assessment. Such controls can be reinforced controls (related to particular irregularities in the catalog of measures), cross-checks or other exchanges of information with other control bodies.

The risk assessment is done **once a year** in December by a computerized system. The planned output is **discussed with inspectors**. **Adjustments** according to the inspector's opinion are possible. **Swopping** controls and/or samples during the year are also feasible. Inspectors are informed on a monthly basis of the (quantitative) progression of the risk assessment.

Operators having notified mass catering activities are **automatically subject to an additional inspection**. On the other hand, operators whose activity concerns only

backing off in combination with retailing of prepackaged goods are **not included in the risk assessment.**

In general, additional inspections are **unannounced** inspections. The inspector **choses** the subject and timing of the additional inspection and sampling. The Certisys control manual provides for background information to make such choices.

The assessment itself is based on the **weighting of all relevant factors available in the Certisys database**, which are obtained during the controls and supplied by the operators themselves. The algorithm to determine the weight of each factor in the assessment is the result of trial-and-error of several (> 5) years. Regarding the **history of the measures/sanctions**, information going back over 5 years is taken into account (N-1: according to a table taking into account different measures; N-2:50% of the value of N-1; N-3: 33%; N-4: 25% and N-5: 20%)

Based on the current risk assessment and data about irregularities found during a particular year, the statistical evaluation shows that there is **no correlation between the annual evaluation of risk of each operator and the non-compliances found**. This means both that the operators where non-compliances were found were not all initially considered as being risky operators in the risk assessment and that the operators which were considered as risky are able to correct and improve in such a way that no non-compliances are found during the next inspection. The most important conclusion to be drawn from this statement is probably that it is crucial to maintain a continuous and minimum "control pressure" on all operators. The current application of the annual verification of compliance covering all aspects of the Regulation for all operators is a crucial tool for the identification of any kind of non-compliances (related to production rules but also to labeling rules).

The risk assessment approach is found to be **useful to accelerate** the finding of irregularities and apply measures like those mentioned in Art 30.1 of Reg 834/2007. However, **identification of fraudulent operators** requires additional, different and subtler information and evaluations.

Finally, the effectiveness of the risk assessment is highly influenced by the **competence of inspectors**: the more detailed the information supplied by the inspector to the certification department, the better the decisions (measures) and the impact of those decisions. The creation of the list of operators with highest risk of non-compliance is the result of a task -conducted at the end of each December- giving particular weight to available data for each operator. Once this is done, inspectors are invited to pay attention to any kind of risk occurring during the on-the -spot investigation by determination of the impact of irregularities found

5.1.2 Implementation

Criteria used as input for the risk assessment to determine the amount of additional controls and samples per operator are the following:

Additional controls*	Sample takings*
History of the non-compliances (decreasing weight from N-1 till N-5)	History of the analytical results (and subsequent decisions) (decreasing weight from N-1 till N-5)
Factor NOP (reducing risk level)	

	Date of notification
	Use of a spraying device dedicated exclusively to organic production (risk reducing factor)
Date of the last inspection	Date of the last sample taking
Mass catering (automatic additional inspection)	
Mixed operations	
Type of crops produced (farmers only)	
Number of suppliers (not for farmers)	
Type of certified products	
Volume of organic products placed on the market	
Growth rate	
Complexity of the operator's activity	
Absence of organic sales (farmers only) (reducing risk level)	

** more detailed information about the weight determination and individual importance of each factor in the algorithm can be requested via tom.nizet(at)certisys.eu*

The assessment takes into account the requirements from the Competent Authorities to

- conduct a minimum number of additional controls and take a minimum number of samples in the year N which cannot be less than 60% of then the number of operators under control of the CB at the first of January of this year N.
- conduct an additional inspection for every operator at least once every 4 years.

The outcome of the risk assessment per operator is the set of two numbers representing the amount of additional inspections to be conducted and the number of samples to be taken. The total number of additional inspections planned and samples to be taken exceeds the required legal minimum. Certisys management decided that one operator should not be subject to more than 10additional controls or samples yearly.

Currently, the operators evaluated as operators with the highest risk-level are those operators who place great volumes of organic products on the market.

5.2 Debio

5.2.1 Concept of Debio's risk assessment

Debio has two kinds of risk assessments:
a. Risk assessment after annual inspection based on fixed criteria
b. Risk assessment by the inspector

- Risk assessment after annual inspection based on fixed criteria

The annual risk assessment of the operator is based on a questionnaire filled out by the inspector directly after the annual inspection. As a consequence, risk assessment is carried out continuously. The questionnaire contains questions about characteristics of the operator, and each question has different answer-options linked

to a number. The numbers are summed and when the sum is over the action- limit, it triggers an additional inspection.

The items of this questionnaire are based on the requirements from the regulation and inputs from the inspectors. They are revised annually.

In agriculture, questions concern the type of business (organic/conversion/mixed), the type of sales (local/national), changes, the nature of the operation (simple/complex), parallel production characteristics, purchasing of inputs, quality system, documentation, deviation history.

In processing and imports, questions refer to the type of business (organic/parallel), changes or stable (new), type of activities, number of products (few with no changes, many changing frequently), providers (regular, spot), production site (separated/shared), risk of GMO contamination, deviation history.

- Risk assessment by the inspector

The inspector can decide about additional inspections when he or she thinks this is necessary. The only requirement is that the inspector needs to give the reason for this additional inspection. The type and focus of the inspection is decided by the inspector. The number of this kind of inspections is dependent on the working situation for the inspector.

5.2.2 Classification and output

As a consequence of the EEA agreement between Norway and the European Union, Norway is part of the EU internal market as regards trade in organic products. The organic regulations are part of the EEA agreement, and are fully implemented in the Norwegian regulation. Due to the system of the EEA agreement, it takes some time before new EU regulations come into force in Norway. For the time being, it is still Regulation 2092/91 that is implemented in Norway. As a consequence, the number of additional inspections is still quite low in Norway (ca. 5 %).

5.3 Ecocert France

5.3.1 Concept of Ecocert's risk assessment

The risk assessment process is based on operators' risk criteria based on Reg. (EC) 834/2007 and specific requirements by national authorities. It is complemented by others risk criteria selected each year based on results of the previous year's inspection plan.

Each operator is inspected at least annually. The risk assessment process determines at the beginning of the year for each operator a minimum number of additional inspections as well as the sampling frequency. Specific investigations related to the operator profile are requested for these additional inspections. In general, additional inspections are unannounced inspections.

With this process, at minimum 10% of additional inspections and sample takings are assigned at the beginning of the year. As National Authorities require more than 10% of additional inspection per year (up to 100% for processors), other additional inspections are selected during the year:

- by inspectors based on their own risk assessment: they have to motivate and record risk criteria for each additional inspection and sampling;
- by certification and analysis officers based on results of inspections, alerts and external information.

5.3.2 Implementation

At the beginning of each year, a specific operator risk review is managed by the Risk Manager with the participation of the Evaluation and Certification Managers. This review is based on an appraisal of the main issues which occurred in organic production during the past year (alerts, frauds, pesticides...).
During this review:

- results of the annual risk assessment process are evaluated (type, number of deviances and analysis results);
- risk criteria are updated depending on these results;

After the review, an operator risk note is calculated for each operator based on specific risk criteria.
In 2015, criteria used as input for the risk note calculation of operators are the following:

Internal operator characteristics (size, locations, subcontractors)
Parallel production
Previous irregularities and infractions in the past year
New operators (less than 3 years)
Exemptions

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Products and activities:
Those criteria are not directly integrated in the risk note calculation of operators. Each year, there is a selection of specific products and activities with higher risk based on irregularities of the past year. For the riskiest activities and products selected, more than 10% of additional inspections are assigned.

5.4 GfRS

5.4.1 Concept of GfRS' risk assessment

The risk assessment is a method based on **specific criteria** based on the **specific requirements** of Reg. (EC) No. 834/2007 and its implementing rules, the corresponding EU guidelines and the corresponding national legislation.

The concept of risk assessment at GfRS is designed to work on three levels:

I. Operators
All operators must deliver a description of the production unit including specific measures to comply with Regulation (EC) No. 834/2007 (Article 63 (1 b) of Reg. (EC) No. 889/2008). This description is updated in a regular frequency whenever substantial changes take place. Processors and feed mills must deliver additional procedures according to Article 26 of Reg. (EC) No. 889/2008, in particular No. 2 and 4 of this section.

II. Inspectors
As GfRS is obliged to implement a systematic competence management for its staff and inspectors according to Point 6.1.2 of ISO 17065, systematic and targeted trainings need to be conducted in order to enable staff officers and inspectors to systematically focus on critical aspects on operator level during inspections.

III. Reviewers/Certification officers
All operators are classified in different risk categories annually during review. This classification is checked during the certification decision. All operators are at least inspected annually. The risk category determines the type of annual inspection (unannounced/announced, their frequency (1-4), the sampling frequency and the frequency of cross checks).

5.4.2 Implementation

I. Operators
The formats for the description of the production unit foresees an open text box which needs to be filled in by the operator and which defines specific measures.

For processors and feed mills, a form is available detailing examples of critical points during the production process as well as exemplary preventive measures. A guide was developed on behalf of one federal state showing how to implement the concept according to Article 26 of Reg. (EC) No. 889/2008[11].

II. Inspectors
A curriculum for risk-based inspections was developed in the Leonardo-project IRM Organic[12]. GfRS is using the output of this project actively. A performance review is conducted annually for each inspector and reviewed prior to the design of trainings by internal trainers.

Internal trainer teams are appointed prior to each training. They are responsible for the proper design and implementation of the particular inspector training, taking into account risk management during inspections based on the operator documentation. The trainings became more and more interactive in the recent five years and actively use contributions by the inspectors.

III. Reviewers/Certification officers
Reviewers/Certification officers conduct once a year, if required because of irregularities occurring also additionally during the calendar year, the risk classification of operators. The result of this risk classification is documented in the database.

In general, additional inspections are unannounced inspections. Either inspectors are ordered by certification officers to focus on specific risk areas or they act according to their own choice, based on the information in the operator file, which is always handed out completely to the inspector.

Criteria used as input for the risk assessment are the following:

[11] https://www.umwelt.nrw.de/fileadmin/redaktion/PDFs/landwirtschaft/OCP_Broschuere_NRW.pdf
[12] www.irm-organic.eu

Internal operator characteristics (size, complexity, staff turnover, supplier stability, subcontractors)
Parallel production
Market relevance of the operator
Liability risk of the operator
Type of certified products (shelf-life)
Previous irregularities and infractions in the past three years
Implemented quality management system (reduces risk)

The output determines type and frequency of inspections, the sampling and cross checks frequency.

In 2014, GfRS started to compare the cases of severe infractions and irregularities detected annually with the risk classification of the same operator. A tendency seems to be that the only factor determining the risk of severe infractions and irregularities is the history of non-compliances. This goes in line with the results of the CERTCOST project.

An issue gaining more and more relevance within risk assessment and management is the sanctioning policy: GfRS focusses on a quick reaction for "low-level sanctions" in case of deviations detected during inspections, based on the opinion that this makes operators aware of requirements and draws their attention to the EU-legislative provisions. Regular team-meetings for severe irregularities and quick follow-up are held since three years.

5.5 Skal Biocontrole

5.5.1 Concept of Skal's risk assessment

Skal has two types of risk assessment:
- Risk Assessment of the operator
- Risk Assessment of a specific sector / production chain

I. Risk Assessment of the operator
The risk assessment of the operator is done once a year. On the basis of weighed criteria, Skal has developed a query in the database which presents in a descending order the operators with the highest risk level.

For the operators with the highest outcome, an additional inspection (and if relevant an additional sample taking) is scheduled. Beside the inspections based on risk calculation, Skal executes 100 additional inspections at newly registered operators. The operators involved are randomly selected two times a year (in February and July over the half year before).

Every half year, Skal defines the three points of the regulation (per sector production and processing) for which the most non-conformities where found. Skal executes 200 additional inspections on these specific points at the operators of these sectors.

All additional inspections are determined by the certifiers. The inspection itself is scheduled by the central Planner.

II. Risk Assessment of a specific sector or production chain
The team of Certifiers defines, based on information they get, which sectors, chains / parts of the regulation can be risky at certain periods of the year. This decision is made on data like inspection reports of the inspectors, signals given by the inspectors beside their reports, information of other CB operating in the organic sector, information of the Food Safety Authority and the Customs or local authorities, notifications of companies who are registered by Skal, notifications of stakeholder organizations and consumers, media, etc.

This is a continuously process: in quarter 3 of the previous year the certifiers start analyzing and defining sectors, and this process will be continued during the year. Every two weeks, the team of Certifiers meets together to discuss the progress and possible new items. Every Certifier is responsible for one or more risk items.

5.5.2 Classification and output

Skal developed a tool to start in 2016 in order to calculate the risk points of each organic operator. In this calculation the following criteria are taken into account:

Non-conformities of the last two years (divided by severity)
Turnover in organic products
Only organic production or organic and conventional production
Company type (agricultural, import, processing, trading, storage)
Amount of certified organic products
The operator is part of a Dutch organic quality program (reduces risk)

Examples of sectors production chains which are involved with additional inspections and/or samples are:

- Growing of ornamental flowers
- Use of pesticides and allowed seed material
- Use of dry and clean litter in winter period
- Surface of outdoor area for poultry (measuring)
- Import
- Stock registration of processing companies

The output for 2016 is 700 additional inspections (not included the re-inspection based on a major non-conformity) and 300 samples. These additional inspections and samples have to be taken on unique companies as if more than one additional inspection is executed at the same operator, the amount of additional inspections becomes higher.

The minimum requirements for the number of additional inspections and samples by Skal are the ones required by the European Regulation: 10% of additional inspections and 5% of samples. For 2016, it is foreseen to execute an additional inspection at 18% of the operators and samples are 8% of them.

6 Good practices and recommendations

6.1 Control body-level: Examples of good practices

Based on the desk study, the outcome of the EOCC survey and the CBs practices analyzed in this study, the Task Force elaborated the following recommendations for CBs:

- Create more relevant operator's declaration forms to evaluate risk awareness of the operators. Document the system according to Article 26 of Reg. 889/2008 for processing units in your operator files;
- Work more on the output of your risk assessment: what to do during additional controls and when to do additional controls?
- Do not focus only on one instrument (additional inspections), as other tools as sampling and cross-checks are sometimes more relevant;
- Do not focus on a risk assessment which is only based on the risk classification of the operator. During the year, a lot of signals of possible incidents happen. Create a structure to analyze and include them into your risk assessment system.
- Be aware of the fact that the first signs of non-compliance can be determined by your inspectors. Invest in a good and adequate training scheme to be sure that they will see the right things at the right moment;
- Contact and inform your National Authority and the Accreditation Body about your risk assessment. Discuss the criteria and the outcome with them.

6.2 EOCC level

During its works, the Task Force Risk Assessment identified the following recommendations for the EOCC-Board:

- Initiate works on the risk assessment at operators' level. All operators must know where they have a risk concerning the organic status of their company/process/products. Invite the sector, for instance via IFOAM-EU, to take part in this process;
- Work on an improved system for the operator declaration and for the system of organic critical points and discuss it with operators and relevant stakeholders;
- Facilitate the identification of critical periods of risks for specific productions/crops by CBs, for example in views of establishing calendars;

- Think over how to present this outcome to as many CBs as possible;

- Facilitate a workshop to share the results and discuss other options. Invite CBs who are not EOCC members and/or not active in the organic sector.

6.3 Perspectives for further development of risk assessment

- In the framework of the current revision process of the organic Regulation, and as it considers the operators' self-assessment as a key element, the Task Force asks for the extension of the provisions of Art. 26.2 of Reg. 889/2008 regarding the identification of critical steps of the production by the processors should be extended to all operators;

- There is a need for a more harmonized model of Risk Assessment. The scope of this Task Force did not allow to bring applicable, balanced guidelines which would fit for all CBs active in the organic sector;

- Therefore the Task Force suggests to extend the mandate and duration of this Task Force and assign it with the development of guidelines for risk assessment schemes of control bodies and authorities based on validated criteria.

ANNEX

Relevant EU-legislation for risk-assessment in the organic sector

Regulation 882/2004

Recital 13

The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or Quality Assurance Programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules. Ad hoc controls should be carried out in case of suspicion of non-compliance. Additionally ad hoc controls could be carried out at any time, even where there is no suspicion of non-compliance.

Recital 34

In order to have a global and uniform approach with regard to official controls, Member States should establish and implement multi-annual national control plans in accordance with broad guidelines drawn up at Community level. These guidelines should promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy should take a comprehensive, integrated approach to the operation of controls. In view of the non-binding character of certain technical guidelines to be established it is appropriate to establish them by means of a consultative Committee procedure.

Article 3

General obligations with regard to the organisation of official controls

1. Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Regulation taking account of:

(a) identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;

(b) feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;

(c) the reliability of any own checks that have already been carried out; and

(d) any information that might indicate non-compliance.

[…]

Article 15

Official controls on feed and food of non-animal origin

1. The competent authority shall carry out regular official controls on feed and food of non-animal origin not included in the scope of Directive 97/78/EC, imported into the territories referred to in Annex I. It shall organise these controls on the basis of the multi-annual national control plan drawn up in accordance with Articles 41 to 43 and in the light of potential risks. The controls shall cover all aspects of feed and food law.

[…]

5. A list of feed and food of non-animal origin that is, on the basis of known or emerging risk, to be subject to an increased level of official controls at the point of entry into territories referred to in Annex I shall be drawn up and updated, in accordance with the procedure referred to in Article 62(3). The frequency and nature of these controls shall be laid down in accordance with the same procedure. At the same time, the fees related to such controls may be established in accordance with the same procedure.

Article 16

Types of checks on feed and food of non-animal origin

1. The official controls referred to in Article 15(1) shall include at least a systematic documentary check, a random identity check and, as appropriate, a physical check.

2. Physical checks shall be carried out at a frequency depending on:

(a) the risks associated with different types of feed and food;

(b) the history of compliance with the requirements for the product concerned of the third country and establishment of origin and of the feed or food business operators importing and exporting the product;

[…]

3. The Member States shall ensure that physical checks are carried out under appropriate conditions and at a place with access to appropriate control facilities allowing investigations to be conducted properly, a number of samples adapted to the risk management to be taken […]

Article 42

Principles for the preparation of multi-annual national control plans

[…]

2. Each multi-annual national control plan shall contain general information on the structure and organisation of the systems of feed and food control, and of animal health and animal welfare control in the Member State concerned, in particular on:

(a) the strategic objectives of the plan and on how the prioritisation of controls and allocation of resources reflect these objectives;

(b) the risk categorisation of the activities concerned; […]

Article 43
Guidelines for multi-annual national control plans

1. The multi-annual national control plans referred to in Article 41 shall take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2). These guidelines shall in particular: […]

(b) identify risk-based priorities and criteria for the risk categorisation of the activities concerned and the most effective control procedures; […]

Article 46
Community controls in third countries

[…]

3. The frequency of Community controls in third countries shall be determined on the basis of:

(a) a risk assessment of the products exported to the Community; […]

The criteria for determining risk for the purpose of the risk assessment referred to in point (a) shall be decided in accordance with the procedure referred to in Article 62(3).

Regulation 834/2007

Article 4
Overall principles

Organic production shall be based on the following principles:

(a) the appropriate design and management of biological processes based on ecological systems using natural resources which are internal to the system by methods that: […]

(iv) are based on risk assessment, and the use of precautionary and preventive measures, when appropriate; […]

Article 27
Control system

[…]
3. In the context of this Regulation the nature and frequency of the controls shall be determined on the basis of an assessment of the risk of occurrence of irregularities and infringements as regards compliance with the requirements laid down in this Regulation. In any case, all operators with the exception of wholesalers dealing only with pre-packaged products and operators selling to the final consumer or user as described in Article 28(2), shall be subject to a verification of compliance at least once a year.

Regulation 889/2008

Article 26
Rules for the production of processed feed and food

[…]
2. Operators producing processed feed or food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.

Article 65
Control visits

1. The control authority or control body shall carry out at least once a year a physical inspection of all operators.

2. The control authority or control body may take samples for testing of products not authorised for organic production or for checking production techniques not in conformity with the organic production rules. Samples may also be taken and analysed for detecting possible contamination by products not authorised for organic production. However, such analysis shall be carried out where the use of products not authorised for organic production is suspected.

3. A control report shall be drawn up after each visit, countersigned by the operator of the unit or his representative.

4. Moreover, the control authority or control body shall carry out random control visits, primarily unannounced, based on the general evaluation of the risk of non-compliance with the organic production rules, taking into account at least the results of previous controls, the quantity of products concerned and the risk for exchange of products.

Article 88
Control arrangements

2. The measures to be taken by operators, as referred to in Article 63(1)(b), to guarantee compliance with the organic production rules shall include the indications of measures referred to in Article 26.

3. The control authority or control body shall use these measures to carry out a general evaluation of the risks attendant on each preparation unit and to draw up a control plan. This control plan shall provide for a minimum number of random samples depending on the potential risks.

Article 90
Control visits

The control visit referred to in Article 65 shall comprise a full physical inspection of all premises. Moreover, the control authority or control body shall make targeted visits based on a general evaluation of the potential risks of non-compliance with the organic production rules.

The control body or authority shall pay particular attention to the critical control points pointed out for the operator, with a view to establishing whether the surveillance and checking operations are carried out correctly.

All the premises used by the operator for the conduct of his activities may be checked as frequently as the attendant risks warrant.