



Heads of European Food Safety Agencies

Private Assurance Schemes Working Group

Guidance Document

Introduction to Public-Private Cooperation in the safety of the food chain: shared interests, separate responsibilities

© Heads of Food Safety Agencies [2017]

This report was elaborated under the Heads of European Food Safety Agencies (HoA) by a working group of 10 Member States, chaired and coordinated by the Food Standards Agency (FSA) UNITED KINGDOM and General Directorate for Food (DGAL) FRANCE.

Responsibility for the information and views set out in this document lies entirely with the authors.

BELGIUM, Federal Agency for the Safety of the Food Chain (FASFC); **DENMARK**, Danish Veterinary and Food Administration (FVST); **FINLAND**, Finnish Food Safety authority (EVIRA*); **FRANCE**, General Directorate for Food (DGAL); **GERMANY**, Federal Office of Consumer Protection and Food Safety (BVL); **IRELAND**, Food Safety Authority of Ireland (FSAI); **NETHERLANDS**, Food and Consumer Product Safety Authority (NVWA); **Norway**, Norwegian Food Safety Authority (Mattilsynet); **SWEDEN**, National Food Agency (SLV); **UNITED KINGDOM**, Food Standards Agency (FSA).

Reproduction is authorised provided the source is acknowledged.

**Since 1 January 2019 named Ruokavirasto: The Finnish Food Authority began its operations on 1 January 2019 when the Finnish Food Safety Authority, the Agency for Rural Affairs and part of the IT services of the National Land Survey of Finland were merged into one single Authority.*

Introduction

The purpose of this document is to provide a reference point for Competent Authorities when considering the extent to which and in what way they make use of private quality assurance schemes in their risk based official control systems for food and feed. This document does not intend to change regulatory requirements, replace regulatory oversight, outsource official inspection work, impose the use of private quality assurance by industry; nor does it constitute any approval, recognition or endorsement of private quality assurance schemes.

In February 2016, the Heads of European Food Agencies (HoA) agreed a position statement (attached as annex 1); this document builds on that statement.

Table of contents

Title	Page
Introduction	2
Table of contents	3
1. Private Quality Assurance Schemes	4
2. Interactions between public and private sector – considerations	5
3. General principles for the cooperation between public and private parties	6
4. International considerations	8
5. Regulatory framework for taking account of private quality assurance schemes	9
6. Use of private quality assurance schemes to inform official controls	12
Annex 1 – Heads of Agencies Position paper on private assurance schemes	14
Annex 2 – Case studies: France, the Netherlands and the UK	16
Annex 3 – Case studies: Finland, Denmark, Norway and Sweden	20
Annex 4 – Case studies: Belgium	23
Glossary	25

1. Private quality assurance schemes

Global trade in food, feed and raw materials to produce food and feed products has grown exponentially over the last decades. Emerging markets and expanding trade has brought the diversity of food safety regulations and standards in different countries into focus. At a global scale an increasing number of consumers have easier access to fresh and processed foods. This means new challenges for the sourcing of raw materials, the processing of the food and the flow rate in the supply chain. New technologies could introduce new hazards. These developments mean a big challenge for industry to manage all these risks.

Food business operators (FBOs) organise their supply chains to balance profitability, market access and to secure the safety of their food and feed products. Since the 1990s the food and feed supply chain –mainly retail driven- introduced private standards (norms) for the production of safe food and feed. Customers of FBOs want to have more assurance on food safety of their purchases by auditing the suppliers themselves or by demanding a certificate provided by a third party (i.e. a body independent of the FBO; so called third party auditing by a certification body). This implies certification bodies that have been accredited by a competent and recognised accreditation body verify compliance of food business operators with the applicable requirements of the private food safety standard. Certification Programme Owners (CPOs) put in place governance, a standard, audit integrity programmes, requirements for auditor competencies, options for unannounced audits, and requirements for management commitment and the management of certification bodies. Compliance with these conditions is assessed by CPOs as part of the agreements they have with certification bodies. Accreditation bodies, in turn, assess the competence, impartiality and performance capability of certification bodies and their staff in order to certify against particular food safety requirements contained in the standards. FBOs can voluntarily make use of (international) food and feed safety standards and PQAS. Standardisation and certification are important tools to improve food and feed safety. In Europe nearly all manufacturers producing retailer ('own label') brands are certified.

A PQAS which provides a certificate consists of:

1. A standard (a norm) and
2. Requirements and regulations for certification.

Standards are documents that provide 'requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose'¹. Standards might be developed by an independent organisation or by an independent CPO.

¹ Definition of the International Organisation for Standardisation (ISO). www.iso.org

A Certification Body (CB) is accredited by an Accreditation Body –mostly a governmental organisation- to perform assessments, inspections or audits on site and to certify an establishment when it operates according the standard. A FBO is voluntarily certified by a third party certification body against one or more standards, but in the supply chain customers can ask for (more or specific) assurance. This may result in more certificates for the same scope (like food safety).

2. Interaction between public and private sector - considerations

Many PQAS operate across a number of Member States (MS) and beyond. This reflects the global supply chains of the FBOs concerned and the harmonisation of food safety regulation across the EU. Given the overlaps between certain private standards and EU regulations for food safety, many governments have become interested in exploiting this synergy to remove duplication of effort and improve knowledge of the functioning of the food supply chain. In 2014, HoA made the decision to set up the Private Assurance Schemes working group to explore these synergies.

It is recognised that many PQAS concerned with food and feed safety are built on the principles of Codex Alimentarius² ; other PQAS are based on areas in which the CPO has identified gaps. Private certification can require greater technical expertise on particular products, materials or processes in addition to more frequent inspections than those provided by the CA. These PQAS can help differentiate a product in the marketplace, but in order to be credible they need to be robust, effective and operate with independence.

PQAS that operate on a global level involve many stakeholders along the supply chain and this may influence the development of PQAS. Cost of compliance can be significant for a FBO, particularly in a developing country but can lead to standardised production supply and access to markets.

Due to their organisational structure, PQAS tend to be able to adapt more quickly and modify the standard in comparison to the timeframe generally involved in introducing legislation. Reliable certification is essential for PQAS and competition among certifiers cannot impact negatively on consistency or reliability of certification.

Public standards remain the main influence on some national markets, but PQAS can play a supporting role in enhancing food safety. Where there is cooperation between public and private parties in regard to PQAS, the general principles in section 3 below could be taken into consideration.

² The Codex Alimentarius or "Food Code" was established by FAO and the World Health Organisation in 1963 to develop harmonised international food standards, which protect consumer health and promote fair practices in food trade

3. General principles for the cooperation between public and private parties

Introduction

PQAS may be viewed as a tool to strengthen National Food Control Systems and CAs may take the performance of PQAS into consideration for several reasons. The main reason should be to improve the effectiveness of CA oversight rather than the reduction of CA oversight. When authorities can rely on the work of PQAS there is opportunity to reduce duplication of activity.

Information and data exchange between the CA and CPOs may assist in gaining and maintaining confidence in the performance of the PQAS. CAs may also use this information and data to:

- Inform the CA's risk based approach to Official Controls (OCs) e.g. use of meta data to contribute to the CA's analysis of trends and emerging issues
- Target resources to FBOs with a higher risk profile than those in a suitable PQAS
- Support identification of risks to health e.g. use of individual FBO data to identify and follow up on areas of non-compliance or to target unsafe situations

Common grounds

Improving feed and food safety in the supply chain should be a common interest shared by all those with an interest in the food chain

CAs, CPOs and food businesses can work together to develop reliable schemes that suit the needs of all three, but responsibilities must remain strictly separate.

In a well-functioning supply chain, certification/private inspection can play a supporting role in OCs. The CA might take into account the certification/private inspection and/or accreditation results when prioritising its OCs. In doing so, the CA checks if and to what extent a specific PQAS and/or certificate contributes to compliance with legislation.

Duplication of activities can be avoided, and synergies can be exploited. When the CA takes into account PQAS in their official controls it still retains its own responsibilities. Information and knowledge can be exchanged between public and private parties.

Competent Authority

The CA is responsible for the delivery of OCs. The CA supervises compliance and intervenes where required (enforcement). Consideration of using PQAS should never lead to any restriction of the CA's legal duties or responsibilities.

For governments that choose to assess international schemes, CAs of those governments may cooperate and may share information such as data, knowledge and experiences.

Food Businesses

FBOs are responsible for food and feed safety and for the compliance with relevant legislation.

It is up to the FBO itself whether it participates in private assurance schemes. The CA does not play any role in this except where a legal framework is in place regulating public and private interaction.

Certification Programme Owners

The CPO decides the standard, scope and method of the PQAS and the requirements and regulations for FBOs to be admitted. The CPO appoints and, as part of its governance (requirements and regulations for certification), oversees the performance of one or more CBs to undertake scheme assessments³.

Certification Bodies

A CB is independent from the PQAS and is appointed by the CPO to undertake assessments of member businesses and issue certification confirming that businesses meet the requirements of the PQAS standard(s). CBs are usually accredited against the relevant International Standard by the national accreditation service to assess and issue certification confirming that a member business meets the requirements of the PQAS standard(s)

The Global Food Safety Initiative

With a vision of *safe food for consumers everywhere*, food industry leaders created the [Global Food Safety Initiative](#) (GFSI) in 2000; notably to reduce food safety risks, audit duplication and costs while building trust throughout the supply chain. Within GFSI, benchmarking provides the framework for recognition of food safety schemes using a process of comparison with the GFSI Guidance Document to determine equivalence. GFSI asserts that all GFSI recognised schemes and standards contain requirements that go beyond those laid down in the Codex General Principles of Food Hygiene Code of Practice. GFSI recognised schemes include independence between the CPO and the CB.

³ Some countries use the term assessments to describe this activity, some countries use the term audits

The daily management of GFSI is undertaken by [the consumer goods forum](#) (CGF), a global industry network, and works to deliver its objectives of:

1. Reduce food safety risks by delivering equivalence and convergence between effective food safety management systems
2. Manage cost in the global food system by eliminating redundancy and improving operational efficiency
3. Develop competencies and capacity building in food safety to create consistent and effective global food systems
4. Provide a unique international stakeholder platform for collaboration, knowledge exchange and networking

4. International Considerations

As outlined above, voluntary private standards for food⁴ safety are increasingly used to provide business-to-business assurance in the food supply chain. Food Business Operators (FBOs) are responsible for producing safe food⁵, and membership of a private assurance scheme (including compliance with its standard) can assist in demonstrating commitment to this responsibility.

Some governments – in the EU and beyond – have already developed policies on PQAS. Information exchange on the use of PQAS is taking place on an informal basis between governments on a global scale. When used appropriately, governments can benefit from better targeting of resources and increased access to food safety information, while industry may also benefit from adapted supervision by the competent authority.

Codex

The Codex Committee on Food Import/Export Certification Systems (CCFICS) has, in July 2017, agreed a new work proposal on regulatory approaches to third party assurance in food safety.⁶

⁴ For clarity reasons, the document refers to food sector but is also applicable to the feed sector

⁵ GFL EU General Food Law, article 17

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

⁶ http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-733-23%252FWD%252Ffc23_08e.pdf

This work will promote a harmonised approach and inform the development of international guidance on the use of third party certification schemes to strengthen National Food Control Systems.

5. Regulatory framework for taking account of PQAS

Following a succession of food crises in the late 1990s, the European Commission drafted a white paper to design a new, modernised regulatory framework to recover a damaged consumer confidence.

This white paper led to the drafting of the Hygiene Package; a regulatory framework which consists of 6 EU regulations, intended for food and feed business operators and for competent authorities. Core principles of the food law are laid down in regulation (EC) 178/2002⁷. These principles have considerably changed the way the food industry is regulated by giving primary responsibility for the safety of foodstuffs to the food business operators who produce them, as stated in article 17:

“Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.”

Meeting this requirement should be attained by using risk analysis and HACCP based principles as stated in article 5 of regulation (EC) 852/2004⁸.

The hygiene package, in regulation (EC) 882/2004⁹ also lays down requirements for CAs, in order to ensure OCs are carried out in a harmonised and consistent manner throughout the EU. In particular, programming of OCs should be risk based, as stated in article 3. This programming should take into account criteria such as “identified hazards with the products” or the “operators' past record as regards compliance with (...) food law”, but also “the reliability of any own checks that have already been carried out”.

These own checks can of course be linked directly with the food safety management system put in place by the FBO in accordance with articles 4 and 5 of regulation (EC)

⁷ REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

⁸ REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the hygiene of foodstuffs

⁹ REGULATION (EC) No 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

852/2004, and notably internal audits, but also the use of external independent assessments such as those carried out by PQAS.

Indeed, PQAS were developed concurrently to EU regulation. Being certified against PQAS can be a customer requirement, but most PQAS include strong requirements for food businesses to manage and maintain efficient product/ process and/ or food safety management systems. There is no clear evidence and only little experience yet that certified FBOs are performing better than non-certified FBOs. Nevertheless, it can be argued that a systematic and structured approach to food safety management generally increases the level of compliance and mitigates the risks.

Taking into account PQAS in the programming of OCs is made even clearer in the new official control regulation (EU) 2017/625¹⁰, in article 9, where it is stated that “Competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency, taking account of (...) the reliability and results of own controls that have been performed by the operators, or by a third party at their request, including, where appropriate, private quality assurance schemes(...)”.

There is also regulatory basis to take in to account these schemes during the completion of an official control in accordance with article 10 of regulation (EC) 882/2004. This is outlined below by way of an example.

Certification to a PQAS that has been assessed and proven to meet most or all regulatory requirements can be an important factor in influencing the type, frequency and/or intensity of the oversight activities, **but cannot replace an official control**.

An example of using Private Quality Assurance Scheme information during official controls

Article 10 of regulation (EC) 882/2004 describes tasks to be carried out during an official control:

- (a) Examination of any control systems that feed and food business operators have put in place and the results obtained;
- (b) Inspection of:
 - (i) primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food;
 - (ii) raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food;

¹⁰ REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products,

- (iii) semi-finished products;
- (iv) materials and articles intended to come into contact with food;
- (v) cleaning and maintenance products and processes, and pesticides;
- (vi) labelling, presentation and advertising;
- (c) Checks on the hygiene conditions in feed and food businesses;
- (d) Assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with Community legislation;
- (e) Examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;**
- (f) Interviews with feed and food business operators and with their staff;
- (g) The reading of values recorded by feed or food business measuring instruments;
- (h) Controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators;
- (i) Any other activity required to ensure that the objectives of this Regulation are met.”**

Points “e” and “i” above include private quality assurances schemes.

As part of the certification process for PQAS, food businesses are assessed, at predetermined frequencies, by CBs against the PQAS standard(s) Conclusions from these assessments are compiled in a report which is sent to the FBO.

These reports list non conformities found by the CB assessor.

Each non conformity should be dealt with within an action plan and be resolved in the appropriate time frame having regard to the requirements of the scheme and agreements between the FBO and the assessor/ auditor.

These reports can be a key to start an official control. Officials may wish to request sight of the most recent report as part of their official control to assist their assessment of the FBOs capacity and reactivity to address non conformities.

They might also indicate areas where non compliances were found during PQAS assessments and not during previous OCs. These areas can be investigated during the OC.

For these reasons, MS should ensure that staff performing OCs are suitably authorised to access these documents as stated in article 4, point 2 e of regulation (EC) 882/2004.

6. Use of Private Quality Assurance Schemes to inform official controls

The HoA Working Group on Private Assurance Schemes has identified a range of approaches being taken in Europe to the use of PQAS. Some countries are actively exploring and making use of PQAS, some countries are developing their position and policies for use of PQAS and give a lower priority or are more reluctant to using PQAS. Where countries are making use of PQAS, their approaches fall broadly into 3 groups and these are outlined below.

These 3 groups have 2 principles in common:

- FBOs are responsible for complying with legislation
- Participation in a PQAS by FBOs is voluntary

France, the Netherlands and the UK

France, the Netherlands and the UK take a similar approach that can be summarised:

- The contact for the CA is generally the CPO
- The CA invests resource to undertake an assessment of the PQAS (governance, criteria and method testing: design, existence, operation)
- The CA accepts / recognises the PQAS
- The CA may then adapt their supervision of certificated members of recognised PQAS (e.g. adapt the frequency, content, focus, intensity, alternative methodology (e.g. administrative / remote digital supervision) of official controls);
- There are processes in place between the CA and recognised CPOs for information exchange
- The CA uses information generated by the scheme and processes in its supervision/ surveillance (e.g. meta information, current certificates, audit reports)

Further detail of individual country approaches is contained in annex 2.

Denmark, Finland, Norway and Sweden – The Nordic view

Denmark, Finland, Norway and Sweden share the view that PQAS adds value to FBOs' own check systems.

FBOs can use any PQAS which is useful for their business, and the results of using this scheme can be taken into account in OCs performed by the CA. This places greater demands on the officials regarding competence areas. When it comes to approval of PQAS by the CA, it is not seen as feasible to build such an extra burden for FBOs and the CA.

In the Nordic countries, the current approach from the CAs towards the use of FBO's information from PQAS is:

- The CA addresses the FBO directly in all official control matters and control situations.
- The CA has no direct contact with CPOs or CBs.
- In its control activity, the CA uses available information and results from a FBO's participation in a PQAS as an ordinary and integrated part of its evaluation of the FBOs compliance with the regulatory requirements.
- A FBO that demonstrates a high compliance with the regulatory requirements and a good internal control system will, whether this control system involves participation in a PQAS or not, result in a lower frequency of inspections and audits from the CA (risk-based control).
- In order for a PQAS to be recognised as an important part of a FBOs internal control system, the FBO itself must declare that the PQAS covers all relevant EU regulations and legal requirements concerning food and feed safety.

Further detail of individual country approaches is contained in annex 3

Belgium and France

FBOs must implement food safety management systems in order to ensure the production of safe food. They can help themselves with sectoral guides to good practices or standards.

CAs can choose to take an active part in the recognition and validation of sectoral guides or the drafting of standards.

To valorize the commitment of certain FBOs using these tools, CAs can choose to approve CBs to carry out audits or inspections against these documents. This approval usually involves the accreditation of CBs in accordance with the relevant standards (norm ISO/IEC 17065, ISO/IEC 17021-1 or ISO/IEC 17020).

FBOs can then benefit from the system in various ways: 'smileys', decreased OC frequency or lower annual contributions.

Further detail of the Belgian approach is contained in annex 4.

HEADS OF FOOD SAFETY AGENCIES POSITION PAPER ON PRIVATE ASSURANCE SCHEMES¹¹

Background

Voluntary private standards for food safety are increasingly used to provide business-to-business assurance in the food supply chain. Food Business Operators (FBOs) are responsible for producing safe food¹², and membership of a private assurance scheme (including compliance with its standard) can demonstrate commitment to this responsibility.

Many private assurance schemes (PAS) operate across a number of member states. This reflects the global supply chains of the FBOs concerned and the harmonisation of food safety regulation across the EU. Given the overlaps between certain private standards and EU regulations for food safety, many member states have become interested in exploiting this synergy to remove duplication of effort and improve knowledge of the functioning of the food supply chain. This possibility is provided for in the official controls regulation.¹³ This provision is also further developed in the future Official Control Regulation.¹⁴

Some governments – in the EU and beyond – have already developed policies on private standards, adjusting their official interventions (type, scope and frequency) accordingly. When used appropriately, governments can benefit from better targeting of resources and increased access to food safety information, while industry may also benefit from reduced inspections/audits and more effective intervention by the competent authority.

Heads of Food Safety Agencies position

FBOs are responsible for the production of safe food and feed. Competent authorities are responsible for oversight, official controls and enforcement. Private assurance schemes occupy a voluntary position to provide additional safety assurance to businesses.

In a well-functioning supply chain, certification and private inspection can play an important role in ensuring compliance. The recognition and acceptance by member states of private assurance schemes has the potential to increase efficiency in official controls, by removing duplication of effort. Competent authorities, private scheme owners and food businesses can work together to develop reliable schemes that suit

¹¹ For clarity reasons, the document refers to food sector but is also applicable to the feed sector

¹² GFL EU General Food Law, article 17

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

¹³ Regulation (EC) 882/2004 (article 3, 1 (c)). 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 the reliability of any own checks that have already been carried out.

¹⁴ The future Official Control regulation in article 9, 1 (d), Competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency, taking account of the reliability and results of own controls that have been performed by the operators, or by a third party at their request, including, where appropriate, private quality assurance schemes, for the purpose of ascertaining compliance with the rules referred to in Article 1(2).

the needs of all three, but responsibilities must remain strictly separate. Private systems can support official controls, but cannot replace them.

Private assurance schemes should be deemed as reliable before they can be taken into account in a member state's delivery of official controls, including if and to what extent a certification to a specific private assurance scheme contributes to compliance with legislation. The CA might take into account the results of private assurance activity (if made available to the CA) when prioritising its compliance tasks, and might adapt its way of conducting official controls on condition it can rely on the performance of the private assurance schemes involved.

Though member states have their own considerations about the extent to which and in what way they make use of private schemes in their risk-based official controls systems for food, sharing experiences between countries is essential to remove duplication of effort, create an understanding of good practice, and ensure a level playing field for businesses.

Annex 2

France approach to recognition of private quality assurance schemes

In France, the Ministry of Agriculture, namely the General Directorate for Food (DGAL) is responsible for food safety of foodstuff of animal origin.

In accordance with articles 3 and 10 of regulation (EC) 882/2004 of 29 April 2004 on OCs performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, recognition of PQAS by the DGAL can lead to:

- The inclusion of a new factor in the risk basis programming of OCs
- The adaptation of the content of OCs

A thorough assessment is put in place in order to determine whether the PQAS provide sufficient guarantees for the CA.

Recognition of PQAS is organised in different steps in France:

- Self-assessment against set criteria. In order to fulfil this assessment, a questionnaire is provided to the CPOs.
- Self-assessment analysis by the DGAL with possible request for further information.
- Shadow audits carried out by the DGAL: official inspectors normally performing official controls are recruited and trained to carry out these audits. A code of conduct was established and has to be agreed by both the CB auditors and official inspectors. This code includes provisions to guarantee that official inspectors carrying out the audit are neutral and are not involved in routine OCs of the certificated companies, and that PQAS audits give all the necessary information to the official inspector in order to carry out the shadow audit in good conditions.

If these three steps give acceptable results a first cycle of observation is put in place before full recognition is given.

This cycle will enable DGAL to monitor the performance of the PQAS and participating CBs: inspectors will report all major non compliances they find in certified companies to the DGAL. This data (anonymised) will be compiled and submitted to the scheme owners. Where shortfalls are identified, corrective actions will be expected.

After that, full recognition for a determined period of time will be implemented.

Monitoring of recognised PQAS will be put in place and implemented by DGAL.

In case of shortfalls, the DGAL can contact the CPO to discuss corrective actions or suspend the recognition.

In France, OC results are made public and are published on the internet as well as via ratings FBOs can stick on their windows. Due to a lack of resources, it is not possible for the DGAL to respond to inspection requests by FBOs themselves.

To address this issue, the DGAL took lead to write a standard with the support of several restaurant managers' association. This standard has been published by AFNOR, the French national organisation for standardisation and its International Organisation for Standardisation member body; under the number NV V01-015. Currently, other retail sectors are working with DGAL to draft new standards (butchery for example).

Accredited CBs would be able to audit against this standard (or upcoming standards) and deliver the FBO a “smiley” sticker attesting that the company was inspected against a recognised standard. While this inspection would not replace an OC, it would enable FBOs to display their conformity with food hygiene requirements.

This project is currently being considered by the Ministry's Legal Services and has not yet been implemented.

The Netherlands approach to recognition of private quality assurance schemes

In 2006 the idea was born to look for the synergy between the public and private supervision of food safety controls. Main reason was to avoid duplication in order to reduce the administrative burden for industry and to save public resources. It should be one of the elements in a more risk based approach. As a result of this initiative the competent authority (NVWA) developed adapted supervision in several areas. There were no clear and strict criteria in place those days, only the performance of the private scheme counted. Performance in terms of having a food safety standard in place, independent audits or inspections, taking corrective measures where necessary and high level compliance with legislation for companies.

For the business to consumer (B2C) schemes, NVWA started in 2008, together with 3 interested certification programme owners (CPO, or scheme owner), to develop the way to acceptance. NVWA set the first list of criteria with a focus on the scope of food safety, unannounced inspections, integrated sampling and a high level of compliance.

In 2013, after the horse meat scandal, the Minister of Health and the State Secretary of Economic Affairs installed a task force in order to regain consumers trust in food. So here it became more a political item. One of the outcomes of this task force was the objective to strengthen the supply chain by better and more transparent private assurance (private certification). A set of criteria was published in 2014, CPOs were asked to raise the bar to the level of these criteria and submit the scheme for an assessment. NVWA took the role – as an independent organisation - to assess the schemes and conclude whether or not the schemes met these criteria. The schemes that pass the assessment are published as 'accepted' on the website www.ketenborging.nl.

After the assessment and the acceptance NVWA starts the monitoring and evaluation of each accepted scheme. This is the start of the continuous improvement cycle and further public-private cooperation. NVWA and the CPO will exchange information in order to raise the level of compliance and to mitigate remaining risks. The information exchange with CPOs is also expected to give NVWA a much better view on risks in the supply chain and specific sectors. In case a private assurance scheme is not able to maintain a high level of performance NVWA will start the exit procedure, which means a scheme will be no longer accepted.

NVWA can and should adapt its supervision for the affiliated businesses under the accepted schemes. Adapted supervision (e.g. lower inspection frequency, audits/inspections can be shortened, different focus during the audit/inspection) can differ from business to business. It depends on the risk profile of the business, in which the history of compliance is a major indicator. This approach fits a risk-based supervision model where good-willing and good-performing companies gain more trust and resources can be focussed on the companies that do not comply on a high level or commit fraud.

UK approach to recognition of private quality assurance schemes

Current Approach

In the UK, the use of PQAS to inform regulatory approach has been introduced using the concept of 'Earned Recognition'.

CPOs wishing to seek FSA approval for their assurance scheme must meet an established set of criteria to demonstrate the robustness and independence of the scheme. FSA approval is formalised through a Memorandum of Understanding between the FSA and the CPO.

Underpinning this approach is the understanding that different forms of reliable assurance can have value in building an intelligence led approach to delivering OCs.

The most significant examples of this approach in the UK are in the dairy and animal feed sectors, where sector-wide assurance schemes are well established and membership typically represents a significant proportion of the industry.

Under this approach, FBOs who are members of FSA approved CPOs, have been assessed as compliant by the CA and who then maintain high standards of compliance with food or animal feed law benefit from reduced frequency of OCs.

The degree to which the frequency of OCs is reduced is dependent upon the inherent risk of the operation, with higher risk businesses, such as feed manufacturers, attracting less of a reduction than those considered to be lower risk.

The management and governance of the process includes quarterly meetings with the CPOs, review of data from the CPOs highlighting the type and frequency of any non-conformances identified, review of management information on supervisory audits carried out to ensure the effectiveness and consistency of the PQAS assessments themselves and formal annual review.

CPOs are required, as part of the MoU, to inform the FSA immediately should anything be identified that represents a serious risk to public or animal health. Data on non-conformances is shared with local authorities to inform focused intervention or targeted guidance.

Regulating Our Future

The FSA has commenced a major transformation programme, Regulating Our Future (ROF), to modernise and re-shape the regulatory regime for food.

ROF is taking a whole system approach, seeking to understand what information is available from a wider range of sources and how this could be used in the future to gain assurance that food is safe and what it says it is, and public health is protected.

The assurance standard (i.e. what businesses need to be able to demonstrate) will be set by the FSA and include the competence of persons providing assurance data.

It is anticipated that the new model will allow data from multiple assurance providers including PQAS to be taken into account. ROF will explore how PQAS can support (not replace) OCs; this may mean official interventions are adjusted by nature, frequency and intensity as a result of the assurance provided by these alternate means.

Critically, the FSA will remain the overarching competent authority with oversight of the system.

The Finnish system of utilising private certification schemes in official controls

The instructions given to local authorities by central competent authority (Evira) to make official inspections at food business operators' and their establishments are based on the Finnish rating system of FBOs called OIVA. In this system FBOs are rated on the basis of their results in official controls and these results are also published. If the food business operator uses a certification scheme, it is taken into account in the inspection process, as any other data which the FBO presents as part of their own check system in the inspection (cf. EU Regulation of official controls).

Evira has classified the FBOs to ten different risk categories on the basis of their activities and volume of these. Risk class defines recommended inspection frequencies and duration of an inspection. The frequencies vary from one inspection in 3 years to 12 inspections per year. In case the FBO has achieved Excellent (A) OIVA-scoring in 6 consecutive inspections and the recommended inspection frequency is at least 2/y is the frequency reduced to half.

In the Finnish system the compliance level of FBO is reflected in OIVA-results, which includes an incentive for FBO to improve their performance. The benefit from using private certification schemes should be visible in OIVA-scoring (better compliance=better scoring) and thus automatically lead into a possibility to get reduced inspection frequency.

Evira has as a pilot shadowed some audits performed by certification bodies at FBOs' establishments, made comparison between inspection criteria and certification scheme criteria, and noticed some relevant things to consider when working with private schemes which need attention when moving forward utilising information of these audits.

The pilot study revealed some possibilities to benefit from the use of PAS in official controls, such as:

- PAS could ensure compliance with legislation in certain specific requirements, in particular in product safety (e.g. management of allergens)
- PAS audit could possibly replace one official inspection/year
- certain requirements could be inspected less frequently in OC, if results from PAS audits are favourable
- some areas could be inspected in OC less thoroughly, if covered by PAS audits (e.g. temperature controls)

Evira is going to continue evaluating added value of private schemes in official controls. Private scheme needs to show to what extent scheme's criteria cover the legislation. What comes to approving of a certification scheme/program by the competent authority, it is not seen feasible to build such an extra burden for food business operators and authorities. Rather the opposite, governmental program is seeking for diminishing the bureaucracy. In addition, competent authorities don't wish to imply that food business operator needs to apply for approval of a certain certification scheme/program and pay for that service.

The Danish system of utilising private certification schemes in official controls

In January 2017 the Danish Veterinary and Food Administration (DVFA) introduced a voluntary scheme where FBO's can apply for being registered as third party certified. When the FBO applies for being registered it's on an individual company basis. The FBO has to declare that its certified food safety management system fulfils the legal requirements. The certification of the food safety management system must cover all food activities and food legislative areas. It's possible to get small activities out of the scope and the certification. The certification shall be carried out by a certification body that is accredited by an accreditation body which is signatory to the EA (European co-operation for Accreditation) Multilateral Recognition Agreement. The certification body must be accredited to certify to the type or standards that form the basis for quality management system. DVFA does not assess the certification scheme.

The DVFA control if FBO's certified food safety management system is sufficient. Information about the FBO in the audit report made by the certification body is used as a basis for inspection, e.g. about deviations and how the FBO has taken care of them and areas inspected. Usually all areas must be inspected by DVFA during 1 or 2 years but some areas may only be audited by third party.

In January 2017 DVFA started to classify the FBOs in risk categories on the basis of their activities and volume of these. Risk category defines individual basic inspection frequencies. The inspection frequencies are based on consumer base, processes, products, activities and vulnerable consumers. Standard inspection frequency goes from 4 inspections per year to a frequency as and when required. FBOs who are registered as third party certified gets fewer basic inspections. They automatically get one inspection less per year if they have an inspection frequency higher than one per year.

DVFA will evaluate the scheme ultimo 2017.

The Norwegian system of utilising private certification schemes in official controls

In Norway, no formal system for using results from private certification schemes/programs in official controls has yet been introduced. NFSA has just started a work aiming to classify FBOs in risk categories, based on their activities and history of compliance with the legal requirements. In this work, FBOs internal control systems and participation in private certification programs/schemes will also be considered. Results from such systems will probably be used in the same way as in Finland, leading to a lower inspection frequency from the CA when the results show high compliance with the legal requirements.

The Swedish system of utilising private certification schemes in official controls

The National Food Agency (NFA) is currently looking into how PAS, private assurance schemes under accreditation, can be used as a tool for official control for food business operators. The objective is to find more tools and roads for FBOs to demonstrate compliance and as a consequence obtain reduction in official control.

Since some years PAS can be used as a tool for control in the primary sector. An evaluation of the system in this area 2016 revealed that the County Administrative Boards, responsible for control in the primary sector, use the PAS tool relatively scarce.

The Belgian approach to recognition of private quality assurance schemes

In Belgium, the system in place for the control of the FBOs is risk based and consists of routine inspections, sampling and voluntary validation/certification of the self-checking system (SCS) through audits. These audits are mostly performed on basis of approved national sector guides covering the GHP and HACCP. The audits can be performed by CA officials or can be delegated by the CA to auditors of external CBs. The planning and the implementation of OCs is adapted for FBOs with a validated/certified SCS: they are less inspected by the CA (and pay a lower annual financial contribution). This system has the advantage to decrease the workload for the CA and it also allows for focus of official controls on FBOs who are more potentially at risks (no validated/certified SCS).

As regards PQAS, some of them are also taken into account in the risk-based OCs but to a limited extent and under very specific conditions. In this context, two approaches are currently applied in Belgium.

Approach 1 is called the rule “80-20”: it is based on the fact that the Belgian CA accepts audits performed on basis of three GFSI-recognised PQAS but only in certain cases and for a limited activity. These PQAS are BRC Global Standards, IFS and ISO 22.000. Audits performed on basis of these schemes can only be valorised for residual activities when the following cumulative conditions are respected:

1. The residual activities represent less than 20% of the turnover of the company,
2. The other activities (the remaining activities represent at least 80% of the turnover of the company) are covered by a certificate resulting of an audit based on a national sector guide approved by the Belgian CA,
3. There is no approved national sector guide for the activities mentioned under point 1.

The system of OCs is therefore adapted in such a way that a BRC Global Standard, IFS or ISO 22000 certificate covering the activities mentioned in point 1 can be valorised in the same way as explained above for validated/certified SCS (based on approved national sector guide).

Approach 2 is called the “equivalence procedure”: it is based on the fact that the Belgian CA accepts the PQAS to be declared fully equivalent to a national approved sector guide. The PQAS falls under the equivalency if a series of cumulative conditions are respected, namely:

- The CPO draws up cross-references tables between the scheme and the approved national sector guide to demonstrate the equivalence (the scope, the requirements for the FBOs and the requirements for the CBs must be covered),
- The audits on basis of the PQAS must be carried out by CBs that are approved by the CA for the national sector guide,
- While performing audits on basis of the PQAS, CBs must respect the approval conditions put in place by the CA,

- The requirements concerning the content of the certificate that the CBs shall issue must be fulfilled,
- The requirements concerning the communication of the audit results to the CA must be fulfilled.

The system of OCs is therefore adapted in such a way that a “PQAS-equivalent” certificate can be valorised in the same way as explained above for validated/certified SCS (based on approved national sector guide).

Key-words: audit, self-checking, national sector guide

Audit: means a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled (~ISO 19011)

Self-checking: all measures taken by operators to ensure that the products in all stages of production, processing and distribution under their control meet the legal requirements regarding food safety, to the quality of the products (under the competency of the competent authority), to the traceability of the products and the supervision of the effective compliance with these requirements (Belgian Royal Decree of 14 November 2003 concerning the self-checking, the mandatory notification and the traceability in the food chain).

National sector guide: document, written by a sector organization and intended to operators of this sector, and which contains instructions to comply with legal requirements regarding self-checking (incl. hygiene, traceability). The document must be approved by the competent authority.

Glossary/ Definitions

Accreditation: third-party attestation related to a body conveying formal demonstration of its competence to carry out specific tasks. In the EU¹⁵, accreditation shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity

Accreditation Body: not-for-profit organisations, either government owned or under agreement with government, charged with ensuring that participating Certification Bodies in the country are subject to oversight by an authoritative body. Accreditation Bodies play a key role in the accredited certification process and ensuring international consistency in conformity assessment.

Certification: third-party attestation related to products, processes, systems or persons. Certification can be a useful tool to add credibility, by demonstrating that your product or service meets the expectations of customers

Certification Body: The third party companies that provide certification services are known as Certification Bodies (CBs). The CBs are appointed to assess or audit against recognised Standards through a formal agreement with the Certification Programme Owner (CPO) combined with the scope of their accreditation.

Certification Programme Owner: the legal entity responsible for a scheme that sets a standard and the requirements for CBs to operate assessments/ audits and to guarantee impartial and competent certification/ recognition

Private Quality Assurance Scheme: The private quality assurance schemes mentioned in this document are voluntary self-monitoring systems initiated by private bodies that do not have a designated legal task. It concerns systems that supervise the (affiliated) individual FBOs. This supervision can be done by a trade or branch organisation, or by a third party certifying body

Standard: a norm, a set of rules or principles used as a basis for judgment.

¹⁵ Article 2(10) of Regulation (EC) No. 765/2008