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AUDITING THE FOOD BUSINESS ESTABLISHMENTS BY THE CONTROLLING AUTHORITIES

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SUMMARY

From the side of the controlling authorities the most serious challenge will be the auditing system. Especially, as regards the preparation of the necessary forms and training of the auditors with the goal to introduce objectivity and transparency.

The audited will have to cope with the production of evidence, as they will have to support their claims of safe food production not only at the time of an audit, but also when no controlling authority is present.

Communication is the basis of success. All the parties involved will have to reason and their reasoning must be within the objectives given by the food law (and animal welfare laws, when appropriate).

INTRODUCTION

With the new hygienic legislation a new duty for both controlling authorities and food business operators was set – audits. Many small and medium establishments have no direct experience with audits so far. What audits are and how to cope with the new tasks is for some of the involved still not completely clear, and thus potentially frightening. In principle, however, an audit is quite simple procedure, if properly trained personnel in a cooperating environment do the task. Most problems are expected in evidence gathering by the food business operators and non-compliances definitions by auditors. Discussion and proper feedback between auditors and the audited party will be necessary to make the audits a useful controlling tool.

LEGISLATIVE BACKGROUND

The duty to do audits for the controlling authorities and to submit themselves to audit is given by the Regulation 882/2004 [1] (on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules) and consequently by the Regulation 854/2004 [2] (laying down of specific rules for the organisation of official controls on products of animal origin intended for human consumption), stating that the

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scope of the specific control rules should mirror the scope of the specific hygiene rules for food business operators laid down in Regulation (EC) No 853/2004 [3].

DEFINITIONS

Definitions are important. They explain what the meaning of the specific term is so that there is no mistake or mislead. They should be, simple, clear and use uniform terms. Or shouldn't they? While mostly they are, some details may need more explanation to prevent later misunderstanding. There are many definitions in the above-mentioned legislative texts, but in relation to the audit as a new duty of the controlling authorities and food business operators, these are probably the most interesting.

"Competent authority" means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country;

"Official control" means any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules;

"Control plan" means a description established by the competent authority containing general information on the structure and organisation of its official control systems.

"Audit" means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;

"Inspection" means the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and animal welfare rules (Regulation 882/2004);

"Inspection" means the examination of establishments, of animals and food, and the processing thereof, of food businesses, and their management and production systems, including documents, finished product testing and feeding practices, and of the origin and destination of production inputs and outputs, in order to verify compliance with the legal requirements in all cases (Regulation 0854/2004);

"Non-compliance" means non-compliance with feed or food law, and with the rules for the protection of animal health and welfare;

"Corrective action" means an action to eliminate the cause of a detected non-compliance or other undesirable situation.

AUDIT

Audit is a procedure with a quite rigid protocol. The protocol is such because of the need of transparency and objectivity.

An audit is not a surprising event. It is always announced, terms are discussed and agreed between the controlling authority and the food business operator. Auditor(s) are supposed to see the premises at their best.

During the audit, all the production-related documents are checked and compared with the on-site production processes to find out whether the legislative requirements are met. The auditor communicates with the food business operator not only to demand what he/she) needs but also about his/her observations. At the audit closing meeting, the auditor summarises the findings of the audit and discusses it with the food business operator during the audit.

After the audit, an audit report is written. It describes the course of the audit, specifies who was doing the audit and who was present at the audit as the food business operator's representative and also the audit's findings. The findings are a list of compliances and non-compliances explaining which legislative requirements were met and which were not. Evidence on which the statements are built should be mentioned.

The controlling authority that organises the audit evaluates the report and the information about the audit outcome(s) are sent to the food business operator. If necessary, there is a list of necessary production system improvements that are required to provide for full compliance with the legislative requirements along with the terms.

The food business operator may not agree with the audit outcome and may appeal.

THE PROBLEMS

A group of potential problems is in the **management of audits**. The first question is **who will do the audits**. The controlling authority is only required to organise audits and may not have resources to do them directly.

A third party can be appointed, as there are bodies providing the audits professionally, e.g. auditing of companies supplying retailer branded food products for supermarkets. They have the know-how but their services are expensive and they do not have enough auditors (usually) to cover all controlled premises. Also, they would not (probably) have an easy access to the inspection-related documentation that is a very useful source of evidence.

The second option is to delegate the personnel of the controlling authority that does inspection tasks otherwise. The inspecting officers are already familiar with the production environment and legislative requirements but the problem is that most of them do not have auditing experience (and sometimes they are already emotionally shaped and therefore not suitable for an objective judgement of certain premises). It remains on the controlling authorities to decide and authorise the proper auditors. The decision may not be easy and straightforward though, as there are uneasy financial and personal matters to consider.

An important part of audit management is **preparation of the audit system**. It should specify the methodology of the audit, all the necessary protocols and list the necessary questions that need to be answered during an audit. Because of the need of transparency and objectivity, the audit questionnaire should be not only prepared but also discussed with all the auditors, in order to make sure that all proper questions are asked in a proper way and that the audits will be done in a standard manner that would not put any of the audited premises into a disadvantage.

An important part of the audit system development is to set rules for distinguishing “minor” non-compliances from “major” non-compliances. Whereas the minor non-compliances with the legislative requirement present an indirect threat for consumer’s health, the major non-compliances are a likely reason for production of food that cannot be considered safe at reasonable probability. Some non-compliances are easy to distinguish in this respect. E.g. failure to thermally treat food that requires thermal treatment (e.g. heating at pasteurisation/sterilisation or freezing at low incidence cysticercosis) presents a major non-compliance. Other cases may cause health risks indirectly and the probability is rather low (e.g. missing signatures at some documents). However, in specific situations also the supposedly minor non-compliances may lead to unacceptable health risk and become major non-compliances (e.g. in a case of easily penetrable packing foil on fresh meat that was displayed in a shop and complaints were not adequately processed). Therefore all non-compliances should be thoroughly analysed and decision about their character should be based on available evidence. Discussion of possible cases and their impact on health safety of the produced foods should be a part of auditors training and always an open chapter in the discussion between controlling authorities and controlled subjects.

Collecting of evidence for audit report statements is important because of possible legal consequences. Deciding what kind of evidence to use for what situation is also a matter of an audit system preparation. Pre-prepared audit forms summarising the protocol, audit questionnaire and report are intended to enforce uniformity even more. How to fill them and what kind of vocabulary is expected to be used is a part of necessary training of the auditors.

It helps a lot if the food business operators understand the purpose and benefits of audits as a part of controlling activities. Therefore, a part of audit management should be a pre-audit communication with the food business operators explaining them its legal background and reasoning the benefits. Especially small and medium enterprises that do not have direct audit-related experience may see the audit as another source of trouble or even as a tool of their doom. Such psychological attitude makes the auditing much more demanding for all involved parties.

Organising individual audits may be, at the beginning, a problem too. First obstacle may be to get an agreement from the audited food business operator. She/he may decide to postpone the audit indefinitely so that it would not happen at all, if pos-

sible (objections against the time of audit or against the auditor). Therefore, there should be a legal framework limiting the delays and allowing for an audit, even if the food business operator does not agree with the proposed terms.

Also, there is a question of the **person of the auditor**. Ideally, the auditor is acquainted with the audited environment. From within the controlling authorities, it is the inspection officers who are the most familiar with it. Therefore, it may seem that they are the best for auditing the controlled premises, too. Or aren't they? During an audit, it is possible to use the inspection documents as a source of information and evidence. It may happen that while seeking for audit-related evidence the auditor finds non-compliance in inspection activities. If those non-compliances are a personal fault of an inspecting officer (which is the same person as the auditor), the question is whether the inspection fault(s)-related non-compliances will be mentioned in the audit report. This parallel inspection and auditing by one officer may also cause problems due to possible interference into the system of internal audits of the controlling authorities. It is my (personal) best estimation that the auditor should not audit premises in which she/he has other direct controlling duties as the audit loses character of an "independent examination". The situation can change later, when audits will be the primary controlling activity and inspections will serve as a secondary source of evidence and feedback.

An audit should be independent and objective. From it comes that the auditor should not be under outside pressure. In real life, however, there are limits influencing the auditing tasks. One of them is **a time limit** given for a specific audit. The time limit is usually given by the audit arranging authority and it may happen that the auditor finds it inadequate (for an inexperienced auditor it is almost always short) and tries to use more of the allotted time for direct auditing tasks, while limiting the necessary communication with the food business operator. This may lead to a series of problems. First, the information flow is usually limited on informing the food business operator only about non-compliances, shaping thus his emotions negatively against audit, auditor, and controlling authorities with consequent loss of trust and finally, complicating the non-compliance correction. Very harmful in this respect is if only an incomplete list of non-compliances is discussed at the audit final meeting and the full list is sent later through the audit final report. Very rigid time limits may be a cause for an incorrectly prepared audit report, usually stripped down from many important details explaining situation leading to non-compliance and the evidence of the non-compliance. Lack of information can make subsequent enforcement of improvements complicated if they are necessary.

The audit starts with an audit-opening meeting. Here, the auditor informs the food business operator about the purpose of the audit and about its supposed course. All these information were already delivered at the pre-audit communication, but the auditor needs to be sure that all the involved parties know what and why is going to happen.

As the definition of the audit states, the audit means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives. The question is what is hidden behind the words "planned arrangements". Both the audited and auditor should have in mind the same meaning. Let us consider the more realistic explanation that the planned arrangements are some plans of the food business operator describing how she/he (wants to arrange the production so that the legislative requirements are met (not the explanation that the legislative requirements are the planned arrangements to be followed, because from the audit definition it comes that the goal is to determine whether facility's activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives – the legislative requirements). The extent of the plans may vary from almost zero to full-fledged system of GMP and HACCP. There is a trend to require a "simple plan for simple premises". Simple plans, while they may satisfy needs of inspections, may fail during an audit.

The auditor must **check the plans** and find out whether they cover all the legislative requirements. This may be very uneasy if the plans, or their parts,

are mostly or entirely in a verbal form. Here it comes to the experience of the auditor and his/her ability to seek for the truth. In this respect it is very important to keep in mid the basic difference between an inspection and audit. While the inspection seeks for what is in compliance now and here, the audit seeks for the functionality of the entire production system and, within it, how it can cope with localised non-compliances (how they are identified and how are the corrections leading to full compliance arranged for). Therefore, the more verbal-based plans, the more thorough is the evidence gathering about their functionality. If the evidence is verbal only again, it is very likely that the system is not functional.

The production plans should cover all the legislative requirements. One of them is the presence of food safety programmes and procedures based on the HACCP principles [4]. Just auditing those may require a lot of time. If there were more than one auditor, it would be an advantage if they split their efforts and one specialises on the HACCP.

As the legislative texts are not always entirely clear or allow for different explanation, the communication between the auditor and the audited may be vital for evaluating whether the principal objectives of the legislation requirements - a high level of consumer protection with regard to food safety [5] are met. Rigid-minded dogmatic persons may halt the audit entirely and it does not matter on which side they stand.

After checking whether the production is planned in any manner, the audit proceeds with evaluation whether the **production follows the plan**. Quite often non-compliances between plans and production reality are found. It is always a bad sign, because it demonstrates lack of interest in planning. These non-compliances may be 1) enhancements of the plan or 2) malpractice. While the first option is welcomed and easily inserted into plans as part of corrective actions, the second option demonstrates a loose approach to planning again. While the plans, especially their written part, are a good evidence about a system presence and can be scrutinised, the production reality can be observed only at a given moment and therefore, it does not necessarily show everything that is necessary to consider when evaluating its compliance with the plan. Because at an audit, as mentioned earlier, the functioning of the system is observed, the auditor seeks for other evidences than direct observation that the production follows the plan. Here it comes to gathering and analysing all available forms of **records produced during production**. It is a general trend that with smaller production capacity, the record keeping is smaller (the same problem, especially in the case of verification and validation, was quite frequently found after HACCP-based systems had been introduced). When direct evidence is not available, indirect proofs of following the plan must be found (or the statement would be “there is no evidence that the plan is followed”). If there is evidence that the final product is consistently safe, the production is correctly done despite the lack of formal planning and record keeping. The term “consistently safe”, however, is a matter of discussion. Compliance with the required microbiological criteria [6], with maximum tolerated limits of contaminants [7] and use of only approved constituents [8] can be a good start. The object of more subjective discussion may be the frequency of sampling and sometimes the choice of the correct sampling and analysing procedures. All the detail, however, should be explained clearly in the HACCP.

During the audit, the auditor needs to be accompanied by a food business operator or his/her representative. There are several reasons for this: 1) the auditor needs evidence to be gathered and the food business operator is to provide it. It may be documents, working environment arrangements or explanations of what is observed. Therefore, whoever accompanies the auditor, she/he must have access to all the documents and premises and all the necessary authorisations; 2) the audit is to be objective and transparent – during the audit, the auditor informs the food business operator about his/her findings, both compliances and non-compliances and if needed, her/his reasons; 3) the food business operator is a witness and his/her confirmation of the audit findings is very important.

When the information is gathered, the auditor needs some time to process it. It is an advantage if she/he is not under time pressure. The reason is to sort out the findings, compare them with the standards (the legislative requirements), and prepare

some notes for the audit-closing meeting.

The closing meeting is a necessary part of an audit. Here the auditor informs the food business operator about the audit course and about his/her findings. It may seem redundant but it is vital because of the need of the audit's transparency and objectivity. The food business operator should be informed about all the findings, and it is useful if the information starts with what is good. If only non-compliances are mentioned (e.g. under time pressure), the attitude of the food business operator toward audits is to be negatively formed and all the following activities may be more difficult then. However, it is very important to inform the food business operator about all the non-compliances that will be mentioned in the audit report. Any further non-compliance mentioned later in the final report may give reason to announce the audit as non-transparent, and may also complicate the corrective arrangements.

The audit findings are to be discussed, if the food business operator wants it and she/he may clarify possible misunderstanding or arrange for corrective actions immediately (if possible – the corrective actions may be arranged for until the audit is over, but the auditor should not erase the matching non-compliance, but make a note of having it corrected during the audit). Whether the auditor gives the food business operator a list of non-compliances or not is a matter of the audit management and instructions given to the auditor by the controlling authority.

A statement signed by the food business operator that she/he was informed about (listed) audit findings is an important document preventing possible future complaints.

The audit report is formulated on the basis of the audit questionnaire and associated notes. It should be prepared with a clear mind and emotionally detached. Therefore, it may be not prepared the very next day after the audit. Long gap between the audit and audit report preparation, however, can cause loss of information (kept in memory) and postpone the auditing process via slowing the flow of information.

The easiest way of preparing the final report is to fill a final report form. It is a part of the audit management to prepare it and specify what is to be mentioned in it. Because of the variations between the enterprises, the instructions cannot be entirely specific. The content, the vocabulary and the formulation of the statements within the audit report form are a matter of training, experience and feedback between auditors controlling authorities and food business operators. Any statement should be carefully formulated, as it will have an impact on the audited enterprises. All the available evidences are to be mentioned and, if possible, attached to the report. The auditor should keep in mind that it will be the controlling authorities that will evaluate the report and that they will formulate enforcement, if necessary. Therefore, stating the related legislative requirements, especially in case of non-compliance, makes all further report processing much easier and straightforward.

The final report is processed by the audit arranging controlling authorities. They must analyse many audit reports and because of the need of objectivity, they need to have them prepared with comparable precision. If they need to clarify any statement, they have to approach the auditor and ask for explanation. It is sometimes misunderstood as lack of trust. But only entirely clear formulations can be a basis for an **audit result** formulation. Here, the controlling authorities formulate how does the audited facility comply with the legislative requirements and what is the consequence. Often it is a statement that some corrective actions are to be taken to comply entirely. The audit result is delivered to the audited food business operator as soon as possible with suggested terms for the correction of listed non-compliances. If the audit-closing meeting was done correctly and all non-compliances backed up by solid evidence, there are no surprises and no appeals are expected. However, the food business operator may appeal, if she/he finds any reason (e.g. non-existing non-compliance, non-transparent and/or non-objective audit process, preoccupied auditor, inadequate non-compliance category, improper corrective action terms, etc). The appeal should be objective and based on solid evidence.

It can be expected that the first round of audits will bring a lot of dispute between the controlling authorities and the audited enterprises. Hopefully, it will be a constructive dispute leading to clarifying terms and improvement of the auditing process.

SAŽETAK

REVIZIJA SUBJEKATA U PROIZVODNJI HRANE

Najozbiljniji izazov u radu kontrolnih nadležnih tijela bit će sustav revizije. To se posebice odnosi na pripremu potrebnih obrazaca i obuke revizora s ciljem uvođenja objektivnosti i transparentnosti.

Posebno značenje imaju evidnecije kako bi se udovoljilo zahhtjevima proizvodnje sigurne hrane, ne samo u vrijeme revizije, nego i kada kontrolna nadzorna tijela nisu prisutna.

Komunikacija je temelj uspjeha. Sve zainteresirane strane svoje prosudbe će donositi u skladu s ciljevima obuhvaćenima Zakonom o hrani (kao i zakonima o dobrobiti životinja, kada je to potrebno).

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BAKTERIJSKO ONEČIŠĆENJE MESA ŠARANA

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SAŽETAK

Na uzorcima mesa šarana (Cyprinus carpio L.) koji su uzeti iz tri ribnjaka u Slavoniji, obavljena je bakteriološka pretraga 3 i 48 sati nakon eutanazije. Svrha rada bila je dokazati razinu bakterijskog onečišćenja i stupanj higijenske ispravnosti ribe nakon određenog vremena pohrane. Bakteriološkom pretragom ustanovili smo da je 20 - 30% uzoraka ribe nakon 48 sati pohrane na temperaturi do +4 °C bilo onečišćeno aerobnim mezofilnim bakterijama i enterobakterijama u većem broju od dozvoljenog prema odredbama Pravilnika o mikrobiološkoj ispravnosti namirnica (NN 40/01). S obzirom na rezultate valja predložiti da je nakon ulova ribe nužno provoditi sve mjere radi sprečavanja onečišćenja nepoželjnim mikroorganizmima, a vrijeme od nabavke ribe do pripreme u domaćinstvu maksimalno skratiti.

Ključne riječi: *meso šarana, bakteriološka pretraga*

UVOD

Riba zauzima važno mjesto u prehrani ljudi zbog svoje lake probavljivosti i veće zastupljenosti nezasićenih masnih kiselina. Najvredniji sastojci ribljeg mesa su bjelančevine, koje uz masti i ugljikohidrate čine osnovu pravilne prehrane. Dakako, uz te osnovne sastojke meso riba sadrži važne mineralne tvari i to: fosfor, kalcij, kalij, željezo u većoj, a jod, cink, arsen, olovo u manjoj količini te vitamine A, D i B kompleksa (Kulier, 1996).

Otprilike 25% svih primarnih poljoprivrednih i ribljih proizvoda gubi se svake godine upravo zbog kemijske razgradnje i mikrobiološkog onečišćenja (Baird-Parker, 2000). Većina ulovljenih šarana prodaje se u svježem stanju. No, ako se odmah ne prodaju

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