Food Control 60 (2016) 31–43

Contents lists available at ScienceDirect

Food Control

journal homepage: www.elsevier.com/locate/foodcont

Review

Relevance of microbial finished product testing in food safety management

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ARTICLE INFO

Article history:
Received 16 April 2015
Received in revised form
1 July 2015
Accepted 7 July 2015
Available online 10 July 2015

Keywords:
Sampling
Verification
Microbiological food safety

ABSTRACT

Management of microbiological food safety is largely based on good design of processes, products and procedures. Finished product testing may be considered as a control measure at the end of the production process. However, testing gives only very limited information on the safety status of a food. If a hazardous organism is found it means something, but absence in a limited number of samples is no guarantee of safety of a whole production batch. Finished product testing is often too little and too late. Therefore most attention should be focussed on management and control of the hazards in a more proactive way by implementing an effective food safety management system. For verification activities in a food safety management system, finished product testing may however be useful. For three cases studies; canned food, chocolate and cooked ham, the relevance of testing both of finished products and the production environment is discussed. Since the level of control of different processes can be largely different it is beneficial if the frequency of sampling of finished products and production environments would be related to the associated human health risk, which can be assessed on the basis of risk assessment and epidemiological data.

1. Introduction

Assurance of food safety moves more and more from end- or finished product testing to proactive food safety management. A food safety management system in a food processing company includes both control and assurance activities. Control activities are aiming at prevention or reduction of a food safety hazard and are typically related to product and process controls (Luning, Bango, Kussaga, Rovira, & Marcelis, 2008). Preventive measures are prerequisite programs such as cleaning and sanitation, temperature control of the production environment, hygiene of the workers etc. elaborated in order to avoid contamination or outgrowth of microbial contaminants. Interventions in a production process are more focussed on reduction or even elimination of a certain contamination for instance by heat treatments. On the opposite, assurance activities in a food safety management system have the objective to provide evidence that products and processes are within set specifications. Examples of assurance activities are sampling, validation, verification, documentation (Luning et al., 2009). Therefore, the food businesses focus on the design and implementation of food safety management systems to guarantee food safety as demonstrated in a quantitative European study by Luning et al. (2015) and a Belgian study by Jacxsens et al. (2014). Since finished product sampling is valuable in some specific situations, for instance for traditional lot testing with hold/release or verification testing (see Buchanan and Schaffner (2015) for a good discussion on this subject), there is still much focus on finished product criteria and testing of finished products against set specifications. However, differences between criteria for products coming from production lines with different levels of control do not really exist, although more confidence could be given to a product from a well-managed processing line than from a batch of products

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http://dx.doi.org/10.1016/j.foodcont.2015.07.002

that complies only with specific microbiological criteria without any information on process control.

Up to now, microbiological criteria given in Codex Alimentarius standards or in legislations (e.g. EC2073/2005), are mostly expressing the safety or hygiene standard of the product present on the market. However, in legislation, especially for environmental criteria, sometimes more long term process hygiene criteria are appearing (e.g. EC2073/2005). For efficient food safety control, it would be beneficial if this trend continues and would cover food safety management criteria. This would contrast with the use of microbiological criteria as sole measure of control, since due to statistical aspects and the heterogeneous distribution of contaminants (Jongenburger et al. 2012), the level of control of all achievable sampling plans is generally not appropriate.

One example where historical results can be used to reduce the frequency of end product testing already exists. In the EU legislation (EC2073/2005) for *Salmonella* analyses of minced meat, meat preparations and carcases, sampling can be reduced to fortnightly if satisfactory results have been obtained for 30 consecutive weeks or if the national or regional *Salmonella* control programme demonstrates that the *Salmonella* prevalence is low. If a similar approach could be applied for other food processes a reduction of microbiological tests could contribute to cost savings, still providing safe food to the consumers. The concept could be applied to all types of food processing operations. If past performance can demonstrate the effectiveness of prerequisite programs and the hazard control system (*e.g.* HACCP) at all steps of the food production process is implemented, from development and design to implementation and long-term monitoring, the frequency of microbiological testing could be reduced.

Following certain severe outbreaks, a risk management reaction may be to set new microbiological criteria. This happened for example after the EHEC/STEC outbreak related to sprouts in Germany, where new criteria were developed for this organism in this particular commodity (EU 209/2013, taken up into EC 2073/2005). However, as explained below, taking 5 samples of 25 g from a batch and showing they are all free from the pathogen, does not show that the whole batch is safe. In addition, the EU Regulation 209/2013 prescribes sampling of at least 0.5% of all batches of seeds and testing of 5 times 200 ml irrigation water. Although the latter test will make the detection of localised contaminations much more probable, the advised frequency is at least once a month, which again implies that occasional contaminations might easily be missed. The basis of the number of samples, frequencies and quantities of material to be analysed is often not easy to decide upon. Although these types of criteria do help to verify and detect occasionally deviations, they are not sufficient to guarantee full control (Jongenburger, den Besten, & Zwietering, 2015).

2. Sampling, validation, verification

By now, there is a general understanding that *control* of safety is only to a very limited extent supported by finished product testing. Good management should be based on evidence that hazards are well under control and that the interplay between initial levels of organisms, reduction, recontamination and growth is supplying a final level or prevalence of the hazard that is appropriate (Fig. 1). Whether these phenomena are well under control needs to be based on solid information (*validation*) that can be partly based on sampling (CAC, 2008). Especially data on initial levels and prevalence of microbiological contaminants in raw materials and the environment can be based on sampling, but is mainly done for investigating baseline data and general trends. For information on phenomena like reduction, survival, transfer and growth of microorganisms along the production process or even the whole food chain, information from specific experiments (e.g. challenge tests), databases, scientific literature or predictive microbiology could be combined to determine proof of sufficient control.

If in this manner, by *validation*, a process is shown to be under control, this can be *verified* by finished product testing at the food industry level and by epidemiology on governmental level. Neither absence of the microbial hazard in finished products, nor the lack of evidence for an epidemiological link, is proof that a process, and consequently the safety of food products, is under control. On the other hand, if finished products are not complying or if there is a strong epidemiological link, this can be an indication that a process is not under control. Therefore sampling as a verification activity may be a useful tool.

It can be stated that finished product sampling is a relevant part of the verification of a food safety management system, but that it is more the totality of information that provides the confidence, than the sampling only. A food safety dossier containing only abstract proofs of validation will not be sufficient without real field-data. However, finished product field data alone are not a proof of appropriate control either.

3. Which information is needed?

In many countries it is mandatory for food-manufacturers to work in accordance with Codex principles of Hazard Analysis Critical Control Point (HACCP) (CAC, 2003). Therefore, in most factories there should be historical records and other information available on the performance of applied processes and history of the product. This type of information is feeding the food safety management system and assuring that food safety in finished products is under control.

Depending on the time period for which production has been running the amount of historical data available will vary. Important records are those collected during monitoring at different steps in the production process (Table 1) and include process parameters such as time, temperature, pressure etc. Other important information covers results of microbiological tests on the prevalence or contamination level in the environment, incoming raw materials, semi-finished and finished products. This could be tests for foodborne pathogens (e.g. if following an investigation or root cause analysis testing for pathogens is deemed appropriate), but results on indicator or spoilage organism are often more relevant as the prevalence of pathogens normally is very low.

Initially, when only little data for a process (line) is available, finished product sampling is useful as a verification tool to guarantee that the product and process meet set specifications. Sampling of raw material will be important to identify relevant hazards and to show how effective the inactivation during processing is. The prevalence in raw materials may be high(er), but this is not necessarily a major problem if microorganisms are sufficiently eliminated during the production process. Increase or decrease in prevalence and concentration of the hazard in the raw material can be indicative of deviations.

Monitoring results at CCPs are vital as these are related to information on the variability and consistency of process parameters (critical and/or operational limits). Relevant records for thermal processes are for example pressure, temperature and holding time. For other processes times for acidification or cooling are central. Sampling of the production environment is relevant to show the potential for recontamination, especially in case of line start-up and packaging change-overs. As the environment is large and multiple sources of contamination routes are present (e.g. food contact surfaces, hands of personnel, air, water), the sampling plan should be well designed, targeting the most likely sources of recontamination, preferably close to the line where the product is not