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Assessment of food allergen management in small food facilities

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ABSTRACT

In terms of public health, food allergen management (FAM) is one of the major areas of food safety management, required by standardised food safety management systems (FSMSs). This study involved performing an evaluation of the scope of application of FAM and identification of non-conformity areas in 24 small food production facilities where FSMSs are implemented. Conformity with the 41 criteria was evaluated by the semi-structured interview method with direct on-site observation. The percentile Conformance Index (CI) and the relative Conformance Index (CI_{REL}) were established, calculated by the relativisation methods (i.e. evaluation and metrisation), applied in quality engineering. The highest level of non-conformities in the 7 groups of criteria established in the form of a questionnaire was found in Cleaning (CI 29.6-47.2%, Cl_{REL} 0.03-0.32), Transport & Storage (CI 30.6-54.2%, Cl_{REL} 0.05-0.69) and Hazard Awareness (CI 27.8-59.3%, CIREL 0-0.52). Factors which make it difficult to implement FAM included access to the validated methods of assessment of cleaning effectiveness in removing specific allergens, as well as good practices in separation of allergenic and non-allergenic materials during transport and storage, and personnel training in allergen control. These findings show clearly that implementation and certification of standardised FSMSs is a guarantee of implementation of FAM on a higher level of conformity with the evaluation criteria compared to those facilities which apply only the Codex HACCP principles. The conformity indexes CI and CI_{REL} proposed in this paper can be applied not only to determine the areas of non-conformity for FAM, but they can also be used to characterise and monitor FAM-related elements of FSMSs as part of self-evaluation and continuous improvement.

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1. Introduction

Food allergens affect the health and life of people with hypersensitivity caused by some food components and such allergens are identified as a severe food safety hazard and their management is one of the fundamental areas of food safety management systems (Cianferoni & Spergel, 2009; Crevel & Cochrane, 2014; Dzwolak, 2015; Röder & Weber, 2016; Stein, 2015). Reduction of the risk of unwanted allergic reactions in food consumers requires that certain food allergens should be eliminated from the diet (FARRP, 2008; Gendel, Khan, & Yajnik, 2016). Such an elimination diet will not be effective unless a person with a food allergy is informed in a reliable manner by food producers about allergens present in food (Dupuis et al., 2016; FARRP, 2012; Mortimore & Wallace, 2013). Therefore, the Codex Alimentarius Commission (CAC) FAO/WHO (CAC, 1991) recommends that information on allergens should be

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http://dx.doi.org/10.1016/j.foodcont.2016.08.019 0956-7135/© 2016 Elsevier Ltd. All rights reserved. placed on labels of food products. Furthermore, legal regulations in the USA (USFDA, 2004) and EU legislation (OJEU, 2011) impose an obligation on food producers to label food in regard to food allergens. This obligation in Poland has been in force since 2007 under a Regulation of the Minister of Agriculture and Rural Development of 10 July 2007 on foodstuff labelling (MARD, 2007).

Regardless of the obligatory regulations of the food law, supervision of food allergens is required by all voluntary standards which lay down the requirements for food safety management systems, such as BRC (BRC, 2015a), IFS (IFS, 2014), ISO 22000 (ISO, 2009) and SQF (SQFI, 2012). However, the scope of the control measures applied in regard to food allergen management (FAM) resulting from the requirements of those standards is much broader than just labelling food products required under the food product regulations (Dzwolak, 2015; FSA, 2006; Taylor & Hefle, 2005).

These control measures include such issues as identification of food allergens, preventing cross-contamination with allergens in freight, storage of raw materials and food additives (RW&FA), during the production process, as well as during storage of finished products (Dzwolak, 2015; Muñoz-Furlong & Sampson, 2008; Röder







& Weber, 2016; Taylor & Hefle, 2005). Separation of food which contains allergens from those which does not (FDE, 2013), as well as elimination or reduction of allergen residues from the surfaces that are in contact with food by washing and disinfection (Jackson et al., 2008) are important elements of preventing cross-contamination with allergens (Crevel, Taylor, Pfaff, & Alldrick, 2014; Stein, 2015). Preventing cross-contact can be executed by appropriate production scheduling: first, those products are manufactured which do not contain allergens or which contain allergens present in all products, and only after that are those products manufactured which contain specific allergens, present only in some products (AFGC, 2007; Dzwolak, 2015; FARRP, 2012; FDE, 2013; FSA, 2006).

Because of the specific conditions in which small businesses operate (limited financial and human resources, deficiency of knowledge on food safety management, etc.) food safety elements are more difficult to implement than in medium and large companies (Dzwolak, 2014, 2016). Considering this and the fact that FAM affects health and life of consumers, it is necessary to determine the scope of the application of FAM measures in small food production companies. The aim of the study was to evaluate the degree of implementation of control measures regarding food allergens in small food production facilities, as well as identification of major non-conformities and the corrective activities aimed at improvement of FAM.

2. Materials and methods

2.1. Food facilities characteristics

The study dealt with systems of food safety management in the FAM area. The scope of the study included 24 small food production facilities situated in the north of Poland, 17 of which held certificates of BRC and IFS (3), ISO 22000 (10), BRC (2), HACCP (2), and 6 declared implementing and following the Codex HACCP principles (6) or ISO 22000 standard (1) without certification (Table 1).

2.2. Questionnaire development and validation

The study was carried out by a semi-structured direct interview on site. Seven main topics (A-G) were investigated through developed questionnaire: hazard awareness, food allergen identification, cross-contamination, cleaning, labelling and management (Table 3). The questionnaire with 37 questions was based on the available literature on FAM (FARRP, 2008; FDE, 2013; IFR; Taylor & Hefle, 2005) and on requirements laid down in food safety management standards such as BRC (BRC, 2015a), IFS (IFS, 2014), SQF (SQFI, 2012) and ISO 22000, i.e. ISO/TS 22002-1 (ISO, 2009). The questionnaire validation was carried out with a group of 12 randomly selected food quality or food safety representatives and/ or managers, which resulted in making some questions more precise and expansion of the questionnaire to include 41 questions (Table 3).

2.3. Data collection

Data were collected between March 2015 and January 2016, in direct interviews on site with personnel responsible for food quality and food safety management systems (management representatives or food safety/quality team leaders) in these food production facilities.

2.4. Evaluation of compliance

Compliance with the checklist was verified with a 5-point scale of evaluation (Kolman, 2009), the method applied in quality

engineering to evaluate non-measurable quality criteria. The evaluation scale was developed by establishing level of conformance and criterion fulfilment (Table 2).

2.5. Conformance Index CI and CI REL

A Conformance Index (*CI*) has been developed for this study; it expresses the percent of compliance with the evaluation criteria (check list) for 7 FAM areas (Table 3). The index is calculated from the following formula:

$$CI_{A-G} = AMES_{24}^{-1} \sum_{i=1}^{n} Es \times Q_{FF_i}$$

where: $CI_{A-G} - CI$ values calculated for established 7 food allergen management areas A-G (Table 3), *Es* – evaluation score (0.1–0.9), Q_{FF} – quantity of food facilities complying with an appropriate evaluation score, *AMES*₂₄ – adjusted maximal evaluation score equal 21.6, calculated as a product of total quantity of studied food facilities, (24), and maximal evaluation score (0.9).

If any of the criteria were not applicable at the facility (N/A), then $AMES_{24}$ was calculated by deducting from $AMES_{24}$ the product of the number of facilities with the N/A status and the maximal evaluation score (0.9).

The *CI* expressed in percent was transformed into relative state (Kolman, 2009), with respect to the whole variability range of all the 41 criteria under analysis by the formula:

$$CI_{REL} = \frac{CI_{cur} - CI_{min}}{CI_{max} - CI_{min}}$$

where: CI_{REL} – relative state of CI, $1 \ge CI_{REL} \ge 0$, CI_{cur} – current CI for the evaluation criterion under analysis, CI_{max} – the maximum value of CI for the evaluation criteria variability range under analysis, CI_{min} – the minimum value of CI for the evaluation criteria variability range under analysis.

The values of *Cl_{REL}* as calculated are shown as radar charts for the groups of criteria under analysis A-G (Fig. 1a–g).

3. Results

3.1. Evaluation of compliance

3.1.1. Hazard awareness (A)

Personnel training in FAM basics (A1) was not carried out in over one-third (37.5%) of the facilities (Table 3). Full training was carried out in nearly 30% of the facilities (score 0.9), whereas training for part of the personnel was carried out in 33.3% of the facilities (score 0.5 and 0.7). In over half of the facilities (62.5%), there was no list of forbidden food allergens which personnel cannot bring in with their private food (A2). Full (documented) information in this regard was passed on every 6th facility (rating 0.9), whereas such information was communicated orally in every 5th facility (rating 0.7). No (N/A) documented FAM procedures or programmes were found in every 7th facility (A3). Although such documents existed in 11 facilities (score 0.7 and 0.9) in their full (33.3%) or partial (12.5%) form, they were made available to personnel only at 6 (25%) facilities.

The largest number of unfavourable ratings (0.1, 0.3 and 0.5) was given in regard to technical personnel of maintenance departments (A4 - 87.5%). Slightly lower (68%) unfavourable ratings were given in connection with external persons visiting food facilities (A5).

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