Allergen labelling and use of advisory labelling “May contain traces of [*allergen*]”

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Nordic enforcement projects

An enforcement project is a fixed-term project that examines compliance with the regulatory framework in a sector or for a particular food group. The company inspections are coordinated in terms of timing and content, thereby providing valuable information about the subject at a particular point in time. Generally speaking, a guidance document is prepared and the project begins with a training course for inspectors. In an enforcement project, the inspection body also uses other tools, such as information and collaboration with sector organisations and other bodies, to encourage companies to comply with the regulatory framework.

1. Summary

In 2010–2012, Norway, Sweden, Denmark and Finland collaborated in a Nordic inspection campaign about allergen labelling and use of advisory labelling “May contain traces of [*allergen*].” Norway coordinated and managed the project, and the Nordic Council of Ministers provided funding via the NMF Group (Nordic Working Group for Food Safety and Consumer Information).

The background to the project was that accurate labelling of allergens is crucial for the health of people who suffer from allergies. If allergens listed in Annex IIIa of the EC Directive (2000/13/EC with amendments) are not presented in the ingredient label, this can present a serious health risk for people with allergies. Furthermore, widespread use of the advisory labelling “May contain traces of [*allergen*].” is making it harder for people with allergies to choose products.

One aim of the project was to encourage food companies to take responsibility for accurate labelling of allergens on their products. The project also aimed to increase companies’ awareness and knowledge of allergy safety, and thereby improve procedures for advisory labelling. Another aim was to develop a common standpoint on the use of advisory labelling and to promote Nordic co-operation.

Norway and Sweden held a joint training programme for inspectors, while Finland and Denmark held their own national training projects. The training focused on legislation, current issues, how the inspections were to be carried out and how the findings were to be reported. Training also included lectures by doctors about allergies. Workshops focused on various inspection situations and how these situations could be resolved.

During the project period, national meetings were held in the participating countries, attended by the food sector, allergy associations and other resource personnel.

1.1 Product assessment

A total of 464 companies were inspected, and allergen labelling and advisory labelling was assessed on 1,095 products. The numbers of labelling inspections and audits of the companies’ internal controls varied between the countries, as did the numbers of inspected product categories. This should be taken into account when interpreting the results, and the results in the respective countries are not directly

comparable with one another. Consequently, the results presented focus on types of deficiency and measures to reduce the amount of advisory labelling “May contain traces of [*allergen*]” on products.

The results showed that allergen labelling on 219 products (20%) was deficient.

Deficient labelling of allergens according to the allergen list (2000/13/EC with amendments) comprised the highest percentage for all countries, 14.5% of all products (159 products in total). The next highest proportion of labelling deficiencies in all countries entailed labelling where ingredients did not comply with the recipe, 9% (97 products in total). These are deficiencies that the food authorities in the Nordic countries regard as very serious.

A positive result was that only few deficiencies were found relating to language and readability of the text on the labelling.

A significant proportion of the products had advisory labelling, with the most commonly used text being “May contain traces of [*allergen*].” This advisory labelling was mainly used because the same equipment was used for several different products and because the equipment was difficult to clean. Another reason for using advisory labelling was that suppliers of raw materials/finished products use this type of advisory labelling, which is then transferred to new products by producers and importers without reassessment.

Misleading advisory labelling was recorded for 116 products, which is approximately 11% of the total. The main reason for the deficiencies was that the companies had used the advisory labelling without conducting a satisfactory review of their production procedures. In certain cases, another observation was that the national labelling and the foreign labelling (e.g. English) did not correspond.

The inspections also considered whether the labelling was misleading in relation to criteria set by the Nordic working group. The aim here was to test the practical application of these criteria and the results would then form the basis of a discussion paper and draft criteria for advisory labelling. Conditions for the use of advisory labelling were that the allergen was to be uncontrollable and occur sporadically, and its allergic effect on consumers documented. When these test criteria were applied, more deficiencies were observed.

1.2 Audit of the companies’ internal controls

In this project, each country carried out as many inspections as were possible, given the limited project period. However, this time restraint prevented the participating countries from carrying out a statistically certain number of inspections for all the areas under examination. The results showed that the same types of deficiencies and the same problems occurred in all participating countries, so we chose to combine

some results from the companies' internal controls. This would give us a picture of the types of deficiencies that occur in internal controls and an indication of the scale of these deficiencies.

The results of the audit of company procedures for internal inspections showed a large number of deficiencies in all countries. An overall picture of procedures to ensure accurate labelling of allergens showed that 45% of companies had one or more deficiencies.

Results also showed that a significant proportion of companies had one or more deficiencies in terms of appropriate procedures in their internal controls for managing allergens.

The inspection item that examined whether companies followed their own procedures revealed deficiencies in a significant proportion of the companies – 8% did not check for compliance with their own internal procedures.

Another issue examined was whether companies considered all allergens in their risk analyses. Results showed that some companies did not consider all allergens in the risk analysis. Allergens must be labelled in accordance with the regulatory framework, so their exclusion from the risk analyses of many companies is a serious deficiency.

An overall assessment (all countries) of procedures to prevent contamination of raw materials and finished products with allergens revealed deficiencies in some of the companies.

Another issue examined was whether companies had procedures in place to ensure that premises and equipment were satisfactorily cleaned. Results showed a significant number of deficiencies.

The project results indicate that food companies have not sufficiently accepted that allergens are a real danger for certain consumer groups. A consequence of this can be that process controls in terms of allergen safety are inadequate, resulting in for example incorrect labelling and contamination with allergens.

The project group has also prepared a discussion paper and draft criteria for the use of the advisory labelling "May contain traces of [*allergen*]." The objective is to promote discussion both nationally and within the EU about the formulation of common guidelines for appropriate use of advisory labelling.

2. Background and implementation

2.1 Background

In the spring of 2010, the Nordic Council of Ministers decided to carry out a project in the form of a joint Nordic enforcement campaign on the theme of allergen labelling and use of the advisory labelling “May contain traces of [*allergen*].”

The background to the project was that allergen labelling, including the management of allergens, is a major issue today. The theme is very important in the allergy field and is a constant issue for inspection bodies. Initiatives are also being implemented within the EU, the food industry and international organisations, because the labelling of food with the advisory text “May contain traces of [*allergen*].” seems to be on the increase and variations of the advisory text are becoming increasingly common. For people with allergies, the situation presents difficulties, such as when trying to choose a suitable food.

It is important that consumers can rely upon the labelling on food products being accurate. It is particularly important for people with allergies to and/or intolerance of certain types of food ingredients. Food labelled wrongly in terms of allergens can lead to anything from physical discomfort to a life-threatening condition.

Focus on the issue should help to ensure that companies have a well-founded justification for labelling with the advisory text, and should help to stop its unnecessary use.

Experiences from an earlier joint Nordic project have shown that joint Nordic enforcement campaigns are an effective way of working, relating to skills enhancement, production of materials and implementation of inspections.

2.2 Objectives

Impact objectives of the project

- Companies take responsibility for accurate labelling on their products
- Labelling about the allergen content is accurate
- Companies have appropriate procedures for use of the advisory text “May contain traces of [*allergen*].”

- Common policy in the Nordic countries about when companies can label products with “May contain traces of [*allergen*]”
- Increased knowledge about allergens
- People with allergies can trust that labelling is accurate
- People with allergies can make safe choices regarding food
- Greater range of food suitable for people with allergies
- Authorities, consumer organisations and the food sector have a common understanding of what the label “May contain traces of [*allergen*]” means and how it is to be used

Outcome objectives of the project

- Joint training for inspectors
- Carry out x audits (also joint) at retail chains, producers and importers
- Check for compliance with the regulatory framework about allergen labelling
- Check the use of the advisory text “May contain traces of [*allergen*]”
- Produce checklists and other inspection tools
- Prepare a common Nordic official standpoint on the use of advisory labelling “May contain traces of [*allergen*]”, etc.
- Final report
- Information to companies, consumers, media and inspection bodies about the project and results

2.3 Organisation

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Project Manager: Siri B. Svinddal (from June 2011), NO, Gyrd O. Gjevestad (until June 2011), NO

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Project Assistant: Tuva Lundebj Haagenzen, responsible for entering and processing data, NO

A Nordic project group was set up to work with overall planning and organisation. Norway organised its own national working group to carry out the inspections, while in the other Nordic countries the contact persons organised the work.

2.4 Legal basis

This inspection campaign was based on the following legislation:

- 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 Food Safety Authority and laying down procedures in matters of food safety.
- Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (Hygiene Regulation).
- Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 (with amendments) on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (Labelling Directive).

This project report, for the sake of simplicity, uses the term “allergens” instead of the phrase “ingredients that cause negative reactions in receptive persons” that is used in the Labelling Directive.

2.4.1 *Labelling of ingredients*

Allergens that must always be stated in lists of ingredients are stipulated in the Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 (with amendments) on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (Labelling Directive). It is important to note that labelling requirements also apply to ingredients that contain allergens.

Food companies must have systems in place to ensure compliance with the legislation. Food companies at all stages of the production, processing and distribution chain within the businesses under their control must ensure that food or feeds satisfy the requirements of food law that are relevant to their activities and must verify that such requirements are met (see Article 17.1 in Regulation (EC) No 178/2002).

This means that every company must have systematic procedures in place to ensure that the final product is accurately labelled in terms of allergens. All labelling must be accurate. It must not mislead the consumers in matters of its nature, properties or composition (2000/13/EC).

2.4.2 *Advisory texts – hygiene regulations and the companies’ responsibility*

According to Article 5.2 a) of the Regulation (EC) 853/2004, food companies must establish, implement and maintain a permanent procedure or procedures based on HACCP (Hazard Analysis and Critical Control Points) principles, i.e. identify hazards that must be prevented, eliminated or reduced to an acceptable level. The company must also comply with the requirements in Annex II of the Hygiene Regulation about general hygiene regulations for all food companies.

In this examination of the application of advisory text on labelling, the focus is on the company’s own assessment and whether there is an assessment that is relevant to the issue.

2.5 Implementation

In the introductory work, the project group decided that the following products were to be considered:

- Ready-made and semi-manufactured foods (packet soup, gravy, casserole dishes, etc)
- Breakfast cereals (e.g. Corn Flakes, muesli)
- Bread, cakes, biscuits, baking mixture (bread, pancakes/waffles, cakes)
- Sweets and snacks
- Desserts (ice cream, pudding, jelly, etc)

In each company, the labels on 2–3 products were inspected. Products both with and without advisory text about allergens were inspected.

These products were chosen because they are part of a normal diet of people with allergies. The food sector and consumer associations also had input on the choice of products. Furthermore, advisory labels about allergens are common on these products, which are produced in all Nordic countries.

Both producers and importers were included in the project. Inspections were also carried out in head offices of retailers, which can be both producer and importer.

Guidelines to the project were prepared, aimed at giving an overview and providing necessary information for the implementation of the inspection campaign. The guidelines were adapted to each country and contained general information about the campaign and information about how it was to be implemented. Checklists were also prepared for product inspection and for audit of internal controls at producers and importers.

2.5.1 Training and information

Norway and Sweden held a joint two-day training course in Norway for inspectors, while Finland and Denmark held their own national training courses. Approximately 350 inspectors took part in the training courses.

The training focused on legislation, current issues, how the inspections were to be carried out and how the findings were to be reported. Training also included lectures by doctors about allergies. Workshops focused on various inspection situations and how these situations could be resolved.

Advance information about the inspection campaign and training courses was given at the Nordic Food Control Conference in Denmark 2011. In each country, information was presented to inspectors, the food industry and consumer associations. Preliminary results were presented at the Nordic Food Control Conference in Finland 2012.

The project has also prompted many articles in trade journals and training programmes organised by the food industry, associations, etc.

2.5.2 Joint inspections

Joint inspections were held in Denmark on one occasion, involving inspectors from Denmark, Sweden and Norway. In addition, two joint inspections were carried out in Sweden, involving inspectors from Sweden and Norway. The purpose of these joint inspections was to exchange experiences and to ensure a standard interpretation of the legislation. These inspections were experienced as a positive element in the project, and agreement was reached on common values relating to various issues. The companies that were inspected were represented in the Nordic countries, and the inspection gave them a common Nordic assessment of their internal controls and allergen labelling. Assumptions for the joint inspections were that issues were discussed beforehand and that inspectors had detailed examples that could be discussed.

3. Results

In this section, the results of the product inspections and the audits of the companies' systems for internal controls are presented.

For a small number of companies and products, results are missing for certain questions. Consequently, the percentages in the table and figures are based on the actual number of answers to each specific question. Follow-up inspections were carried out at a few companies in Norway and Denmark. Consequently, the percentages in the figures for internal controls are based on the number of inspection visits.

The number of labelling inspections and audits of companies' own control systems varies quite considerably between the countries. The product categories inspected also vary. Companies were chosen for inspection largely on the basis of a risk assessment. Implementation of the project can also be affected by how food inspection activities are organised in the Nordic countries. Norway and Denmark have a centralised (state) food inspection organisation with direct authority over the inspection bodies. In Sweden and Finland, municipalities act independently and the central authority has an advisory/governing role. When interpreting the results, these differences should be considered. The results in the various countries are therefore not directly comparable with each other.

3.1 Product assessment

A total of 1,095 products from 464 producers and importers were inspected through 512 inspection visits. The number of products and companies in each country is shown in Table 1.

Table 1 Number of products and companies inspected

Country	Number of products	Number of companies
Norway	643	252
Sweden	86	41
Finland	87	47
Denmark	279	124
Total	1095	464

The number of inspection visits was as follows: Norway 293, Denmark 131; for Sweden and Finland the number of inspection visits was the same as the number of companies.

3.1.1 Product categories

Figure 1 Product inspections: proportions by product category

Figure 1 shows the product categories used in the inspections. Bread, cakes and biscuits comprise the largest proportion of products inspected in Norway and Finland, while in Denmark and Sweden the largest proportion was ready-made and semi-manufactured food.

Figure 2 Proportion of products where the allergen labelling in the ingredient list was unsatisfactory

Figure 2 shows that the deficiencies in ingredient labelling on the products were as follows: Norway 23.3% (149 products), Sweden 18.6% (16 products), Denmark 13.3% (37 products), and Finland 20.7% (17 products).

Figure 3 Ways in which the ingredient labelling was unsatisfactory

Figure 3 shows that a total of 219 products were incorrectly labelled. Of these, 149 were in Norway, 16 in Sweden, 37 in Denmark, and 17 in Finland. Most cases of incorrect labelling involved the allergen not being stated in accordance with the labelling requirement in the allergen list (2000/13/EC). For Norway, this applied to 106 products (71.6% of 149), for Sweden 11 products (68.8% of 16), for Denmark 31 products (83.8% of 37) and for Finland 11 products (64.7% of 17), so the labels on a total of 159 products did not comply with regulations concerning allergens.

The second highest percentage was for cases where ingredients shown on the label did not correspond with the recipe. For Norway, this applied to 65 products, for Sweden 7 products, for Finland 4 products and for Denmark 21 products, a total of 97 products. Unpermitted category names had been used in Norway on the labels of 30 products (20.3% of 149), in Denmark on one product (2.7% of 37) and in Finland on 10 products (58.8% of 17). In Sweden, no such labelling deficiencies were found. Some of the products lacked ingredient labelling.

3.1.2 Readability and language

Figure 4 Proportion of products where readability of text on the label was unsatisfactory

Figure 4 shows that the labelling text was readable on over 90% of the inspected products in all countries. In the few cases where the text was hard to read, this was because the text was too small, the colours unclear or because the label easily became detached. In three of the four countries, the labels on more than 98% of the products contained satisfactory language. Examples of deficiencies on this aspect were that the label contained no Nordic text, that the text included words that are not the same in the Nordic languages, and that the English text did not match the Nordic.

3.1.3 Advisory labelling

Figure 5 Proportion of products with advisory labelling

Figure 5 shows the proportion of products that had/did not have advisory text on the labels. Products were mostly chosen on a risk basis and so the results do not give a general picture of how common advisory labelling is on the products on the market. In Norway 38.4% (247 products) of the inspected products had advisory labelling, in Sweden 45.3% (39 products), in Denmark 34.1% (95 products) and in Finland 22.8% (19 products).

Figure 6 Types of advisory labelling

Figure 6 shows that the most commonly used advisory labelling was “May contain traces of [allergen].” Other texts observed were “Contains traces of [allergen]”, “Made on the same production line as products containing [allergen]”, “Made in the same premises as products containing [allergen].”

Other texts used included “Possible contamination with [allergen]”, “Produced in the same premises as [allergen]”, “Supplier has labelled this product with advisory text about allergens.”

Figure 7 Reasons why companies use advisory labelling on their products

Figure 7 shows that the most common reason for using advisory labelling is that the company uses the same equipment/production line for several products. This applied to 202 of the 400 products with advisory labelling. Other reasons stated were difficulties in cleaning equipment and premises, sub-suppliers had labelled raw materials with this type of advisory text, and the food retailers had decided that the product should have an advisory label.

Figure 8 Proportion of products with advisory labelling that was misleading (394 answers from a total of 400)

Figure 8 shows that a significant proportion of the advisory labelling on the inspected products was misleading. The proportions of products with misleading advisory labels were as follows: Sweden 38.5% (15 products), followed by Norway, 32.6% (79 products), Finland 26.3% (5 products) and Denmark 18.1% (17 products). The reason why advisory labelling was deemed misleading was largely because companies use such labelling for no satisfactory reason. In some cases, it was also observed that the national labelling did not correspond to the foreign labelling (e.g. English).

Figure 9 Proportion of products with advisory labelling that was misleading according to set criteria

Figure 9 shows the proportion of products with advisory labelling that was misleading according to the criteria set by the project group. The aim was to test how these criteria work in practice and so provide data for a discussion paper and draft criteria on advisory labelling. For example, if advisory labelling is to be used, the allergen must be uncontrollable. When these criteria were applied, many deficiencies were observed.

3.2 Audit of internal controls

Internal controls relating to allergens were audited in 464 companies and through 512 inspection checks.

3.2.1 Procedures for allergen labelling

Figure 10 Overall assessment of internal procedures for allergen labelling in companies in the Nordic countries

Figure 10 shows an overall assessment for the Nordic countries of internal procedures to ensure accurate labelling of allergens. Forty-five percent of the companies (232 companies) had one or more deficiencies in terms of appropriate procedures in their internal controls for managing allergens. The percentages give an overview of all types of deficiencies in internal control procedures relating to allergens in all inspected companies.

This part of the study assessed:

- Results from the labelling inspection in relation to any internal procedures
- Whether the division of responsibility in the area is clear and known
- Procedures for preparing labels, translations, and supplier checks
- Procedures for delivery inspection
- Procedures for training and skills

Figure 11 Whether companies have appropriate procedures to ensure accurate labelling of allergenic ingredients. Results shown by country.

Figure 11 shows whether there were appropriate procedures in place for allergen labelling. Results for Denmark showed that 35 of 131 companies inspected did not have satisfactory procedures to ensure accurate labelling of allergenic ingredients. In Finland, this applied to 22 of 47 inspected companies, in Norway 161 of 293 and for Sweden 14 of 41 inspected companies had deficiencies in this respect.

3.2.2 Allergens in risk analysis

Figure 12 Whether all allergens have been included in the risk analysis

This part of the study assessed:

- Which allergens were involved in production processes
- Procedures for mapping possible allergens
- Procedures in the production process to prevent contamination of raw materials and products with allergens
- Procedures regarding allergens when there is a change of supplier
- Procedures for changing/updating recipes

The results showed deficiencies in 190 companies regarding inclusion of all allergens in risk analyses.

3.2.3 Procedures for preventing contamination

Figure 13 Overall assessment of whether companies have appropriate procedures for preventing contamination of raw materials and finished products with allergens.

Figure 13 shows whether companies had procedures to prevent contamination of raw materials and finished products with allergens. The results, which are for the Nordic region as a whole, show that 15% of companies had deficiencies. Fifteen percent of the companies were not assessed.

This part of the study assessed:

- Procedures for flows, zone division, storage facilities for raw materials and finished products, e.g. use of the same tools/equipment in handling/storing various ingredients
- Whether the division of responsibility in the area is clear and known
- Training/expertise regarding allergens

Figure 14 Whether companies have appropriate procedures for preventing contamination of raw material or finished product with allergens.

Figure 14 shows the results for the different countries regarding prevention of contamination. Deficiencies were observed for 7% of the companies inspected in Sweden (i.e. 3 companies), 14% in Denmark (18 companies), 17% in Norway (49 companies) and 19% in Finland (9 companies). Note that the columns called “import” and “not assessed” show the percentage of companies to which this question was not applicable.

Figure 15 Whether companies have procedures to ensure that premises and equipment are satisfactorily cleaned

This part of the study assessed:

- Procedures for cleaning relating to allergens (cleaning agent, frequency and method)
- Procedures for maintenance to ensure appropriate cleaning
- Procedures for cleaning inspection
- Whether the responsibility in this area is clear and known
- Training/expertise regarding allergens

Procedures to ensure that premises and equipment are satisfactorily cleaned were assessed. Results revealed deficiencies as follows: Denmark 14% (18 companies), Finland 17% (8 companies), Norway 13% (38 companies) and Sweden 7% (3 companies). Note that the columns labelled “import” and “not assessed” show the percentage of companies for which this question was not applicable. These are companies that do not have their own production processes that can be inspected directly. A total of 67 companies in the four countries had deficiencies in their internal controls.

Figure 16 Overall picture of whether companies in all countries follow their own procedures in internal controls relating to allergens

Figure 17 Overall assessment of whether the companies have procedures in their internal controls relating to allergens

Deficiencies were observed in 21% of the companies in Denmark (27 companies), 3% in Norway (90 companies), 36% in Finland (17 companies) and 37% in Sweden (15 companies). “Not assessed” in this diagram means information was not provided.

Figure 18 Overall picture of whether companies in all countries follow their own procedures in internal controls relating to allergens

Figure 18 shows overall results for the four countries regarding checks of whether companies followed their own procedures for allergens in their internal controls. In 23% of the companies (118), deficiencies were observed. Examples of deficiencies were unclear procedures, irrelevant procedures, and that applicable procedures were not followed because they had not been updated.

4. Evaluation

The EU food regulations are largely harmonised with those of countries in the EEA collaboration, which in this project applies to Norway. This should ensure consumer safety, but it also ensures free trade of goods between the Member States and the EEA countries. Even if the regulatory framework is the same in the Nordic countries, various interpretations can bring about different practices in the different countries. For companies that trade the same products in several Nordic countries, different procedures can create different conditions.

Consequently, one of the aims of the project was to promote standardised practices in the allergen field. It is vital that companies are familiar with the regulatory framework. Another important aim was to make companies aware that they must take allergens seriously and set up good procedures for production and labelling of their products. They must do their utmost to prevent contamination with allergens where possible.

4.1 Product assessment

4.1.1 Labelling of ingredients

Allergenic ingredients are to be labelled, regardless of quantity. This is regulated at EU level. The list of ingredients on a product is the most important aid for consumers when checking the contents of the food they are buying, both in terms of nutritional content and allergens. In production of some ingredients, including additives, allergens can be used that can then be transferred to the final product. One finding of this study was that the final product is not always labelled accurately in terms of content of applicable allergens. The 14 allergens that are to be labelled regardless of quantity are expected to be addressed through good inspection procedures in the food companies. The project has shown a significant number of deficiencies in the labelling of ingredients.

The largest proportion of deficiencies involves allergens not being labelled according to the allergen list (2000/13/EC). The next highest percentage for all countries was that the ingredients list did not correspond with the recipe. These are deficiencies that the Nordic food inspection bodies see as very serious deficiencies.

On 41 of the products examined, the unpermitted designation of composite ingredients is also serious. Allergens that are part of the

composite ingredients are not clearly shown. This result also raises the issue of whether staff training on the matter of labelling is adequate. In particular, staff members responsible for product labelling should be very familiar with labelling legislation. This also applies to import companies.

This is a serious labelling deficiency, and means that people with allergies are not receiving necessary information about what the products contain. It is particularly serious that the project has shown some of the products even lack an ingredient list and that there were cases where the list did not match what the products actually contain (the recipe).

In many companies, deficiencies were shown in updating of labelling after changes to the recipe. For other companies, there can be various reasons why labelling did not match the actual content. For example, the use of new suppliers or the supplier changing ingredients can lead to errors that the food company does not discover due to the lack of procedures for checking for changes after a change of supplier.

These are deficiencies that are unacceptable. In view of the consequences for people with allergies, incorrect labelling of so many products is very serious, and indicates shortcomings in the companies' procedures for labelling products.

Positive results included that there were few deficiencies relating to language and readability of the text on the labelling.

4.1.2 Advisory labelling

Four hundred of the total of 1,095 products had advisory labelling. The expression "May contain traces of [*allergen*]" was the most commonly used text.

This type of labelling is only regulated via provisions about misleading labelling. There is no definition of what a "trace" involves in terms of quantity or how sporadically it can occur in a production series. For the inspection bodies, it is vital that emphasis is placed on checking that companies have assessed the issue of advisory labelling and that the companies have established procedures to address the issue.

Advisory labelling appeared mainly because the same equipment was used for several different products. The second most common reason was that the equipment was difficult to clean. Other reasons were that suppliers of raw materials/imported goods use the "May contain traces of [*allergen*]" text on their labels, and these goods are then used without further assessment of whether or not the end product justifies such advisory labelling. It is of the utmost importance that companies have good procedures in place for checking their suppliers' products and have internal controls set up to ensure they have relevant information before deciding whether to use advisory labelling.

These results raise the issue of whether companies are really doing their utmost in risk management to avoid the unnecessary use of advisory labelling. The companies should carefully consider what risk management measures can be used to avoid unnecessary such labelling.

Misleading labelling with the phrase “May contain traces of [allergen]” was discovered in 116 products, i.e. 29%. The primary reason for the deficiencies was that the companies had used advisory labelling without first carrying out a satisfactory review of its production processes regarding the risk of “traces of [allergen].”

The project also included the pilot study of criteria for the use of advisory labelling. The result of this indicated a need for improvements to companies’ risk management procedures in view of the needs of people with allergies.

The lack of threshold values, provisions that stipulate what a “trace” is, and set levels for the amounts at which consumers with allergies start to react, cannot justify the fact that some companies use such labels uncritically without carrying out any form of evaluation.

If companies have carried out an analysis and found grounds for advisory labelling, then the use of such labelling may be acceptable. It is important to emphasise that it is the company’s responsibility to assess whether advisory labelling is really necessary as the ultimate risk management measure.

It is important that companies do everything possible to avoid contamination with allergens, but what is sufficient is determined in each individual inspection. The aim of the project is to draw the food sector’s attention to the problem of using advisory labelling uncritically. The use of such labelling should be based on assessment of the production circumstances in each case.

4.2 Audit of internal controls

The audit of companies’ procedures for internal controls showed a large number of deficiencies in all countries. An overall picture for the four countries with regard to procedures that ensure accurate labelling of allergens showed that 45% of the companies had deficiencies.

The number of audits varied from country to country. The results must therefore be seen in the light of this disparity, which must be taken into account when the results are analysed.

However, even if the number of inspections varied between participating countries, the same deficiencies and the same issues were discovered in all countries. We therefore decided to combine some results for internal controls in order to illustrate the type of deficiency and to provide an indication of the scale of these deficiencies, even though the amount of data for each country is not sufficient to give a completely accurate picture.

Twenty-nine percent of the companies had one or more deficiencies in appropriate procedures for managing allergens in their internal controls.

The part of the study that focused on whether companies followed their own procedures showed that 69% did follow their procedures, while deficiencies were observed in 23%. This was not assessed in 8% of the inspections. The results showed that some companies did not consider all allergens in their risk analyses. Allergens must be labelled in accordance with regulations, and their exclusion from the risk analyses of several companies is serious.

An overview (all countries) of procedures for preventing contamination of raw materials and finished products with allergens revealed deficiencies in 15% of the companies. This was not assessed in 15% of the companies.

The audits comprised examinations of whether companies have procedures in place to ensure that premises and equipment are satisfactorily cleaned, and a significant number of deficiencies were found.

Results indicate that companies have not sufficiently accepted that allergens present a serious danger for certain consumer groups. This may explain deficiencies in internal controls with regard to allergy safety, resulting for example in allergy contamination and incorrect labelling.

The outcome goals of the project have been reached in that a significant number of inspections were carried out with regard to allergen labelling and internal control procedures. The plan to produce a guide with checklists, and arrange joint training courses, was successfully accomplished. A joint discussion paper and draft criteria for the use of advisory labelling was produced; it will be used as input to the discussion in the EU about advisory labelling “May contain traces of [allergen].”

The impact goals cannot be measured yet. Time will tell whether the project will encourage companies to make changes in their allergen labelling and internal controls relating to allergy safety. In particular, the project group feels that it is important that companies review their use of advisory labelling to ensure that it is justified and based on evaluation.

4.2.1 Discussion paper and draft criteria for advisory labelling

The project group stresses the importance of achieving a common understanding in the use of the advisory labelling (“May contain traces of [allergen]”). The project group has prepared a discussion paper and draft criteria for use of the text “May contain traces of [allergen].” The aim is to contribute to the discussion, both nationally and within the EU, about production of common guidelines for appropriate use of advisory labelling.

5. Conclusion

A large proportion of the companies inspected in the project were chosen on the basis of risk. The Nordic food inspection bodies have observed that there are products on the Nordic market that are incorrectly labelled in terms of allergens. This entails a risk for consumers with allergies, ranging from mild to life-threatening reactions as a result. The Nordic food inspection bodies are of the view that incorrect labelling of ingredients is a serious deficiency, particularly regarding allergens.

It is the responsibility of the food companies to ensure that products are accurately labelled and that they have functioning internal controls for allergy safety. This also applies to import companies.

The results of the project indicate the companies have not sufficiently accepted that allergens are a real danger for certain consumer groups. This may explain deficiencies in internal controls with regard to allergy safety, resulting for example in allergy contamination and incorrect labelling.

The results also show that some companies use the advisory label “May contain traces of [*allergen*]” without sufficient analysis of whether the product can actually contain traces of allergens. As a result, consumers with allergies are finding it increasingly difficult to choose their everyday food.

6. Sammanfattning

Norge, Sverige, Danmark och Finland har under 2010–2012 samarbetat inom ett projekt i form av en Nordisk kontrollkampanj om allergenmärkning- och varningsmärkning av allergener (kan innehålla spår av). Norge har haft rollen som projektledare. Nordiska Ministerrådet har via NMF-gruppen (nordisk arbetsgrupp för matförvaltning och förbrukarinformation) gett medel till projektet.

Bakgrunden till projektet var att korrekt märkning av allergener är avgörande för allergikers hälsa. Avsaknad av märkning av allergener som finns upptagna i allergilistan (2000/13/EG med ändringar, bilaga IIIa) kan utgöra en allvarlig hälsorisk för en allergiker. Vidare kommer ett utbrett användande av varningsmärkning innebära att det blir svårare för allergikerna att välja produkter.

Målet för projektet var att företagen tar sitt ansvar för att märkningen av allergener är korrekt på sina produkter. Dessutom hade projektet som mål att öka företagarnas kunskaper i allergisäkerhet så att företagen har bra rutiner för användandet av varningsmärkning. En målsättning var också att utarbeta en gemensam hållning för användandet av varningsmärkning samt att främja det nordiska samarbetet.

Norge och Sverige genomförde en gemensam utbildning inom området för deltagande inspektörer medan Finland och Danmark genomförde utbildningen som nationella utbildningsprojekt. Vid utbildningarna fokuserades det på lagstiftning, aktuella problemställningar inom området och på hur kontrollen skulle genomföras samt hur rapporteringen skulle ske. Utbildningstillfällena innefattade även föreläsningar av läkare om allergier. I workshops arbetades det med olika kontrollsituationer och hur dessa kunde lösas.

Under projektperioden har det ägt rum nationella möten i de medverkande länderna, där livsmedelsbranschen, allergiförbund och andra resurspersoner deltagit.

6.1 Produktvärdering

Sammanlagt kontrollerades 464 verksamheter och på 1095 produkter kontrollerades märkning med avseende på allergener och varningsmärkning. Antalet märkningskontroller och kontroll av företagarnas egenkontroll varierade mellan länderna. Även de kontrollerade produktkategorierna varierade i antal. Vid tolkning av

resultaten bör dessa skillnader tas i beaktande. Resultaten i de olika länderna är därmed inte direkt jämförbara med varandra. I redovisat resultat fokuseras därför på typ av avvikelse och åtgärder för att reducera varningsmärkning på produkter.

Resultaten visar att 219 produkter (20 %) hade avvikelser beträffande märkning av allergener.

Att allergener inte har märkts enligt allergilistan (2000/13/EG med ändringar) utgör i procent högsta andelen för alla länder totalt 159 produkter (14,5 % av alla produkter). Att ingrediensmärkningen inte stämmer med receptet utgör den näst högsta andelen i procent för alla länder med totalt 97 produkter (9 %). Detta är avvikelser som de nordiska tillsynsmyndigheterna ser som mycket allvarliga avvikelser.

Positiva resultat i kontrollerna var bland annat att det var få avvikelser på språk och läsbarheten av märkningen.

En betydande andel av produkterna hade varningsmärkning. Varningsmärkning "kan innehålla spår av" utgjorde den mest använda varningsmärkningen. Orsaker till att varningsmärkning användes var till största del att samma utrustning används till flera olika produkter och att utrustningen är svår att rengöra. Andra orsaker var bland annat att leverantörer av råvaror/färdigvaror märker varorna med varningstext som sedan förs över till nya produkter av producenter och importörer utan vidare värdering av märkningen.

Avvikelse beträffande att varningsmärkningen var vilseledande noterades i 116 produkter och utgjorde ca 11 % av totala antalet produkter. Anledningen till avvikelserna var i första hand att verksamheterna hade använt varningsmärkning utan att ha gjort en tillfredsställande genomgång av sin produktion. I vissa fall kunde man även konstatera att den nationella märkningen och den utländska märkningen (t.ex. på engelska) inte överensstämde.

Kontrollen omfattade dessutom en fråga om märkningen var vilseledande utifrån kriterier som arbetsgruppen ställt upp. Målet med denna fråga var att testa hur dessa kriterier fungerar i praktiken och på så sätt få bakgrundsmaterial för utarbetande av diskussionsunderlag och kriterier för varningsmärkningen. För att få märka med varningstext skulle t.ex. allergenet vara okontrollerbart, sporadiskt förekommande och dokumenterad. Då dessa testkriterier användes kunde man konstatera mera avvikelser.

6.2 Värdering av egenkontroll

I detta projekt har varje land utfört det antal kontroller som varit möjliga att utföra under den avgränsade projektperioden. Det medför att de deltagande länderna inte kunnat utföra ett statistiskt säkert antal kontroller för alla de områden som kontrollerats. Av resultaten ser vi likväl samma typer av avvikelser och samma problem i alla deltagande

länder. Vi har också av den anledningen valt att slå ihop några resultat från egenkontrollen för att få en bild av vilken typ av avvikelser som förekommer och en indikation på omfattningen av dessa avvikelser.

Resultaten av granskningen av verksamheternas rutiner för egenkontroll visar ett stort antal avvikelser i alla länder. En samlad bild för alla länder med hänsyn till rutiner som säkerställer korrekt märkning av allergener visade att 45 % av verksamheterna hade en eller fler avvikelser på denna punkt.

Vidare visades det sig att en betydande del av företagen hade en eller flera avvikelser vad gäller ändamålsenliga rutiner för hantering av allergener i egenkontrollen.

Kontrollpunkten för om verksamheten följer sina rutiner konstaterades avvikelser i en betydande andel av företagen. I 8 % av kontrollerna var det inte värderat.

På frågan om hänsyn har tagits till alla allergener i faroanalysen visar resultaten att det är verksamheter som inte tagit hänsyn till alla allergener i faroanalysen. Att de angivna allergenerna som skall märkas efter regelverket inte är med i faroanalysen för flera verksamheter är allvarligt.

En översikt (alla länder) på rutiner för att förhindra kontaminering av råvaror och färdiga produkter med allergener, visar att en del av verksamheterna har avvikelser.

På kontrollpunkten om företaget har rutiner som säkerställer att lokaler och utrustning blir tillfredställande rengjorda konstaterades ett betydande antal avvikelser.

Projektets resultat tyder på att företag inte i tillräcklig utsträckning har noterat att allergener är en verklig fara för vissa konsumentgrupper. En följd av detta kan vara, att processkontrollen vad gäller allergisäkerhet är bristfällig med t.ex. allergenkontamination och felmärkning som följd.

Projektgruppen har vidare utarbetat ett diskussionsunderlag och förslag till kriterier för bruk av varningstexten "kan innehålla spår av." Målsättningen är att på så sätt kunna bidra i diskussionen både nationellt och inom EU för utarbetande av gemensamma rättningslinjer för ändamålsenligt bruk av varningsmärknings.

7. Appendices

- Appendix 1. Legislation and links.
- Appendix 2. Discussion paper and draft criteria for the use of the advisory text “May contain traces of [*allergen*].”

7.1 Appendix 1

Legislation and links:

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 Food Safety Authority and laying down procedures in matters of food safety. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002R0178:20090807:SV:PDF>.

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (Hygiene Regulation). <http://eur-lex.europa.eu/LexUriServ/>

[LexUriServ.do?uri=CONSLEG:2004R0852:20090420:SV:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0852:20090420:SV:PDF).

Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 (with amendments) on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (Labelling Directive, consolidated version). <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2000L0013:20110120:SV:PDF>.

7.2 Appendix 2

Labelling with “May contain traces of [*allergen*]” – discussion paper and draft criteria

Use of advisory labelling on food packaging comprising the text “May contain traces of [*allergen(s)*]” is increasing. The use of this type of labelling without sufficient justification is limiting the range of food available to people with allergies.

Through the work carried out in the Nordic Working Group for the project *Labelling of allergens and use of advisory text “May contain traces of [*allergen*]”*, representatives from the food safety authorities in Norway, Sweden, Denmark and Finland have jointly prepared this document, which proposes draft criteria for the use of allergen advisory labelling. The objective of this document is to contribute to the discussion when aiming to reach consensus on this matter in the Nordic region and in the EU.

Draft criteria for use of advisory labelling “May contain traces of [allergen]”

When the conditions listed below are met, then labelling with “May contain traces of [allergen]” can be considered well-founded and can therefore be used. The use of other allergen advisory labelling, such as “Contains traces of [allergen]”, or “Made on the same production line as [allergen]” is not recommended.

Conditions for food producers

The producer is responsible for planning the production process in such a way that the risk of contamination with allergens is reduced. Where relevant, the producer must also consider allergens in the risk analysis.

Labelling with “May contain traces of [allergen]” should only be used as a final option when the risk of contamination with allergens on a specific production line is:

1. *Uncontrollable*, i.e. it is impossible to control the entire production process
 - e.g. part of the production equipment is not accessible for cleaning, or cannot be cleaned with water.
2. *Sporadically occurring*, i.e. identified through, for example
 - Analysis of an allergen that is homogeneously distributed in the product or in the form of visible parts/shavings on the production equipment even after cleaning
 - Through inspection of the cleaning process
 - Verified allergic reaction in consumers.

Conditions for importers or introducers of food

The importer must ensure that the producing company can show that the allergens listed on the advisory labelling comply with the conditions presented above for use of the advisory labelling “May contain traces of [allergen].” This can be shown either through documentation or by an inspection of the manufacturing premises by the importer.

Allergen labelling and use of advisory labelling “May contain traces of [allergen]”

In 2010–2012, Norway, Sweden, Denmark and Finland collaborated in a Nordic inspection campaign about labelling of allergens and use of advisory labelling (“May contain traces of [allergen]”). The background to the project was that accurate labelling of allergens is crucial for the health of people who suffer from allergies. If allergens listed in Annex IIIa of the EC Directive (2000/13/EC with amendments) are not presented on a product label, this can present a serious health risk for people with allergies. Furthermore, increased use of the advisory labelling “May contain traces of [allergen]” is making it harder for people with allergies to choose products.

One aim of the project was to encourage food companies to take responsibility for accurate labelling of allergens on their products. The project also aimed to increase awareness and knowledge in food companies about allergy safety, and thereby improve procedures for advisory labelling about allergens. Other aims were to develop a common standpoint on the use of advisory labelling and to promote the Nordic co-operation.