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Needs and difficulties of food businesses in the substantiation of health and nutrition claims

Hegyí, A.¹; Viola, K.²; Gyuró, Á.³; Sebők, A.⁴; Vidry, S.⁵; Putz, P.⁶; Bánáti, D.⁷

Corresponding author: Adrienn Hegyí

¹ a.hegyi@campdenkht.com Campden BRI Hungary Ltd., 1096 Budapest, Haller u. 2, Hungary

² k.viola@campdenkht.com Campden BRI Hungary Ltd., 1096 Budapest, Haller u. 2, Hungary

³ a.gyuro@campdenkht.com Campden BRI Hungary Ltd., 1096 Budapest, Haller u. 2, Hungary

⁴ a.sebok@campdenkht.com Campden BRI Hungary Ltd., 1096 Budapest, Haller u. 2, Hungary

⁵ svidry@ilsieurope.be International Life Sciences Institute Europe, 1200 Brussels, Avenue E. Mounier 83, Box 6, Belgium

⁶ pputz@ilsieurope.be International Life Sciences Institute Europe, 1200 Brussels, Avenue E. Mounier 83, Box 6, Belgium

⁷ dbanati@ilsieurope.be International Life Sciences Institute Europe, 1200 Brussels, Avenue E. Mounier 83, Box 6, Belgium

Abstract

The food industry has been struggling with existing guidance on how to prepare health claim dossiers. Hence the EU-funded project PATHWAY-27 seeks to provide a more tailored guidance.

Within this project, robust guidelines for the food industry will be developed. The guidelines will be applicable to bioactives and bioactive enriched foods in general, to facilitate health claim documentation and dossiers.

Based on a questionnaire, information on the needs and difficulties of the food industry in reaching the requirements established by the national and EU authorities (EFSA) was gathered. Particular emphasis was placed on scientific, economic, technical and technological barriers.

Keywords: health claim; nutrition claim; questionnaire; survey; guideline

1. Introduction

Interest in healthy eating and living is growing, and the food sector has been trying to satisfy related interests and needs. However, there are still many gaps in the available knowledge of the food sector on how to accomplish such a product development. (FoodDrinkEurope, 2011)

The process of 'creating' a health claim is subject to many strict rules (EC No 1924/2006) and the food industry must follow a complex and challenging procedure to meet the requirements established by national and EU

authorities (i.e. the European Food Safety Authority (EFSA)). Moreover, only a small proportion of the claim dossiers submitted to EFSA (mostly vitamins and minerals) were awarded a positive opinion recently. (European Commission, EU Register, 2013; European Commission, 2006)

Based on the general strategy of the EU-funded project PATHWAY-27 (Pivotal Assessment of The effects of bioactives on Health and Wellbeing. From human genoma to food industry), a guidance document will be prepared that will inform and assist the food industry sector, especially SMEs, to produce bioactive-enriched foods (BEF) with supportive health claims in line with EU legislation.

As a first step, a questionnaire was developed to collect and identify the needs and difficulties of the industry/SMEs in establishing and submitting health and nutrition claims for food products enriched with health-promoting bioactives.

This article presents the results of the survey and aims to give a general overview on the concept of the questionnaire.

2. Material and Methods

A health claim is any statement about a relationship between food and health. The European Commission authorises different health claims provided they are based on scientific evidence and can be easily understood by consumers. The European Food Safety Authority (EFSA) is responsible for evaluating the scientific evidence supporting health claims. The Commission draws up lists of health claims including the different types of authorised and rejected health claims in the EU. There are two types of health claims: 'enhanced function claims' and 'reduced risk claims'. (European Commission, 2012) Nutrition claim means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

(a) the energy (calorific value) it

- (i) provides;
- (ii) provides at a reduced or increased rate; or
- (iii) does not provide; and/or

(b) the nutrients or other substances it

- (i) contains;
- (ii) contains in reduced or increased proportions; or
- (iii) does not contain;

Nutrition claims are only permitted if they are listed in the Annex of Regulation (EC) No 1924/2006. (European Commission, Food Safety, 2013)

For the purpose of analysing the needs and difficulties of the food industry/SMEs in establishing and submitting health and nutrition claims, a dedicated questionnaire was developed in English and was translated into five languages (French, German, Hungarian, Italian and Spanish). The full English version of the questionnaire is presented in Annex I.

The survey focused on the main areas of the PATHWAY-27 project, namely on the implementation of the requirements established by national and EU authorities, as well as the European legislation; the needs and

difficulties of the industry/SMEs in establishing and submitting health and nutrition claims for food products enriched with health-promoting bioactives; and on the innovation potential and competitiveness of SMEs. In accordance with the concept of the project, the questionnaire was divided into 3 sections:

- General information about the respondent company
- Competitiveness and innovative indicators of the company
- Better understanding of the companies' view in terms of product development with health and nutrition claims

Based on the aim of the survey, the following inclusion criteria and sample quotas were applied:

- Food industry including food manufacturers, food ingredient suppliers, bioactive compounds producers and relevant service providers.
- Balanced 40% from large companies and the other 60% from SMEs.
- Functional food companies, that have already had product with health and nutrition claim(s) and those ones that are planning to develop such products, ideally 50-50%.

The questionnaire was distributed among food enterprises and other relevant sectors, to estimate the current situation within the food industry related to health and nutrition claims.

Combined methods were applied for data collection in order to increase the response rate.

1. Online questionnaire
2. Paper-based questionnaire sent by post or email
3. Phone interview
4. Personal interviews

The questionnaire was completed anonymously and all responses were treated as strictly confidential.

The questionnaire was sent out to 2594 companies from which 167 responses were collected from 17 countries (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Hungary, India, Italy, Portugal, Romania Spain, Sweden, Turkey and United Kingdom and USA) by the 25 project partners broadly distributed in Europe and by companies not participating in the project through the international business networks of the project partners. After the first data check, 42 questionnaires were excluded due to invalid and unusable answers. Therefore, 125 questionnaires were assessed as valid (fully completed).

3. Results and Discussion

Sample characteristics

In order to achieve the most appropriate responses, flexibility was allowed and minor deviations were accepted in the predefined inclusion criteria.

The survey focused on the highlighted food sectors, considering the main areas of the PATHWAY-27 project. Respondents were coming from the following areas:

- red and white meat, poultry and meat products
- fish and fish products
- **egg and egg products***
- **dairy products***

- processed fruit and vegetables
- **grain products, cereals, industrial bakery and pastry, confectionary, snacks***
- combined products
- beverages
- oils and fats
- dry goods, other ingredients and supplements
- other

**relevant food areas for PATHWAY-27 project*

63% of the companies providing sufficient response were food manufacturers, 26% were food ingredient suppliers, and 6% were related service providers. Only 5% of the companies represented other types of businesses, such as distributor of dietetic products, transformation and characterisation of plastics, consultant, fast food supplier, crop protection products and seed manufacturer and test kit supplier (Figure 1.).

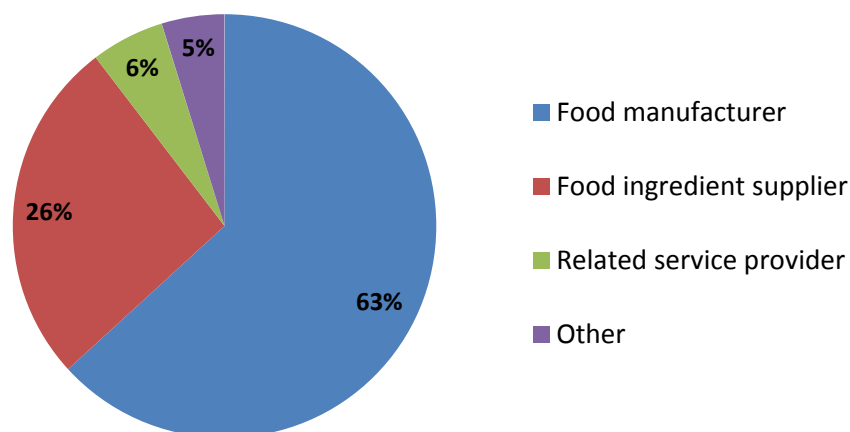


Figure 1: Type of the companies

Figure 2. shows the distribution (%) of the department or function of the respondents. Most of the respondents were from the research and development area, and a considerable number (19%) of the respondents were from quality control and management departments.

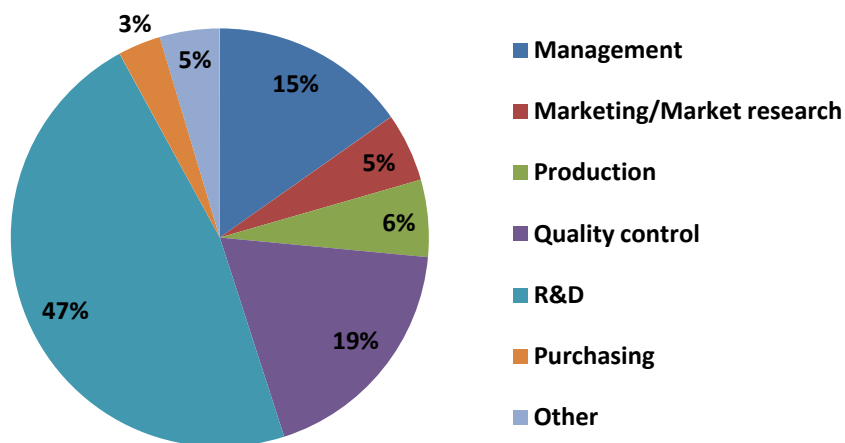


Figure 2: Department/function of the respondents

The size of the companies is shown in Figure 3. 44% of the respondents were large companies and 56% of them were SMEs. This distribution is close to the filtered criteria (balanced 40% from large companies and the other 60% from SMEs).

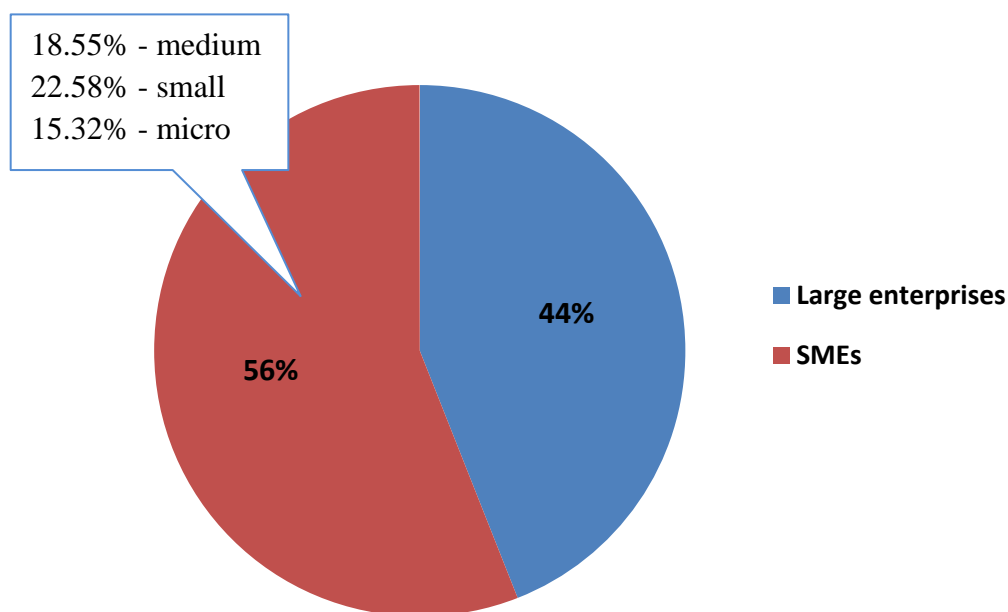


Figure 3: Size of the companies

Table 1: Definition of an SME (European Commission, 2014)

Company category	Employees	Turnover	or	Balance sheet total
Medium-sized	< 250	≤ € 50 m		≤ € 43 m
Small	< 50	≤ € 10 m		≤ € 10 m

Micro	< 10	≤ € 2 m	≤ € 2 m
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Breakdown by product scope, at the medium or large sized companies are shown in the following list.

Distribution of the product scope of the large companies by the number of the respondents:

- Grain products, cereals, industrial bakery and pastry, confectionary, snacks (17)
- Dairy products (14)
- Dry goods, other ingredients and supplements (12)
- Beverages (7)
- Oils and fats (6)
- Red and white meat, poultry and meat products (5)
- Combined products (5)
- Processed fruit and vegetables (4)
- Fish and fish products (1)
- Egg and egg products (1)
- Other (5)

Breakdown by product scope of the small and medium sized companies by the number of the respondents:

- Grain products, cereals, industrial bakery and pastry, confectionary, snacks (22)
- Dry goods, other ingredients and supplements (16)
- Processed fruit and vegetables (13)
- Oils and fats (11)
- Dairy products (11)
- Beverages (10)
- Red and white meat, poultry and meat products (7)
- Combined products (7)
- Egg and egg products (6)
- Fish and fish products (5)
- Other (6)

Competitiveness and innovation indicators

In “Competitiveness and innovation indicators” section of the questionnaire, indicators for measuring innovation and competitiveness were elicited.

36% of the respondents were of the opinion that the use of health and nutrition claims has strong (strong, very strong or extremely strong) contribution to the success of a company. (Figure 4.)

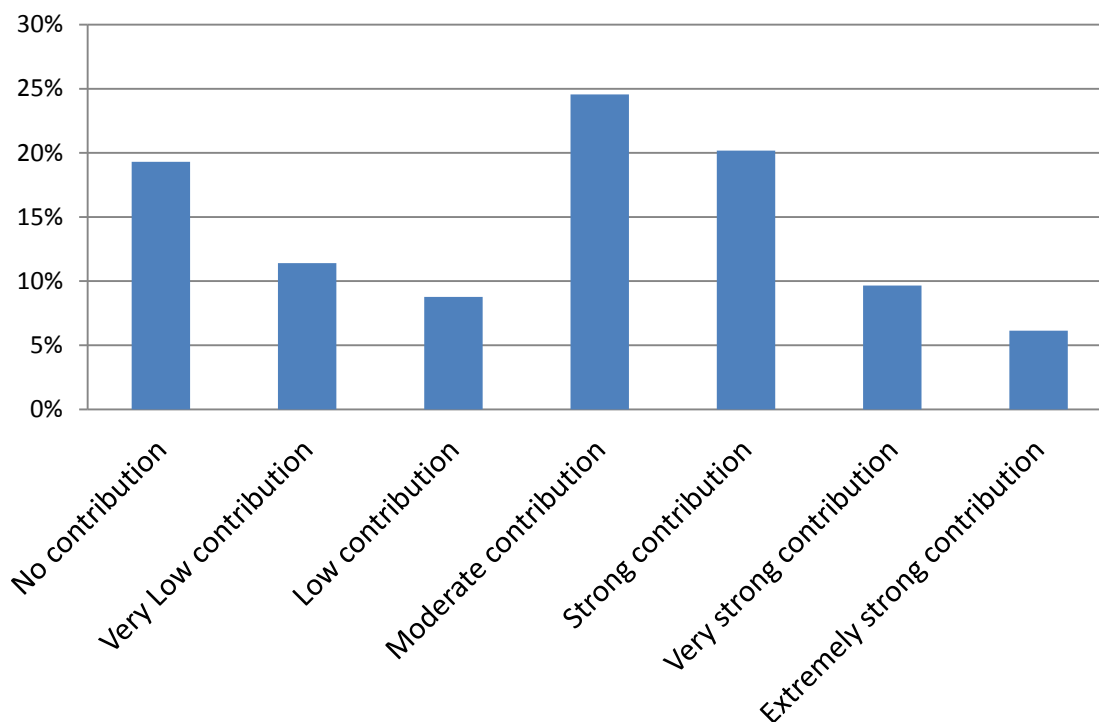


Figure 4: Perceived contribution of health and nutrition claims to the success of the company

The most important factor highlighted as contributing to the success of the company in the market was the profit, followed by factors related to good sales performance. Surprisingly, the third important ‘category’ was in relation to marketing, consumers’ satisfaction and loyalty. The number of new customers achieved in the domestic market was significantly more important than the number of new customers achieved in the export market. According to the answers, it seems that market share and revenue were more important to large companies than to SMEs.

Use of health and nutrition claims

Figure 5. shows the distribution (%) of the respondents related to the use of health and nutrition claims on their products. 61% of the respondents use or plan to use health claims, while 39% did not produce products with health claims or with nutrition claims, nor were they planning to use health or nutrition claims on their products.

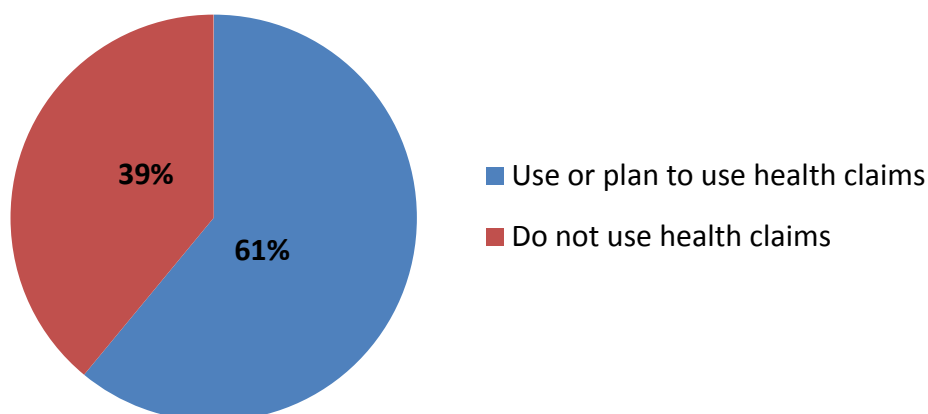


Figure 5: Using health claims on products

Information about the companies which do not use health or nutrition claims on their products and do not plan to use claims

Figure 6. shows that the main reasons for not using health claims were: i) lack of adequate resources/facilities, ii) insufficient return on investment expected, iii) lack of financial resources. 25% of the companies stated not to have enough experience in health claim substantiation, so they deemed the development process too risky. Less than 10 respondents listed the following comments as a reason:

- they are not interested,
- they do not have qualified people for the related analyses,
- they do not trust in the feasibility of such project's results,
- they set up health claim submission process in the past but it failed.

Other difficulties highlighted by the respondents were mainly in connection with the national authorities. The lack of positive EFSA opinions has caused insecurity about submitting or re-submitting a dossier. In addition all the companies stated that the communication with the national authorities and EFSA was very difficult, hence making the submission procedure and the requirements unclear for them.

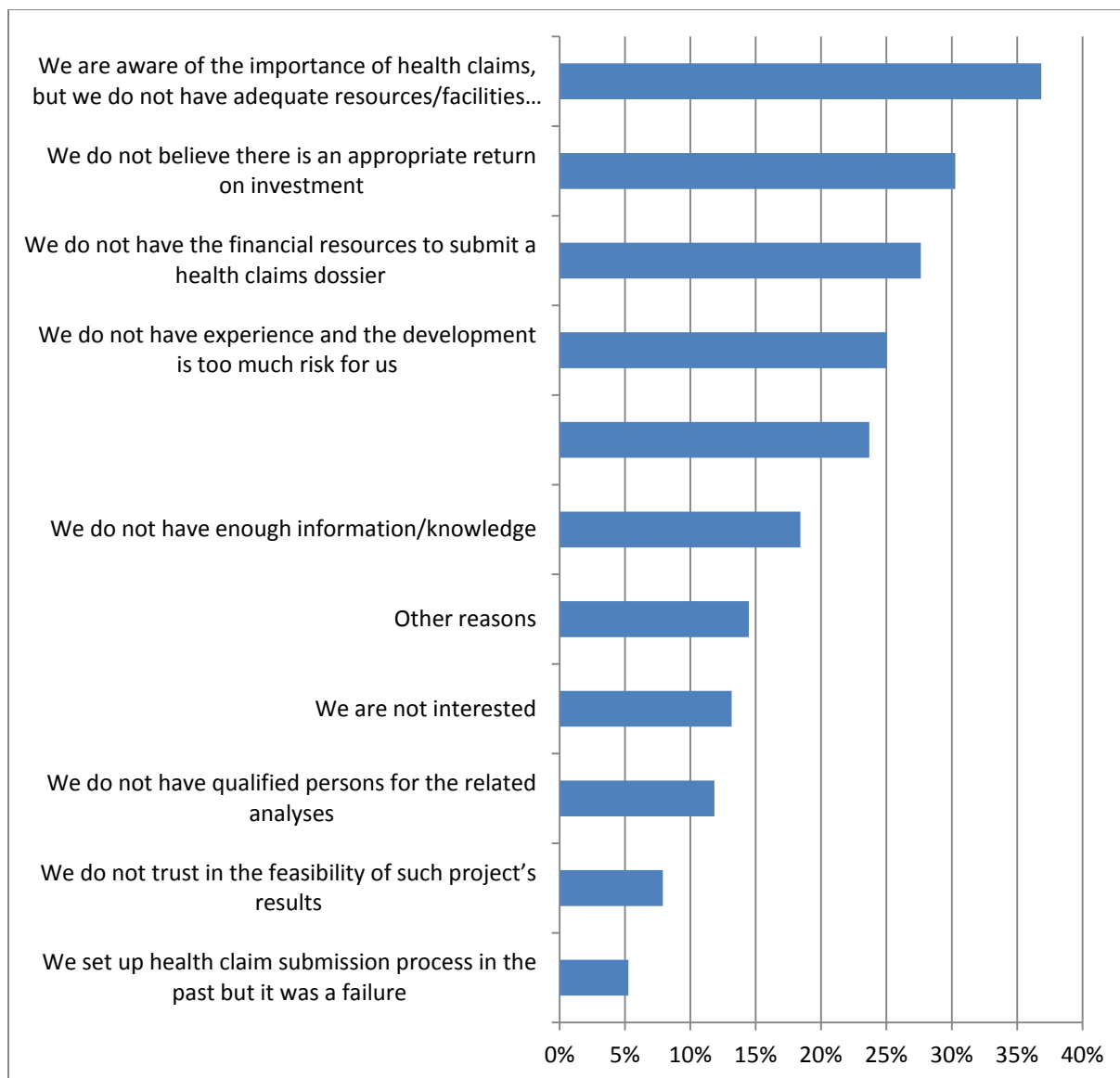


Figure 6: Reasons of why the companies do not use health claims on the products

Information about the companies which use health or nutrition claims on their products or plan to use health claims

27% of the respondents have already submitted health claim dossiers to EFSA (1-20 dossier/s per company), but the number of dossiers approved was very low. The most popular products on which the companies used or planned to use health claims were cereal products, bakery, confectionary, dairy products and beverages.

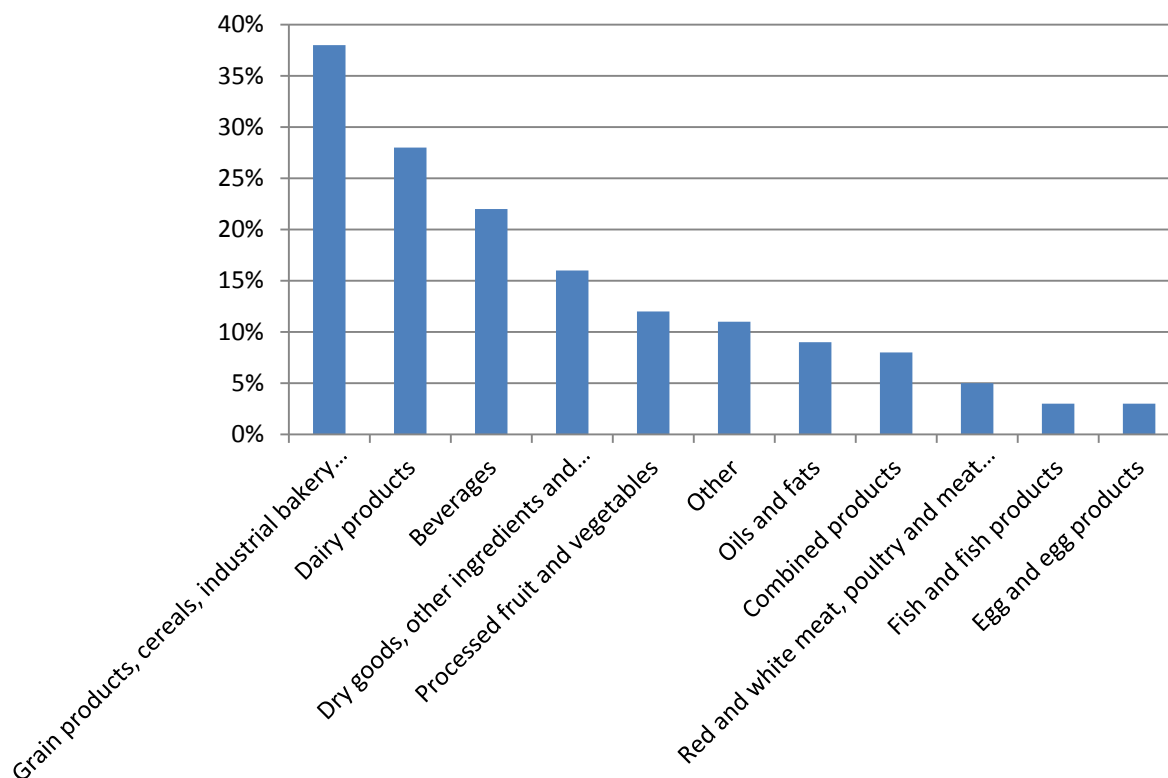


Figure 7: Products on which the companies use or plan to use health claims

More than half of the companies use external support during the health claim substantiation, and some of these companies were not familiar with the official guideline (Guidance for applicants on health claims) provided by EFSA. The following issues were suggested to be added to the document:

- Acceptable, representative clinical models of the general population,
- Valid protocols, valid biomarkers, valid claim formulation,
- Study design and type of research strategy,
- Reporting of study results,
- More specific definition/list of appropriate measurement techniques.

More than 80% of the companies thought that it was difficult to substantiate a health claim (Figure 8.). They also needed support with collecting scientific data/information in general, and information about consumers' requirements and behaviour in particular. Furthermore, they preferred the idea of working with a consultancy company and guidelines for carrying out tests and studies.

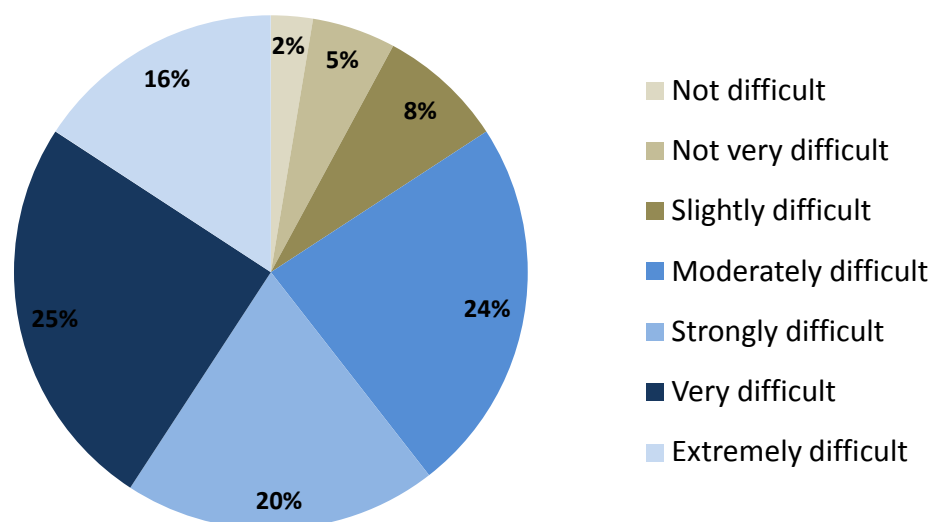


Figure 8: Perceived difficulty of the substantiation of a health claim

Barriers during nutrition and health claim substantiation

The questionnaire measured the influence of scientific, economic, technical and technological barriers during health claim substantiation. The following key difficulties were determined by the respondents:

The lack of markers to be used and accepted by EFSA, difficulties in establishing the relationship between the food and the claimed effect, difficulty in setting up experimental design and human intervention studies, and the lack of human intervention studies related to bioactive ingredients were found as the most important scientific barriers. In terms of the technical/technological barriers, there were no large differences within the listed factors:

- Lack of communication with the national and/or EU authorities;
- Lack of guidelines/supporting documents;
- Lack of specialised human resource;
- Lack of communication within the company;
- Lack of knowledge (how best to conduct RCT, statistics);
- Lack of specific technology;
- Lack of applicable technology;
- Lack of tools (specific material to evaluated results);
- Difficulties in food characterisation (e.g. polyphenols).

However, the lack of comprehensive guidelines caused more difficulty than the lack of communication within the company. The most important economic barriers were the costs for human intervention studies and the

health claim dossier, the length of the process of authorisation and uncertainty about the return on investment. The lack of connection with the research and development area was not a critical barrier. It appears that the communication within companies works fairly smoothly, which might be explained by the standardised company product development procedures.

A factor analysis of the scientific, technical/technological and economic barriers was carried out, from which five main factors emerged:

1. factor: Clinical study, test design
2. factor: Labelling
3. factor: Intellectual property rights
4. factor: Technology
5. factor: Too much effort in an uncertain business environment

1. factor: Clinical study, test design

In this group the most important difficulties and barriers were connected to the human intervention studies, which is a necessary element of the health claim substantiation. The respondents thought that the following barriers most influenced the health claim substantiation: i) difficulties in the setting up of experimental design and carrying out human intervention studies; ii) difficulties in establishing the relationship between the food/constituent and the claimed effect; iii) lack of existing human intervention studies set-up related to the presence of bioactive ingredient; iv) cost of conducting human intervention studies if no relevant data are available; v) lack of access to human and clinical study providers; vi) poor access to relevant scientific data; and vii) difficulties in finding, extracting, stabilising and integrating the appropriate bioactive ingredient.

2. factor: Labelling

The second factor was connected to the labelling of the products, which is a dominant part of using health and nutrition claims on foods. The most important barriers were: i) lack of information regarding labelling and ii) compliance with labelling legislation.

3. factor: Intellectual property rights

Within this factor the most important barriers was related to intellectual property rights. This is a particular problem in that after successful substantiation the claim can be used by the competitor companies as well. The most influencing barriers were: i) difficulties with intellectual property rights and ii) inappropriate protection for use of successful health claims.

4. factor: Technology

Regarding technology as a factor, respondents viewed the following barriers as most relevant: i) lack of specific technology; ii) lack of applicable technology; and iii) lack of tools (specific material to evaluate results).

5. factor: Too much effort in an uncertain business environment

Management of businesses in an uncertain environment causes a high level of insecurity during the product development phase. For this reason the following difficulties were identified by the respondents as the most

influencing factors: i) return on investment not guaranteed; ii) rising input costs; iii) lack of internal resources; iv) unfair commercial practices; and v) length of the process of authorisation.

4. Conclusions

In the field of industry surveys in general, 5-10% response rate is a common and acceptable rate. In spite of the relatively low response rate (6.4%; 4.8% valid), we conclude that the survey successfully reached the target audience, because the majority of the respondents were from the proposed target groups (from SMEs category and real users) and/or were more or less experienced on product development with health and nutrition claims. The low response rate might be considered as a limitation, but the number of valid questionnaires (125) was a sufficient number for carrying out a quantitative evaluation and to identify the hot topics for the development of an industry guideline on the development of foods with health claims.

More than half of the respondents stated that product development with health and nutrition claims was a very difficult process due to the scientific, economic, technical and technological barriers discussed in the article. However the majority of the respondents saw clear benefits despite the complicated development process; more than half of the respondents stated that the development of products with health and nutrition claims can contribute to market success.

Having a well-founded view on the most important scientific, technical/technological and economic barriers, it can be stated that industry has to face several difficulties and barriers during the process of the health claim substantiation: The lack of markers to be used and accepted by EFSA; the difficulties in establishing the relationship between the food and the claimed effect; the difficulty in setting up experimental design and human intervention studies; and the lack of human intervention studies related to active substance were found as the most important scientific barriers. In terms of the technical and technological barriers there were no large differences among the listed factors, but the lack of comprehensive guidelines caused more difficulty than the lack of communication within the company. According to the respondents' opinion, the most important economic barriers were the cost of the human intervention studies and the health claim dossier; the length of the process of authorization and the fact that the return of investment is not guaranteed. The lack of connection with research and development area was not perceived as a critical barrier. To compare this statement with the technical one, it seems that internal communication within the surveyed companies works fairly smoothly.

Even though, human studies are likely to remain expensive, and the amount and quality of data required for a successful dossier is probably not going to change soon, the necessity of the guidelines intended to be developed within the PATHWAY-27 project, got a confirmation, as companies could get a clearer picture on what is needed in case they decide to develop products with nutrition or health claims.

Together with evidence from previous literature and knowledge from the project partners, these results will build the basis for the preparation of the PATHWAY-27 guidelines targeted at the food industry.

Acknowledgements

This industry survey would not have been possible without the contribution of food industry stakeholders. The authors wish to express their gratitude to all the respondents who were helpful and provided input for the survey.

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Reference list

- European Commission, 2013. EU Register on nutrition and health claims.
<http://ec.europa.eu/nuhclaims/?event=search> (accessed: 19/12/2014)
- European Commission (2012). Food Safety, Labelling and Nutrition, Health & Nutrition Claims, Health Claim.
http://ec.europa.eu/food/food/labellingnutrition/claims/health_claims_en.htm (accessed: 26/01/2015)
- European Commission (2013). Food Safety, Labelling and Nutrition, Health & Nutrition Claims, Nutrition Claim.
http://ec.europa.eu/food/food/labellingnutrition/claims/nutrition_claims_en.htm (accessed: 26/01/2015)
- European Commission (2014). Enterprise and Industry, What is an SME?
<http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/> (accessed: 13/17/2014)
- European Commission (2006). Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Official Journal of the European Union L 404/9, 3-18.
- FoodDrinkEurope, Competitiveness Report, 2nd September 2011, Brussels.

Appendices

Annex I. QUESTIONNAIRE TO INDUSTRIES

SECTION 1 – GENERAL INFORMATION ON YOUR COMPANY

1.1 Type of the Company (Please tick the relevant box!)

- Food manufacturer
- Food ingredient supplier (raw material handler, added-value processors/suppliers)
- Related service provider
- Other (please specify) _____

1.2 Please indicate your department/function in your Company (Please, tick more than one box if applicable!)

- Management
- Marketing/Market research
- Production
- Quality Control
- Research & Development
- Purchasing
- Other (please specify) _____

1.3 Country where you are personally based:

1.4 Total number of employees in your company (in case of more than one manufacturing site, please reply for your branch only) (Please tick the relevant box!)

- More than 1000 employees
- 251 to 1000 employees
- 51 to 250 employees
- 11 to 50 employees
- 10 employees or less

1.5 Turnover of your company (million Euros) as sub-divided by the EU* (**Please tick the relevant box!**)

- More than 100 m €
- 51 m € to 100 m €
- 11 m € to 50 m €
- 3 m € to 10 m €
- 2 m € or less

*<http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/>

Company category	Employees	Turnover	or	Balance sheet total
Medium-sized	< 250	≤ € 50 m		≤ € 43 m
Small	< 50	≤ € 10 m		≤ € 10 m
Micro	< 10	≤ € 2 m		≤ € 2 m

1.6 Please indicate the product scope of your company! (**Please tick more than one box if applicable!**)

- Red and white meat, poultry and meat products
- Fish and fish products
- Egg and egg products
- Dairy products
- Processed fruit and vegetables
- Grain products, cereals, industrial bakery and pastry, confectionary, snacks
- Combined products
- Beverages
- Oils and fats
- Dry goods, other ingredients and supplements
- Other (please specify) _____

SECTION 2 – COMPETITIVENESS AND INNOVATION INDICATORS

2.1 How much does the development of products with health claims contribute to the success of your company in the market? **(Please tick the relevant number!)**

No contribution	Very Low contribution	Low contribution	Moderate contribution	Strong contribution	Very strong contribution	Extremely strong contribution
1	2	3	4	5	6	7

2.2 How do you measure your success in the market? Please indicate the importance of the following indicators in the measurement of success!

(Please tick the relevant number!)

Indicators	Importance						
	Not important	Slightly less important	Slightly important	Moderately important	Important	Very important	Extremely important
Number of new successful prototypes produced in lab environment	1	2	3	4	5	6	7
Number of prototypes that go through factory trials successfully	1	2	3	4	5	6	7
Number of products launched onto the market	1	2	3	4	5	6	7
Reaching new market or consumer segment	1	2	3	4	5	6	7
Higher and added value products for the consumers	1	2	3	4	5	6	7
Increasing consumer loyalty	1	2	3	4	5	6	7

Indicators	Importance						
	Not important	Slightly less important	Slightly important	Moderately important	Important	Very important	Extremely important
Number of new customers achieved in the domestic market	1	2	3	4	5	6	7
Market share	1	2	3	4	5	6	7
Export share	1	2	3	4	5	6	7
Sales volume	1	2	3	4	5	6	7
Revenue	1	2	3	4	5	6	7
Profit	1	2	3	4	5	6	7
Number of new customers achieved in the export market	1	2	3	4	5	6	7
Time after launch to reach certain sales/market share	1	2	3	4	5	6	7
First launch by food manufacturer which includes a specific/new ingredient	1	2	3	4	5	6	7
Please, indicate if you consider any other indicators:							
	1	2	3	4	5	6	7
	1	2	3	4	5	6	7
	1	2	3	4	5	6	7

SECTION 3 – USE OF NUTRITION AND HEALTH CLAIMS IN THE COMPANY

3.1 Does your company produce products (including ingredients that qualify for a health claim) with health claims? **(Please tick the relevant box!)**

Yes No

3.2 Does your company produce products (including ingredients) with nutritional claims? **(Please tick the relevant box!)**

Yes No

Please specify _____

3.3 Do you plan to use health claims on your product/s (including ingredients)? **(Please tick the relevant box!)**

Yes No

3.4 Are you interested in using health claims on your product/s (including ingredients)? **(Please tick the relevant box!)**

Yes No

If the answer is “No” in question 3.1, 3.2, 3.3 and 3.4, please go to question 3.16!

3.5 How many health claim dossier(s) did your company submit to EFSA?

3.6 How many of these health claim dossier(s) were successfully accepted by EFSA?

3.7 What kind of health claims is your company interested in? **(Please tick more than one box if applicable!)**

Health claims describing or referring to:

the role of a nutrient or other substance in growth, development and the functions of the body /Article 13, (a)/;

psychological and behavioural functions /Article 13, (b)/;

slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or the reduction of the available energy from the diet /Article 13, (c)/;

- reduction of disease risk claims /Article 14, (a)/;
- claims referring to children's development and gut health (Prebiotics and Probiotics) /Article 14, (b)/.

3.8 For what kind of products does your company use or plan to use health claims? **(Please tick more than one box if applicable!)**

- Red and white meat, poultry and meat products, please specify _____
- Fish and fish products, please specify _____
- Egg and egg products, please specify _____
- Dairy products, please specify _____
- Processed fruit and vegetables, please specify _____
- Grain products, cereals, industrial bakery and pastry, confectionary, snacks, please specify _____
- Combined products, please specify _____
- Beverages, please specify _____
- Oils and fats, please specify _____
- Dry goods, other ingredients and supplements, please specify _____
- Other, please specify _____

3.9 **Where do you get your information on health claims from?**

(Please tick more than one box if applicable!)

- Scientific papers/review**
- Professional journals**
- Books**
- Guidelines
- EFSA/FDA/national agencies web pages**
- Internet**
- Professional e-groups forums**
- Seminars/courses**
- Conferences/workshops**
- Monitoring, benchmarking competitors' products, companies**
- Other (please specify)**

3.10 Do you use any external support during the health claim substantiation? (Please tick the relevant box!)

Yes No

If yes, please specify what kind of agency:

- Consultancy/advisor
- Research institute
- University
- Supplier
- Food Industry Federation
- Food Control Authority
- Customer
- Other, please specify: _____

3.11 What do you think about the information provided in the official guideline (Guidance for applicants on health claims) provided by EFSA? (Please tick more than one box if applicable!)

- I do not know the guideline
- Comprehensive
- Clear instructions
- Unclear instructions
- Not detailed enough
- Too professional/technical
- Lack of certain information, (please, specify): _____
- Other (please, specify it): _____

3.12 How difficult is it for you to substantiate a product (including ingredients) with health claims? (Please tick the relevant number!)

Not difficult	Not very difficult	Slightly difficult	Moderately difficult	Strongly difficult	Very difficult	Extremely difficult
1	2	3	4	5	6	7

3.13 How strong is the influence of scientific, economic, technical and technological barriers during health claim substantiation? (Please score the difficulties, barriers or put an X if the barriers are not relevant for you!)

Barriers/difficulties	Not relevant	Influence						
		No influence	Very slight influence	Slightly influence	Moderate influence	Strong influence	Very strong influence	Extremely strong influence
SCIENTIFIC								
Poor access to supportive scientific data		1	2	3	4	5	6	7
Poor quality of the data on human intervention studies		1	2	3	4	5	6	7
Poor quality of the data on other studies (e.g. animal)		1	2	3	4	5	6	7
Lack of existing human intervention studies set-up related to the presence of active substance		1	2	3	4	5	6	7
Difficulties in establishing the relationship between the food/constituent and the claimed effect		1	2	3	4	5	6	7

Barriers/difficulties	Not relevant	Influence						
		No influence	Very slight influence	Slightly influence	Moderate influence	Strong influence	Very strong influence	Extremely strong influence
Difficulties in finding, extracting, stabilising and integrating of the appropriate active substance		1	2	3	4	5	6	7
Lack of access for human and clinical study providers		1	2	3	4	5	6	7
Difficulties in the setting up experimental design and carrying out human intervention studies		1	2	3	4	5	6	7
Lack of markers, to be used, accepted by EFSA		1	2	3	4	5	6	7
Lack of information regarding labelling		1	2	3	4	5	6	7
Compliance to legislation of labelling		1	2	3	4	5	6	7
Ethical problems (to conduct human studies)		1	2	3	4	5	6	7
Difficulties with intellectual property rights (To keep the market advantages in longer term after the approval of the health claims.)		1	2	3	4	5	6	7

Barriers/difficulties		Influence						
	Not relevant	No influence	Very slight influence	Slightly Influence	Moderate influence	Strong influence	Very strong influence	Extremely strong influence
Inappropriate protection for use of successful health claims (to ensure appropriate return on investment)		1	2	3	4	5	6	7
Other, please specify:								
		1	2	3	4	5	6	7
		1	2	3	4	5	6	7
		1	2	3	4	5	6	7
Barriers/difficulties		Influence						
	Not relevant	No influence	Very slight influence	Slightly Influence	Moderate influence	Strong influence	Very strong influence	Extremely strong influence
TECHNICAL AND TECHNOLOGICAL								
Lack of communication with the national and/or EU authorities		1	2	3	4	5	6	7
Lack of guidelines/supporting documents		1	2	3	4	5	6	7
Lack of specialised human resource		1	2	3	4	5	6	7
Lack of communication within the company		1	2	3	4	5	6	7

Barriers/difficulties		Influence						
	Not relevant	No influence	Very slight influence	Slightly influence	Moderate influence	Strong influence	Very strong influence	Extremely strong influence
Lack of knowledge (how best to conduct RCT, statistics)		1	2	3	4	5	6	7
Lack of specific technology		1	2	3	4	5	6	7
Lack of applicable technology		1	2	3	4	5	6	7
Lack of tools (specific material to evaluated results)		1	2	3	4	5	6	7
Difficulties in food characterisation (e.g. polyphenols)		1	2	3	4	5	6	7
Other, please specify:								
		1	2	3	4	5	6	7
		1	2	3	4	5	6	7
		1	2	3	4	5	6	7
Barriers/difficulties		Influence						
	Not relevant	No influence	Very slight influence	Slightly influence	Moderate influence	Strong influence	Very strong influence	Extremely strong influence
ECONOMIC								
Lack of market information		1	2	3	4	5	6	7

Barriers/difficulties	Not relevant	Influence						
		No influence	Very slight influence	Slightly influence	Moderate influence	Strong influence	Very strong influence	Extremely strong influence
Lack of connection with the research and development area		1	2	3	4	5	6	7
Lack of internal resources		1	2	3	4	5	6	7
Length of the process of authorization		1	2	3	4	5	6	7
Return of investment not guaranteed		1	2	3	4	5	6	7
Unfair commercial practices		1	2	3	4	5	6	7
Rising input costs		1	2	3	4	5	6	7
Cost of conducting human intervention studies if no relevant data are available		1	2	3	4	5	6	7
Cost for preparing the health claim dossier		1	2	3	4	5	6	7
Lack of enforcement of health claim regulation by member states		1	2	3	4	5	6	7
Other, please specify:								
		1	2	3	4	5	6	7
		1	2	3	4	5	6	7

Barriers/difficulties	Not relevant	Influence						
		No influence	Very slight influence	Slightly influence	Moderate influence	Strong influence	Very strong influence	Extremely strong influence
		1	2	3	4	5	6	7

3.14 Where do you need additional support in the process of preparation of a health claims dossier?

(Please tick more than one box if applicable!)

- Collection of market information
- Collection of information about the requirements and behaviour of the consumers
- Collection of scientific data/information
- Making connection with the research and development area
- Knowledge of the process for developing a health claim dossier
- Collection of information about the prohibited and accepted health claim dossiers
- Purchasing the appropriate compounds/raw materials
- Establishing the relationship between the food/constituent and the claimed effect
- Finding the appropriate active substance
- Extracting the appropriate active substance
- Stabilising the appropriate active substance
- Integrating the appropriate active substance in the food matrix
- Carrying out proper shelf-life test
- Carrying out human studies
- Carrying out other studies (e.g. animal)
- Calculation of the nutrition profile of the product
- Labelling
- Set up health claim dossier
- Communication with the national and/or EU authorities
- Preparation the whole health claim dossier
- Other, please specify _____

3.15 What types of knowledge/information transfer activities are preferred by your company? (Please tick more than one box if applicable!)

- Personnel consultations with experts
- Exhibitions and workshops about the health claim products and processes
- Training course about the process of the submission/authorisation of health claims
- Guidelines for carrying out the different tests and studies
- Platform for dossier pre-assessment
- Consultancy company (preparation and complete of the health claim dossier)
- Professional website focusing on nutrition and claims
- E-net discussion forum
- Other (please, specify it): _____

IF YOUR COMPANY DOES NOT SUBMIT HEALTH CLAIMS DOSSIERS:

3.16 Are there any reasons why you do not use health claims within your company? (Please tick more than one box if applicable!)

- We are not interested;
- We do not trust in the feasibility of such project's results;
- We do not believe there is an appropriate return on investment;
- We do not have enough information/knowledge;
- We do not have experience and the development is too much risk for us;
- We are aware of the importance of health claims, but we do not have adequate resources/facilities to carry out the submission process within the company;
- We do not have qualified persons for the related analyses;
- We do not have the financial resources to submit a health claims dossier;
- We set up health claim submission process in the past but it was a failure;
- A dossier provides short term market advantages and but with excessive efforts in the substantiation. The difficulty is that the accepted health claim cannot be used by the competitors. (intellectual property rights).
(Please describe which difficulties you have met) _____
- Other reasons (please describe) _____