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## **RESEARCH TENDER CALL**



## **TENDER INFORMATION DOCUMENT**

**Project Reference No.: 07-2018**

**Project Title:**

**“Socioeconomic cost of food hypersensitivity on the island of Ireland”**


**1. *Objective/Knowledge Gap***

The aim of this project is to estimate the annual socioeconomic costs associated with having a diagnosed food hypersensitivity. Validated diagnostic methodologies have been developed for food allergy or coeliac disease and are routinely used in clinical practice. Therefore, the scope of the research will be restricted to those consumers on the island of Ireland who have been medically diagnosed with food allergy or coeliac disease. Specifically:

- a) To determine the food hypersensitivity-related *direct* health care costs per capita per annum for consumers on the island of Ireland with food hypersensitivity.
- b) To determine the food hypersensitivity-related *indirect* costs per capita per annum for consumers on the island of Ireland with food hypersensitivity.
- c) To determine the *intangible* costs of food hypersensitivity for consumers on the island of Ireland with food hypersensitivity.
- d) To determine the annual direct and indirect costs of food hypersensitivity to the health care systems on the island of Ireland.

**2. *Background***

Food hypersensitivity (FHS) is a condition in which the body adversely reacts to normal food constituents. Although the term covers a wide range of illnesses, for practical purposes it is used here with regard to food allergy and coeliac disease for which established diagnostics tests are available. Food allergy is an exaggerated IgE-based

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immunological response to food proteins and coeliac disease is an autoimmune disorder based on a hypersensitivity to gluten. A wide range of food intolerances usually result from enzymatic dysfunction and generally do not include an immunological element. These conditions adversely impact the health and well-being of many people on the island of Ireland. Even conservative prevalence estimates suggest that anywhere between 10 to 15% of the population are affected which translates at up to 900K people on the island of Ireland.

The symptoms of a food allergic reaction can range from mild to severe but even mild symptoms such as rhinitis, nausea and vomiting can be incapacitating; severe allergic symptoms can actually be life-threatening. Symptoms of food intolerance and coeliac disease are generally not as severe. That said, they can still be incapacitating and inadequate dietary control can predispose to more serious chronic health issues; coeliac disease is a risk factor for osteoporosis and certain types of intestinal cancer. Food allergy and coeliac disease can be accurately diagnosed by physiological testing combined with patient history. However, the same cannot be said for the food intolerances, most of which are still lacking validated diagnostic tests.

### **Socioeconomic costs associated with food hypersensitivity**


Living with a food hypersensitivity presents a number of challenges. Unlike other diseases in which most costs are borne by the health care system, a food hypersensitivity can represent a disproportionate burden on an individual's (or their family's) finances. The costs are disproportionately higher in childhood than adulthood<sup>1</sup>. The socioeconomic costs associated with food hypersensitivity can be divided into three categories: direct, indirect and intangible<sup>2</sup>. A framework exists to determine all three categories (at least with regard to food allergy<sup>2,3</sup>)

- Direct costs are those borne by FHS consumers, and their households, as a consequence of their FHS including medical and insurance costs, FHS-related living and travel expenses, and lost earnings, etc.
- Indirect costs include lost productivity and opportunities (lost days at school and/or work, loss of earnings, etc.), restricted activity days, reduction in human capital, impacts on time, etc.
- Intangible costs include impacts on health-related quality of life (pain, suffering, inconvenience, etc.), standard of living, perceptions of physical and emotional well-being, etc.

<sup>1</sup> Patel D.A., Holdford D.A., Edwards E., Carroll N.V., Estimating the economic burden of food-induced allergic reactions and anaphylaxis in the United States. *J. Allergy Clin Immunol* 2011; 128:110-5.

<sup>2</sup> Fox M., Voordouw J., Mugford M., Cornelisse J., Antonides G. and Frewer L., Social and Economic Costs of Food Allergies in Europe: Development of a Questionnaire to Measure Costs and Health Utility. *Health Serv Res.* 2009 Oct; 44(5 Pt 1): 1662–1678.

<sup>3</sup> Miles S, Fordham R, Mills C, Valovirta E, Mugford M. A framework for measuring costs to society of IgE-mediated food allergy. *Allergy* 2005;60:996–1003.

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Direct and indirect costs are measurable in monetary terms. Intangible costs are more difficult to measure in monetary terms and are indicated by self-reported health status, loss of well-being and loss of economic welfare experienced as a consequence of having a FHS.

#### Direct costs associated with food hypersensitivity

As there is no 'cure' for food hypersensitivity, the risk of exposure is managed through strict adherence to an avoidance diet. This presents its own logistical and financial challenges including the need to source alternative food products. Avoidance diets are more easily achievable in theory than in practice and this generates a lot of anxiety for both the people affected and their families, particularly where the impact of exposure can be severe such as with a severe food allergy<sup>4</sup>.

Medical and healthcare costs such as GP and consultant visits can be significant depending on the severity of the food hypersensitivity. Research has shown that those with food allergy visit their healthcare professional more times per year and the incurred healthcare costs are therefore greater. Data from the UK NHS shows that hospital admissions due to food allergy increased by 6.4% between February 2013 and 2014<sup>5</sup>. This did not factor in the cost of oral immunotherapy, if indeed this treatment is available at all. The Europrevall project found a positive relationship between food allergy severity and health care costs (this includes the cost of rescue medications such as adrenaline autoinjectors)<sup>5</sup>. However, for statistical reasons, this outcome was specific only to those countries where this survey was carried out. It is worth noting that direct medical costs are only a small portion of the total economic burden of food hypersensitivity<sup>6</sup>. The study found that these costs also represent a tangible cost burden on the health services where resources required for the diagnosis of food hypersensitivity, in addition to those required for support and education, compete with other pressures on limited health care resources especially in publicly funded health systems<sup>7,8,9,10</sup>.

#### Indirect costs associated with food hypersensitivity

There may also be indirect costs for the food hypersensitive consumer in terms of the impacts on their own (self-reported) potential such as lost hours for medical reasons, shopping, lost productivity and opportunities in employment and education, lost earnings, etc.<sup>11</sup>. They also include costs due to the impact of mortality on earnings and

<sup>4</sup> Patel N, Herbert L, Green TD., The emotional, social, and financial burden of food allergies on children and their families. *Allergy Asthma Proc.* 2017 Mar 1; 38(2):88-91.

<sup>5</sup> Margaret Fox, M. et al., Health sector costs of self-reported food allergy in Europe: a patient-based cost of illness study. *Eur. J. Pub. Health*, Vol. 23, No. 5, 757-762.

<sup>6</sup> Gupta R., Holdford D., Bilaver L., Dyer A., Holl J.L. and Meltzer D., The economic impact of childhood food allergy in the United States. *JAMA Pediatr.* 2013 Nov; 167(11):1026-31.


<sup>7</sup> Liew WK, Williamson E, Tang ML. Anaphylaxis fatalities and admissions in Australia. *J Allergy Clin. Immunol.* 2009; 123:434-42.

<sup>8</sup> Mullins RJ, Dear KB, Tang ML. Time trends in Australian hospital anaphylaxis admissions in 1998-1999 to 2011-2012. *J Allergy Clin. Immunol.* 2015; 136:367-75.

<sup>9</sup> Turner PJ, Gowland MH, Sharma V, et al. Increase in anaphylaxis-related hospitalizations but no increase in fatalities: An analysis of United Kingdom national anaphylaxis data, 1992-2012. *The Journal of Allergy and Clinical Immunology.* 2015; 135(4):956-963.

<sup>10</sup> Branum AM, Lukacs SL. Food allergy among children in the United States. *Pediatrics.* 2009;124:1549-1555.

<sup>11</sup> Posnett J.J.S., Indirect cost in economic evaluation: the opportunity cost of unpaid inputs. *Health Econ* 1996; 51:13-23.

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household production. Indirect cost estimates require access to broader economic data, much of which is publically available<sup>12</sup>.

#### Intangible costs associated with food hypersensitivity

There are also the intangible costs in terms of the impacts on the food hypersensitive consumer's quality of life. For instance, food allergy has been shown to have a strong negative impact on health-related quality-of-life scores for all age groups and in parents of allergic children<sup>13,14,15</sup>. These scores are also worse for food allergy compared to other paediatric chronic diseases, such as Type 1 Diabetes<sup>16</sup>. Intangible costs may be independent of direct and indirect costs; a Swedish study in 2014 concluded that while direct and indirect household costs were statistically higher for food allergic children but not food allergic adolescents, food allergy adversely impacted intangible costs in both groups<sup>17</sup>. Intangible costs are more difficult to estimate in monetary terms than direct or indirect costs due to measurement difficulties. However, the application of health state utility methods may facilitate the evaluation of intangible costs.

A more accurate estimation of the 'cost of illness' associated with having a food hypersensitivity can clarify some of the associated socioeconomic consequences, particularly for low income families<sup>18</sup>. This will assist in the development of appropriate and cost-effective regulatory frameworks for consumer protection. 'Cost of illness' estimation could potentially be used to influence health care services including targeted and cost-effective interventions. These could include more accurate substitution of foods in a person's diet, improved education policies for relevant stakeholders and consumers, more targeted and timely diagnosis of food hypersensitivity based on the latest evidence, and improvements in self-management methods for those affected. Cost estimations may further encourage food businesses to implement effective traceability and labelling strategies regarding allergenic foods and ingredients in line with national and international regulations and to be more proactive in providing safe solutions for their customers. They may also highlight a need to reduce the allergenicity of foods through better food processing.

<sup>12</sup> Jansson S.A., Protudjer J.L., Arnlinde Heibert M., Bengtsson U., Kallström-Bengtsson I., Marklund B., Middelveld R.J., Rentzos G., Sundqvist A.C., Åkerström J., Östblom E., Dahlén S.E. and Ahlstedt S., Socioeconomic evaluation of well-characterized allergy to staple foods in adults. *Allergy*. 2014 Sep;69(9):1241-7.

<sup>13</sup> DunnGalvin A, Hourihane JOB. Health-related quality of life in food allergy: Impact, correlates, and predictors. 2016 Bundesgesundheitsbl © Springer-Verlag Berlin Heidelberg.


<sup>14</sup> Cummings, A.J. et al., The psychosocial impact of food allergy and food hypersensitivity in children, adolescents and their families: a review. *Allergy*, 2010. 65(8), pp.933-45.

<sup>15</sup> Strinnholm Å, Hedman L, Winberg A, Jansson SA, Lindh V, Rönmark E., Health Related Quality of Life among schoolchildren aged 12-13 years in relation to food hypersensitivity phenotypes: a population-based study. *Clin Transl Allergy*. 2017 Jul 3;7:20.

<sup>16</sup> Avery NJ1, King RM, Knight S, Hourihane JO., Assessment of quality of life in children with peanut allergy. *Pediatr. Allergy Immunol.*, 2003 Oct;14(5):378-82.

<sup>17</sup> Protudjer J.L., Jansson S.A., Heibert Arnlinde M., Bengtsson U., Kallström-Bengtsson I., Marklund B., Middelveld R., Rentzos G., Sundqvist A.C., Åkerström J., Östblom E., Dahlén S.E., Ahlstedt S. Household costs associated with objectively diagnosed allergy to staple foods in children and adolescents. *J Allergy Clin Immunol Pract*. 2015 Jan-Feb;3(1):68-75

<sup>18</sup> Minaker L.M., Elliott S.J. and Clarke A. Exploring low-income families' financial barriers to food allergy management and treatment. *J Allergy (Cairo)*. 2014: 160363.

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### 3. **Approach**

The research will identify target groups for evaluation and, where data is missing, utilise appropriate instruments (surveys, questionnaires, etc.) to generate relevant data to achieve the stated objectives. The choice of case studies for all aspects of the research must be based on a valid medical diagnosis/clinical history of the FHS. An accurate estimate of the prevalence of food allergy and coeliac disease in the population in both jurisdictions on the island of Ireland will be necessary. Methodologies that have already been validated will be employed in the determination of direct, indirect and intangible costs. All information generated during the research must be statistically representative of the food allergic and coeliac population cohorts. Appropriate statistical (age- and sex-matched) controls must be included in the study design to account for response bias, standards of living, the representativeness of the study populations, etc. Cost estimates must be fully controlled by comparison to non-FHS households.

### 4. **Technical Specification**

- (a) Scope of research
- (b) Literature review
- (c) Qualitative and quantitative work
- (d) Analysis
- (e) Data handling and Reporting
- (f) Quality assurance


#### **(a) Scope of the research**

The scope of the research will encompass medically-diagnosed food allergic and coeliac population cohorts in both jurisdictions on the island of Ireland, with reference to the wider populations as controls. The research will investigate the direct, indirect and intangible costs of food allergy and coeliac disease to the affected consumer and the health care systems in both jurisdictions.

#### **(b) Literature review**

A full and thorough review of the literature concerning the socioeconomic costs of food hypersensitivity (specifically with regard to food allergy and coeliac disease) should be carried out. This will include:

1. Peer reviewed publications and also a full search of the grey literature including government and other organisation reports, conference proceedings, etc. pertaining to the island of Ireland and internationally.
2. An evaluation of methodologies used elsewhere to determine the costs of food hypersensitivity, including validated questionnaires, the use of focus groups, statistical modelling, sensitivity analyses, etc. The most suitable

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methodology/methodologies required to ascertain the socioeconomic cost of food hypersensitivity on the island of Ireland will be identified.

### (c) Qualitative and quantitative research

It is envisaged that the successful applicant will utilise data already available from a wide variety of sources. Some of this data may be difficult to access in which case it must be shown that the necessary authority to access and utilise same are in place. It is also envisaged that a number of survey instruments and questionnaires to generate missing data will be necessary.

### (d) Analysis


This research will involve an estimation of the disease burden attributable to food allergy and coeliac disease on the island of Ireland. It will require that a cost estimate be calculated for both conditions in terms of the associated direct, indirect and intangible costs. For each component, the researcher will be required to give a detailed and transparent explanation of how these costs are arrived at, and a comparison with other national and international methods will be required. The final results will be presented as a range, from which a mid-point estimate can be used as the most reliable approximation to the costs of food allergy and coeliac disease on the island of Ireland.

### (e) Data Handling and Reporting

1. The contractor will submit to **safefood**, on a six monthly basis, a summary interim report containing details of the progress for each deliverable of the project.
2. The contractor is responsible for collating all results and a final report will be submitted to **safefood** on completion of the study.
3. All forms, documentation and electronic files must be retained by the contractor until further notice for **safefood** in case of issues arising after the completion of the research.

### (f) Quality Assurance

1. To ensure transparency and reproducibility, all data sources used in the research must be specified, and all data used must be explicitly specified and justified.
2. **safefood** will liaise with the contractor(s) during the course of the research to assess how the work is being carried out.

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## 5. **Proposed Activities/Deliverables**


- a) Systematic literature review.
- b) Report on the prevalence of food allergy and coeliac disease in both jurisdictions on the island of Ireland.
- c) Report on the direct, indirect and intangible costs of food allergy and coeliac disease on the island of Ireland from the perspective of the affected consumer.
- d) Report on the direct costs to the health care systems on the island of Ireland for treating food allergy and coeliac disease. Where possible, this should be broken down into constituent costs by type of expense, including General Practitioner consultations, hospital admissions, hospital day cases, outpatient attendances and pharmaceutical prescriptions, etc.
- e) Submission on a 6 monthly basis of a summary report on progress.
- f) Recommendations for communications opportunities including the identification of target audiences for research findings. This can include the health services, government departments and agencies, consumers, the food service sector and associated bodies and organisations, the food industry and associated bodies and organisations, etc.
- g) Recommendations for future **safefood** interventions.
- h) Analysis of the final dataset, collation of the results and drafting of a final report to be submitted to **safefood** within the 21 month study period.

## 6. **Evaluation of Tenders**

Tender bids will be evaluated according to the quality of proposals and applicants using the following criteria:

### **Quality of the proposal:**

- ✓ Anticipated deliverables;
- ✓ Research method and facilities;
- ✓ Value for money;
- ✓ Potential for application;
- ✓ Work plan, including the overall timeframe.

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### Quality of Applicants:

- ✓ Experience in subject area;
- ✓ Quality Assurance and Quality Control measures in place.

### 7. **Duration of Project**

Estimated duration of the project: Total of 21 months. A detailed timescale of research should be submitted by the applicant. Preference may be given to an application that can achieve the objectives in shorter timeframes.

### 8. **Tender Application Forms and Guidelines**

The Tender Application Form and associated Guidelines can be downloaded from [www.safefood.eu](http://www.safefood.eu). They can also be obtained by emailing [research@safefood.eu](mailto:research@safefood.eu), quoting the project reference number **07-2018**. Alternatively please contact **safefood** as per the details below.

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**The closing date** for receipt of applications by **safefood** is no later than **4pm on Friday 5<sup>th</sup> October 2018**.