

GOVERNMENT'S ANALYSIS,
ASSESSMENT AND RESEARCH ACTIVITIES

Johanna Suomi, Peppi Haario, Arja Asikainen, Maija Holma,
Annika Raschen, Jouni Tuomisto, Suvi Joutsen, Jenni Luukkanen,
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Costs and Risk Assessment of the Health Effects of the Food System

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Tiivistelmä <p>Ruokajärjestelmän kansanterveydellisten vaikutusten kustannukset ja riskinarviointi -hankkeessa tutkittiin biologisten, kemiallisten ja ravitsemuksellisten esimerkkien avulla ruokaan ja ravitsemukseen liittyviä terveydellisiä ja taloudellisia riskejä Suomessa sekä valvonnan kustannusvaikuttavuutta. Hankkeessa avattiin esimerkinomaisesti suomalaisen ruokaan liittyvien terveyshaittojen syitä ja seurauksia ja etsimään niille soveltuvia riskinhallintakeinoja. Ruoasta johtuvien terveyshaittojen ilmeneminen vie aikaa, siten vahvakin panostus niiden hallintaan ilmenee väestötasolla vasta vuosien tai vuosikymmenien kuluessa. Hankkeen tulosten perusteella esitetään useita toimenpide-ehdotuksia, joista tärkeimpinä 1. ruokajärjestelmän kansanterveydellisten vaikutusten riskien arvioinnin syventäminen ja laajentaminen erilaisten terveyshaittojen vertaamiseksi, 2. elintarvikevalvonnan ja terveydenhoidon kustannus-hyöty-analyysit ja 3. ohjauskeinojen tutkimus muutosten suunnittelua varten.</p> <p>Ravinto on tärkein väestön terveyteen vaikuttava tekijä, ja terveyteen voidaan vaikuttaa ravitsemuksella ja elintarvikkeiden turvallisuudella. Hankkeessa tehdyn selvityksen perusteella tarkastelluista tekijöistä suurinta tautitaakkaa aiheuttivat hedelmien ja kasvien riittämätön kulutus ja liiallisen suolan ja tyydyttyneen rasvan saanti, joista aiheutui vuodessa 36 000, 29 000, 32 000 ja 9 200 haittapainotetun elinvuoden (DALY) verran tautitaakkaa. Erityisesti suolan ja tyydyttyneen rasvan saannin vähentäminen on kustannusvaikuttava tapa vähentää tautitaakkaa.</p> <p>Suomessa saavutetusta suhteellisen korkeasta elintarvikehygienian tasosta huolimatta vuosittain ilmenee jopa tuhansia elintarvikevälitteisiä infektioita, minkä lisäksi elintarvikkeiden vierasaineet lisäävät kuluttajien tautitaakkaa. Biologisista elintarvikevaaroista listeria-bakteerin aiheuttama tautitaakka oli suurin, noin 670 DALYä vuodessa, kemiallisista suurin taakka aiheutui lyijystä, noin 570 DALYä vuodessa. Suurin osa valvontakustannuksista kohdistuu yrityksille. Sen vuoksi skenaarioilla, jotka vaikuttavat eniten yrityksiin on myös suurimmat taloudelliset vaikutukset.</p> <p>Tämä julkaisu on toteutettu osana valtioneuvoston selvitys- ja tutkimussuunnitelman toimeenpanoa. (tietokayttoon.fi) Julkaisun sisällöstä vastaavat tiedon tuottajat, eikä tekstisisältö välttämättä edusta valtioneuvoston näkemystä.</p>			
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Referat <p>Kostnaderna och riskbedömning av livsmedelssystemets folkhälsoeffekter -projektet granskar hälso-och näringsrisker genom biologiska, kemiska och näringsmässiga exempel från både en hälso- och ekonomisynvinkel. Projektet har öppnat orsakerna och konsekvenserna av folkhälsorisker i finsk mat, och beskrivit lämpliga riskhanteringsåtgärder. En manifestering av livsmedelsrelaterade hälsorisker räcker en lång tid. Även en stark ansträngning för att hantera risker visar sig på befolkningsnivån först efter en period av år eller årtionden. Med grund i projektets resultat presenteras ett antal förslag till åtgärder. De viktigaste är: 1. Fördjupning och utvidgning av riskbedömningen inom livsmedelssystemets inverkan på folkhälsan för att jämföra olika hälsorisker, 2. Kostnads-nyttoanalyser av livsmedelskontroll och hälsovård och 3. Forskning av styrningsmedel för att planera förändringar.</p> <p>Kosten är den viktigaste faktorn för befolkningens hälsa, och hälsan kan påverkas av näring och livsmedelssäkerhet. Av de faktorer som undersökts i projektets analys, orsakades den högsta sjukdomsbördan av otillräcklig konsumtion av frukt och grönsaker och överdrivet intag av salt och mättade fetter. De orsakade en sjukdomsbörda av 36 000, 29 000, 32 000 och 9 200 funktionsjusterade levnadsår (DALY) per år. Att minska intaget av salt och mättade fetter är ett synnerligen kostnadseffektivt sätt att minska sjukdomsbördan.</p> <p>Trots den relativt höga nivån av livsmedelshygien som uppnåtts i Finland finns det tusentals livsmedelsburna infektioner varje år, och även föroreningar i livsmedlen ökar belastningen på medborgarnas sjukdomsbörda. Vad gäller de biologiska riskerna var sjukdomsbördan orsakad av listeria störst (runt 670 DALYs per år), den högsta kemiska bördan orsakades av bly (ca 570 DALYs per år). Största delen av kontrollkostnaderna står företagen för. De scenarier som mest påverkar företag har därför också den största ekonomiska påverkan.</p>			
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Abstract <p>The project Costs and Risk Assessment of the Health Effects of the Food System employed biological, chemical and nutritional examples to investigate the health and economic risks of food and nutrition in Finland and the cost effectiveness of controls. The project explored the causes and consequences of the health risks associated with food in Finland and sought appropriate risk-management measures. The onset of foodborne health hazards can be slow, and therefore even strong efforts to control them at the population level may take years or decades. Based on the project results, several proposals for action were presented, the most important of which are to: 1. deepen and broaden the risk assessment of the public health impact of the food system to compare different health risks, 2. undertake cost-benefit analyses of food control and health care and 3. to study policy instruments for change.</p> <p>Food contributes significantly to the health of the population, which can be influenced by nutrition and food safety. According to the project results, the main burden of disease (BoD) was caused by the inadequate consumption of fruit and vegetables and the excessive intake of salt and saturated fats, resulting in disease burdens of 36,000, 29,000, 32,000 and 9,200 disability-adjusted life years (DALYs)/year, respectively. Reducing the intake of salt and saturated fats in particular would be a cost-effective way to reduce the BoD.</p> <p>Despite the relatively high level of food hygiene achieved in Finland, up to thousands of foodborne infections occur every year, and food contaminants increase the BoD on consumers. Of the biological food hazards, Listeria caused the largest BoD, about 670 DALYs annually. Of the chemical hazards, lead caused the largest BoD, about 570 DALYs annually. Most of the control costs are borne by food businesses. Therefore, the scenarios that most affect businesses also have the greatest financial impact.</p>			
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Vocabulary

Term	Explanation
Agent	An external factor that a person comes into contact with that can cause adverse effects. For example, bacteria are biological agents and heavy metals are chemical agents; irradiation is a physical agent.
Biofilm	Structures that consist of bacteria and metabolites they produce and that allow bacteria to attach to surfaces, protect them from physical and chemical stress and provide nutrition
BMDL	Lower confidence limit of the benchmark dose (BMD), which corresponds to a dose that increases the risk of adverse effect with a predetermined amount from the base level of the population. The percentage of increase is shown as subscript. For example, BMDL ₀₁ is a dose that increases a certain risk at population level by 1% compared to that part of the population whose exposure is lower than this dose.
Carcinogenic	Producing cancer
CHD	Coronary heart disease
Complication	Secondary disease, side effect (of treatment); a new disorder related to earlier disease or treatment of disease
Colony forming unit (cfu)	Unit used to estimate the number of viable cells in a sample
Contamination	Degree of contamination/pollution
DALY	Disability-adjusted life year, unit of the burden of disease. DALYs measure the importance of various diseases and risk factors in terms of harm to the population as a whole, that is, premature deaths and years of disability due to illness
Food hazard	Chemical substance or physical or biological factor present in food or the state of food that may have a harmful health effect
Genotoxic	Substance that alters cells' genetic material.
Hard or saturated fats	Saturated fats are fatty acids that only have single bonds between carbon atoms; sources include meat dishes, cheeses, milk products.
HDL cholesterol	High-density lipoprotein, good cholesterol, carries cholesterol away from the surface of blood vessels and thus prevents narrowing of arteries.
IHD	Ischemic heart disease; long-term oxygen deprivation of the heart muscle
Incidence	Occurrence of new disease cases in a certain population and in a certain time period
kg bw	Kilogram per body weight
LDL cholesterol	Low-density lipoprotein, or bad cholesterol, carries cholesterol to surfaces of arteries. High levels of LDL cholesterol in blood indicate arteriosclerosis. Hard fats increase it and soft fats decrease it.
Median	The middle number of distribution in a sorted list of numbers
Meta-analysis	Combining of studies; study that combines several other previous studies of the same subject and method
Mortality	The proportional number of deaths in a population in a certain time period
Mutagenic	Causing mutations, change in genetic material of gametes or somatic cells (cells other than gametes); chromosome or gene mutation.
Neuropathy	Dysfunction of peripheral nerves and/or pathological change
PAF	Population attributable fraction; the fraction of people with a certain illness whose illness can be attributed to the studied agent
Prevalence	Proportion of (illness) cases in a certain population at a certain time or in a certain time period
Risk ratio	Risk among those exposed to the studied factor divided by the risk among the unexposed
Risk factor	Social, economic or biological factor, behaviour or environment that is associated with or increases susceptibility to a particular disease or problem
Scenario	Description of an imaginary situation and subsequent events that make it possible to move from the original situation to this situation

Term	Explanation
Socio-economic	Concerning interaction of social and economic aspects
Burden of disease	The total harm caused by diseases and factors leading to premature death or disability
TEQ	Toxic equivalency quantity, unit used to assess comprehensive effect of mixture of dioxins
Teratogenic	Causing malformation of an embryo
Trans fats	Type of fats that form in industrial processing and in the rumen of ruminants; fatty acids have a double bond, yet the bond is in a configuration that causes negative health effects
Confidence interval	Distance between the maximum and minimum values of a variable
Contaminant	Substance that has not been added to food deliberately but that is prevalent in food due to contamination in primary production, manufacturing, processing, preparation, handling, packaging, transportation or storing or due to environmental contamination. Foreign substances, such as residuals of insects or animal hairs are not included in this definition.
Vegetables	Succulent plants or parts of plants used as food (root vegetables and greens), can also mean berries, fruits, mushrooms and cereals
µg	microgram, 1×10^{-6} g, one millionth of a gram
pg	picogram, 1×10^{-12} g

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1 Introduction

1.1 Background

Food contributes significantly to the health of the population through nutrition and food safety in both the European Union (EU) and in Finland (University of Washington 2019). However, detected and reported foodborne illnesses are only a fraction of the actual cases, as the vast majority remain unreported. The consequences of diseases are mainly determined by the impact of air pollution, infectious diseases or poor nutrition (malnutrition; excess intake of, for example, saturated fat, salt and sugar; or overweight) on human health. The long-term consequences of biological, chemical or physical hazards related to food and drinking water have been studied less.

Nutritional factors have a major impact on the health of Finns. The Western pattern diet typically comprises food that is too high in energy, saturated fat, salt and added sugar (Nordic Council of Ministers 2014). Excessive energy intake leads to overweight and may predispose people to certain cancers. Saturated fat increases the level of harmful low-density lipoprotein (LDL) cholesterol in the blood and therefore increases the risk of cardiovascular disease. High salt intake is associated with high blood pressure and death due to stroke and coronary heart disease. A diet rich in fruits, berries and vegetables protects against cardiovascular disease and is likely to prevent certain cancers. Dietary whole grains have been associated with a reduced risk of cardiovascular disease and type 2 diabetes. Fish consumption is linked to lower cardiovascular mortality, whereas red and processed meat increase the risk of colon and rectal cancers (Nordic Council of Ministers 2014). Nutritional health hazards are usually the result of a long-term unhealthy diet, and preventing the associated public health risks requires a permanent change in Finns' eating habits.

The Finnish Food Safety Authority Evira (now the Finnish Food Authority) has identified nearly 20 foodborne biological hazards (Hallanvuo & Johansson 2010) and about 30 chemical substances or groups of substances that may have a significant impact on the health and well-being of Finns (Hallikainen et al. 2013). Some chemicals are carcinogenic, and some are acutely toxic. Most chemical and toxin exposures are associated with potential effects of chronic long-term exposure, particularly in vulnerable populations. In addition to acute food poisoning, biological food hazards can cause sequelae.

Food chain quality management systems and controls aim to limit these risks. Although a relatively high level of food hygiene has been achieved in Finland, thousands

of foodborne infections occur every year, and food contaminants contribute to the burden of disease (BoD) on consumers (Jaakola et al. 2017). The chronic public health effects of risks related to food hazards are not well known and are not described in a comparable format for prioritization. The costs of risk management for some parts of the food chain have been estimated for Finnish society and companies, but to our knowledge there is no overview of the main cost factors.

Food is by far the most important single determinant of population health. At the EU level, food-related factors are estimated to have caused a total loss of 32,700 disability-adjusted life years (DALYs)/million population in 2015. In Finland, the corresponding estimate was 31,500 DALYs (University of Washington 2019). These hazards arise in the food chain, which is driven by economic, biophysical and socio-political mechanisms (Nesheim et al. 2015), the products of which are used by consumers in accordance with their personal and cultural priorities, preferences and habits. Some of the risks arise from defects in the storage and handling of food in the part of the food chain for which the consumer is responsible. The importance of all the above factors is accentuated as multiculturalism increases (Harris et al., 2015), and successful influencing in them is a way to reduce the cost of illness.

This project (Costs and Risk Assessment of the Health Effects of the Food System, RUORI) aimed to create a comparable general view of the severity of health hazards (individual risk) and their public health significance according to the health hazards and their exposure levels defined by Evira and the BoD methods developed by the National Institute of Health and Welfare (THL) in Finland. In addition, the project utilized the results of ongoing and completed risk assessments by the Finnish Food Authority. Registry data and international estimates were utilized to provide a true picture of the BoD, given that only a minority of mild abdominal symptoms will be diagnosed by a physician. The cost-effectiveness of scenarios seeking to reduce the BoD or costs was assessed.

Finnish food companies aim to double their exports by 2025. Some completed risk assessments based on scientific evidence have already been used to promote exports by demonstrating the high hygiene and low risk level of food raw materials and products (risk assessment projects of the Finnish Food Authority: <https://www.ruokavirasto.fi/en/organisations/risk-assessment/projects-of-risk-assessment/>). Meeting the export conditions of important export countries, such as those in the Eurasian Economic Union, Russia, China and the United States, in a cost-effective way would be particularly important in the future for Finnish companies. Therefore, the export requirements and control conditions were clarified and assessed in this project.

1.2 Aims of the project

The main aims of the project were to:

1. identify the major food- and nutrition-related health and economic risks in Finland and the factors affecting them;
2. classify the risks and the factors affecting them based on the results and thus provide information for risk management;
3. identify food safety needs in relation to export;
4. highlight priority areas for food safety research and information gaps;
5. prepare a current economic cost estimate for the treatment, prevention and control of foodborne diseases; and
6. assess the computational impact of suggested measures, such as de-regulation.

1.3 Assessed hazards and factors

For chemical, biological and physical food hazards and nutritional factors, three to four types of hazards from each group were considered as examples. Their selection was based on the available information on their effects and costs, although the final choice was also influenced by the amount of information available for each hazard. Different hazards can be economically significant, either because of the illness they cause or the cost of risk management. In addition, factors were chosen to target the costs of the various risk management actors (e.g. own-check sampling, official control) and the hazards with health consequences of varying severity (e.g. acute infections, long-term sequelae). Efforts were made to review the costs of control throughout the production process. The economic significance was addressed from several perspectives—illness, control costs, industry and food supply. Risk perceptions and factors affecting political decision making were also considered to the extent allowed by the data. Reported treatment costs for the diseases and epidemics over the period 2014–2016 were related to the number of disease cases that may have been caused by the chosen example food hazards but that were not reported.

The study also aimed to assess the impact of food law flexibility on food safety and the costs of controls and illness. There may be flexibility in the requirements of the legislation, such as exemptions and adjustments, but 'deregulation' must not endanger food safety or increase morbidity ((EC) 862/2004, 13, 853/2004, 10, 853/2004 Art. 17). The possibility of reducing trichinella testing in meat inspection was used as an example of deregulation.

Biological hazards

Four biological hazards, *Listeria monocytogenes*, human norovirus, *Toxoplasma gondii* and *Trichinella* parasitic roundworms, were studied in this project.

Listeria monocytogenes (hereafter 'Listeria') was included in the assessment because the disease is diagnosed more frequently in Finland than in other EU countries each year. There have been national requirements for managing Listeria, but the current microbial criteria in Regulation (EC) No. 2073/2005 sets limits for Listeria in the manufacture and end products of several foodstuffs (safety and hygiene criteria). The consequences of listeriosis can be extremely severe and even fatal, particularly for pregnant women, fetuses, infants, the elderly and those who are immunocompromised, for example, due to chronic illness.

Norovirus is the most common cause of foodborne epidemics in Finland. There have been large seasonal outbreaks and, despite the relatively mild symptoms, significant economic costs due to sick leaves. Norovirus gastroenteritis can be dangerous for immunocompromised individuals.

The effect of **parasitic toxoplasma** was assessed, as toxoplasma is the third most significant pathogen in Europe according to the World Health Organization (WHO). The symptoms range from mild ones to pneumonia, encephalitis and visual impairment. However, there are no risk management practices to prevent the parasite.

Cases of **Trichinella** are very rare in Finland. However, the risk management costs in the form of laboratory tests on slaughtered animals are massive. The possibility of reducing the number of analyses has been discussed. The health consequences of trichinellosis range from mild to severe and even fatal.

Physical hazards

Among the hazards that present physical risks, **foreign objects**, such as broken glass, pieces of metal and wood splinters, and radiation are the most commonly mentioned. Foreign objects can mechanically contaminate food and can cause, for example, asphyxiation or tooth damage. According to the information gathered in this project, companies find the possibility of foreign objects in their products such a severe reputational risk that they are not willing to reduce their own-check measures.

Certain foods can be **irradiated** with ionizing radiation to improve shelf life. Only a narrow range of irradiated foods (spices, hospital food) can be sold in Finland. Food irradiated according to the guidelines is not radioactive. Low levels of radioactivity

may be observed as a result of deposition, mainly in natural products. Background radiation is often more intense than the measured radiation from deposition. In Finland, the Finnish Food Authority supervises the irradiation of foodstuffs, the Customs laboratory controls import, and the Radiation and Nuclear Safety Authority monitors radioactivity levels. Because of the non-existent need for changes in control, the physical hazards were not assessed in terms of public health or economic risks in this project.

Chemical hazards

The chemical hazards of aflatoxins, dioxins and lead were studied in this project.

Aflatoxin was selected for evaluation because maximum permissible levels in foodstuffs have been set in the Contaminants Regulation ((EC) No. 1881/2006 and nationally (MMM 880/2016). Aflatoxin was also one of the chemicals studied in WHO's BoD assessment. Aflatoxin exposure also links to a nutritional aspect, as the consumption of nuts is promoted and exposure to aflatoxins may thus increase. The climate may also become more favourable for the formation of aflatoxins. The importance of aflatoxins is further increased because they are monitored in several food categories. Aflatoxin exposure can have health consequences, as aflatoxins are the most mutagenic and carcinogenic substances known.

Dioxins were selected for evaluation because they are monitored in several food groups and have high analytical costs. Although preliminary results indicate that the levels of dioxins in food have decreased, they may be present in products that are increasingly consumed, such as imported cheeses. Finland has a derogation for the national sale of certain fish species from the Baltic Sea, although they may exceed the limits of EU legislation. Dioxins may cause developmental disorders.

The inclusion of **lead** in the evaluation was justified by the fact that maximum levels of lead for several food categories have been set. Although exposure to lead via food has decreased during Finland's EU membership, the exposure of Finnish 1–3-year-olds is still worryingly high. Potential health consequences of lead exposure include cognitive impairment, hypertension, kidney damage and anaemia.

Nutritional factors

The following key points of concern regarding nutrition in Finland were selected for the evaluation: the inadequate consumption of fruits and vegetables and the excessive intake of salt and fat.

Finns eat too few **fruits** and **vegetables**, even though they are known to have many health benefits. High consumption of fruits and vegetables prevents cardiovascular disease and possibly some cancers. They are high in dietary fibre and protective nutrients (Nordic Council of Ministers 2014). Achieving a feeling of satiety with less energy may help with weight management. According to the European Food Safety Authority (EFSA 2008), it would be possible to prevent some 26,000 cardiac or cerebral infarction deaths in people under the age of 65 in the EU by increasing the proportion of fruits and vegetables consumed.

Almost all Finns get more salt than recommended from their diet (Valsta et al. 2018). There is much evidence that **excessive salt intake** causes hypertension. High salt intake has also been linked to the risk of stroke, cardiovascular disease, stomach cancer and osteoporosis (Nordic Council of Ministers 2014). There has been an attempt to reduce salt intake with a regulation requiring that certain foods be labelled with a warning that the salt content exceeds the regulatory limit. The salt content of food is one of the criteria for products or restaurant items to have the 'Heart Symbol', an initiative launched by the Finnish Heart Association to indicate nutritional quality.

The amount and quality of **fat** affects the healthiness of one's diet. More than one third of Finns get too much fat from their diets compared to recommendations, and most consume more saturated fat than recommended (Valsta et al. 2018). Fat is high in energy, and a high-fat diet can increase the risk of being overweight. Saturated fats increase the level of harmful LDL cholesterol and are a major risk factor for cardiovascular disease. They may also reduce insulin sensitivity and increase blood pressure. Due to the changed production processes in the food industry, the intake of harmful trans fatty acids is currently low (Nordic Council of Ministers 2014). The proportion and quality of fats are also included in the criteria to acquire the Heart Symbol mentioned above.

2 Materials and methods

2.1 Materials

Data related to food control, primary production, production and retailing are derived from the surveys and interviews conducted during the project.

To support the development of the scenarios as a part of the RUORI project, a workshop was held in December 2018. In the workshop, enterprise and supervision experts provided comments and information that was utilized in preparing and editing the scenarios.

2.1.1 Biological food hazards

This project assessed the impact of biological food hazards using WHO estimates. The BoD assessment for biological factors (*Listeria*, Norovirus and *Toxoplasma*) based on the WHO report (WHO 2015) used a method based on morbidity (incidence) that takes into account the incidence of biological agents, the age and sex of the patients, duration of disease, life-years lost due to possible death and disease-related disability weight. The values used in the WHO report to calculate BoD are based on either global estimates or regional data estimates, as appropriate. Biological hazards have no national estimate for Finland, but the estimates are based on data from the European territory, assuming that Finland is a typical European country in this respect. Norovirus and *Listeria* estimates have been updated according to the THL infectious disease register. The burden of trichinellosis was estimated to be non-existent, as no infections have occurred in Finland in the 2010s.

Underreporting of disease cases has not been investigated in Finland. Underreporting is expected to be relatively common in mild illness cases. Tam et al. (2012) estimated that about 94% of patients with gastrointestinal infections do not seek treatment. Overall, reporting activity for biological agents is estimated to be around 10%–30%, meaning that 70%–90% of those infected are not included in the reports.

2.1.2 Chemical food hazards

The BoD assessment of aflatoxins relied on the WHO report calculation, which was updated with values of Finnish exposure from the EFSA report (EFSA 2018) and from Finnish liver cancer registry data, and the assumption that the prevalence of hepatitis

B in Finland is 0.5%. The EFSA estimate is based on the national food consumption data The Finnish Type 1 Diabetes Prediction and Prevention Study (DIPP) (Kyttälä et al. 2008), Findiet 2012 (Helldán et al. 2013) and data on peanut levels collected from all EU countries. It does not include other sources of aflatoxins, such as, inter alia, tree nuts.

The lead exposure of Finns has been studied in Finnish Food Authority projects (Finnish Food Authority 2019d). The exposure of adults (Suomi 2019) and children from 1–6 years of age (Suomi et al. 2015) has been statistically (probabilistically) estimated from the national food consumption data DIPP (Kyttälä et al. 2008), Findiet 2012 (Helldán et al. 2013) and official and own-check samples analysed in Finland. Findiet studies represent the food consumption of the Finnish population well, but no such information exists for children, as DIPP data has been collected only from one area and all the studied children had a gene that predispose them to type one diabetes. Therefore, the study had limited capability to represent Finnish children. The BoD assessment was based on exposure estimates using the THL model.

Exposure to dioxins was not evaluated, as the BoD was recently estimated in the [GOHERR project](http://en.opasnet.org/w/Goherr_assessment) (http://en.opasnet.org/w/Goherr_assessment) using WHO's assessment, thus updating the calculated dioxin levels in Baltic Sea fish and dl-PCB-related disease in Finland.

2.1.3 Nutritional factors

Finns' consumption of fruits and vegetables and intake of salt and saturated fat are derived from the National Findiet 2012 and 2017 surveys (Helldán et al. 2013; Valsta et al. 2018). Estimates of the BoD related to the underconsumption of fruits and vegetables and the excessive intake of salt were strongly based on the global burden of disease (GBD) calculations of the Institute for Health Metrics and Evaluation (IHME) (University of Washington 2019). For excessive salt intake and underconsumption of fruits and vegetables, IHME data were updated according to intake data from the latest Findiet study in 2017 (Valsta et al. 2018). The BoD caused by saturated fat was evaluated using the IHME data on cardiovascular and vascular disease cases and the amount of fat intake in Findiet studies. Unlike trans fat, the BoD caused by saturated fat has not been separated into its own factor in the IHME GBD database. In Finland, the recommended dietary fat intake is 25%–40% of the total energy intake, and the recommended intake of saturated fat is less than 10% of the total energy intake.

In the IHME data, the underconsumption of fruits and vegetables was considered separately, causing the acceptable daily intake to be higher than the Finnish recommendation. The underconsumption of vegetables for IHME data means less than

400 g/day (University of Washington 2019b). The underconsumption of fruits means less than approximately 310 g/day. The limit for the underconsumption of fruits and vegetables (710 g in total) used in IHME data differs from the daily intake of 500 g according to Finnish Nutrition Recommendations (VRN 2014). In IHME data, excess salt intake refers to the consumption of more than 2.5 g/day, which also differs from the recommended daily intake of up to 5 g according to Finnish dietary recommendations.

IHME GBD (University of Washington in 2019) was used in the RUORI project and classifies fresh, frozen, cooked, canned and dried vegetables, including legumes, as vegetables, but this does not include canned vegetables preserved with salt or vinegar, nuts, seeds and starchy vegetables, such as potatoes and corn. Fruits are classified as fresh, frozen, cooked, canned and dried, but this does not include fruit juice or fruit preserved with salt or vinegar. It was assumed that berries belong to the same category as fruits, but this is not apparent from the IHME definitions.

2.2 Methods

2.2.1 Surveys

To find out about current costs, food control units, the Finnish Food Authority's control department and the Customs laboratory were surveyed. Primary production facilities, food production facilities and retail stores were surveyed separately. They were asked for control or own-check working hours and annual sampling and laboratory costs related to the food hazards studied in this project. In addition, the costs of complaints of food poisoning in 2014–2016, the means used to control food hazards, the proportion of non-compliant food samples in the samples examined and the cost of obtaining and using the Heart Symbol were examined. The survey for the control authorities addressed the same issues and contained the same control measures targeted at food business operators over the period 2014–2016 based on the factors examined in the project.

The survey was originally formulated as an electronic Webropol survey that was sent to the Retail Federation (PTY), the Travel and Restaurant Association (MaRa), the Food Industry Association (ETL), Customs, local control units and the Finnish Food Authority control units. Due to the low number of responses, the survey, which was open in October–December 2018, was re-opened in January–February 2019. The survey was supplemented with telephone interviews with the same set of questions as the original survey. Eight replies were received from the authority and 35 from primary production facilities, food production facilities and retail operators. Due to the low

number of responses, the missing information was supplemented with information obtained through data mining.

The Export section of the Finnish Food Authority was also interviewed regarding the importance of chemical, biological and physical food hazards, nutritional factors and their control over food exports.

2.2.2 Assessment of burden of disease

The BoD is a metric to measure a population's loss of health. It combines years lived with disability (YLD) and years of life lost (YLL) due to attributable mortality. BoD is measured in DALYs (Hänninen & Knol 2011). BoD is calculated as follows:

$$BoD = YLL + YLD. \quad (1)$$

Nation-level assessments of BoD have been done by IHME (University of Washington, 2019c) and by the WHO Global Health Estimates (GHE) project in recent years. Both constantly update their methods and the data used. From the data used by the IHME, it is possible to retrieve national estimates of BoD for diseases and risk factors, including nutritional factors.

Assessing BoD relating to different factors, in this case nutritional ones, can be done using a few basic methods. Which method to use depends on the dataset used. Methods based on epidemiological relative risk (RR) and unit risk (UR) can be seen as primary methods (Figure 1). These methods can be used to estimate the population attributable fraction (PAF) for an exposure agent. PAF describes the portion of a population's morbidity that can be attributed to a certain exposure factor. PAF combined with the total burden of a disease (or if that is lacking with the total incidence rate of the disease) gives the BoD attributable to the exposure factor (BoDa). In this project, the PAF approach has been used to calculate the BoD of aflatoxins, dioxins and nutritional factors.

If data required for calculating the PAF are not available, the BoD can be calculated from estimates of the disease cases caused by the exposure factor and the estimated severity and length of a case of disease. The calculations are based on the following equation:

$$BoD = L \times Dw \times n, \quad (2)$$

where L is the length of the disease or, in case of death, the number of life years lost to premature death, D_w is the severity of the disease (in case of death 1) and n is the number of cases. This method has been used in this project to calculate the BoD caused by biological factors. It leans heavily on a WHO report in which the BoD of food-related factors was assessed.

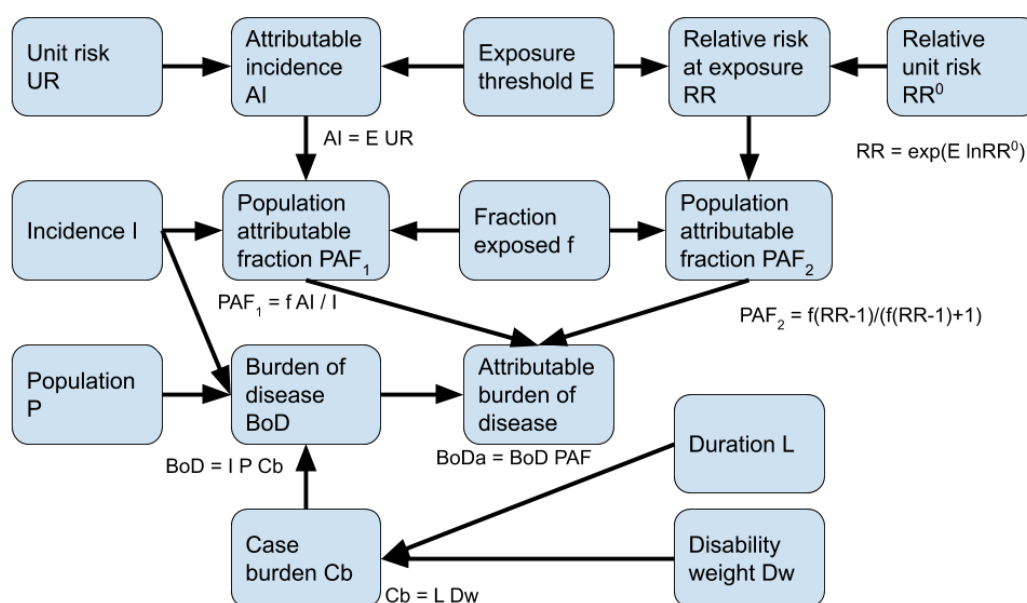


Figure 1. The calculation model for burden of disease. The blue boxes represent parts of the model and arrows the data required for calculations. Where possible, the equation used in the part of the model is shown next to the box. All exposure factors and health responses were calculated using the same model, but because of the differing initial data the calculations started from different places in different cases. Relative risk was used for exposure factors for which the risk is relative to the prevalence of the disease in a population (e.g. factors increasing the risk of heart disease). Unit risk was used in situations where the risk is independent of this (e.g. a developmental disorder of teeth caused by a dioxin is not dependent on any other developmental disorders or tooth damage). The figure has been modified from Hänninen & Knol, 2011.

BoD is often reported for a certain year (e.g. calculated with data from 2016) or for 'the present' if the initial data is not all from the same year but approximately correspond to the time the assessment was made, as is the case for this report. In the latter case, the results are reported as BoD/year (DALY/year) or the BoD caused by one year of exposure. However, this phrasing contains some assumptions, so it is important to take care when interpreting results.

First, the result does not mean that all harm caused by exposure manifests during the same year. For example, liver cancer caused by aflatoxin can manifest decades after exposure, and one death from cancer can shorten the patient's life by multiple years. However, in the calculations all harm, including future harm, will be allocated to the

year of exposure. Harm occurring far in the future tended to be discounted or assessed as less severe than immediate harm, but this practice has mostly been abandoned. This report does not discount health impacts.

Second, a PAF tends to allocate health impacts to different exposure factors, assuming that it directly tells about the behaviour of the disease. However, it is not possible to say, even with very accurate observational data, how the health of the people would have progressed if the exposure studied had not occurred. They may have fallen ill with some other disease, in which case the health benefit would be smaller than estimated and the harm from this other disease bigger than estimated. Epidemiological research also has the limitation that the observed difference in loss of life years in populations with different exposures cannot be directly converted into numbers of disease cases without additional assumptions. A similar limitation exists for impact assessments. In this report, we have assumed that the PAF tells everything relevant about these sources of error. This field of problems is also described in Chapter 8, section 8.4.

2.2.3 Cost-effectiveness analysis

Cost-benefit and cost-effectiveness analyses are commonly used to compare the costs and benefits of alternative measures. In a cost–benefit analysis, costs and benefits are described in monetary terms, while in a cost-effectiveness analysis, costs are expressed in monetary units and effectiveness is represented with a non-monetary indicator. In this project, cost-effectiveness calculations are used to assess the effect of various policy measures on public health. The status of and impacts on public health are described by the commonly used DALYs (WHO 2003), while the costs are calculated in euros. Such a cost-effectiveness calculation can help to determine how to maximize health impacts when financial resources are limited. The method makes it possible to compare the relative costs of different measures and to choose the most efficient one. In this project, DALY estimations are not converted into monetary terms.

This cost-effectiveness analysis consists of three steps. First, it defines the costs for the current situation—the baseline case. Then it does the same for each of the policy options, that is, the different future scenarios. Expenditures considered for the cost estimation are monitoring expenses for the Central Food Safety Authorities (including the Finnish Food Authority and Customs), for municipalities and for companies. Also included in the calculations are the health care expenditures required to treat the health impacts caused by exposure to the hazardous substances studied and the correlated productivity losses. Depending on the substance, further cost factors might be included; these are addressed separately.

The cost-effectiveness of an individual measure can be best described by the average cost-effectiveness ratio (ACER), as shown in Equation (3):

$$ACER = \frac{Cost}{Effect} \quad (3)$$

Based on the ACER, it can be shown which scenarios are most effective. It should be kept in mind that also the temporal dimension of the analysis is important. Generally speaking, actions geared towards children have the greatest potential for cost-effectiveness, as the duration of action in this case is longest (Hutubessy et al. 2003). Some actions are cost effective only in the long term, over several decades, while others are effective in the short term. In this study, a cost-effectiveness analysis will be conducted for 2014–2016. However, a three-year review does not allow long-term impact assessment, which should be taken into account when interpreting the results.

Monitoring expenditures

Food safety controls are defined by Finnish law, specifically the 23/2006 Finnish Food Act (Elintarvikelaki 23/2006). According to this act, the competent control authorities are the Finnish Food Safety Authority (Ruokavirasto), the Regional State Administrative Agencies and the municipal control authorities. The food industry itself also engages in own check to safeguard the quality of their products. Control costs are calculated at the Finnish level and are therefore comparable to DALY figures. In this project, monitoring costs were mapped based on a survey sent to the different monitoring authorities.

Costs for central food safety authorities

The central food safety authorities refer to the Finnish Food Safety Authority (now the Finnish Food Authority) and the Finnish Customs. The costs from Evira and Finnish Customs have been collected individually from the actors themselves and are summed up in the cost-effectiveness analysis.

Costs for municipal control authorities

Municipal control authorities enact food controls at the municipal level. In many cases, municipalities have cooperated, leading to the creation of 60 municipal control bodies in Finland. All 60 were asked to complete the survey. Eight responded to the survey

and provided data regarding their monitoring practices and the related costs. The obtained data set was cleaned, and, where possible, missing values were imputed using means. Based on the data, the total monitoring costs per variable can be calculated for each respondent. These individual totals consist of three parts (Equation 4):

$$\text{Total costs} = \text{labour costs} + \text{sampling costs} + \text{control costs}. \quad (4)$$

Labour costs refer to the expenses resulting from the authorities' staff doing their jobs (Equation 5). The authorities indicated the time that their staff spent working on food safety monitoring activities in total, which was measured in work months per year. These were multiplied by the average employee costs (€4,061.667) in the sector, according to Statistics Finland. Additionally, the authorities provided information about the percentage of time spent on monitoring each of the different hazardous substances researched.

$$\begin{aligned} \text{Labour Costs} = & \text{htkk p.a.} \times \text{€4061.667} \\ & \times \% \text{ of time spent monitoring variable } x \end{aligned} \quad (5)$$

Sampling costs include both the costs arising from the actual act of sampling and from analysing the samples. Depending on the way in which the municipalities indicated their sampling costs, two alternatives were available to compute the sampling costs. If the authorities conducted the sampling and analysis themselves, they provided the sampling and analysis expenditures individually per hazardous substance investigated. That value was then used (Equation 6a):

$$\text{Sampling costs 1} = \text{Sampling costs indicated}. \quad (6a)$$

Alternatively, some municipalities used analysis packages offered by third parties. In those cases, the municipalities provided the price per package and the number of variables tested for. To obtain a cost estimate per factor, Equation 6b was applied:

$$\text{Sampling costs 2} = \frac{\text{analysis package costs}}{\text{number of variables in package}}. \quad (6b)$$

Finally, control costs were summed for the three-year period 2014–2016. As presented in Equation 7, the annual costs for controls were estimated:

$$\text{Control costs} = \frac{\text{indicated control costs}}{3}. \quad (7)$$

To estimate the total cost level for the whole of Finland, the percentage 13.3% (eight out of 60 municipalities responded) was used.

Costs for regional state administrative agencies

In most cases, Ruokavirasto takes care of these controls. Consequently, regional state administrative agencies will not be considered as separate cost-incurring control authorities in the analysis.

Costs for companies

The methodology is very similar to the one used for municipal control authorities. There are approximately 3,100 food business operators of which 35 responded to the survey.

Again, the obtained data was cleaned and completed through imputation. Two companies were excluded from the analysis due to empty responses, reducing the number of usable surveys to 33.

The total monitoring costs per variable were calculated for each respondent using Equation (4). However, the labour costs are higher in the private sector and were obtained using Equation (8):

$$\text{Labour Costs} = \text{htkk p.a.} * €5200.083 * \text{\% of time spent monitoring variable } x. \quad (8)$$

Sampling costs for companies were calculated in the same way as for municipalities using Equations 6a and 6b, depending on how the data was provided. The final part comprises control costs, which are also expenses for the companies. The companies were asked to indicate their expenses bundled for the chemical, biological and nutritional variables per year. To obtain the separate costs per variable, the bundled costs were divided by the number of variables in one category, as shown by Equation 9:

$$\text{Control costs} = \frac{\text{indicated control costs}}{\text{number of variables in category}} \quad (9)$$

Equivalent to the case of the municipalities, the total costs per variable and per company were calculated by summing up the different cost categories. To estimate the national annual control costs per variable, the costs needed to be scaled. Based on the Finnish Food Authority's registry of companies active in the Finnish food sector, 4,791 companies were identified. The number does not include retail or catering companies. Using this as an estimation of companies in the food sector having to monitor at least some of the substances studied in this research gives a percentage of 0.69%. The company costs calculated in the project are a rough estimate.

Current situation and future scenarios

To conduct a cost-effectiveness analysis, it is necessary to compare the current level costs to the costs anticipated in future scenarios. Both costs were assessed following the same scheme, combining monitoring costs, health care costs connected to the substance, productivity losses and, where necessary, other costs. The way the costs are calculated is explained in the substance-specific sections (Chapters 3–6).

3 Biological hazards: Examples, current status and scenarios

This chapter goes through the examples of biological food hazards explored in the RUORI project. For each example, the report describes its impact on consumer health, its prevalence in food, information on the exposure (intake) and related morbidity of the population living in Finland, the BoD associated with the hazard and the current costs of surveillance and morbidity. After presenting the current situation, the scenario studied in the project and its impact on disease burden and costs will be described.

Detailed assumptions and calculation codes used to calculate disease burden estimates can be found on the Opasnet Web Workspace [RUORI page](http://fi.opasnet.org/fi/Ruori) at <http://fi.opasnet.org/fi/Ruori>

3.1 *Listeria monocytogenes*

3.1.1 Health effects

Listeria is a species of pathogenic bacteria that causes a serious disease called listeriosis in humans. Listeriosis carries a mortality rate of about 20%–30% in at-risk groups (Barbuddhe & Chakraborty 2009). Pregnant women, the elderly, newborns, transplant patients and others with reduced immunity are at risk for listeriosis. In people with impaired immunity, *Listeria* usually causes serious illness, such as meningitis or encephalitis and/or sepsis, which can be fatal (Doganay 2003). In pregnant women, listeriosis manifests as a mild illness that resembles the common flu (fever, chills, muscle aches and headaches) and can lead to miscarriage or premature labour (Doganay 2003; Farber & Peterkin 1991). In neonates, the disease manifests as sepsis in labour or as meningitis later. In healthy adults and children, *Listeria* does not usually cause symptoms, but foods high in *Listeria* can cause self-limiting gastroenteritis. Generally, the onset of symptoms occurs with a high dose of *Listeria* (100,000–1

million colony forming units/g [cfu/g]). However, very low concentrations (even less than 10–10,000 cfu/g) have been reported to cause illness in at-risk groups (Hallanvuo & Johansson 2010).

3.1.2 Prevalence in food and current status in Finland

Listeriosis is mainly a foodborne infection associated with inadequately heated or contaminated food, particularly fish and fish products, meat and meat products, vegetables and milk and milk products (Hallanvuo & Johansson 2010).

High-risk foods include those which are eaten without being heated, have a long shelf-life and are able to support the growth of *Listeria*. Such foods include vacuum-packed, cold-smoked and salt-cured fish products; eggs; meat, cold cuts and pâtés; frozen vegetables; and unpasteurized milk and cheese (Hallanvuo & Johansson 2010). *Listeria* is also able to grow at refrigerator temperatures, meaning that even a small amount of *Listeria* in food can grow to harmful concentrations (Farber & Peterkin 1991). The ability to grow in a cold and low-oxygen environment allows *Listeria* to grow to high concentrations while preventing other microbes from growing. In addition, *Listeria* can form stable biofilms that can cause *Listeria* contamination to be a highly persistent problem in manufacturing plants.

Controlling *Listeria* in food is the responsibility of the food business operator. Sampling is mainly focused on ready-to-eat (RTE) food. *Listeria* bacteria are destroyed during heat treatment, so testing foods intended for heating would not make sense. According to the Microbial Criteria Regulation (EC) 2073/2005, samples are taken from RTE foods at meat, fish, dairy, and egg product establishments, food establishments producing vegetable (including sprouts) and fruit products and bakeries. The production environment should also be monitored for the presence of *Listeria*. If a batch of food does not meet the Microbial Criteria Regulation targets, the batch is withdrawn from the market. Depending on the sample, the detection of *Listeria* leads to power cleaning to sampling and withdrawal.

Listeriosis is classified as an infectious disease to be controlled according to the Infectious Diseases Regulation, and clinical laboratories are required to report the finding of *L. monocytogenes*. Listeriosis is more common in Finland than elsewhere in Europe (EFSA, ECDC 2017). Between 2014 and 2016, a total of 177 listeriosis cases were reported to the Registry of Infectious Diseases (on average 59 a year). The median age of those infected was 75 years (range 0–96 years) (Figure 2). Of the cases, 51% (90/177) were women, and 21% of cases died within 30 days of sampling. Information on pregnancy was not reported in the infectious disease register, but based on

laboratory notifications there was one neonatal listeriosis case in 2014, and based on patient interviews in 2016 there was one pregnancy-associated *Listeria* infection (THL 2015, THL 2017b).

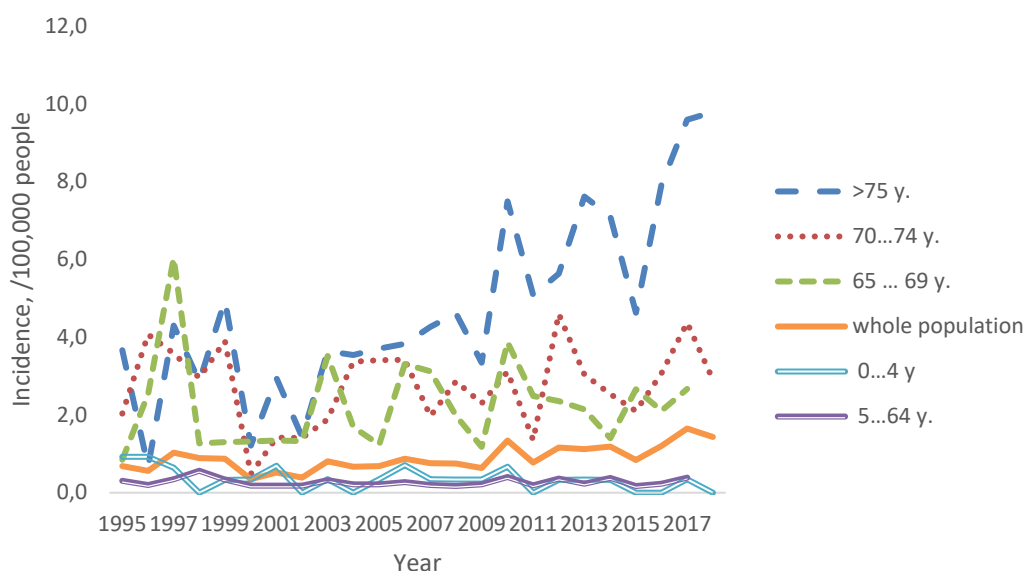


Figure 2. Listeriosis cases in Finland per 100,000 people annually and by age group. In older age groups, the incidence is clearly higher than the average for the whole population. Source: THL Register of Infectious Diseases.

3.1.3 Current burden of disease caused by *Listeria*

The WHO report (2015) estimates that *Listeria* causes an average BoD of 2 DALYs/100,000 people in Europe (range 1–4 DALYs). The incidence used in the WHO estimate, 0.2 cases per 100,000 persons, is approximately six times lower than that in the Finnish registry data, as 46–66 cases were reported per year in 2014–2016 (see Figure 2).

According to WHO, one case corresponds to a burden of 10 DALYs. If the WHO estimate is used as is and is scaled to correspond to the number of cases in the Finnish registers, the burden of *Listeria* disease in Finland will be 650, 460 and 660 DALYs in 2014, 2015 and 2016, respectively.

Estimated distributions for various sequelae and the age distribution of the dead used by WHO differ somewhat from those of Finland, but the mortality distribution of 21% corresponds to *Listeria* mortality reported in Finland. The BoD essentially consists of years of life lost due to deaths. Calculated using the RUORI model, *Listeria* caused 670 (400–950) DALYs/year.

3.1.4 Costs related to surveillance and morbidity

Of the annual regulatory control working time, 1%–10% was spent on *Listeria*. Only one of the responding authorities reported that during the 2014–2016 official control they found food samples that were not allowed (i.e. exceeded the maximum level). Control authorities called for control actions at companies mostly because of *Listeria*.

The appendices of the Finnish Food Authority's guideline document "Elintarvikkeiden mikrobiologiset vaatimukset toimijoille ohje 10501/2" (Evira 2017c) describe the sampling frequencies for own-checks in different food establishments. Sampling frequency (0–24 times a year) is influenced by, among other things, the type of food, the ability of *Listeria* to grow in the product and the amount of annual production. The control authority may lighten the sampling requirement based on good results (Evira, 2017c). Cost estimates were based on average sample sizes for different types of plants.

The cost of a visit to a health centre is €96. Of those with listeriosis, 76% had blood poisoning for which treatment costs are €6,207/case based on data collected by THL, and 14% were treated for meningitis for €7,081/case. As a result, the annual cost of detecting and treating listeriosis was approximately €342,000.

Listeria has to be monitored according to EU Commission Regulation No. 2073/2005. As such, costs result from monitoring by companies and authorities. Additionally, health care and productivity losses cause expenses.

Table 1. Costs associated with *Listeria*

Listeria current situation, costs (thousand €)				
	Labour	Sampling	Control	Total
Finnish Food Authority and Customs				-
Municipal Control Authorities	457	9	15	481
Companies	Not included	5,060	Not included	5,060
Health Care Costs				342
Productivity Loss				30
Total	457	5,068	15	5,913

Listeria is one of the most commonly controlled factors, as 100% of the responding municipalities control it. The monitoring expenses vary greatly, ranging between €60 and €34,500 annually. This leads to an estimation of €491,000 in monitoring costs incurred annually by municipalities. The major part of their expenses are made up of labour costs. The same applies for companies (approximately 70%). In this project, the focus is on the company analysis costs, as the envisioned scenario concentrates on

the number of analysis incidences engineered. The estimation is that almost 43,500 sample analyses need to be conducted in Finland annually. According to the Finnish Food Authority, the analysis per sample costs €116.32. Taking this price as an estimation of average sample analysis costs in the industry, the total cost for companies is €5.1 million.

Regarding health care costs, it was taken into account that on average 59 listeriosis cases occurred annually in the reference period 2014–2016 (THL 2015, 2016c, 2017b). It is assumed that at least one health care visit per case took place, which costs €96. In addition, it is known that 76% of the infected patients developed sepsis. On average, sepsis costs €6,207 and usually requires 10.3 treatment days. Another 14% of the infected patients developed meningitis, which typically requires 10.1 treatment days and has a total cost of €7,801 (Nakari ym. 2014, THL 2014b). Added together, listeriosis treatment costs are €342,000 annually. Estimating the productivity loss requires knowledge about the age structure of the infected patients. According to THL (THL Report 11/2017, p. 21), the median patient age was 74, and 67.2% of the patients were over 64 (THL 2017c). Correspondingly, only about 32.8% or 19 people were of working age. Assuming that the sepsis and meningitis incidence percentage is the same in this age group implies a total of 179 sick days. At a productivity loss of €168/day, this corresponds to €30,000 (THL 2014b). The total health effect costs add up to €372,000 annually (Table 1).

Taken altogether, the occurrence of *Listeria* and its prevention costs at least €5.9 million annually. This estimation excludes company labour costs, company sampling costs and company control costs and is therefore a clear underestimation of the true total costs.

3.1.5 Scenario

As a scenario to reduce the BoD due to *Listeria*, all establishments in the meat and fish sector, cheese dairies and premises producing or importing vegetable and fruit products take samples from the production environment in addition to samples taken as prescribed by the Microbial Criteria Regulation. As many samples are taken yearly from the production environment as the products are presently sampled, and five samples or more are sampled at a time, according to the Microbial Criteria Regulation. All positive batches will be rejected.

The scenario was chosen for the following reasons. The BoD arises from *Listeria* deaths, which could be prevented by controlling infections. The purpose of this sce-

nario is to reduce the number of products contaminated with *Listeria* and thus to reduce the incidence of listeriosis. In the scenario, a decrease in the BoD caused by *Listeria* is the ideal case; however, sampling, cleaning and renovation costs increase.

To determine the cost-effectiveness of the current state and the scenario, a calculation was developed that included meat production facilities, fish establishments, cheese dairies and premises producing raw, cut, grated or otherwise processed vegetable and fruit products. As in the present situation, plant size and production quality will determine the sampling frequency of the products and will also affect the sampling frequency of the production environment.

In the calculation, the current sample numbers for *Listeria* were assumed to be the same as the average sample numbers for products and production environments in the Finnish Food Authority's guideline. The cost of sampling was calculated according to the price of the Finnish Food Authority's *Listeria* assay. This does not take into account other costs of sampling, such as staff costs and analysis equipment costs, but the assumption is that food business operators may conduct a *Listeria* survey for a lower price than that of a single sample analysed at the Finnish Food Authority. The price was not calculated for the rejection of *Listeria*-positive batches because it is not known how large the batches are and what value they have. All *Listeria* strains found in the food chain should be submitted to the Finnish Food Authority; in 2011–2018, an average of 479 strains were delivered annually. The cost of additional sampling due to a positive *Listeria* finding was not included in the scenario.

3.1.6 Cost-effectiveness and impact of the scenario on burden of disease

If the risk mitigation measures in the scenario would eradicate listeriosis in Finland, the BoD would decrease by 670 DALYs/year (range 400–950). Health benefits would be significant, based on an optimistic estimate that the measures would be sufficient for eradication. The probability of this was not assessed, but only the assumed interventions, effects and their costs were used. As the analytic sampling can only target a limited random sample of all products and production batches, even the best random testing can find contamination with a probability that is the product of true prevalence and sampling percentage, assuming random contamination in the production. For example, in cold-smoked fish products, the prevalence has been estimated to be roughly 20%. When the sampling percentage is X%, the residual prevalence would be $20\% \times (100\% - X\%)$. However, possible uneven clustering of contamination and sampling can affect this in ways that are not possible to assess using current information. In the scenario, the theoretical maximum for disease burden reduction was calculated. The realistic estimate strongly depends on the size of the batches of food and how

many batches are being studied, and this information was not available to the project. Instead of a 100% reduction, the actual reduction may be only a fraction of that. Further investigation is needed in this area.

Therefore, it is not possible to estimate by how much the DALYs would really decrease, but the assumption was that there would be a maximum effect, that is, the DALYs become zero.

Table 2. Costs associated with the Listeria scenario

Listeria scenario, costs (thousand €)				
	Labour	Sampling	Control	Total
Finnish Food Authority and Customs				-
Municipal Control Authorities	457	9	15	481
Companies	Not included	6,460	Not included	6,460
Health Care Costs				-
Productivity Loss				-
Total	457	6,469	15	6,941

Companies have to conduct 12,000 additional analyses, with each analysis costing €116.32 (Finnish Food Authority 2019g). The extra costs of the scenario are thus at least €1.4 million annually. Again, it is crucial to remember that these extra costs refer exclusively to the analysis costs. It was already pointed out that not enough information about the cost distribution in companies is available to estimate all cost implications, as other cost aspects might increase as well. The health impact costs are easily described, as they follow the assumption that the additional controls manage to reduce the DALYs level to zero. Zero DALYs implies no health care costs or productivity losses (Table 2).

In summary, the additional costs of the Listeria scenario are about €1 million, with the expectation that the DALYs level decreases to zero. The changes resulting from the scenario are presented in Table 3.

Table 3. Summary of Listeria current status and scenario

Listeria			
	Current situation	Scenario	Change
DALYs	670	0	-670
Costs (thousand €)	5,913	6,941	1,028
	ACER	1,534	€/DALY

3.2 Norovirus

3.2.1 Health effects

Norovirus has been the most commonly reported cause of food poisoning in Finland since 1997 (Hallanvuo & Johansson 2010). Humans are the only known hosts for norovirus, although other animals are known to have similar viruses. Therefore, norovirus infection always requires a person as a source, either direct or indirect. Norovirus is transmitted feco-orally and causes clusters of disease (Terveyskirjasto 2017). A very small amount, even less than 10–100 viral particles, is enough to cause illness. By way of illustration, there are billions of viral particles/g of diarrhea (Patel et al. 2009; Terveyskirjasto 2017). Illness can also be contracted through contact with the aerosols produced during vomiting (Patel et al. 2009).

Norovirus can be contracted throughout the year (Patel et al. 2009), but in Finland most cases are reported from November to March (Terveyskirjasto 2017). Symptoms typically begin 6–48 hours after exposure. Symptoms include the sudden onset of malaise, vomiting (50%–90% of patients), diarrhea (50%–90% of patients), abdominal pain (40%–70% of patients), fever (37%–45% of patients) and muscle pain (Patel et al. 2009; Simonsson et al. 2014). Symptoms typically last 2–4 days, but in immunocompromised people the symptoms may last significantly longer. Mortality is low, particularly in developed countries (Simonsson et al. 2014). Norovirus infections are clearly underreported, as the disease usually disappears on its own and patient samples are seldom taken (Harris et al. 2017; Terveyskirjasto 2017).

3.2.2 Prevalence in food and current status in Finland

Norovirus is easily transmitted from an infected person through food (Hallanvuo & Johansson 2010). In 2014–2016, 62% of the foodborne outbreaks were either caused or suspected to be caused by norovirus transmitted from an infected worker to food (Pihlajasaari et al. 2019). Norovirus has been associated with uncooked vegetables, such as frozen berries imported from abroad, mussels and oysters (Hallanvuo & Johansson 2010; Health Library 2017). When frozen, norovirus remains infectious for up to years. However, it is destroyed by heating food to temperatures above 90 °C for at least two minutes (Finnish Food Authority 2019)

Norovirus is one of the other reported microbial findings in the Infectious Disease Regulation; therefore, clinical laboratories are required to report any finding. In 2016, 41 (46%) of the 89 suspected foodborne outbreaks reported in the THL and Evira Common Register Information System (RYMY) were considered to be norovirus (THL

2017). Norovirus is also the most common cause of waterborne outbreaks in Finland (Zacheus & Miettinen 2011). In 2014–2016, 5,922 cases of norovirus were reported to the Registry of Infectious Diseases, with the median age being 75 (range 0–108) (Figure 3). This reflects the proportion of the population sampled rather than the occurrence of the disease. Indeed, short-term vomiting and diarrhea in healthy individuals are treated symptomatically, regardless of the underlying pathogen. In addition, according to a study by Tam et al. (2012), about 94% of Britons with norovirus infection do not seek treatment. Of the cases listed in the communicable disease register, 57% were women (THL 2015; THL 2017). Figure 4 shows the food sources of norovirus infection in 2014–2016.

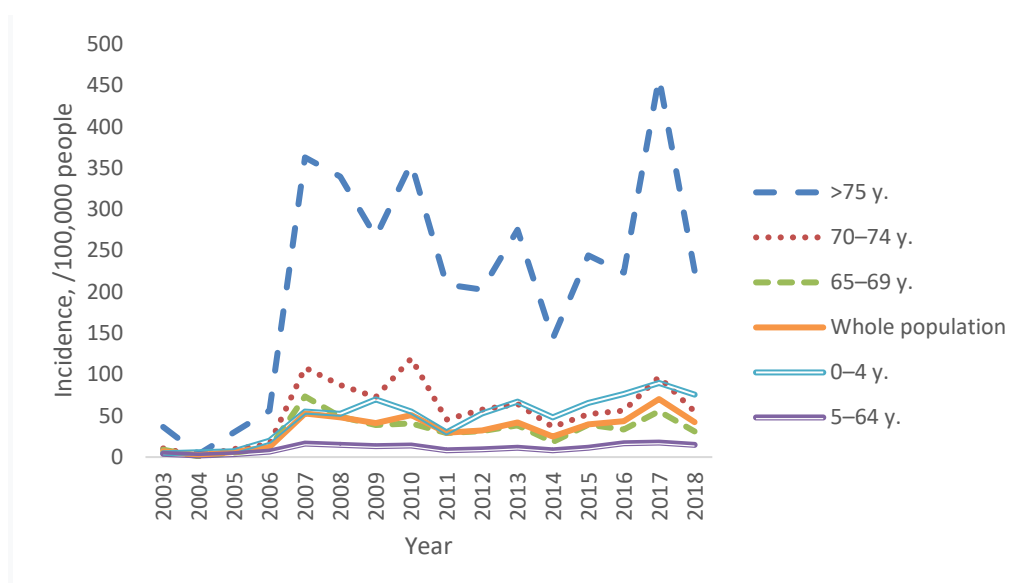


Figure 3. Finnish cases of norovirus per 100,000 people annually and by age group. Source: THL Register of Infectious Diseases.

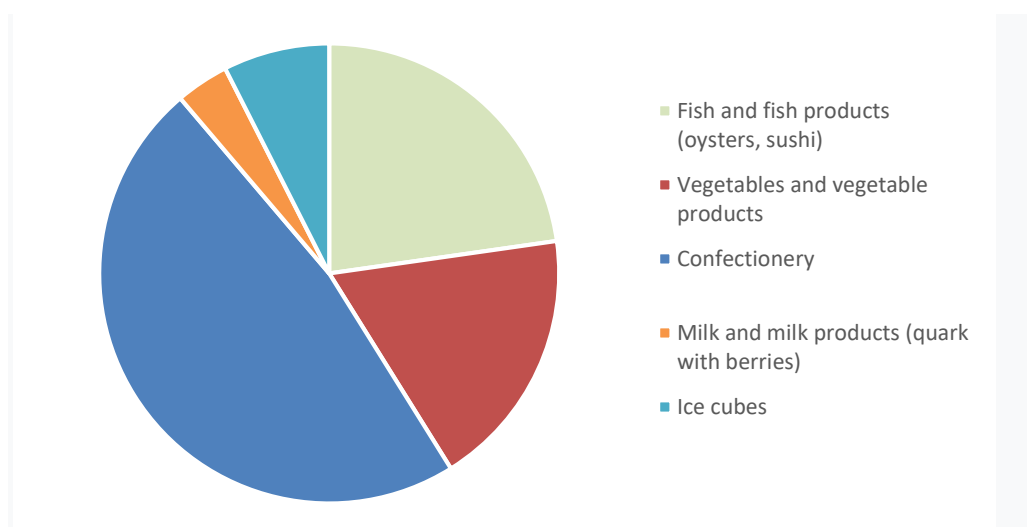


Figure 4. Identified food sources of norovirus infections in 2014–2016. Only about a quarter of the cases caused by food could be connected with a specific product.

3.2.3 Current burden of disease caused by norovirus

WHO estimates that foodborne norovirus caused a BoD in Europe of 4 DALYs/100,000 in 2010 (95% confidence interval 1–8 DALYs/100,000) (WHO 2015). In Finland, this would correspond to a BoD of about 220 DALYs (55–440 DALYs). However, WHO calculations for Finland use the median of the overall case estimate for Europe, which was 1,652/100,000. This is a multi-fold estimate compared to the cases reported in the Register of Communicable Diseases (1,363; 2,164; and 2,395 cases in 2014–2016). However, there is no reliable quantitative information on underreporting in the communicable disease register; therefore, WHO figures have been used in the assessment.

It is not known how many of the cases reported in the communicable disease register originate from food. Evira and THL report on foodborne outbreaks in 2011–2013 (Pihlajasaari et al. 2016) found that 51% were related to eating in restaurants. The most commonly identified cause was norovirus, which was responsible for 20 outbreaks (30% of restaurant-related outbreaks). Of the 131 foodborne outbreaks detected during the reporting period, 48% of the 2,796 people affected were infected with norovirus. An infected food worker was responsible for 64% of the reported foodborne norovirus epidemics involving more than 900 people.

When using the actual case numbers according to the Finnish Register of Infectious Diseases, the above formula and the WHO disease duration (2 days on average, 1–4 days confidence interval) and the disability weight factor (severe 0.281 [0.184–0.399], mean 0.202 [0.132] and mild 0.061 [0.036–0.093]) can be calculated for 2014–2016.

According to WHO estimates, 0.5% of cases are severe, 8.5% are moderate and the remaining 91% are mild. It should be noted that in this calculation, no person is assumed to have died of norovirus. Based on this baseline, the burden of norovirus disease was estimated at 200 (73–430) DALYs/year.

3.2.4 Costs related to surveillance and morbidity

Norovirus is currently monitored only in connection with outbreak investigations. According to a survey, municipal authorities spent between 2% and 10% of their annual working time monitoring norovirus.

The Finnish Food Authority recommends that food workers infected with norovirus take a sufficiently long sick leave, that is, 1–2 symptomless days after the visible symptoms. As the virus is still secreted after this, the worker must be particularly careful with hygienic practices or, where possible, should temporarily switch to tasks that do not involve contact with food.

An average of 1,973 cases of norovirus per year were recorded in the communicable disease register in 2014–2016. The cost of a visit to a health care centre to receive primary care is €72 for norovirus infection. Of those with norovirus infection, 94% do not seek treatment (Tam et al. 2012) and therefore do not end up in the registry. Of the norovirus cases in 2014–2016, 2% applied for emergency care and 0.3%–13% were admitted to hospital. The cost for inpatient care is €213/case.

In the case of norovirus, the costs consist solely of the cost of monitoring the municipalities and the cost of health care. Because companies do not appear to control for norovirus, the overall cost in this case remains relatively low.

Table 4. Norovirus-related costs

Norovirus current status, costs (thousand €)				
	Labour	Sampling	Inspection	Total
Food Authority and Customs				-
Municipalities	474	13	5	491
Companies				-
Health care costs				204
Loss of productivity				6,696
Total costs	474	13	5	7,391

There are no statutory obligations to control norovirus. The municipalities' annual monitoring costs are €490,000. It is unclear whether these costs are the costs of ongoing monitoring or of epidemics. About 95% of the total costs are labour costs (Table 4).

Estimating health care costs is difficult, as only about 6% of cases are reported (Tam et al. 2012). Most cases are resolved through home care. THL registered 1,973 cases in Finland in 2014–2016. This means there are an estimated 32,900 cases of norovirus in Finland each year. Health care costs were assessed separately for reported and unreported cases. The number of registered cases, 1,973, means at least one visit to a doctor (THL 2015, 2016c, 2017b). THL estimates this to cost €72. The cost of hospitalization is €234/day, and it was estimated that 6.65% of patients will be hospitalized (THL 2014b). Due to the short duration of the norovirus (12–72 h) (THL 2016b), one visit to the doctor and a 2-day hospital stay were used in the calculations. Other costs have not been taken into account, as there is no actual treatment for norovirus (RKI 2019). Total health care costs are €204,000 annually. There are no health care costs for unregistered cases, but both registered and unregistered cases result in loss of productivity. Food workers are advised to stay home for 2 days after symptoms disappear (THL 2016b). Thus, it was estimated that an average infection would result in a loss of 2.5 working days at €168 (THL 2014b). In addition, 47% of infections occur in people over 75 who are no longer active in the labour market. Therefore, it is estimated that 15,455 people of working age contract norovirus every year. Note that this figure also includes children who were supposed to have parents staying home to care for them. The loss in productivity is thus €6.7 million/year (Table 4). The total cost of norovirus is €7.4 million/year, most of which is lost productivity.

3.2.5 Scenario

As a scenario to reduce the BoD caused by norovirus, surface samples were taken monthly from November to March from food lines, catering kitchens and other food establishments producing RTE food. Five samples per month would be taken from the kitchens and staff rooms of commercial kitchens, and five samples twice per month would be taken from food production lines and staff rooms of other food premises.

The scenario was chosen for the following reasons. Sampling and cleaning following positive results would reduce the number of norovirus outbreaks because norovirus is a problem, particularly when it ends up in RTE products. Based on surface purity samples, cleaning can be enhanced at the right time. The scenario assumed that 35% of norovirus infections are due to a foodborne outbreak caused by a food worker, so its theoretical maximum efficacy would be this. The actual impact would probably be weaker.

Currently, surface cleanliness samples are only taken in the context of outbreak investigations, which increases the cost of sampling in the scenario. Samples were priced at the University of Helsinki analysis price of €300 for five samples.

3.2.6 Cost-effectiveness and impact of the scenario on burden of disease

The effect of the norovirus scenario was estimated to reduce BoD by 23 DALYs/year (95% CI 0.7–80 DALYs/year). The effect is only a tenth of the total burden of the disease, as only some of the disease cases are transmitted through food. The measures are expected to prevent half of the foodborne outbreaks.

Norovirus outbreaks occur most frequently in November through March, and the source is often food. In the proposed scenario, surface samples will be taken from the cooking areas and premises of personnel. The measures would be implemented in restaurants, canteens and companies producing RTE food. The scenario assumes that the result would be a 35% reduction in norovirus cases.

Table 5. Norovirus scenario-related costs

Norovirus scenario, costs (thousand €)				
	Labour	Sampling	Inspection	Total
Food Authority and Customs				-
Municipalities	308	8	3	319
Companies				23,934
Health care costs				134
Loss of productivity				4,353
Total costs	308	8	3	28,740

The companies pay all the control costs, and these costs form the bulk of the costs of the scenario. For the purpose of calculating the total cost, the number of sites, the number of samples and the cost of one sampling were estimated. The cost of one sample was €74.40, based on University of Helsinki data (University of Helsinki 2019). The number of samples was calculated as follows. In the RTE food sector, 15 samples will be taken twice a month for five months (November–March). The companies have an average of two production lines, so the total number of samples will be 150/item. According to the Food Authority, there are 478 sites in the industry, so a total of 72,000 samples will be taken. In restaurants and canteens, 25 samples will be taken during the control period, five samples/company/month. In 2014–2016, the number of these sites was 10,000, so a total of 250,000 samples will be taken in canteens and restaurants (MARA 2018). The cost increase is obtained by multiplying the number of samples by its unit cost, resulting in an additional cost of €24 million. For an individual company, the additional cost is between €860 and €11,160. It should be noted that cost reduction is not affected by disease reduction (Table 5).

Here, it was assumed that both municipal control and health care would result in savings of 35% for norovirus cases. For municipalities, the savings would be €172,000 and €2.4 million in productivity gains in health care.

The total additional cost of the scenario is €21 million, assuming a 35% reduction in morbidity. If the impact of the measures was less significant, the cost estimate would also increase. If illness is not reduced at all, the extra cost would be almost €24 million. A summary of the change from the current status to the scenario is presented in Table 6.

Table 6. Summary of norovirus current status and scenario

Norovirus			
	Current status	Scenario	Difference
DALYs	220	197	-23
Costs (thousand €)	7,391	28,740	21,349
	ACER	928,209	€/DALY

3.3 Toxoplasma

3.3.1 Health effects

Toxoplasma gondii is a protozoan that causes an infection in humans called toxoplasmosis (Terveyskirjasto 2018). *T. gondii* lives in feline intestinal mucosa cells. A cat is typically infected by eating a small rodent or bird that has parasites in its tissues or is directly infected from the feces of another cat. As a result of the sexual reproduction of toxoplasma in the gut, up to 10 million oocysts/day are excreted in the cat's feces for approximately several weeks. Oocysts, which are environmentally resistant, become infectious under favourable conditions in less than 5 days and can remain in the soil for more than a year, polluting waterways and infecting animals. The infectious dose of *T. gondii* is approximately 10–100 oocysts (Hallanvuori & Johansson 2010).

In humans, toxoplasma infection is usually asymptomatic or causes a mild fever. This may be accompanied by night sweats, fatigue and muscle aches. Symptoms start about 2 weeks (10–21 days) after infection. Fever-free lymph node enlargement is the most common symptom (Terveyskirjasto 2018). In immunocompromised people, toxoplasmosis can cause inflammation of the brain, inflammation of the retina, pneumonia and other kinds of organ damage (Hallanvuori & Johansson 2010). A mother's recent infection with toxoplasma during pregnancy poses a serious risk to the fetus and child.

Particularly in early pregnancy, infection may result in miscarriage or serious permanent injury to the child, such as vision, hearing and brain damage or feverish infections. In most cases, congenital toxoplasmosis manifests as inflammation of the retina in newborns. Other disorders include epilepsy, problems with physical activity and intellectual disabilities.

Diagnosing congenital toxoplasma infection is difficult, and only about 10% of cases are diagnosed if the disease is investigated after birth (Lappalainen & Koskiniemi 1988, Koskiniemi et al. 1989). However, it is a treatable disease (McCabe & Remington 1983; Couvreur et al. 1988; Daffos et al. 1988; Remington & Desmonts 1990). Nine out of 10 congenitally infected children go undiagnosed and untreated, and the disease may progress for years, causing visual, hearing and brain damage (Alford et al. 1974; Wilson et al. 1980; Koppe et al. 1986). However, pre-pregnancy infection is not harmful to the fetus and does not increase the risk of miscarriage. Toxoplasma remains permanently in human cells after infection, typically in the retina (Health Library 2018). Detecting infection during pregnancy and initiating treatment reduce the incidence of congenital toxoplasmosis by about half and alleviate the symptoms of the disease (Koskiniemi 1993).

3.3.2 Prevalence in food and current status in Finland

In addition to the above-mentioned rodent–cat–cat feces pathway, toxoplasma occurs in the form of vesicles in the tissues of several mammals, such as sheep, cattle and pigs. Most people are infected by consuming insufficiently cooked meat, cat feces or food contaminated with cat feces (Terveyskirjasto 2018). The majority of toxoplasma infections are believed to be explained by consuming insufficiently cooked meat (Cook et al. 2000).

The Infectious Diseases Regulation classifies *T. gondii* as a notifiable microbial finding; therefore, clinical laboratories are required to report the finding. In 2014–2016, 98 cases of toxoplasmosis were recorded in the Registry of Infectious Diseases, most of which were identified by finding antibodies. The median age of patients was 39 (range 0–90). The WHO (2015) estimates the incidence of toxoplasmosis in Europe to be 119 (77–188)/100,000 person years. For adults, a higher rate was used because underreporting causes an unknown, risk-diminishing bias in the communicable disease registry. According to a study based on the appearance of antibodies during pregnancy, it is estimated that approximately 130 women each year experience fresh toxoplasma infection. When only about 1 in 10 infections of a mother pass through the placenta to the child, congenital diseases are likely to occur only 10–15 times every year (Lumio 2018).

3.3.3 Current burden of disease caused by toxoplasma

Registry data for infections caused by toxoplasma have been found to be so unreliable that they do not allow for a national calculation of WHO BoD. In fact, it is not known from the Finnish register of infectious diseases what percentage of the infections were acquired from food and other sources, such as cat feces.

The WHO report (WHO 2015 Table A8.2) presents the dietary incidence of *T. gondii* and the BoD/100,000 people. When these values are proportional to the Finnish population (5.49 million people, Statistics Finland 2016) values for morbidity and BoD are obtained.

Table 7. Foodborne cases of toxoplasmosis in Finland, calculated according to the incidence in the European territory. The burden of disease estimates are from the RUORI model. Congenital refers to the infection of the mother during the pregnancy, while acquired refers to infection acquired later through foodborne illness.

	Congenital		Acquired	
	Median	95 % confidence interval	Median	95 % confidence interval
Morbidity	16.5	10.8–37.8	6,530	4,335–10,316
Deaths	0.27	0.108–0.54	0	0–0
Burden of disease (DALY)	110	47–250	320	150–590

The case count values of these calculations are several hundred times higher than those of the Infectious Disease Registry (23, 40 and 35 cases in 2014–2016). It is likely that the actual morbidity and burden of foodborne toxoplasma in Finland is between that listed in the Infectious Diseases Registry and the WHO European estimate.

3.3.4 Costs related to surveillance and morbidity

Currently, toxoplasma is not monitored in food. For uncooked meat, freezing long enough at a sufficiently cold temperature is an effective means of destroying parasites. Adequate heating also kills the parasites. At-risk groups, particularly pregnant women, should be advised on how to avoid toxoplasma (Hallanvuo & Johansson 2010). In 2014–2016, 98 cases of toxoplasmosis were recorded in the communicable disease register. The annual cost of monitoring for toxoplasma is €12 million.

Table 8. Toxoplasma-related costs

Toxoplasma current status, costs (thousand €)				
	Labour	Sampling	Inspection	Total
Food Authority and Customs	-	-	-	-
Municipalities	51	-	0.2	51
Companies	30	15	11,869	11,913
Health care costs				
Loss of productivity				
Total costs	81	15	11,869	11,964

Monitoring toxoplasma is not very common; only 13% of municipalities and 9% of companies monitor it. In addition, it appears to be relatively cheap for municipalities and companies alike in comparison to other hazardous substances. Due to the limited cost data related to toxoplasma, it is difficult to make reliable estimates of the total cost. The cost for municipalities is €51,000 annually, 100% of which are labour costs. The cost for businesses is €12 million, with almost 100% being control costs (Table 8).

Health care costs come from two sources. First, the toxoplasmosis acquired after birth can be from food, soil or cat feces. WHO estimates that 95% of toxoplasma infections are overlooked (WHO 2016). In the remaining 5%, symptoms range from mild fever to effects on viscera (RKI 2018). However, these costs and effects are difficult to determine. Therefore, the focus is on congenital toxoplasmosis.

Congenital toxoplasmosis is acquired during pregnancy, with an average of 17 cases each year. Health effects vary depending on the stage of pregnancy when the mother acquires toxoplasmosis. During the first trimester, it can lead to miscarriage or need to have an abortion, the cost of which is not estimated here. Toxoplasmosis acquired at a later stage usually causes ocular and retinal inflammation, which can result in blindness and brain dysfunction (RKI 2018). Newborns have to be treated with two different antimicrobials for one year (American Academy of Ophthalmology 2019). Here, it was assumed that newborns are monitored monthly at a cost of €19,600, while the unit cost of a health centre visit is €96 (THL 2014b). The cost of the drug is approximately €598/patient. The total cost of health care is therefore €29,800 (Table 6). It is also assumed that one of the parents is on parental leave so that there is no loss of productivity. Of course, symptoms may also occur at a later age, but their cost cannot be estimated here.

3.3.5 Scenario

The reduction of the burden of toxoplasma-related disease was studied in a scenario where all pregnant women are tested for toxoplasma via an antibody test. The scenario assumes that all congenital disease cases will be detected and treated. In addition, all pregnant mothers are given guidance on how to avoid becoming infected.

The scenario was chosen for the following reasons. According to the WHO BoD assessment, toxoplasmosis is the third most important foodborne pathogen in Europe and can cause severe fetal damage. The detection of primary toxoplasma infection during pregnancy and the initiation of specific therapy reduces the incidence of congenital toxoplasmosis by approximately half and alleviates the symptoms of the disease (Koskiniemi 1993). However, most cases of toxoplasmosis are not congenitally acquired; rather transmission occurs through direct food exposure.

Currently, there are no food risk management guidelines in Finland relating to toxoplasma and no monitoring for toxoplasma antibodies during pregnancy. Therefore, the scenario would increase the cost of sampling, even if the cost of morbidity is reduced. The cost of one antibody assay is €30–€40, and the average birth rate was 55,000 children/year in 2014–2016.

3.3.6 Cost-effectiveness and impact of the scenario on burden of disease

The toxoplasma scenario was estimated to reduce the BoD for Finns by 120 DALYs/year (95% confidence interval, 47–250 DALYs/year). Congenital toxoplasmosis causes serious illness in a few people, so the scenario would be very effective for them if implemented as planned. However, the scenario does not help to reduce the amount of toxoplasmosis acquired.

According to the scenario, all pregnant women are tested for toxoplasmosis. It is assumed that congenital diseases will no longer be present.

Table 9. Toxoplasma scenario-related costs

Toxoplasma scenario, costs (thousand €)				
	Labour	Sampling	Inspection	Total
Food Authority and Customs				
Municipalities	51	-	0.2	51
Companies	30	15	11,869	11,913
Health care costs				2,226
Loss of productivity				
Total costs	81	15	11,869	14,191

The toxoplasmosis test is performed during weeks 8–10 of pregnancy at the first visit to a prenatal clinic (RKI 2018). To estimate the number of pregnancies, the number of deliveries is first calculated, and the number of miscarriages must be known. About 15% of pregnancies end in miscarriage, most in the first trimester of pregnancy (HUS 2019). In the absence of more specific information, it is assumed that all pregnant women who will subsequently have a miscarriage are also being tested. The number of births is 55,173, plus the number of stillbirths (163) and the number of miscarriages (8,276) (Statistics Finland 2016b, 2017, 2019). Thus, a total of 63,612 toxoplasmosis tests are required. The cost of one test is €35. Therefore, the annual cost of toxoplasma testing would be €2.2 million (Table 9). The number of children has decreased in recent years, so it is expected that this cost will decrease over time.

The test result may be one of the following: immunity, no immunity or infection. In the case of immunity, no further action is needed (about 20%) (Finnish Food Authority 2019h). Those who are not immune to toxoplasma receive guidance on how to avoid infection. Therefore, the assumption is that no additional cost will arise.

In the case of congenital infection, treatment is started before delivery. Further tests will likely be needed, but this cannot be assessed here. Pregnant women receive the same treatment as newborns for four weeks but at higher doses. The treatment is one tablet of pyrimethamine daily (two tablets on the first day of treatment) and six tablets of erythromycin daily. The cost of the medication is €192/patient, and the total cost is €3,263/year. We assume that one additional visit is required during week 13 of pregnancy. We also assume that this will not result in loss of productivity. The total cost is thus €5,000, which is probably an underestimate because it does not take additional tests into account.

The additional cost in the scenario is €2.2 million, which will result in the disappearance of congenital toxoplasmosis.

A summary of the change from the current status to the scenario is presented in Table 10.

Table 10. Summary of toxoplasma current status and scenario

	Current status	Scenario	Difference
DALYs	460	340	-120
Costs (thousand €)	11,994	14,196	2,202
	ACER	18,346.22	€/DALY

3.4 Trichinellae

3.4.1 Health effects

Trichinella parasites (trichina) are small nematodes. Adult parasites are intestinal parasites whose larval forms live and become infectious in the muscles of the same host animal. Trichinella-associated disease is called trichinellosis. Infection can occur after eating meat containing infectious encapsulated trichinella larvae. The larvae capsules dissolve in the stomach and the released larvae develop into adult trichinae. Adult forms mate in the small intestine, and then females produce larvae that pass through the intestinal wall. The larvae migrate to the striated muscles and encapsulate there. The new host animal gets infected after eating meat containing *Trichinella* larvae (Hidron et al. 2010). There are several species of trichinella (Foreyt 2013). Four of them are found in Finland, all of which can cause trichinellosis in humans. The most prominent species is *T. spiralis*, whose most important host animals are pigs. The most common species in Finnish wildlife is *T. nativa*, which is adapted to arctic conditions and is highly resistant to freezing (Hallanvuori & Johansson 2010).

In most cases, the symptoms trichinellosis in humans are mild to moderate; in severe cases (5%–10%), the symptoms and complications are prolonged and severe. In severe cases, the symptoms (muscle pain, eye symptoms, neuropathies) can last up to 10 years after the underlying disease has healed. The different stages of the parasite's life cycle cause different symptoms. In the first stage, the parasites released in the small intestine cause diarrhoea and abdominal pain, which can last 1–7 days. Gastrointestinal symptoms appear 5–15 days after infection. In the following week (Phase 2), larval invasion may cause fever, puffiness of the eyes and face, conjunctival haemorrhage, headache, cough, shortness of breath, difficulty swallowing and sometimes a spotty skin rash. Migration of the larvae in the muscles causes severe pain, swelling, weakness and sometimes paralysis. In severe cases, there may be encephalitis, cardiac dysfunction, miscarriage, central nervous system symptoms and death. In the third stage, larval encapsulation begins, with symptoms such as desiccation, swelling, extreme dehydration and cardiovascular complications and in severe cases pleural, gastric and intestinal bleeding. In life-threatening cases, the patient

dies during the weeks 4–8 (Clausen et al. 1996). Muscle rigidity symptoms typical of stage three can persist for years after infection. Symptoms due to the migration of larvae may recur after many years (Harms et al. 1993).

3.4.2 Prevalence in food and current status in Finland

Humans typically become infected after consuming raw or inadequately cooked pig meat, wild boar meat, bear meat or meat products made with the blood of those animals that contain trichinellae (Food Agency, 2019f). Pigs can be infected, for example, by eating contaminated rat or food waste (Hallanvuori & Johansson 2010). In Finland, trichinae have been found in wolverines, hawks, polecats, seals, lynx, bears, hoofed animals (e.g. horses), foxes, dogs, cats, eagles, minks, badgers, pine martens, owls, otters, pigs, raccoon dogs, wolves and wild boars (Anon. 2015–2017). Of the animals examined in 2010–2016, trichinella was found mainly in wild boars, seals and bears and once in a pig carcass.

Found in pigs, *T. spiralis* has been classified as another reportable microbial finding in the Government Decree on Communicable Diseases. Therefore, clinical laboratories are required to report any finding. In 2014–2016, trichinellosis was not reported in humans in Finland. The last reported infection was from bear meat in the 1970s (Finnish Food Authority 2019f). Trichinellosis is more common in men than in women (Devleesschauwer, 2015). This is probably related to hunting and eating wild game (Murrell and Pozio, 2000). Those infected are usually adults (Devleesschauwer, 2015). In other Western countries, trichinellosis is increasingly associated with travelling (Foreyt, 2013). Pork consumption is high in Finland, but meat from other animal species that may contain trichinella is not eaten regularly (Helldán et al. 2013).

3.4.3 Current burden of disease caused by Trichinella

The last case of trichinella in Finland was in the 1970s. Therefore, the burden of trichinella was zero in 2014–2016.

3.4.4 Costs related to surveillance and morbidity

Trichinella testing during meat inspection is regulated by the so-called trichinella regulation (EC) 2075/2005. Regulation (EC) 2015/1375 of the European Commission lays down rules for the sampling of carcasses susceptible to Trichinella. Meat in which Trichinella has been detected is not consumed but is rejected, although it is possible

to freeze the meat under certain conditions, according to the time-temperature guidelines given. *Trichinella* testing of pigs in the context of meat inspection may be decreased or eliminated if the pigs have been raised under officially approved controlled housing conditions. To date, there are only a few such pig farms in Finland, but there were none in the 2014–2016 survey period. However, the countries to which pork is exported from Finland require that the carcasses from which the meat originates be tested and found free of *Trichinella*.

In Finland, all four species of *Trichinella* were detected in animals examined during meat inspections in 2010–2016. *Trichinella* was found in one pig carcass of the more than 15 million examined. No trichinae were detected in the 10,000+ horses tested. In contrast, the prevalence of trichinella was 0.3% in wild boar carcasses, nearly 1% in seal carcasses and more than 6% in bear carcasses. In farmed wild boar, trichinae was found almost as frequently as in wild boar (Finnish Food Authority, 2019f). During the same period, *Trichinella* was detected in approximately 30%–40% of the 5,000+ samples taken from wild animals other than those mentioned above. In predatory birds (hawks, owls, eagles), *Trichinella* was only found in about 3% of the samples (Evira 2012; 2012b; 2013b; 2014b; 2015; 2016; 2017b). Treatment costs for trichinellosis in the years studied were €0, as no cases occurred.

Even though no cases of trichinosis have occurred in Finland since the 1970s, monitoring of the parasite must be carried out according to EU rules. Because the scenario focuses on pig carcasses only, the cost estimations will also. In accordance with EU regulations, the occurrence of *Trichinella* in slaughtered animals has to be monitored. This applies to pigs, horses, wild boars and other game animals meant for consumption. It is unclear what proportion of the monitoring expenses indicated by companies and municipalities relates to pork (Commission Regulation (No. 2015/1375)).

The costs are inferred using the number of pig carcasses tested and the testing price for *Trichinella* per carcass. In the period 2014–2016, on average 2.07 million pigs were slaughtered annually, and every pig carcass had to be tested for *Trichinella* (Luke 2019, 2017). Based on a survey of Finnish pig slaughterhouses, the *Trichinella* test costs are €2/pig, including labour costs for sampling and laboratory personnel. This price covers 99% of the pigs slaughtered in Finland. The average price for the remaining 1% is €17.67/pig. For other food-producing animal species tested for *Trichinella*, the average cost is also €17.67/carcass. Additional costs would occur if *Trichinella* is detected. However, the *Trichinella* incidence in pigs is very low. During the period 2010–2016, only one pig was found to be infected with *Trichinella*. Therefore, there are no noteworthy costs due to non-approved carcasses and rejections.

In total, the monitoring costs are estimated at approximately €4.5 million. As no cases of trichinosis have been registered in recent years, no treatment costs or production losses due to infection need to be considered in the cost calculation.

3.4.5 Scenario

The aim in the *Trichinella* scenario was to reduce control costs. In the scenario, *Trichinella* was monitored in all other edible animal species at the present level (in 2014–2016 an average of 2,350 carcasses/year), but the pig carcasses are monitored only in export companies. In the calculations, this was assumed to mean a reduction by half in the analysis of pig carcasses (an average of 2,061,500 pig carcasses/year were examined in 2014–2016).

The selected scenario was chosen for the following reasons. Finland tests slaughtered pigs for *Trichinella* routinely, although it is rarely found in pigs. In 2010–2016, only one carcass of the 15,000,000+ pig carcasses examined tested positive for *Trichinella*. Human infections are also very rare, with the last registered case being in the 1970s. It was therefore assumed that the disease would not increase due to the discontinuation of surveillance and that the cost of surveys would be significantly reduced. As *Trichinella* surveys are considered important in the countries to which Finland exports pork, the continuation of testing in export establishments would probably be profitable, and therefore the scenario does not completely give up on controls.

3.4.6 Cost-effectiveness and impact of the scenario on burden of disease

In line with the scenario, *Trichinella* testing would be reduced so that pigs would only be tested if the meat is meant for export. The health burden of *Trichinella* in Finland is less than 1 DALY/year, so there are no significant health benefits. The effects of the scenario are mainly economic. However, it is possible that the BoD caused by *Trichinella* in Finland will increase. In the absence of testing, it is possible that the parasite is unknowingly transmitted to pigs and thus enters the consumption chain.

The scenario calculations focus exclusively on companies, as it is not expected that the *Trichinella* infection incidence changes under the scenario. Overall, the scenario includes a drastic cost reduction. Based on the Finnish export statistics for the years 2014–2016, roughly 356,400 carcasses were destined for export annually (Luke 2019), which would be the number of tests in the future. This is a significant decrease from the current 2 million annual tests. The expected new cost would be €770,000.

The change from the current state to the state of the scenario is presented in Table 11.

Table 11. Summary of trichinella current status and scenario

Trichinella			
	Current situation	Scenario	Change
DALYs	0	0	0
Costs (thousand €)	4,469	769	-3,700
	ACER	-	€/DALY

4 Physical hazards

Physical hazards are related to, for example, heat, light or concrete objects. The most common physical hazards associated with food safety are foreign objects entering the food. The most common foreign objects found in food are bone chips or rock fragments, but this varies depending on the raw materials and the method of production (Evira 2009). Metal or glass pieces, wooden sticks, jewellery, pens, pins, shots, hair, plasters or even small animals can be found in food. Poorly purified or pre-treated raw materials may also contain foreign objects (ETL 2006).

In principle, foodstuffs should contain no foreign matter. Foreign objects may be removed by an acceptance inspection or a visual or mechanical inspection at the production stage (ETL 2006). In final products, foreign matter findings are rare and almost invariably limited to a single product or batch of products. A few foreign matter defects leading to product recalls are found in Finland every year (Evira 2009).

In addition to possible product recalls, foreign objects can cause cost companies in the form of claims and product spoilage. Controlling foreign objects is important for companies due to the risk of damaging their reputation. At present, risk management is mainly based on own-checks and the actions of the operators. If the own-check requirement level would be reduced, however, companies are likely to continue the same level of control because the requirements for the level of own-check come from customers (consumers and other companies) and not so much from legislation.

Physical hazards do not have a major public health significance in Finland and are not associated with a major BoD. For these reasons, foreign objects were not examined further in this project and no scenario was developed for them.

5 Chemical hazards: Examples, current status and scenarios

This chapter discusses the examples of chemical food hazards explored in the RUORI project. For each hazard, its impact on consumer health, its prevalence in food, information on the exposure (intake) and related morbidity of the population living in Finland, the BoD associated with that hazard and the costs of surveillance and morbidity at present will be described. After presenting the current situation, the scenario studied in the project and its impact on disease burden and costs will be described.

Unlike biological food hazards where the infectious dose does not necessarily depend on the size of the individual, chemical food hazards are often assigned toxicological limits in relation to body weight.

Detailed assumptions and calculation codes used to calculate disease burden estimates can be found on the Opasnet Web Workspace [RUORI page](http://en.opasnet.org/Ruori) at <http://en.opasnet.org/Ruori>.

5.1 Aflatoxins

5.1.1 Health effects

Aflatoxins are toxins produced by moulds of the genus *Aspergillus*. Such moulds typically appear in a product batch as dot-like growths; therefore, the aflatoxin contamination is not evenly distributed in the batch. Aflatoxins have a variety of forms (congeners), of which B1 is the most harmful. At present, the climate in Finland is not very favourable for the growth of aflatoxin-producing moulds, and therefore domestic products contain considerably fewer aflatoxins than, for example, those produced in (sub) tropical countries. An exception to this is aflatoxin M1, which is produced in animals through the use of feed contaminated with aflatoxin B1 and which is excreted in milk. Similarly, in humans, aflatoxin B1 transforms into M1 in the liver and may be excreted in breast milk.

Aflatoxins are carcinogenic, genotoxic, mutagenic, teratogenic and hepatotoxic and are (in mouse tests) immune system suppressants. Aflatoxin B1 is the most mutagenic and carcinogenic chemical known (Herman & Walker) and has been specifically linked to the increased risk of liver cancer at low doses (tens of nanograms/kg body-weight/day). People with hepatitis are particularly sensitive to aflatoxins. In addition to

carcinogenicity, aflatoxins are more commonly toxic to the liver (hepatotoxic) and in mice have been shown to suppress the immune system and thus aggravate brain lesions that develop in toxoplasmosis (World Health Organization 2002).

For aflatoxin B1, a BMDL₀₁ value has been determined for the increased risk of liver cancer in humans—0.078 µg/kg body weight/day. BMDL₀₁ is the lower confidence interval for the dose at which the risk of liver cancer increases by 1% of the risk in the non-exposed population. In humans suffering from hepatitis, the BMDL₀₁ value has been determined to be 0.070 µg/kg bw/day (EFSA 2018). In France, exposure to 12 ng/kg bw/day of aflatoxin is estimated to increase the incidence of liver cancer by 1.5 cases/million people/year (EFSA 2007).

5.1.2 Prevalence in food and current status in Finland

In Finland, about one in five imported batches of foodstuff contain residues of aflatoxins (Evira 2013). Aflatoxins are often found in peanuts and tree nuts, maize, rice (particularly dark basmati rice), corn and soybean meal, other cereals and cereal products, spices, figs, dried fruits, some imported feeds and their ingredients (Evira 2013). Commission Regulation (EC) No. 1881/2006 and its supplementary regulations set maximum levels for aflatoxins in various foodstuffs.

The storage and transport of foodstuffs other than milk may result in a significant increase in aflatoxin levels under conditions favourable to the growth of moulds (i.e. warm and humid conditions). Pasteurization and other heating methods kill moulds and thus prevent growth/unacceptable aflatoxin levels. In addition, milling, extrusion and the like can mechanically lower aflatoxin levels. However, aflatoxins are very persistent in various treatments, such as cooking, roasting, etc., and may therefore still be present in preparations such as roasted nuts or bakery products (Marin et al. 2013).

Finnish aflatoxin exposure due to the consumption of peanut products (EFSA CONTAM Panel 2018) is estimated to be 0.9–1.1 ng/kg bw/day on average for the working-age population, and 95% of the working-age population has an exposure of up to 2.4–3.2 ng/kg bw/day. The estimate is based on the food consumption data of the Findiet 2012 study and the concentration of control samples collected from EU countries. Although the estimate is only for exposure to peanuts and peanut products, the JECFA estimate based on less accurate consumption data (JECFA 2016) places the average exposure to aflatoxin B1 in all foodstuffs in Finland at 0.9 ng/kg bw/day.

5.1.3 Current burden of disease caused by aflatoxins

WHO has estimated the BoD caused by aflatoxins worldwide and regionally (Gibb et al. 2015). In 2010, foodborne aflatoxin exposure was estimated to cause a loss of 636,869 healthy life years, equivalent to 9 DALYs/100,000 person years. For Western European countries, the WHO estimate of healthy life years lost due to aflatoxins was 0.5 DALYs/100,000 person years (95% confidence interval 0.3–0.8).

In Finland, direct use of the WHO estimate would mean an average annual burden of 27 DALYs for 5.4 million Finns. An updated calculation was made using the EFSA (EFSA 2018) estimate of the dietary aflatoxin exposure in Finland. EFSA only estimated aflatoxin exposure from peanut products, but according to the Findiet 2012 data these were consumed more often than most other nuts and in larger amounts than the tree nuts eaten slightly more frequently. An estimate based on peanut products alone thus underestimates the total intake of Finns, but up-to-date information on aflatoxin exposure from all sources is not available. However, the rough intake calculated from the peanut and tree nut aflatoxin content measured in Finland and the food intake indicators of the Findiet 2012 survey are in the same range as the EFSA estimate of the intake of peanuts alone (Suomi, personal communication). Therefore, the underestimation of disease burden is probably not high.

The calculation used an average exposure of 0.85–1.14 ng/kg bw/day (EFSA 2018; values LB and UB) for 25–64-year olds, whose age group comprised 2,835,089 people in 2014, and the average incidence of liver cancer in 2011–2015 (Finnish Cancer Registry) of 115 cases in this age group. For 65–74-year olds, the corresponding data were 0.5–0.67 ng/kg bw/day, with 615,487 people in the age group and 161 cases of liver cancer. The prevalence of chronic hepatitis infection in Finland was assumed to be 0.5%. These data updated the WHO estimate of the BoD due to aflatoxins (Gibb et al. 2015).

The WHO method based on the PAF calculation and the functions described below, which take into account the higher risk of liver cancer for hepatitis B-positive individuals, were used as the disease burden calculation method.

$$PAF_a = \frac{(1 - p) \times HCC_{a-} + p \times HCC_{a+}}{HCC} \quad (9)$$

In the above equation, $HCC_{a-} = b \cdot a$ for hepatitis B-negative individuals and $HCC_{a+} = b \cdot h \cdot a$ for hepatitis B-positive individuals.

In equations, p = the prevalence of hepatitis B infection, HCC = total incidence of liver cancer, a = aflatoxin exposure, b = cancer potential factor of aflatoxin for hepatitis B-negative individuals and h = relative risk of aflatoxin for hepatitis B-positive individuals compared with HPV-negative individuals. The values used by WHO are for 100,000 individuals, $b = 0.01$ (CI 0.002-0.03) and $b * h = 0.30$ (0.005-0.50) (Liu et al. 2010; WHO 2015). In other words, hepatitis B increases the risk of liver cancer by approximately 30-fold.

PAFs (Table 12) were determined from the above calculations, describing the percentage of liver cases caused by aflatoxin exposure.

According to the IHME GBD Database (University of Washington 2019), the total BoD for liver cancer in 2014 was on average 2,499 DALYs (2018–3115) for 25–64-year olds and 2,745 DALYs (2,245–3,311) for 65–74-year olds.

Table 12. Population attributable fractions for liver cancer in Finland

Age group (years)	PAF (lower limit of average exposure)	PAF (upper limit of average exposure)
25–64	0.0024	0.0032
65–74	0.0002	0.0003

Based on the PAFs and the IHME GBD total hepatocellular carcinoma burden, the aflatoxin-induced BoD in 2012 was calculated to be 9.6 DALYs (CI 2.6–28) in the 25–74 age groups.

5.1.4 Costs related to surveillance and morbidity

In Finland, the Finnish Food Authority controls imports of products of animal origin and Customs supervises non-animal products, including third-country imports and to some extent products from the internal market. In terms of the internal market, the control authorities of other EU countries also control foodstuffs; therefore, Finland does not incur any costs for their operation. In many countries, producers also have self-control checks to remove mould fungi that produce aflatoxins or other toxins from the food chain, such as removing damaged or visibly contaminated raw materials at the farm or early stages of the chain.

The Finnish Food Authority compiles annual sector reports on its own control results and reports submitted by other authorities (municipalities, ELY, AVI, Customs, Valvira, the Defense Forces) and reports annually to the European Commission on the achievement of the objectives set forth in the control plan, the controls performed, defects and sanctions (Finnish Food Authority 2019f). The latest control plan report once

again demonstrated that national food chemical monitoring programmes were implemented as planned in 2017 and that the presence of contaminants is low (Finnish Food Authority 2019).

Aflatoxins were examined using official controls in 2014–2016 on over 500 imported foodstuffs (third-country imports or products on the internal market) each year. According to the control plan, 40 samples of feed were to be analysed annually, but the result exceeded the plan (slightly over 50/year). Both imported foodstuffs and feedstuffs are tested for aflatoxin B1 and, in most cases, either total aflatoxins or different aflatoxin congeners separately. In addition, the Finnish Food Authority monitors aflatoxin levels in raw milk from both production facilities and consignments via the national contaminant control programme. In 2014–2016, approximately 410 milk samples were analysed for aflatoxin M1, and residues were detected in four samples. Aflatoxin M1 findings in milk are rare and result in investigations to identify the farms of origin.

According to the survey in this project, 1%–5% of working time/year was spent on aflatoxin monitoring in municipalities. According to the answers, no abnormal food samples (e.g. above the maximum level) for aflatoxin were found in 2014–2016. Only one supervisory authority responding to the survey reported that it had targeted aflatoxin control measures in 2014–2016.

According to the Cancer Registry, 167,024 new cancer cases were diagnosed in Finland in 2013–2017, or an average of 33,400 cases/year. Of these, 2,584 cases of liver cancer occurred during the five-year period, representing an average of 517 new cases/year. Assuming that all cancers cost the same and using the total cost of €1082.8 million proposed by Neittaanmäki et al. (2017) for 2015, the total cost of all cases of liver cancer in 2015 would be approximately €16,800,000. Aflatoxin-induced hepatocellular carcinoma was estimated to occur at less than one case per year in the BoD calculations.

Aflatoxins in food products come with economic costs of about €1.5 million/year. The costs consist of monitoring expenses incurred by Finnish Food Authority, customs, municipalities and companies, as well as health care costs and related productivity loss.

Table 13. Aflatoxin-related costs

Aflatoxin current situation, costs (thousand €)				
	Labour	Sampling	Control	Total
Finnish Food Authority and Customs				255
Municipal Control Authorities	100	0.2	0.3	100
Companies	537	520	36	1,093
Health Care Costs				28
Productivity Loss				4
Total	637	520	37	1,481

At about €260,000, the monitoring of aflatoxins represents the major part of all monitoring costs, which are incurred by Ruokavirasto and Finnish Customs. For the municipalities and companies, the situation is different, as aflatoxin controls come with relatively low expenditures of approximately €100,000 and €1.1 million/year compared to the monitoring of other substances. Overall, the labour needed for aflatoxin controls is the most expensive part of the monitoring (Table 13).

In terms of health effects, aflatoxins are most importantly associated with the development of liver cancer. However, the causality between exposure to aflatoxins and the development of liver cancer is not very strong. In 2015, 33,000 cases of cancer (of all types) were registered in Finland, of which one case (when rounding upwards) could be considered liver cancer related to high aflatoxin exposure. The annual health treatment costs of an average cancer patient are €28,358. Cancer-induced productivity losses are estimated at €4,455 annually. The rounded value of one aflatoxin-induced cancer case totals about €33,000 in health costs. It is worth pointing out that the actual aflatoxin-induced liver cancer incidence is less than one case, meaning that the costs are likely a slight overestimation because there may be years when there are no aflatoxin-induced cases.

5.1.5 Scenario

As a scenario to reduce the BoD caused by aflatoxins, a situation where control of imported nuts is increased and thus consumer exposure is reduced was investigated. Increased controls would target batches of nuts that have had the highest aflatoxin content among the control samples in recent years—pistachios, almonds and peanuts. Ten percent more of these nut batches would be tested, and fewer aflatoxin-contaminated lots would enter the market.

In samples taken over several years under official control, about 16% of pistachio samples, about 5% of peanut samples and about 1% of almond samples have exceeded the maximum level set in EC 1881/2006 for aflatoxin contamination. The current exposure assessment was based solely on exposure to peanut products (EFSA 2018). About 50 peanut products are sampled each year. The scenario was estimated

to reduce aflatoxin exposure in Finnish adults by 0%–5%, which would also reduce the BoD due to aflatoxins.

5.1.6 Cost-effectiveness and impact of the scenario on burden of disease

The disease burden reduction effect of the aflatoxin scenario was estimated to be only 0.24 DALYs (95% confidence interval 0.007–0.86 DALYs). The reason for this is not only low levels of aflatoxins but particularly the high risk of liver cancer in hepatitis B patients only, the percentage of which in the population is very small. The proposed scenario is to carry out 10% more controls of imported nuts, which comes with additional costs but would also decrease health care expenditures.

Table 14. Aflatoxin scenario-related costs

Aflatoxin scenario, costs (thousand €)				
	Labour	Sampling	Control	Total
Finnish Food Authority and Customs				259
Municipal Control Authorities	100	0.2	0.3	100
Companies	537	520	36	1,093
Health Care Costs				28
Productivity Loss				4
Total	637	520	37	1,485

The controls would be conducted by the Finnish Customs and would amount to about eight extra nut samples taken annually. The costs for one control sample are €458.00 when assuming that a maximum of three samples are extracted per batch. Eight extra controls come with an additional cost of €3,664.00, which is incurred by the Finnish Customs Authority and gives a new total of €258,854. The costs for other monitoring actors are not expected to change (Table 14).

The scenario is based on the logic that additional controls correlate with less aflatoxin-contaminated products entering the Finnish market. In 2016, the Finnish Customs Authority found seven non-compliant batches (Evira 2017c). Under the scenario, it is expected that the number of products refused entry to the Finnish market could grow, even if only slightly.

In addition to market entry refusals, aflatoxin contamination might result in recalls if contamination is discovered after placement on the market. It is not possible to estimate these costs within the scope of this research.

According to the DALYs calculations, it is expected that the scenario will reduce the number of DALYs by about 0.24 from 9.6 DALYs to 9.36 DALYs. It is worth remembering that the estimated change in the number of cancer cases is very low, as it was already rounded up to one/year. The health costs thus remain the same in the scenario, and the only change would be additional sampling costs of €3,664 (Table 15).

Table 15. Summary of aflatoxins current status and scenario

Aflatoxins			
	Current Situation	Scenario	Change
DALYs	9.60	9.40	-0.2
Costs (thousand €)	1,481	1,485	4
	ACER	18,320	€/DALY

5.2 Dioxins

5.2.1 Health effects

Dioxins (PCDD/F) refer to chlorine-substituted dibenzo-p-dioxins and furans. Only 17 of these compounds are of toxicological significance. Dioxins are formed, for example, in incomplete combustion and in certain industrial processes. The advancement of combustion and industrial processes over the past decades has reduced the formation of dioxins and their release into the environment.

Polychlorinated biphenyls (PCBs) have been used, for example, in electronic equipment and as hydraulic fluids. Dioxin-like PCBs (dl-PCBs) are compounds with dioxin-like properties and therefore are often assessed together with dioxins. PCBs are internationally banned by the Stockholm Convention but are persistent in the environment.

Dioxins and dl-PCBs can enter the food chain from the environment. Their concentration in foodstuffs is usually given as WHO toxicity equivalents (WHO-TEQ), where each dioxin and dl-PCB in a product is multiplied by its specific WHO toxicity factor (WHO-TEF). The total concentration is the sum of these multiplications. For most toxic compounds, the TEF is one. For dioxins, the TEF values are in the range of 0.0003–0.3, and for dl-PCBs the TEF values are in the range of 0.00003–0.1. Currently, the TEF values published in 2005 (WHO-TEQ 2005) (Van der Berg 2005) are used.

Dioxins and dl-PCBs are fat-soluble compounds that tend to accumulate in food of animal origin and through that in the human body. They interfere with the functioning of

the reproductive system, nervous system and immune system and increase the risk of developmental disorders because they affect hormone function. A population study of boys' serum dioxin levels at 8–9 years of age and their sperm count 10 years later found that sperm levels were reduced to almost half of the control at the lowest exposure level. Based on these results, EFSA set the Dioxin Tolerable Weekly Exposure (TWI) at 2 pg (i.e. 2.0×10^{-12} g) TEQ/ kg bw/week (EFSA Panel on Contaminants in the Food Chain 2018).

5.2.2 Prevalence in food and current status in Finland

The major source of human exposure to dioxins and dl-PCBs is via food, especially food of animal origin. The total intake of these compounds in EU countries decreased by 17%–79% between 2002–2004 and 2008–2010, depending on the Member State and population (EFSA 2012). According to EFSA's latest estimate (EFSA Panel on Contaminants in the Food Chain 2018), the average intake (UB) of dioxins and dl-PCBs (29 compounds) in Finland was 1.8 pg TEQ/kg bw/day for children below school age and 0.97 and 1.09 pg TEQ/kg bw/day for 25–64-year-olds and 65–74-year-olds, respectively. The estimates are based on concentration levels in the EU and on Finnish food consumption studies DIPP and Findiet 2012. According to Findiet 2012 data, the combined mean intake of the 17 most toxic compounds for 25–64-year olds was 0.42 pg TEQ/kg bw/day. According to these estimates, even the mean intake is above the tolerable weekly exposure limit set by EFSA. Even though the levels of dioxins in foodstuffs have decreased, they are still found in foods that have been increasingly consumed, such as imported cheeses. In promoting export, it is worth highlighting the low dioxin content of domestic cheeses.

According to the latest national estimate (THL 2017a), up to 80% of the total intake of dioxins and PCBs in Finland comes from wild fish. In 2017, dioxin and dl-PCB levels in Baltic salmon had fallen to about half of 2002 levels but still exceeded the EU legal maximum levels (Evira 2017). The [GOHERR project](http://en.opasnet.org/w/Goherr_assessment) (http://en.opasnet.org/w/Goherr_assessment) used a survey to collect consumption data and determined that the dioxin exposure from Baltic fish in Finnish adults was 35 pg TEQ/day (**not** /kg bw), while in 2009 it was 67 pg TEQ/day due to higher concentrations. This report uses the results of the GOHERR project as a basis for the BoD assessment.

In the Contaminant Regulation ((EU) No. 1259/2011, (EC) No 1881/2006) Finland has been granted a derogation authorizing the sale of Baltic fish in Finland, even if their levels of dioxins and dl-PCBs are higher than the maximum levels laid down in the Regulation (6.5 pg/g fresh weight WHO-TEQ). Finland's argument has been based in

particular on public health, that is, that the benefits of eating fish outweigh the risks of dioxins. Sweden, however, has highlighted the risks of dioxins and is considering abolishing the derogation on the grounds that other fish are available. The derogation is conditional on providing consumers with [guidelines](https://www.ruokavirasto.fi/en/private-persons/information-on-food/instructions-for-safe-use-of-foodstuffs/safe-use-of-foodstuffs/) for the safe use of fish from the Baltic Sea (available at <https://www.ruokavirasto.fi/en/private-persons/information-on-food/instructions-for-safe-use-of-foodstuffs/safe-use-of-foodstuffs/>). It is also conditional on the annual notification to the Commission of measures to advise on dietary recommendations or to ensure that products not compliant with the maximum levels are not marketed in other Member States. The derogation requires that the effectiveness of these measures be demonstrated and that dioxin levels in fish from the Baltic Sea area are regularly monitored. The commercial use of fish from the Baltic Sea in Finland therefore requires additional controls.

5.2.3 Current burden of disease caused by dioxins

The WHO estimates (WHO 2015) that food dioxins cause an annual BoD of 1 DALY/100,000 inhabitants in Europe (95% confidence interval 0–9 DALYs/100,000 inhabitants). In Finland, this would mean an annual BoD of 55 DALYs (confidence interval 0–495 DALYs/year). The WHO assessment of health responses included hypothyroidism due to pre- and post-pregnancy exposure and reduced male fertility.

The [GOHERR project](#) carried out an updated assessment of the BoD from consumption of Baltic Sea fish. The estimate was based on an estimate of exposure to dioxins and dl-PCBs based on consumption data from the project survey. This benefit-risk assessment took into account the negative health effects of chemicals and the positive effects of vitamins and fatty acids. Negative health responses in the GOHERR assessment included cancer, childhood tooth damage due to exposure during gestation and reduced male fertility. An evaluation of the benefits of fish included the intake of vitamin D, the cardiac benefits of omega-3 fatty acids and the positive effect on infant brain development. In addition, the study included the neurotoxicity risks of methylmercury in children.

It is estimated that Baltic Sea fish are responsible for most of the dioxin exposure from food. According to the GOHERR project, exposure to dioxin and dl-PCB via Baltic Sea fish (without benefits) caused a disease burden of about 40 DALYs in 2009, which decreased to 22 DALYs in 2018 due to reduced dioxin levels.

5.2.4 Costs related to surveillance and morbidity

Maximum levels have been established for dioxins in the EU Contaminants Regulation (EC) No. 1881/2006 and its updated regulations. The maximum levels have been

set for a number of different food categories and are subject to controls both by official agencies (Food Authority, Customs laboratory, municipalities) and by producers and manufacturers themselves.

In national monitoring in 2014–2016, over 70 samples each year were analysed to determine the level of dioxins. According to the survey in this project, in 2014–2016 municipalities spent 2%–10% of their working time/year on dioxin control, and food samples exceeding the maximum levels were found. Only one supervisory authority responding to the survey reported it employed measures to control for dioxins in 2014–2016.

The health effects of dioxins only become apparent years after exposure. Some of the adverse effects, such as impaired fertility, do not require acute medical care; therefore, the associated morbidity costs are difficult to determine.

The incidence of dioxins in foodstuff is associated with economic costs of roughly €27.9 million annually. The costs result from monitoring dioxin levels in food and from research projects but do not include estimations of the costs resulting from health effects (Table 16).

Table 16. Dioxin related costs

Dioxins current situation, costs (thousand €)				
	Labour	Sampling	Control	Total
Finnish Food Authority and Customs				62
Municipal Control Authorities	132	0.09	0.6	133
Companies	483	1,733	25,479	96
Health Care Costs				unknown
Productivity Loss				unknown
EU derogation				40
Total	615	1,734	25,480	27,930

Dioxins are monitored by the Finnish Food Authority and Customs, an activity that costs about €61,600 annually. Municipalities and companies monitor dioxins less frequently; they are assessed by only about 18% of companies and 25% of municipalities. The money spent on monitoring is approximately €132,700, with labour costs constituting the biggest part. The major part of the total cost stems from the activities carried out by companies. It is estimated that companies spend nearly €27.7 million on dioxin monitoring per year (Table 16).

As a part of the reporting duty related to the dioxins derogation, Finland carries out a research project every five years, the budget of which is typically €200,000, leading to annual costs of €40,000.

Dioxins have multiple hazardous effects on human health, such as interfering with the functioning of the reproductive system, the nervous system and the immune system. Because it is difficult to show the effect of dioxins on these systems, at the moment it is not possible to determine health care costs of dioxin exposure.

5.2.5 Scenario

As a scenario aimed at reducing the burden of dioxin-induced disease, the situation where Finland waives its derogation to keep Baltic Sea fish on the domestic market was examined. In the scenario, the consumption of Baltic Sea fish is replaced by the consumption of an equivalent amount of domestic lake fish or farmed fish. This would reduce the dioxin exposure of Finns and the resulting BoD and would reduce the proportion of the population that exceeds the tolerable weekly intake of dioxins. However, the health benefits of eating fish would be maintained as long as total fish consumption was not reduced. The scenario assumes that the health benefits do not change by changing fish species, although herring contains more healthy fatty acids than many typical lake fish, such as pike or zander, and less healthy fatty acids than rainbow trout.

The scenario was chosen for the following reasons. Fish in the Baltic Sea have high levels of dioxins compared to domestic lake fish or farmed fish, and maintaining the derogation requires Finland to regularly investigate the occurrence of dioxins in Baltic Sea fish and to investigate whether consumers are aware of the recommendations. The levels of dioxin in the feed of farmed fish are monitored, and thus the concentration of dioxins in the fish can be controlled.

The scenario assumed that there would be alternative uses for Baltic Sea fish, for example, as feed material, as already today the vast majority of herring goes for feed and not human consumption. However, the selling price of edible herring is considerably higher, so economically this scenario is disadvantageous for fisherman because they will lose income.

5.2.6 Cost-effectiveness and impact of the scenario on burden of disease

The dioxin scenario was estimated to decrease the Finnish BoD by 12 DALYs annually (95% CI from decrease of 67 DALYs to 35 additional DALYs). The scenario envisions that Finns stop consuming Baltic Sea fish altogether. The total costs are expected to remain the same, although the financial impact may be different for the different parties involved. These are excluded from the project.

Table 17. Dioxin scenario related costs

Dioxin scenario, costs (thousand €)				
	Labour	Sampling	Control	Total
Finnish Food Authority and Customs				62
Municipal Control Authorities	132	0.09	0.6	133
Companies	483	1,733	25,479	27,696
Health Care Costs				unknown
Productivity Loss				unknown
EU derogation				40
Total	615	1,734	25,480	27,930

On average, Finnish fishermen landed 149,500 tons of Baltic Sea fish/year during the period 2014–2016. Approximately 89% of the catch was Atlantic herring, 9% was European sprat and the rest consisted of different species (European Union 2017). Since the 1980s, Luke (2016) has observed a decreasing trend in the consumption of herring by Finnish final consumers. Currently, Finns consume only 10% of the herring they used to consume in the 1980s, namely 3.5–4 million kg/year of herring. This correlates to barely 3% of the 133 million kg of herring caught annually in Finland. The majority of the Finnish Baltic Sea catch is used as feed, and export is also high—in the case of herring roughly 40% of the catch. In other words, a relatively small proportion of the fish caught in the Baltic Sea is actually consumed in Finland.

In terms of municipal authorities and companies, it is assumed that the scenario will not noticeably impact their monitoring costs because dioxin levels are not only monitored in fish but also in meat and other products (Commission Regulation No. 1881/2006). Additionally, the exported fish products will need to be monitored. The economic effects of increasing the consumption of lake fish are not taken into consideration.

The reporting and research costs related to the derogation are assumed to continue at an average €40,000/year. The derogation might not be necessary in the long run, but in the short run the costs will remain. The health care costs cannot be estimated at the moment.

All known costs are expected to stay at a constant level (Table 17). The change from the current status to the scenario is presented in Table 18.

Table 18. Summary of dioxins current status and scenario

Dioxin			
	Current situation	Scenario	Change
DALYs	37	25	-12
Costs (thousand €)	27,930	27,930	0
	ACER	0.00	€/DALY

5.3 Lead

5.3.1 Health effects

Lead (Pb) belongs to the heavy metal category. Its levels in agricultural products are affected by natural concentrations in soil and by human activity, such as lead deposition from industry, shooting ranges or other contaminated areas and the previous use of petrol containing lead. Environmental lead ends up in food via contaminated water and food raw materials.

Lead exposure has been linked to a number of health effects, such as kidney damage, miscarriages, nervous system symptoms and an increased risk of hypertension (EFSA 2010). In addition, lead exposure has been linked to developmental disorders of the central nervous system in children and thereby to a decline in IQ (Wani et al. 2015; Flora et al. 2012). Most of the health effects have only been found to be significant at higher levels of exposure than the average consumer: as a result of occupational exposure or at concentrations well above current environmental exposure. Exposure to lead has declined significantly in recent decades, particularly because lead fuels are no longer used and lead-coated water pipes have largely been replaced with lead-free ones. The main dietary sources of lead exposure are foods that are often consumed in high doses, even if their lead levels are not very high.

There is no threshold for the critical effects of lead that could be considered as a reference level for safe intake. EFSA has established benchmark dose levels (BMDLs) for the various health hazards. These are lower confidence intervals for the dose that increases the risk of adverse events by a percentage indicated by the subscript relative to the risk in the non-exposed population. For childhood developmental neurotoxicity, BMDL₀₁ is 0.50 µg/kg bw/day, which corresponds to a blood lead level of 12 µg/l. This corresponds to a decrease in IQ of one point. For kidney toxicity (decreased filtration efficiency of kidneys) the BMDL₁₀ is 0.63 µg/kg bw/day (15 µg/l in blood), and the BMDL₀₁ for a 1% increase in systolic blood pressure is 1.50 µg/kg bw/day (36 µg/l in blood) (EFSA 2010).

5.3.2 Prevalence in food and current status in Finland

As lead is an element, it can be present in trace amounts in all foods. Elevated levels of lead can be found, for example, in spices, game meat and animal offal, molluscs, nutritional supplements and diet foods. To date, there are no legal maximum limits for these foodstuffs.

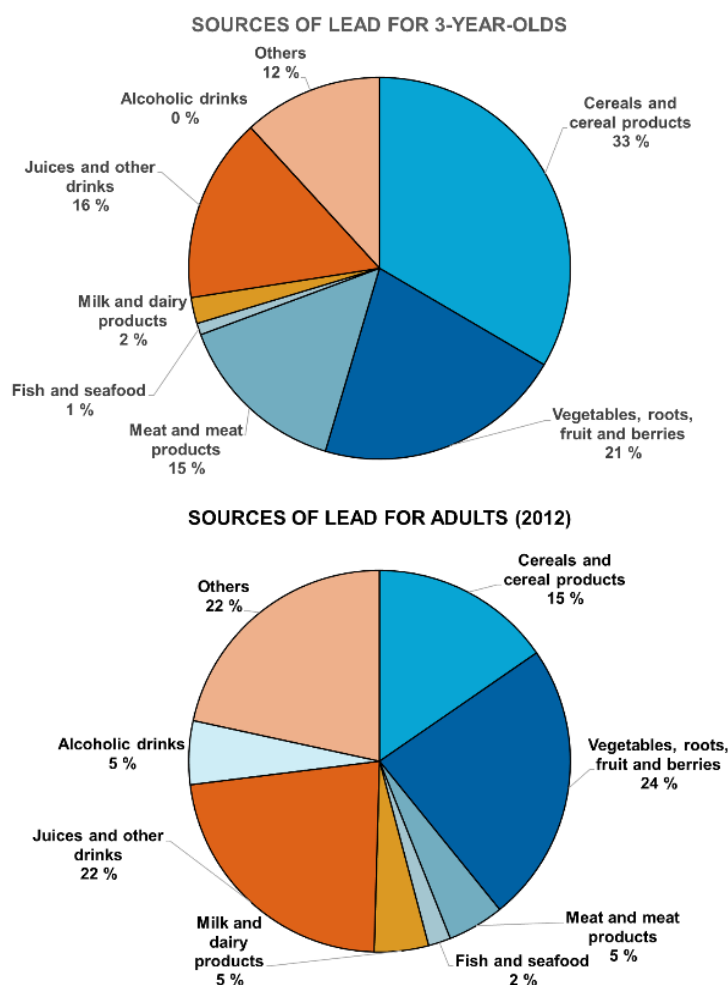


Figure 5. Sources of exposure from food and drinking water in Finland for 3-year-olds (Suomi et al. 2015), above, and working-age Finns according to the consumption data of Findiet 2012 (Suomi 2019), below. After 2010, no lead results above the limit of quantification have been found in monitoring milk samples; therefore, the importance of milk as a source of lead has decreased in the 2010s.

Figure 6 shows the sources of dietary lead exposure for Finnish children and adults. The dietary exposure to lead was assessed in Evira's/Finnish Food Authority's projects based on national food consumption data (DIPP and Findiet 2012 surveys) and occurrence data mainly from samples measured in Finland. As a result of using national concentration data, the exposure is lower than in the estimates previously published by EFSA.

The median exposure of Finnish children aged 1, 3 and 6 is 0.58 µg/kg bw/day, 0.40 µg/kg bw/day and 0.34 µg/kg bw/day, respectively (Suomi et al. 2015). For Finnish 25–74-year olds, the average dietary exposure from foods and tap water is 0.2 µg/kg bw/day (Suomi 2019).

5.3.3 Current burden of disease caused by lead

The health impact assessment used WHO guidelines (WHO 2003b), updated with the findings of Lanphear et al. (2005), on the reduction of IQ in children as a result of exposure to lead. The WHO guidelines are currently being updated, and it is possible that thresholds for the health impact assessment of lead will be lowered. According to the WHO statement (WHO 2018b) and the EFSA assessment (EFSA 2010), there is no safe threshold for exposure.

Among the health effects, we looked at the decline in childhood IQ (mild intellectual disability, IQ below 70) and the increased risk of hypertension in adults. According to the current WHO guidelines (WHO 2003b), these responses should be evaluated for blood lead levels above 50 µg/l. However, Lanphear et al. (2005) showed that a decline in intelligence already occurs with blood lead concentrations of 24 µg/l. Therefore, this threshold is used as the threshold value and the dose response is the unit risk for the decrease in intelligence (0.039 IQ points per each additional 1 µg/l of blood lead concentration). The BMDL₀₁ for neurotoxicity (IQ decrease) as calculated by EFSA is 0.50 µg/kg bw /day, which corresponds to a blood lead level of 12 µg/l (EFSA 2010). However, this value cannot be used as a limit of action for a health impact assessment as such, although it is useful as a reference value for conventional chemical risk assessment.

The exposure of Finnish children aged 1, 3 and 6 to lead in food and tap water (Suomi et al. 2015) corresponds to blood lead levels of 14 µg/l, 10 µg/l and 8 µg/l, respectively. For adults aged 25–74 (Suomi 2019), the blood lead level is 4 µg/l. Adult exposure was found to be so low that no increased risk of hypertension could be detected. More than 5% of 1-year-olds were exposed to dietary lead, leading to elevated blood lead levels above the cut-off value for decreased IQ. For these 3,000+ children, the mean blood lead concentration was 27 µg/l, which would lead to an average decrease of 0.2 points in each child. The calculated BoD due to the decline in intelligence in Finland would be 570 DALYs/year. According to the exposure assessment included in Evira's risk assessment (Suomi et al. 2015), none of the children aged 3 or 6 would exceed the cut-off value for decreased IQ.

5.3.4 Costs related to surveillance and morbidity

Maximum levels for lead have been set in EU Contaminants Regulation (EC) No. 1881/2006 and its updated regulations. Maximum levels have been set for a number of different food categories and they are monitored by official controls (Food Authority, Customs Laboratory, municipalities) and by producers and manufacturers. Lead in do-

mestic drinking water is also controlled, in accordance with the domestic water regulation. The table in Annex II of the Drinking Water Regulation lists the minimum frequency of regular monitoring for different water distribution areas.

Lead analyses were carried out in 2014–2016 by the Finnish Food Authority and the Customs Laboratory on a total of 360 imported foodstuffs and 690 domestic samples related to national contaminant monitoring (including meat and offal from farmed animals). One of the municipal supervisors who responded to the survey reports that 2% of their working time/year is spent on lead monitoring. According to the survey, no abnormal food samples (i.e. exceeding maximum levels) were detected in 2014–2016, and only one control authority responding to the survey reports that control measures were taken for lead during these years.

The health effects of lead typically occur years or decades after exposure. Some of the side effects, such as mental retardation, do not require acute medical care; therefore, the associated morbidity costs are difficult to determine.

The estimated economic costs of lead in food products are nearly €31.8 million/year. The majority of these costs are related to monitoring activities in companies. Due to estimation difficulties, health care expenses and productivity losses are not included.

Table 19. Lead related costs

Lead current situation, costs (thousand €)				
	Labour Costs, €	Sampling Costs, €	Control Costs, €	Total Costs, €
Finnish Food Authority and Customs				41
Municipal Control Authorities	51	0.7	0.3	52
Companies	1,540	552	29 653	31,745
Health Care Costs				unknown
Productivity Loss				unknown
Total	1,591	552	29,654	31,838

Based on the data obtained from the survey, lead is assessed by approximately 20% of companies and 25% of municipalities. The lead monitoring costs for companies are approximately €31.7 million but are comparatively low for municipalities, which appear to spend only around €52,000 (Table 19). In the case of companies, the control costs constitute the biggest cost factor (90% of the total costs), while for the municipalities the labour costs are the most expensive aspect (98%).

Lead exposure has been linked to a number of health effects, such as kidney damage, miscarriages, nervous system symptoms and developmental disorders (Wani et

al. 2015; Flora et al. 2012). Similar to the case for dioxins, it is not possible to allocate these effects using the information currently available. Therefore, further research is needed.

Overall, the cost estimation related to lead is approximately €31.8 million annually. This is most likely an underestimation, as factors such as health care costs and productivity losses are not included.

5.3.5 Scenario

As a scenario to reduce the BoD caused by lead, a situation was investigated whereby fetal exposure to lead is reduced by limiting the lead content in foods that are the major sources of exposure among women of childbearing age. By limiting the dietary exposure of this population, the fetal exposure to lead would also decrease. The scenario focuses on diet foods (meals and bars) and tea powders, out of which 100 extra samples would be taken every year in Finland and ingredients in excess of a certain concentration would be removed. The scenario assumes that this would be achieved, for example, by the addition of new maximum levels in the Contaminants Regulation (EC) No. 1881/2006. This would also lead to control measures elsewhere in Europe and would not constitute an obstacle to the internal market. At present, there are no legal limits for diet foods (meals and bars) or tea powder.

If the levels of lead in diet foods were not higher than the maximum levels allowed for cereal products in the Contaminants Regulation and the maximum levels for lead in tea powder were to be equal to the maximum levels allowed for wines, the lead exposure of Finnish women of childbearing age would decrease 3.7% at age group mean level and approximately 51% for the highly exposed part of the population group (to a level of 0.45 µg/kg bw/day, which is less than the BMDL₀₁ value for lead associated with IQ decreases).

The scenario was chosen for the following reasons. The BoD calculated in the project was related to lead exposure in 1–3-year olds. The main source is industrial baby foods, due to their high consumption. However, these foods already have the strictest limits set by the EU Contaminants Regulation. In the concentration data used in the risk assessment (Suomi et al. 2015), the majority of the industrial baby food samples measured were below the analytical limit of determination, but due to repeated consumption and the low body weight of toddlers, the low concentrations lead to relatively high exposure. It was not considered practical to influence the exposure of Finnish children to lead by tightening the quality standards of children's food from current levels, as access to sufficiently high-quality raw materials could become a problem. Re-

garding raw materials for baby foods, there are stringent quality standards for the levels of many contaminants in food in addition to lead levels. Therefore, the scenario sought to limit lead exposure during the fetal stage.

In the long term, lead levels in food can be reduced by continuing good agricultural practices affecting the heavy metal content in raw materials and possibly favouring those (cereal) cultivars with the lowest heavy metal accumulation, if their other characteristics are suitable for the purpose.

5.3.6 Cost-effectiveness and impact of the scenario

Sensitivity testing was carried out to assess the BoD caused by lead, as many children's lead levels are only slightly below the threshold of 24 µg/l. The value is not determined based on toxicological criteria but because the Lanphear (2005) data did not contain sufficiently lower exposures. Because lead has no physiological function in the body, its hazardous effects may not have any threshold value. Sensitivity testing showed this to be a surprisingly important assumption: only 7% of children initially exceeded the threshold, but assuming an uncertain threshold of 0–24 µg/l, the hazard estimate multiplied from 30 DALYs to 1,100 DALYs/year. As a result, both options were included in the final results. The results should be updated when further studies provide additional illumination of the effects of low exposures. Currently, the estimated BoD is 570 DALYs/year (95% confidence interval 0–4,100).

The lead scenario was estimated to reduce the BoD for Finns by 40 DALYs/year (95% confidence interval 0–210 DALYs). The magnitude of the effect is limited by the fact that only a relatively small part of the total exposure is targeted.

Another important assumption regarding lead is the occurrence of health damage. The IHME Institute has published a handicap weighting factor for IQ below 70, whereby only a small percentage of the population is affected. However, in this assessment, it was assumed that even small changes in IQ are harmful; that is, the health damage is to the entire exposed population.

The EU Contaminants Regulation ((EC) No. 1881/2006) does not set a limit for lead in tea or diet foods. In the proposed scenario, these products would be subject to monitoring.

Table 20. Lead scenario-related costs

Lead scenario, costs (thousand €)				
	Labour	Sampling	Control	Total
Finnish Food Authority and Customs				41
Municipal Control Authorities	51	0.7	0.3	52
Companies	1,540	577	29,653	31,770
Health Care Costs and Productivity Loss				unknown
Total	1,591	577	29,654	31,863

The scenario means annually performing 100 additional laboratory analyses spread randomly over the respective production facilities in Finland. The maximum level of lead envisioned as admissible is 2 mg lead/kg of product. The threshold is adopted from cereals in the case of diet foods and from wine in the case of tea. The assumption is that Regulation No. 1881/2006 is amended to include these maximum levels, which implies that the updated rules apply within the entire European Union market.

The additional control costs are covered by the randomly selected companies. Based on information obtained from the Finnish Customs Authorities, sampling and analysis for lead costs €250/sample. It is assumed here that companies have roughly the same costs and that the price already includes labour costs. The total annual costs for additional controls therefore add up to €25,000/year. The underlying assumption for the extra controls is that more products exceeding the lead limits are found and that their consumption is prevented. In the case that products are found to exceed the allowed lead concentrations, the entire batch is not allowed onto the market. Such a rejection has economic costs. However, as previously mentioned, the costs associated with rejections and recalls cannot be assessed in this project.

Regarding other monitoring actors, the scenario does not envision a change in their practices and therefore no other costs are considered. In addition, estimating the changed health care expenses under the scenario is not possible, given that the current health care costs are unknown.

In summary, the additional costs of the lead scenario are €25,000 and are borne by companies (Table 20). Table 21 shows the change from current status to the scenario.

Table 21. Summary of lead current status and scenario

Lead			
	Current Situation	Scenario	Change
DALYs	570	530	-40
Costs (thousand €)	31,838	31,863	25
	ACER	625.00	€/DALY

6 Nutritional factors: Examples, current status and scenarios

Chapter 6 is about the nutritional factors studied. For each factor, we describe its impact on consumer health, its prevalence in foods, information on intakes in Finland and related morbidity, the BoD caused by the factor and the current costs of surveillance and morbidity. After the presentation of the current situation, the burden and cost of the scenario and the impact factors studied in the project will be described.

Detailed assumptions and calculation codes used in BoD assessment can be found on the Opasnet Web Workspace [RUORI](http://fi.opasnet.org/fi/Ruori) page at <http://fi.opasnet.org/fi/Ruori>.

6.1 Underconsumption of fruits and vegetables

6.1.1 Health effects

Fruits and vegetables are rich in healthful nutrients, such as dietary fibre, vitamin C, carotenoids, folic acid, vitamin E, vitamin K, potassium and magnesium (Nordic Council of Ministers 2018), and other bioactive substances the health effects of which are not fully known (National Nutrition Advisory Board 2014). In a follow-up study of more than 450,000 people, the consumption of fruits and vegetables was associated with a lower risk of death (Leenders et al. 2013). There is convincing evidence that fruits and vegetables are associated with a lower risk of cardiovascular disease (WHO 2003). In the meta-analysis, the lowest risk for cardiovascular disease and overall mortality was observed at more than 800 g/day of fruits and vegetables. A reduction in the risk of coronary heart disease, heart attack, heart disease, and cancer was observed for each additional 200 g/day of fruits and vegetables (Aune et al. 2017).

There is also evidence that fruits and vegetables provide protection against gastrointestinal cancers and lung cancer (Nordic Council of Ministers 2014). The lowest risk for cancer was found when fruit and vegetable consumption was 550–600 g/day (Aune et al. 2017). The abundant use of fruits and vegetables also helps in weight management (Nordic Council of Ministers 2014).

According to WHO, fruit and vegetable consumption should equal at least 400 g/day (about 5 servings a day) (WHO 2003), while the Finnish Nutrition Guidelines (VRN

2014) state that at least 500 g of roots, vegetables, berries and fruits should be consumed each day (about 5–6 servings/day).

6.1.2 Current situation in Finland

According to Finravinto 2017 (Valsta et al. 2018), a Finnish study on the diet and nutrition of adults, on average men consumed 331 g and women consumed 402 g of vegetables (including legumes and nuts), fruits and berries a day. The corresponding figures in the Finravinto 2012 study (Helldán et al. 2013) were 380 g for men and 420 g for women. The age categories in these surveys are slightly different. In 2012, the data was for those aged 25–64, and in 2017 the data was for those aged 18–74. According to Finravinto 2017, only 14% of Finnish men and 22% of Finnish women eat the recommended amounts of fruits and vegetables (Valsta et al. 2018).

Preliminary data from the Natural Resources Institute's Nutrition Balance Sheet 2017 (Luke 2017) show that Finns consumed an average of 65 kg of fruit and 64 kg of vegetables last year, a total of 353 g/day. Consumption figures for fruits and vegetables on the balance sheet are only indicative, as the amount of stock losses and other losses, for example, is not known. The nutrition balance is more about the amount available for consumption than actual consumption (Luke 2017). In addition, the fruits, berries and vegetables picked or cultivated themselves are missing from the nutrition balance figures.

6.1.3 Current burden of disease due to low consumption of fruits and vegetables

GBD studies by the IHME Institute estimated that in the years 2014–2016, the low consumption of fruit caused a burden of 34,500–35,300 DALYs in Finland each year. Seventy-five percent of this burden was due to cardiovascular disease, with the remainder being fairly evenly distributed between cancer, diabetes and kidney damage. The underconsumption of vegetables in 2014–2016 was estimated to have caused an annual burden of 27,100–27,800 DALYs in Finland, which was fully explained by cardiovascular disease. The RUORI model allocated 36,000 (95% confidence interval 19,000–53,000) DALYs/year for the underconsumption of fruit and 29,000 (95% confidence interval 13,000–44,000) DALYs for the underconsumption of vegetables.

6.1.4 Costs related to surveillance and morbidity

The nutritional aspects of fruit and vegetables are not subject to regulatory control.

No direct information has been published on nutrition-related morbidity costs, but according to the IHME Institute (University of Washington 2019), in 2016 the burden of cardiovascular disease in Finland was 730,452 DALYs, 7.3% of which was explained by low fruit and vegetable consumption. The total burden of diabetes and kidney disease in 2016 was 159,800 DALYs, 2.8% of which was due to the underconsumption of fruit. The total burden of tumours in 2016 was 137,218 DALYs, 3.9% of which was due to the underconsumption of fruit.

In 2012, the cost of all cardiovascular diseases accounted for 4% of all sickness cash benefits paid by the Social Insurance Institution (KELA); in other words, circulatory diseases caused 13,000 sickness benefit periods, a total of 76,900 days (Neittaanmäki et al. 2017). According to the same source, there were a total of 21,769 cases of myocardial infarction and coronary heart disease in Finland in 2012, and in 2014 about 12,000 Finns died from coronary artery disease. Medicines for the treatment of cardiovascular diseases are also expensive.

The total cost of cancer in 2011 was estimated at about €750 million, of which the direct costs were €623 million. The Ministry of Social Affairs and Health estimated that the total cost of cancer would increase to 1.08 billion euros in 2015 and will increase to 1.5 billion euros in 2020 when it is estimated that over 33,000 Finns will have cancer. Approximately 30% of the estimated total treatment costs in 2015 will come from inpatient care, 28% from outpatient care and 24% from medicines. According to data from the early 2010s, the cost of treating one cancer patient is approximately €30,000 (Neittaanmäki et al. 2017).

Eating fruits and vegetables has positive health effects. The following is an estimate of the health costs of increasing fruit and vegetable consumption. Other costs, such as control costs, are not taken into account as they may not have any health implications.

Obesity and overweight are major and independent health risks. However, they are also linked to the idea that eating high levels of fruits and vegetables is a substitute for eating other, unhealthy foods, thus facilitating weight management. However, obesity and overweight were not considered in this project because obesity management is linked to diet and physical activity as a whole, and it would have been very difficult to distinguish any single scenario that could have been studied in the same way as other scenarios of this project.

The health effects take into account the three major diseases caused by the underconsumption of fruit and vegetables—cardiovascular disease, diabetes and tumours. The costs of these diseases are based studies by Neittaanmäki et al. (2017) and THL (2014b). The costs include treatment costs, drug costs and loss of productivity. The

loss in productivity was estimated at €168/working day lost. There was no information on kidney disease and tumours, which is why the following figures are underestimated. A study from the University of Washington (2019) was used to estimate the proportion of fruit and vegetables. The costs were €9.7 million for cardiovascular disease, €360,000 for diabetes and €29.6 million for cancer. The total cost is €39.6 million.

6.1.5 Scenario

To increase the consumption of fruit and vegetables, a situation where the value-added tax (VAT) on fresh fruits and vegetables is eliminated was investigated. However, the scenario assumed that the same amount of money would still be spent on fruit and vegetables. That is, a price reduction would increase the amount of fruits and vegetables consumed, although this is likely to overestimate the impact.

The scenario was chosen after concluding that the elimination of the VAT on fresh fruits and vegetables would allow the majority of the population to increase their fruit and vegetable consumption, regardless of their socio-economic status. According to the literature, reducing the price of fruits and vegetables is the most effective way to increase their consumption (Cobiac et al. 2010; Dallongeville et al. 2019). A report on the impact of health-based food taxation on citizens' health status and health inequalities (Kotakorpi et al. 2011) looked at the changes in consumption that would result from reducing the VAT on fruits and vegetables from 13% (currently 14%) to zero. Consumer prices for these products would then fall by around 11.5%. For the sake of simplicity, these calculations assumed that tax changes would be passed on in full to the price of fruits and vegetables (Kotakorpi et al. 2011).

The scenario to remove the VAT from fruits and vegetables was dealt as one scenario since the change in VAT would be the same for both fruits and vegetables. Because the scenario does not propose removing the VAT only from fruits or only from vegetables, separate ACERs do not offer any added value. For this reason, a common ACER is calculated for fruits and vegetables.

The increased consumption of fresh fruits and vegetables would have direct public health effects by reducing the burden of cardiovascular disease and various cancers.

6.1.6 Impact of the scenario on burden of disease and its cost effectiveness

Eliminating the VAT on fruits and vegetables was most effective in all the scenarios examined. For fruits and berries, the effect was 3,300 DALYs (95% confidence interval 160–7,700 DALYs, standard deviation 2.100), and for vegetables, pulses and nuts it was 2,100 DALYs (95% confidence interval 88–5 5 200 DALYs, standard deviation 1.400). The reason for good impact of this scenario is that changes in the VAT affect the eating habits of the entire nation.

The scenario proposes the complete abolition of the VAT of 14% on fruits and vegetables. This would affect government tax revenues, household disposable income and corporate profits.

Table 22. Costs related to eliminating the VAT on fruits and vegetables

	Current situation /thousand €	Scenario (thousand €)
Finnish Food Authority and Customs	-	-
Municipal Control Authorities	-	-
Companies	-	-
Health Care Costs (including productivity losses)	39,635	33,800
→ Cardiovascular Diseases	9,714	8,284
→ Diabetes	359	306
→ Tumours	29,562	25,210
Forgone tax income (state)	-	310,065
Additional Household Net Income		- 191,133
→ Additional Income	-	- 310,065
→ Additional Spending	-	118,932
Total Costs	39,635	152,732

There are a number of financial implications of removing the VAT. The state loses tax revenue, and households save the same amount and allocate part of this money to buying fruits and vegetables. In 2014–2016, households spent €950 on fruits and vegetables (Statistics Finland 2019b). Thus, total expenditure on fruits and vegetables in Finland (about 2.66 million households, Statistics Finland 2019b) was €2.5 billion/year (including taxes). The VAT accounts for €310 million of the total expenditure.

According to Kotakorpi et al. (2011), the change in demand resulting from eliminating the VAT on fruits and vegetables would be 5.37%. As a result, the additional expenditure of households on fruits and vegetables is €119 million. This saves €191 million for other uses. This would also result in increased revenues for companies, but this is not considered. The increased consumption of fruits and vegetables would reduce

DALYs by 14.7%. Correspondingly, health care costs would be reduced by €5.8 million (Table 22).

The total cost of the scenario would be €152.7 million compared to the current state (€39.6 million); however, the DALYs would also fall. Overall, this scenario would result in an additional cost of €113.1 million.

A summary is presented in Table 23.

Table 23. Summary of the underconsumption of fruits and vegetables current status and scenario

Fruits and vegetables			
	Current Situation	Scenario	Change
DALYs	65,000	59,600	-5,400
Costs (thousand €)	39,635	152,732	113,097
	ACER	20,944	€/DALY

6.2 Excessive intake of salt

6.2.1 Health effects

According to WHO, reducing salt intake is one of the most cost-effective ways to improve population health. To that end, WHO has set a target of a 30% global reduction in average salt intake (WHO 2013).

There is ample evidence of the hypertensive effect of excessive salt intake. Reducing salt intake lowers blood pressure with the highest effect to them with hypertension but is also detectable in people with normal blood pressure (WHO 2012).

High salt intake increases the risk of stroke and has also been linked to other cardiovascular diseases (WHO 2012, Nordic Council of Ministers 2014, Jayedi et al. 2018). Due to its powerful hypertensive effect, it may increase overall mortality (WHO 2012). In addition, high salt intake has been found to be associated with gastric cancer (He & MacGregor 2010; D'Elia et al. 2014), osteoporosis and the worsening of asthma symptoms (He & MacGregor 2010).

6.2.2 Prevalence in food and current status in Finland

Table salt consists of sodium chloride. Sodium is naturally present in most foods and is also intentionally added. The salt content listed on food packaging includes both the salt added to the food and the sodium naturally present therein. The salt content is obtained by multiplying the total sodium content of the foodstuff by 2.5.

The recommended salt intake for adults is 5 g/day, equivalent to 2 g of sodium. The recommended intake of salt for 2–10-year olds is up to 3–4 g/day. Adding salt is not recommended for infants (VRN 2014).

Salt intake in Finland has declined in recent decades thanks to cooperation between different actors and legislators (VRN 2014), but according to Finravinto 2012 this decline has ceased (Helldán et al. 2013). According to the most recent population survey (Valsta et al. 2018), there has been no change in Finn's salt intake in recent years. Salt is still overused, and the recommended daily intake of 5 g/day is exceeded by 86% of women and 98% of men (Valsta et al. 2018). According to the Finravinto 2017 study (Valsta et al. 2018), men received an average of 8.7 g/day and women 6.4 g/day. The main sources of salt for Finns were meat, egg and cereal products (Valsta et al. 2018).

6.2.3 The burden of disease due to excessive salt intake at present

The IHME Institute estimates that in the 2014–2016 period, excessive salt intake in Finland caused an annual burden of 26,400–27,100 DALYs, which accounted for more than 90% of the burden of cardiovascular disease. In the RUORI model's estimation, this result was scaled for current salt intake in Finland and the changes brought about by the Heart Symbol scenario. In the current state of the RUORI, the burden due to salt intake was 32,000 DALYs/year (95% confidence interval 7,800–58,000 DALYs).

6.2.4 Costs related to surveillance and morbidity

Salt is not subject to regulatory controls except for ensuring that labelling is appropriate.

According to studies by the IHME Institute, in 2016 the annual BoD for all cardiovascular diseases in Finland was 730,452 DALYs. Of these, 3.4% were linked to salt intake, particularly coronary heart disease, stroke and cancer. The total burden of diabetes and kidney disease in 2016 was 159,800 DALYs, of which 0.5% was due to excessive salt intake. The total burden of tumours in 2016 was 137,218 DALYs, of which 1.3% were due to excess salt intake. The total cost of cardiovascular disease and cancer (Neittaanmäki et al. 2017) is presented above in connection with the costs of the underconsumption of fruits and vegetables.

Excessive salt intake has adverse health effects. For this reason, EU Regulation 1169/2011 requires the salt content of foodstuffs be declared. The costs arise mainly from controlling salt intake and the effects of its overuse.

Although there are no actual upper limits for salt levels, there are different labels, such as the statutory High Salinity Label or the Heart Symbol, to help consumers choose products (WHO 2013). The cost of controlling municipalities and companies varied greatly. The cost of controlling companies ranged from €0–€400,000. The reason for controlling salt content may be different from that for controlling other harmful substances. Food businesses can modify the flavour, composition or shelf life of their products by adding salt. For this reason, the cost of monitoring companies is not taken into account here. The same applies to municipalities and other authorities.

The health effects take into account the three major diseases caused by excessive salt intake—cardiovascular disease, diabetes and tumours. The costs of these diseases are based on studies by Neittaanmäki et al. (2017) and THL (2014b) and include treatment costs, drug costs and loss of productivity. Productivity losses were estimated at €168/one lost working day. No information was available on the costs of salt-related kidney disease and tumours, which is why the following figures are underestimates. The IHME study of the University of Washington (2019) was used to estimate salt content. The costs were €4.5 million for cardiovascular disease, €64,000 for diabetes and €9.9 million for cancer. The total cost was €14.4 million.

6.2.5 Scenario

The scenario to reduce salt intake was to investigate a situation where staff restaurants would only offer lunches that meet the Heart Symbol requirements. The scenario was assumed to target the working-age population eating in staff restaurants. According to the Taloustutkimus (2010), around 63 million meals were prepared in staff restaurants in 2009, which corresponds to catering to some 279,000 employees on each working day of the year. Of those who had access to a staff restaurant, about half (35% of women and 30% of men) used it (Raulio 2011).

The project compared the nutrient content of a typical six-week menu at a staff restaurant and similar Heart Symbol-compliant meals. The information came from a large food service company. Averages of salt were calculated for regular lunch and Heart Symbol lunch. Different types of meals according to main course (sauce, piece food, soup, casserole) were chosen randomly from the six-week menu for four different options each day. In the example calculations, bacon ham sauce was chosen to represent the sauce main course and ham sauce was chosen for the corresponding Heart Symbol lunch. Salmon patties were selected to represent the piece food, sausage soup represented the soup and meat-and-pasta casserole represented the casserole, and for each of them was selected a corresponding Heart Symbol meal. Potato, rice, pasta and other side dishes of the main meals were selected similarly.

The average regular lunch had 3.2 g of salt and the Heart Symbol lunch had 2.4 g. At weekly levels, salt intake was estimated to decline 3.3–5.1 g by switching to lunches that meet the Heart Symbol requirements. The nutrient content of the meals also included side dishes. The estimate was compared with the calculations in the Heart Association Report (Finnish Heart Association 2016), which estimated the use of salt to decrease 4.2–5.2 g. However, the Heart Association did not take into account items such as spreads, drinks or salad dressings. Previously (Raulio et al. 2017), it was also shown that replacing conventional foods (raw materials were not included) with Heart Symbol-compliant foods would reduce salt intake by 10%.

This scenario was chosen because switching from high-salt to low-salt meals would reduce the average salt intake of the population and thus reduce the burden of cardiovascular disease due to excessive salt intake. Today, 98% of men and 86% of women exceed their salt intake recommendations (Valsta et al. 2018). The realization of the scenario would lead the majority of the population to have the recommended salt intake. It has been estimated (Jula 2011) that decreasing salt consumption by 1 g every day would save on average €70 million/year in health care costs on the population level. Most salt comes from industrial foods and meals outside the home (VRN 2014), so the importance of workplace eating in relation to salt intake is important.

6.2.6 Impact of the scenario on burden of disease and its cost effectiveness

The Heart Symbol meals only affect about 5% of the population, that is, the working-age population who eat at staff restaurants. However, Heart Symbol meals are quite effective in that population. Salt reduction was estimated to reduce the BoD by 440 DALYs/year (95% CI 100–990 DALYs/year see table 26).

In the scenario, state-subsidized meals in staff restaurants will be limited to Heart Symbol-compliant meals.

Table 24. Costs related to excessive salt intake

	Current situation (thousand €)	Scenario (thousand €)
Finnish Food Authority and Customs	-	-
Municipal Control Authorities	-	-
Companies	-	-
Health Care Costs (including productivity losses)	14,442	14,244
→ Cardiovascular Diseases	4,524	4,462
→ Diabetes	64	63
→ Tumours	9,854	9,719
Total	14,442	14,244

Only short-term effects are considered. The number of people dining at staff restaurants is not expected to change, and the monitoring costs of the Heart Association will not increase. Heart Symbol meals would reduce DALYs by about 1.38% (0.3–3.1%), resulting in a reduction in health care costs of approximately €200,000 (Table 24). The new total cost is therefore €14.2 million, which, under the assumptions of the scenario, is only health care costs. As a result, the BoD will decrease by 440 (97–990) DALYs.

The assumptions are that staff restaurants will comply with the Heart Symbol criteria, that production costs will not change and that lunch prices will remain unchanged. The governmental expenses are not expected to increase due to the subsidized lunches.

A summary is presented in Table 25.

Table 25. Summary of excessive use of salt current status and scenario

Salt			
	Current Situation	Scenario	Change
DALYs	32000	31560	-440
Costs (thousand €)	14,442	14,244	-199
	ACER	-451	€/DALY

6.3 Excessive intake of saturated and trans fats

6.3.1 Health effects

Dietary fats can be divided into soft (unsaturated) and hard (saturated) fats based on their physical properties and health effects (THL 2016). Saturated fats refer to fatty acids with only simple bonds between them. Trans fatty acids act in the body like saturated fats (THL 2016). Saturated and trans fatty acids are also commonly referred to as hard fat (Helldán et al. 2013).

Saturated fats increase total cholesterol and harmful LDL cholesterol. The most favourable effects on total cholesterol and LDL cholesterol were observed when saturated fatty acids were replaced with polyunsaturated fatty acids (Mensink 2016; Schwab et al. 2014) or monounsaturated fatty acids (Schwab et al. 2014).

Epidemiological research presents methodological challenges in studying the role of fatty acid intake in the development of later-life cardiovascular disease. For example, not all studies have found an association between saturated fat and disease responses (e.g. Souza et al. 2015, Zhu et al. 2019). In a recent review (Clifton & Keogh 2017), reducing saturated fat intake or replacing saturated fats with carbohydrates reduced overall mortality, although no reduction in coronary heart disease or cardiovascular events was demonstrated. Instead, replacing saturated fats with polyunsaturated fatty acids, monounsaturated fatty acids or good-quality carbohydrates reduced the incidence of coronary artery disease (Clifton & Keogh 2017). Previous clinical studies and a WHO 2003 study have also shown that replacing saturated fatty acids with polyunsaturated fatty acids reduces the risk of coronary heart disease (Micha & Mozafarian 2010).

In addition, saturated fat intake may be associated with unfavourable changes in insulin metabolism, which is a risk factor for type 2 diabetes. There are also preliminary indications about the adverse effects of saturated fat on blood pressure and the risk of ovarian cancer (Nordic Council of Ministers 2014).

Trans fatty acids also increase LDL cholesterol and additionally reduce health-friendly HDL cholesterol (Nordic Council of Ministers 2014). Their intake has been found to be related to the risk of cardiovascular disease (Zhu et al. 2019), total mortality and cardiovascular mortality (Souza et al. 2015).

6.3.2 Prevalence in food and current status in Finland

Saturated fat is obtained from meat and meat products, butter and blended spreads, cheese and liquid dairy products and vegetable fat spreads and oils (Helldán et al. 2013). Some vegetable fats, such as coconut and palm fat, contain high levels of saturated fat (Helldán et al. 2013). Trans fatty acids are obtained either directly from animal foods or from industrially cured fats. Trans fatty acids are also produced in ruminant rumen by bacteria (Nishida et al. 2009), which is why trans fatty acids are naturally found in food from ruminants. The main source in Finland is dairy products. Another source of trans fatty acids are industrially cured vegetable oils. However, today, instead of curing transesterification is commonly used, whereby no trans fatty acids are formed during the process. In Finland, the margarine industry shifted away from esterification in the 1990s, so the current soft plant margarines are not relevant for the intake of trans fatty acids (THL 2015).

Among other things, food labels indicate the nutritional composition of a product (Evira 2018) and the saturated fat content. At present, only saturated fats are counted; the amount of trans fat is not reported (Evira 2014). Currently, trans fatty acids are not considered to be such a health hazard in Finland that their inclusion on labels is justified (Evira 2018). In other EU countries, the intake of trans fats is higher than in Finland, so in the future there may be requirements for limiting or labelling trans fats at the EU level (Evira 2018).

In the Finnish Nutrition Recommendations (VRN 2014), the recommended fat intake is 25%–40% of total energy, of which less than 10% is saturated fat. Trans fatty acid intake should be as low as possible (Helldán et al. 2013) and should remain below 1% of total energy.

According to the Findiet 2012 and 2017 studies, most of the saturated fat intake of working-age people in Finland comes from dairy products, meat dishes and dietary fats (Helldán et al. 2013, Valsta et al. 2018). Milk and butterfat and bovine fat contain 3%–5% trans fatty acids, soft margarines contain 0%–1%, industrial fats contain 0%–7% and deep-frying fats contain 0%–2% (THL 2014). According to both Findiet 2012 and 2017, milk, fats and meat were the main sources of trans fatty acids in the diets of the Finnish working-age population (Helldán et al. 2013; Valsta et al. 2018).

According to the Findiet 2017 study, the proportion of fats in the total energy intake of 18–74-year olds was 37.7% for women and 38.7% for men (Valsta et al. 2018). Saturated fatty acids accounted for 14% (28 g/day) of total energy for women and 15% (38

g/day) of total energy for men. According to the Findiet 2017 study, trans fatty acid intake was 0.4% of total energy. Finns' trans fatty acid intake is very low, so it has no significance for health at the population level (THL 2014). Instead, according to the latest information, 95% of the population consumes too much saturated fatty acid (Valsta et al. 2018).

6.3.3 The burden of disease due to excessive fat intake at present

In Finland during 2014–2016, the excessive intake of trans fats was estimated to have caused a BoD of 2,300–2,400 DALYs due to cardiovascular diseases (University of Washington 2019).

In 2016, Wang et al. published country-specific calculations on the health effects of saturated and trans fatty acids. The WHO ICD-10 classified coronary heart disease (CHD) was the health response in the calculations. The country-specific case-volume data used were from WHO data (WHO 2019). Fat intakes were based on country-specific data or, in their absence, on more extensive data from several countries. The dose responses (relative risk, RR) used in the calculations, with uncertainty, were based on published meta-analyses from European and American studies. Country-specific estimates of the number of cases caused by fats were published as additional material, from which the Finnish material was taken. Fat-related CHD deaths were calculated using the population causality (PAF) method with the formula:

$$PAFi = \frac{\int_{x=0}^m R Ri(x) Pi(x) dx - \int_{x=0}^m R Ri(x) P' i(x) dx}{\int_{x=0}^m R Ri(x) Pi(x) dx}, \quad (10)$$

where PAFi is the proportion of the population by age, gender and country; x is the amount of fat from the diet; Pi (x) is the probability distribution of dietary fat content by age, sex and country; P0i (x) is the optimum amount of dietary fat by age and sex; R Ri (x) is the age- and sex-specific multivariate adjusted mortality risk ratio of fat intake x relative to the optimal intake level; and m is the maximum intake of fat from the diet. The exact distributions used in the calculation are described in OpasNet at <http://fi.opasnet.org/fi/Ruori>.

PAF from calculations of Wang et al. (2016) was updated with the consumption of saturated fats found in the Findiet 2017 study (Valsta et al. 2018). The calculation was performed with a simple ratio assumption using the formula below, where E is the exposure and E10 is the upper limit of the optimal exposure.

$$PAF_{Fin} = \frac{PAF_{Wang} \times (E_{Fin} - E_{10})}{E_{Wang} - E_{10}} \quad (11)$$

The intake data of the Findiet 2017 study are slightly different in terms of age grouping than that in Wang et al. (2016), so data for the 25–69 age group were used for the 25–64 age group and data for the 70+ age group were used for the 65–74 age group. In addition, Statistics Finland's Death Registry data on the number of deaths due to ischemic heart disease in 2012 were used (Table 26).

Table 26. Updated data for saturated fat health effect calculations (average and 95% CI)

Age (years)	IHD ¹⁾ amount	Intake (Findiet 2017) (%E ²⁾)			PAF; saturated fatty acids (intake >10%E)		
		Average	Lower li- mit	Upper li- mit	Average	Lower li- mit	Upper li- mit
25–64	1 914	13.8	13.7	13.9	0.067	0.054	0.081
70+	9 185	12.9	12.7	13	0.047	0.033	0.061

1) deaths from ischemic heart disease

2) percent of energy intake.

The IHME Institute's GBD data provided the total BoD deaths due to ischemic heart disease in 2012. When combined with the population study of the Wang study (2016), the burden of saturated fat was calculated (Table 27).

Table 27. Burden of disease from saturated fats (average and 95% CI) according to RUORI model

Age (years)	Saturated fatty acids (intake >10 %E)		
	Average	Lower limit	Upper limit
25–69	4,200	3,300	5,200
70+	4,900	3,400	6,500
Total	9,200	7,400	11,000

In Finland, the burden caused by saturated fat was estimated at 9,200 DALYs/year. This is clearly less than the major risk factors examined, that is, excessive salt intake and the underconsumption of fruits and vegetables. However, only BoD caused by ischemic heart diseases were considered for saturated fats, while for salt, fruits and vegetables DALYs had been possible to determine also for other diseases such as other cardiovascular diseases, tumours and diabetes. However, the issue is complicated, as eating too much saturated fat can easily lead to overweight, which is an independent risk factor for BoD. Measures to reduce saturated fat intake might thus reduce overall energy intake and thus overweight, significantly increasing the impact at the same time.

6.3.4 Costs related to surveillance and morbidity

Saturated fats and trans fats are not subject to regulatory controls except for ensuring that labelling is correct.

According to studies by the IHME Institute in 2016, the burden of cardiovascular disease in Finland was 298,000 DALYs, of which 0.7% was attributed to trans fats. Trans fat intake was not estimated to have an effect on other health effects. The total cost of cardiovascular disease is presented in the context of the underconsumption of fruits and vegetables.

Excessive fat intake is very similar to salt intake. For example, the same EU Regulation 1169/2011 defines how companies should report the fat content of their food products, especially saturated fats.

In terms of control costs, the situation is similar to that of salt. Legislation does not set limits for fat content; therefore, this review focuses on health care costs. Of the health effects, cardiovascular disease is the clearest effect, which is why this report focuses exclusively on it (WHO 2003; Uauy et al. 2009). The burden of excess saturated fat intake in this project, estimated at 9,200 DALYs/year, was 3% of the total cardiovascular disease burden estimated by the IHME Institute (University of Washington 2019a) in 2016. This gives us a cost of almost €400,000/year in health care costs. At present, it is not known whether excess saturated fat causes non-cardiovascular disease (Micha & Mozaffarian 2010; Schwab et al. 2014).

6.3.5 Scenario

To reduce the intake of saturated fat, the same scenario was studied as in the case of excessive salt intake, that is, replacing typical staff restaurant meals with Heart Symbol meals. The project calculated an average of 12.9 g of saturated fat in the regular lunch and 5.4 g in the Heart Symbol lunch. On a weekly basis, saturated fat intake was estimated to decrease 22.0–58.1 g by switching to lunches meeting the Heart Symbol criteria. The other assumptions in the scenario were the same as in the salt scenario.

The scenario was chosen for the following reasons. The shift from high saturated fat to low saturated fat meals reduces the average saturated fat intake of the population and the resulting burden of cardiovascular disease. At present, 95% of Finns consume too much saturated fat (Valsta et al. 2018). A study published in 2017 (Raulio et al. 2017) showed that replacing regular foods with foods that meet the Heart Symbol criteria decreased the intake of saturated fat from the current 14 E% to below 10 E%,

the recommended level. Lunch meals are especially important because they are eaten by a large number of Finns and can serve as a model for other meals of the day, thus improving the quality of the diet and the nutritional habits of the population (STM 2010). By investing in mass catering, there would be a significant public health benefit.

6.3.6 Impact of the scenario on burden of disease and its cost effectiveness

Heart Symbol meals at staff restaurants affect only about 5% of the population, although they are quite effective in that section of the population. Reducing saturated fat intake was estimated to reduce the BoD by 530 DALYs/year (95% confidence interval 310–800 DALYs/year). The scenario is identical to the salt scenario.

Table 28. Costs related to the excessive consumption of saturated fats and trans fats

	Current situation (thousand €)	Scenario (thousand €)
Finnish Food Authority and Customs	-	-
Municipal Control Authorities	-	-
Companies	-	-
Health Care Costs (including productivity losses)	399	376
→ Cardiovascular Diseases	399	376
Total	399	376

The number of people dining at staff restaurants is not expected to change, and the cost of Finnish Heart Association supervision will not increase. The post-scenario DALY will be down 5.8% from the current 9,200 DALYs to 8,670 DALYs. This will also reduce health care costs by €23,000 (Table 28). The assumption is that staff restaurants will comply with the Heart Symbol criteria, that production costs will not change and that lunch prices will remain unchanged. The governmental costs of state-subsidized lunches is not expected to increase.

A summary of the change from the current state to the state of the scenario is presented in Table 29.

Table 29. Summary of excessive consumption of saturated fats and trans fats current status and scenario

Saturated fats and trans fats			
	Current Situation	Scenario	Change
DALYs	9,200	8,670	-530
Costs (thousand €)	399	376	-23
	ACER	-43.39	€/DALY

7 Food safety requirements for export

Food exports are important to Finland, and the goal is to double them to €3 billion by 2025, according to Business Finland's Food from Finland programme. The good reputation and safety of Finnish food is the key to exports. In this project, the food safety requirements for exports were mapped by interviewing experts from the Export Team of the Finnish Food Authority.

The importance of national contaminant control, microbiological control programmes and animal disease control in Finland's food export industry was emphasized in the interview responds. The information requested by the countries Finland exports to include the content and implementation of the control plans regarding the previously mentioned fields and sometimes the results of the previous year's control programmes. The target countries of export may also require that the maximum levels of contaminants permitted in Finland or the EU be compared with their own corresponding limits. In addition, some target countries require the Central Authority (Finnish Food Authority) to carry out more frequent inspections of export establishments than is otherwise done. For example, in 2018, 20 control missions were conducted to verify that the requirements set for facilities nationally and by the exporting countries were met, and 22 audits were conducted to determine how well inspectors had realized the special characteristics of export. Each of these inspections lasted for at least one day and always involved at least two officials.

In addition to surveys on contaminant control, the exporting countries sometimes come to the authorities with more specific inquiries about individual chemical food hazards, such as additives, and their approval process. If controlled substances are detected (in the analyses of the target country) or if the previous year's control results are not provided, the export permit for that food, the export permit for an individual establishment or the export of a specific food category (such as fishery products) may be compromised.

It is essential to check for *Listeria*, *Salmonella*, *Campylobacter* and *Trichinella* when export-ing food and feedstuffs. Biological hazards also include all major and dangerous animal diseases, such as any World Organisation for Animal Health -listed animal diseases and other pathogens of interest to the target countries. The low prevalence of salmonella achieved through self-control and surveillance in Finland for decades is an important factor facilitating the export of food. Therefore, experts consider it important to check for salmonella when exporting food. It is also important to check for

many other zoonotic agents. For example, countries must consider the impact of African swine fever on pork exports. Many countries require that Finland's export permit for pork guarantees that Finland is free of African swine fever. This applies both to farmed pigs and to wild boar. Depending on the food, *Listeria* controls are of particular importance for Russian, Chinese and US exports; *Listeria* findings may result in plant-specific export bans on goods to these countries. Some countries importing Finnish goods may also require that every pig carcass, at least for export, be examined for trichinae, and some countries require that the pigs for export originate from an area that has been free of trichinae for a certain period. In recent years, genetically modified organisms (GMOs) have also been featured prominently in Russian exports, for example.

So far, there have been very few issues regarding drug-resistant microbes in exporting countries, although the situation worldwide has worsened significantly in the last 10 years. In its response to microbiological control programmes, Finland also mentions the control of resistant microbes, even if not directly asked.

Nutritional factors for food exports are not significant from an official point of view, but they may be of commercial importance. Countries importing Finnish goods are interested in the cleanliness and safety of food imported from Finland, but there is no discussion on nutrition at the official level. The exception is genetically modified products, but even in this case, exporting countries consider the safety aspect. It is the responsibility of export companies to determine the requirements of the destination country, for example, with regard to labelling.

In conclusion, reducing the control of biological or chemical hazards for Finnish food exports could lead to the need for new export negotiations and further clarifications or, at worst, export bans. Therefore, the reduction of controls was examined as a scenario only for trichinella but in a way that could meet current or future export conditions. In other words, a situation where only slaughter pigs for export would be investigated would not affect people's illness but would significantly reduce costs for companies.

8 Conclusions

8.1 Main results

The main objectives of the project were to identify the major health and economic risks related to food and nutrition in Finland (Objective I) and to classify them to provide information for risk management (Objective II). Another objective was to estimate the costs of treatment, prevention and control of foodborne diseases. According to the study, the biggest risks are related to nutritional factors. The results indicate that the increased consumption of fruits and vegetables and the reduction of salt and saturated fat in the Finnish diet would increase the amount of healthy life years by tens of thousands of years and save millions of euros.

Another objective (Objective III) was to identify the food safety requirements of exports. According to the study, the reduction of controls could lead to problems with export requirements. Finland's export destinations particularly monitor the control of biological and chemical hazards, and the absence or weakening of controls could, at worst, lead to export prohibitions.

The project identified a number of research areas and information gaps (Objective IV), which are discussed in Chapter 8, sections 8.3 and 8.5. The most important requirements are more accurate and comprehensive registry data and cost information, as well as information on the incidence, concentration and dose response of different food hazards. More consumer research is needed in this area.

For each of the exemplary factors causing health problems used in the project, calculations for the current status were conducted (Objective V). Proposals for progress on the examined health hazards were evaluated from a public health and cost perspective using scenarios (Objective VI). The most influential of these involved nutritional changes in the diet (Tables 30 and 31 and Figure 6). Table 30 summarizes the BoD and total cost of studied hazards in 2014-2016, as defined in the previous chapters. The impacts of the scenarios on BoD and costs are presented in Table 31.

Table 30. The annual burden of disease in Finland caused by the example factors and the current total costs caused by the exposure agents

Agent	Burden of disease (DALY in a year), average (95 % CI)	Main source	Total costs calculated in the project (million €)
Listeria	670 (400–950)	WHO, updated with the case data from the Finnish case registry	5.9
Norovirus	200 (73–430)	WHO, updated with the case data from the Finnish case registry	7.4
Toxoplasma	460 (250–740)	WHO, based on the incidence in Europe (acquired infection)	12.0
Trichinella	0	No cases in Finland after the 1970s	4.5
Physical hazards	not calculated	-	-
Aflatoxins	9.6 (2.6–28)	WHO, updated with Finnish exposure levels, cancer registry data and liver cancer burden of disease from IHME GBD	1.5
Dioxins	37 (4.8–110)	GOHERR project	2.9
Lead	570 (0–4,100)	Calculated in the project from Lanphear 2005 and Finnish exposure data	31.8
Underconsumption of fruits	36,000 (19,000–53,000)	IHME GBD	39.6
Underconsumption of vegetables	29,000 (13,000–44,000)	IHME GBD	
Excessive use of salt	32,000 (7,800–58,000)	IHME GBD	14.4
Excessive use of saturated fat	9,200 (7,400–11,000)	IHME GBD; Wang 2016	0.4

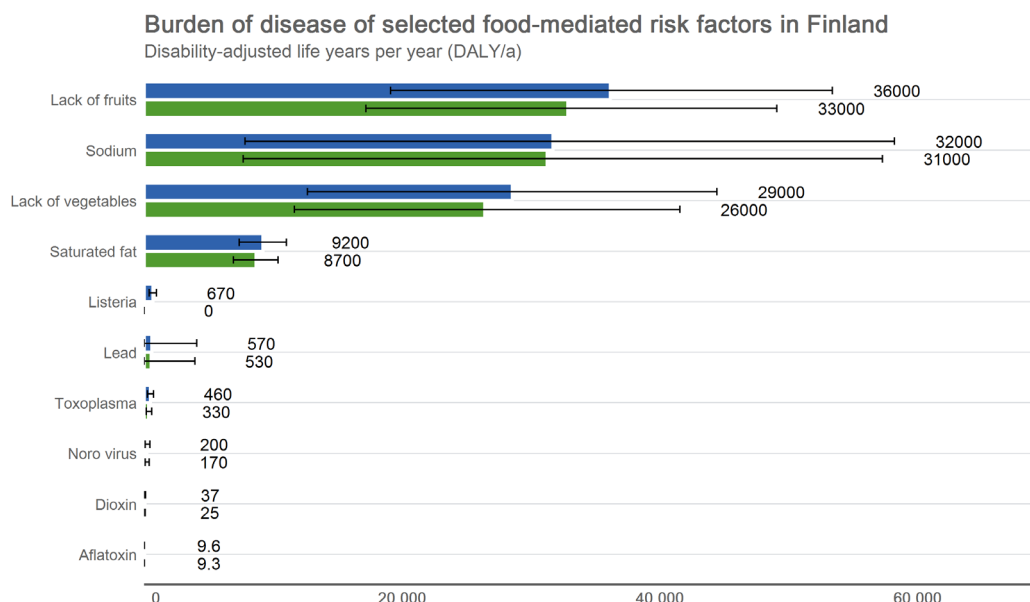


Figure 6. Disease burden in Finland of exposure agents assessed in RUORI project. The current estimate is shown with a blue bar, and the green bar shows the situation after the scenario to reduce the risk. It can take decades to develop a chronic disease, so the burden accumulates during several years; therefore, the impact of scenarios manifests slowly. This is unlike acute diseases that show immediate effects. There are several data sources, notably WHO and Washington University (for more details, see the text for each exposure agent).

Table 31. Change of burden of disease and costs in the scenarios shown for each exposure agent. The average cost-effectiveness ratio (ACER) is the total cost in relation to the total health benefits.

Agent	Change of burden of disease (DALYs/year), average (95% CI)	Change in costs (million €)	ACER (€/DALY/y)
Increased fruit consumption	-3 300 (-7700 ... -160)	+ 113.10 ¹⁾	20,944
Increased vegetable consumption	-2 100 (-5200 ... -88)		
Listeria	-670 (-950 ... -400)	+1.03	>1,534
Decreased intake of saturated fat	-530 (-800 ... -310)	-0.02	-43
Decreased intake of salt	-440 (-990 ... -97)	-0.20	-451
Toxoplasma	-120 (-250 ... -47)	+2.20	18,346
Lead	-40 (-210 ... 0)	+0.03	625
Norovirus	-23 (-80 ... -0.7)	+21.35	928,209
Dioxins	-12 (-67 ... +35)	0	-
Aflatoxins	-0.2 (-0.9 ... -0.08)	+0.004	18,320
Trichinella	0 (0 ... 0)	-3.70	-

1) The cost estimations refer to the combined fruit and vegetable scenario. To calculate the ACER value, the costs for the combined scenario and the sum of the DALY reductions were used.

8.2 Conclusions drawn from the results

Food is a major contributor to the health of the population, both in terms of nutrition and food safety. In the RUORI project, the nutritional factors, especially the inadequate consumption of fruits and vegetables, had the greatest impact on the BoD of Finns. This underconsumption causes a loss of tens of thousands of DALYs each year because of cardiovascular disease and cancer, among other things. The excessive intake of salt had the second greatest impact, affecting the health of Finns by the loss of tens of thousands of DALYs. The intake of saturated fat was also a major public health problem. Of the biological food hazards, *Listeria* was the major contributor to public health, with a burden of about 700 DALYs, which was greater than the combined BoD of norovirus, toxoplasma and trichinella. The annual BoD of the chemical hazards lead, aflatoxins and dioxins was approximately 600 DALYs in total, and the burden of lead was the largest of these three factors.

There is no unambiguous formula for converting DALYs into costs. According to the literature, the cost of one DALY in the Western world is often estimated between €10,000 and €100,000. However, some practices for change have evolved. In the UK, for example, it is relatively easy to get approval for projects where the reduction of one DALY is achieved by investing less than €10,000, but investing more than €30,000 requires other significant justification.

Food control costs are a major expense. A number of national and international regulations, such as the so-called microbial criteria regulation and the contaminants regulation, determine the acceptable criteria for foods. Compliance, for example, monitoring to ensure concentrations are below the maximum levels, is monitored via companies' own-check systems and via official control. Based on the project results, by implementing the scenarios the best health benefits would result from an increase in fruit and vegetable consumption (€113 million), while increasing the supply of Heart Symbol meals would save €220,000 in total costs.

Due to the many years of own-checks by companies and official control, the BoD related to biological and chemical food safety in Finland is relatively low. If food controls were reduced to reduce costs, the situation could quickly deteriorate, as, for example, one additional *Listeria* case already corresponds to an increase in the BoD of 10 DALYs. In addition to public health, reducing controls could hamper trade, particularly exports.

Most of the costs of control fall upon companies. Therefore, the scenarios that affect mostly businesses also have the greatest financial impact. The dioxin and trichinella scenarios are the most economically efficient, as both DALYs and costs are reduced.

The norovirus scenario is the most ineffective, as a reduction of one DALY unit costs €1million.

Currently, food control focuses mainly on managing biological, chemical and physical hazards. However, according to this study, nutritional factors are of major importance for public health, and further consideration should be given to ways of influencing them through legislative and other guiding methods. Guiding methods for nutrition have recently been reviewed in the 'The Components of and the Steering Instruments for the Finnish Food Environment' report (Erkkola et al. 2019). According to an extensive literature review, most research evidence of non-economic guiding methods related to the effectiveness of standards and regulations, nutritional labelling and the combination of different guiding methods. Food choices can also be guided by financial aspects, such as taxes and subsidies.

Food safety was found to be essential for Finnish food exports. Most attention in export negotiations and reporting on continued exports is paid to biological and chemical food hazards and their national control. *Listeria*, *Salmonella*, *Campylobacter* and porcine trichinae are the biological hazards of most concern in exporting, and the countries of export specifically want information on their prevalence and control. For chemical food hazards, the target countries require information on the control of contaminants and on control results. In addition, the target countries may require more frequent inspections of approved establishments. Reducing controls on biological and chemical food hazards could lead to export bans or the need to reopen export negotiations. In contrast, nutritional factors are not essential in relation to exports.

It should be noted that the scenarios did not address situations where the moderating of hygiene controls could lead to a dramatic increase in some pathogens. Consequently, it cannot be directly deduced from the minor effects of the scenario whether exposure would be insignificant to public health in all circumstances.

The BoD and the costs of the factors selected for the project were identified through scenarios that were considered most feasible by a joint workshop of companies, authorities and researchers. In light of the project outcomes, the following results were obtained:

- **Abolition of VAT on fresh fruits and vegetables.** It is estimated that an increase in fruit consumption as a result of the scenario would reduce Finns' BoD by 3,300 DALYs annually, and an increase in vegetable consumption would reduce Finns' BoD by 2,100 DALYs. This scenario has an additional cost of €113 million due to tax loss and the ACER of approximately €21,000/DALY.

- **Replacing staff restaurant meals with Heart Symbol meals.** It is estimated that a reduction in saturated fat intake as a result of the scenario would reduce the BoD for Finns by 530 DALYs/year, and a decrease in salt intake would reduce the BoD for Finns by 440 DALYs/year. Only about 5% of Finns are affected by this scenario, but for them it has an effective health promoting effect. The scenario reduces costs by €222,000.
- **Reducing the number of Listeria infections through control measures.** The scenario assumes that increasing sampling and rejecting all positive food samples would result in zero cases of listeriosis, which is a clear overestimation of the effectiveness of the measure. The impact of the scenario on the BoD of Finns would thus be no more than 670 DALYs. The cost of the Listeria scenario is approximately €1 million and the ACER is theoretically at best €1,535/year of DALYs.
- **Reducing the number of norovirus infections by analysing surface samples.** This scenario involves analysing samples from commercial kitchens and food premises manufacturing RTE foods during the period when most norovirus infections occur. It is estimated that the scenario would prevent up to 35% of norovirus infections, and the BoD for Finns would be reduced by 23 DALYs. The cost of the Norovirus scenario is €21.3 million, and the ACER is €930,000/DALY.
- **Testing pregnant women for toxoplasmosis.** This would reduce the BoD by up to 120 DALYs by eliminating congenital cases of toxoplasmosis. The additional costs would be €2.2 million, with an ACER of €18,346/DALY.
- **Limiting the control of Trichinella only to slaughterhouses exporting pigs.** The number of carcasses to be tested was assumed to be the same as the number of pigs to be exported. The impact of the scenario on the Finnish BoD was estimated to be insignificant, but its cost would be reduced by €3.7 million.

The results of the scenarios concerning the major causes of foodborne diseases in Finland are presented above. The Trichinella scenario is particularly interesting because of the savings of control costs.

During the project, a number of information gaps were identified, the most significant of which are detailed in sections 8.3–8.5. The results provide preliminary guidance on what cost-effective measures could be taken to further investigate without compromising public health. The project did not comment on the extent to which or the order in which changes should be made.

Due to the lack of information, the project estimates are subject to uncertainty, and it is recommended they be refined through further national research. However, regarding the BoD, some conclusions are solid and would not change much with further studies. For example, the nutritional factors have a large BoD, and the BoD for chemical factors, with the exception of lead, was small, especially when compared with the concern they typically provoke.

8.3 Dearth of information

The cost-effectiveness assessments of the project did not take into account the costs of the rejected products, as their share could not be estimated based on the information available.

A survey on the costs of official control and own-checks carried out in the project provided only a limited number of answers. For example, there were no answers from restaurants or grocery stores. Due to the lack of information, it was assumed that the food hazards in stores are indirectly controlled by an own-check system, avoiding cross-contamination, monitoring temperatures, etc., and that only surface hygiene samples to control general hygiene are collected in stores. In addition, it was assumed that there are precise criteria for ensuring the safety of raw materials and food in the supply contracts and that there is no production of food at grocery stores.

The cost of controlling domestic water was not included in the cost estimates. According to estimates by the Finnish Water Utilities Association, the total cost of domestic water control by authorities in 2018 was approximately €3 million (Riina Liikanen, personal communication), but the contributions of chemical and biological hazards to the total cost could not be determined. Of the chemical hazards studied, only lead has limits in the Domestic Water Regulation; aflatoxins and dioxins are not present in household water.

The information collected via the survey derived from a variety of sources, and its coverage has been correlated, for example, with the numbers from OIVA registers of first destinations and premises manufacturing RTE food.

Only some of the morbidity costs associated with the scenarios were only available; therefore, assumptions had to be used in assessing cost effectiveness. Similarly, the BoD was partly based on assumptions and international estimates, as national data were not available.

8.4 Limitations and assumptions

Assessments of the BoD involve methodological simplifications in order to compare different exposures and health responses together. For example, when calculating numbers of cases, it is not usually possible to know whether the reduction in life expectancy in the population is because some people lose several years or because many people lose a smaller number of years. Similarly, it is not clear how to calculate the BoD for diseases from which people would have fallen ill or died had they not died from another disease. In addition, a reduction in exposure leads to a reduction in the BoD and thus an increase in the burden of some other diseases due to population aging. The changes are therefore dynamic, and the various diseases interact with each other.

Simplifications and assumptions about the behaviour of diseases are thus necessary. Therefore, the BoD should be considered a statistical indicator of the magnitude of the various factors. Calculated case numbers do not mean that a given exposure would kill an estimated number of people each year. Although we estimate the causal relationships considered to be real, due to the nature of the BoD we mean that the burden is attributable to a particular exposure, even when we speak of causation, because we do not know the true number of cases. Not all data were available for the years 2014–2016. Depending on the factor, the project utilized data that is as close as possible to these years, for example, food consumption data for 2017 and exposure estimates based on 2012 food consumption data. Estimates of BoD (DALYs) were determined using a variety of methods and data from different sources, possibly with varying degrees of accuracy in the absence of completely comparable data.

The analysis of nutritional factors was based on the IHME GBD data, where the recommended limits for the consumption of fruits and vegetables and the limits on salt intake differ from the Finnish nutrition guidelines. Thus, the BoD caused by nutritional factors may be either overestimated or underestimated compared to the calculation of BoD in accordance with Finnish nutrition guidelines. In addition, IHME GBD results may overlap, resulting in a higher estimate of BoD. The BoD of biological food hazards was mainly determined based on WHO calculations by adjusting the estimate for Europe according to case data from the Finnish Register of Infectious Diseases. Other assumptions in the burden of biological hazard calculations are thus based on international estimates, which may lead to either overestimation or underestimation. Biological factors are associated with underreporting, as only cases where a patient was referred to a doctor and was tested and the test results were reported are included in the register. These may represent only a few percent of actual cases. For example, 94% of norovirus cases are internationally estimated to be unregistered (Tam et al. 2012), and in the subset of foodborne cases the underreporting is probably similar. Finnish data on the frequency of underreporting have not been studied. It

should also be noted that the BoD assessment for biological food hazards only takes into account acute diseases and that the burden of sequelae remains unknown.

The aflatoxin BoD was determined based on WHO calculations by adjusting the estimate based on data from the Finnish Cancer Registry and utilizing an international estimate of exposure due to the consumption of peanut products. The BoD for other chemical food hazards was determined based on national estimates.

8.5 Further research requirements

In the future, it would be important to conduct a broader study of the BoD due to food and nutrition and the costs associated with it, as this project was a pilot project that mapped the available information and identified the major informational gaps. For example, there was a lack of national data about underreporting related to registers, which may differ significantly from international estimates due to different societal structures and practices. Therefore, it would be necessary to clarify the proportion of patients entering the registers in relation to all cases of the disease in question in Finland.

More accurate calculations would require comprehensive information on the prevalence and concentration of different health-related factors for different foods and categories of food at critical points in the food chain. The current data is typically based on conclusions based on very small number of measurements. However, there may have been a lot of measurements with background information, but these data are not available to researchers. The observation made in this report also suggests that own-check samples are frequently taken and investigated but that large-scale use of the results is left to up to individual companies. Often, only the results with findings and not the ones where nothing was found are reported from analyses conducted in research projects. Reporting all the analyses would provide information for setting the results in proportion.

The authorities have made numerous recommendations on food safety and nutrition, but so far, no comprehensive study has been carried out in Finland on how aware consumers are of these recommendations, whether they are being followed and which methods would be most effective in reaching the various population groups. The Finns are not a cohesive group, so the survey should cover a wide range of population groups to find, for example, the regional, economic and ethnic differences (possibly influenced by language barriers) and to take them into account for improving communication. Similarly, it should be studied how familiar different companies are with

legislation and the degree to which they comply with legislation and recommendations. There may also be demographic differences affecting product safety in the way different businesses work.

Studies have often focused on the food chain from the farm to the shopping bag, but many of the biological and some chemical food hazards are significantly influenced by the consumer's behaviour at home beyond official control. The Finnish Food Authority's Risk Assessment Unit has developed a method for food consumption interviews that also explores the factors involved in the handling and storage of food at home and thus provides information relevant to risk assessment that goes beyond conventional food interviews, such as the Finravinto studies. Applying the method to data collection, particularly for risk groups such as the elderly or pregnant and breastfeeding women, would provide valuable insight into both public health promotion and targeting official controls, but the Authority's current budget does not allow this. Data collection would only be possible with separate funding.

Factors influencing consumer eating habits, such as the impact of the environment, for example, by highlighting healthy choices and making them easy to choose, have been studied in Finland (Erkkola 2019). In this project, it was assumed that it is possible to influence consumer choice by lowering the price of fruits and vegetables by intervening in taxation and by adjusting the nutritional content of subsidized lunches with limitations on salt and saturated fat. The terms of government-sponsored meals should also be looked at from a public health perspective, for example, with regard to the composition of school meals and by targeting lunch voucher subsidies only on healthy foods.

In addition, it would be necessary to carry out a more detailed assessment of the costs of control and own-checks, which would include costs for operators, for example, in terms of refurbishment and extra cleaning. Further research is also needed to identify the most cost-effective and efficient testing and risk-management methods.

Methods to replace surveys should be developed. Whether targeted at businesses, authorities or individual citizens, they provide information that is otherwise unavailable. Unfortunately, fewer and fewer respondents respond to surveys. In addition, besides willingness, the interviews require a lot of resources. Therefore, research tools are desperately needed in place of survey and interview studies.

8.6 Recommendations

Food is associated with cultural perceptions and a great deal of emotion, and it is not easy to control the way it is prepared, served or eaten. Food is a matter of common concern to us, which is why there is a daily need for it to meet our physical and mental requirements. Deficiencies in food safety and nutrition are detrimental to public health, whether in the short or long term. Using example cases, this project aimed to study the causes and consequences of the health risks associated with food in Finland and to find appropriate risk management measures. The onset of foodborne health hazards takes time, and so even the strongest efforts to control them at the population level will take years or decades.

In the scenarios, the theoretical maximum for reduction of the BoD was calculated. Realistic estimates strongly depend on several factors, for which sufficiently accurate information was not available. The actual decrease may be only a fraction of what the project estimates; therefore, further studies are needed to refine the estimates.

Based on the results of the project, several proposals for action are suggested, the most important of which are the following:

- The risk assessment of the impact of the Finnish food system on public health needs to be deepened and expanded so that the various health hazards can be directly compared.
- The costs of food control and nutrition-related health care should be further evaluated and compared with the benefits (cost–benefit analysis). In particular, it should be determined what kind of food control is effective in preventing health hazards and what kind of control measures could be eliminated without adverse effects.
- The nutritional factors addressed in the report pose a significant BoD, and attention should be paid to the associated remedies. The potential of legislation, taxation, communication and other means to promote health must be explored openly. At the same time, when planning changes, the means by which the effects of steering are measured and evaluated must be planned and financed.

8.7 International comparison and the value of control

Figure 7 shows the BoD due to dietary risk factors (excluding malnutrition) on the one hand and hygienic risk factors (including handwashing, clean drinking water and sanitation) on the other. Thus, foodborne microbes are not specifically included, but the figure gives a reasonable estimate for microbial diseases for a comparison of countries.

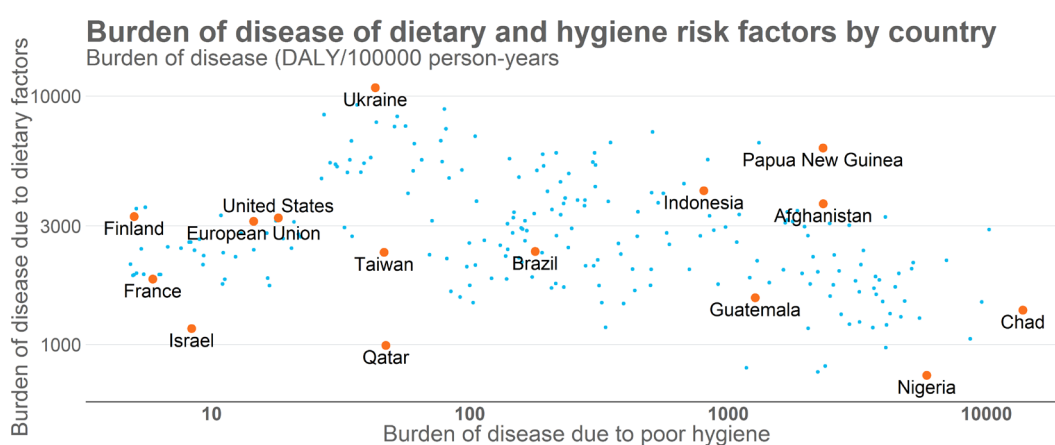


Figure 7. Burden of disease (DALY/100,000 person years) by country due to dietary and hygienic risk factors (Washington University, 2019c)

Note that the scales are logarithmic and dietary risks show 10-fold differences but that hygienic risks may show more than thousand-fold differences between countries. Finland is an average Western European country in terms of dietary risks but is among the world's best in terms of hygienic risks. The numbers in Figure 7 can be compared with the results in this report by scaling them to the Finnish population, that is, by multiplying them by approximately 50.

The global comparison shows that there is a lot to do to reduce dietary risks. Even if the BoD is reduced by half, we only approach levels where many countries already are, so the level should be achievable in theory. Of course, making cultural changes, including to food culture, is always challenging.

In contrast, almost no country has reached a better situation in terms of hygienic risks than Finland. Therefore, the focus should be on issues that might deteriorate the current good situation. For example, the salmonella risk in Finland is very low even when compared with close neighbours, and this situation should be maintained. However, even if our hygienic situation deteriorated to the average EU levels, the absolute BoD

would increase by only 500 DALY/year. A similar improvement should be easily achievable with dietary changes.

In the RUORI project, it turned out to be difficult to find information about the impacts of food monitoring on hygiene. It would be important to be able to estimate the impact of changes in monitoring on disease burden. With hygiene, the interest is specifically in whether monitoring can be reduced without adverse health impacts. The monitoring is typically obligatory, and therefore no data or experiences emerge regarding alternative approaches.

The situation can be improved in two different ways. First, the actions should be documented in cases where quality problems emerge. Data about rejected batches and other actions help to estimate what risks were avoided when a quality issue was identified, that is, what the value of monitoring was. *Trichinella* is an interesting, extreme case; because positive samples are never found, the monitoring has no impact on actions in practice, even if batches were rejected in a theoretical case of a contamination. Therefore, the value in contamination reduction is zero, and all benefit comes from maintaining a good reputation. Regarding other microbes, RUORI did not have similar information available, even if the food industry probably had it in their own files. Collaboration could make this data available for societal use.

Second, experiments can be performed on one hand in the production chain (dioxin removal was tested in fish oil production, and it appeared so effective that concentration monitoring is no longer necessary) and on the other hand in identifying the most useful monitoring points (the preventive approach of hazard analysis and critical control points is still a good practice).

The dietary situation is different. Food items can be produced by standardizing the health-related constituents to a healthy level. The dietary quality is predictable and is adjustable by the producer. Additional challenges are in influencing individuals' behaviour in a way that results in an overall healthy diet.

Also in this area, experiments could produce new additional value. Even the limited experiment about basic income produced important information about what aspects can be affected by basic income and what aspects cannot. Similarly, healthy food taxation, sugar tax or Heart Symbol meals and their effectiveness and applicability should be studied using experiments. Successful approaches could then be scaled up. The food industry and retail market obviously make their own experiments and supposedly are well aware of how the sales of a product can be increased by good layout, pricing or packaging. However, the objectives are partly contradictory to public health. It is also difficult to see how these trade secrets could be made available to society to promote health.

A summary conclusion can be made based on the country-wise comparison of dietary and hygienic risks. Monitoring is most valuable in situations where the quality of raw materials, processes and end products vary significantly. Then monitoring is an effective way to guide processes to be more healthy, for example, by rejecting contaminated batches. In poor hygienic conditions, the importance of hand washing is known without having to measure, and with high-quality processes there is little to reject. With dietary issues, the variation in quality is not in the products but rather in the choice of individuals to consume healthy or unhealthy products. There are probably large variations in the knowledge and perception of dietary risks as well. These should be studied and understood better to help design actions that improve public health.

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