

Collaboration

Independent Science to Support Food Safety and Public Health Protection in Ireland

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Abstract

The Food Safety Authority of Ireland (FSAI) is a science-based independent government agency dedicated to protecting consumers' safety and interests in the area of food safety, hygiene and authenticity. This article briefly describes the role and structure of the FSAI and focuses on its scientific advisory body, the Scientific Committee.

The current FSAI Scientific Committee is composed of a Chair and 14 members appointed by the Minister for Health in February 2021 for a five-year term. The members of the FSAI Scientific Committee are independent scientists from a broad range of disciplines in the food field, but not from the food industry. They act on a voluntarily basis and advise the FSAI Board on scientific matters underpinning food safety and nutrition through the adoption and publication of scientific reports. These scientific opinions are based on the latest and best scientific information and data available.

Throughout the history of the FSAI, the FSAI Scientific Committee and its subcommittees have proven crucial in assessing risks to consumers from food, which underpins strong risk management decisions and the development of policies that ultimately benefit overall public health. Some recent examples of scientific opinions adopted by the FSAI Scientific Committee are summarized in this article and the current and future work of the Committee is outlined.

Key words

Scientific Committee, FSAI, Ireland, food safety, risk assessment.

1. An introduction to the Food Safety Authority of Ireland (FSAI)

The FSAI was established in 1998 under the Food Safety Authority of Ireland Act, 1998 (Government of Ireland, 1998), which came into effect on 1 January 1999, meaning that it is one of the world's very first food safety agencies operating independently from government departments or ministries. The FSAI is a science-based independent government agency dedicated to protecting consumers health and interests in the areas of food safety, hygiene and authenticity through the enforcement of EU and national food legislation in Ireland.

The FSAI regulatory oversight of the food chain -from the farm gate to the consumer- is enabled through service contracts with 33 individual state agencies and government departments. Service contracts set out an agreed level and standard of food safety activity that the official agencies will perform on behalf of the FSAI. The FSAI's role is to coordinate the activities of these official agencies with the clear purpose of ensuring that consumers in Ireland, as well as consumers of Irish food in countries across the world, have access to safe food and trustworthy food information.

The vast majority of the FSAI enforcement work and that of the frontline agencies goes relatively unnoticed by the general public, with the exception of the food incidents notifications and the monthly publication of infringement notices given to food businesses that are found to be in breach of EU or Irish food law, sometimes putting consumers health at risk. However, over the 21+ years of its existence, the FSAI has come to international prominence on a few occasions.

One occasion was in 2013 when, after a two-month long investigation, the presence of significant amounts of undeclared horse meat was identified in beef products sold on the Irish market, which subsequently became an EU-wide problem known as 'the horsemeat scandal' (O'Mahony, 2013). This issue resulted in an increased awareness around food fraud among EU consumers and policy makers and a greater interest both by government departments and the food industry in the use of laboratory analyses, particularly targeted DNA analysis, to ensure the integrity of many meat and plant-based products.

The organizational chart of the FSAI is shown in Figure 1.

The FSAI reports to the Irish Minister for Health, who appoints the members of the FSAI Board and, in consultation with the Board, the members of the FSAI Scientific Committee and the FSAI Consultative Council. In February 2021 a 15-member Scientific Committee were appointed for a 5 year term.

The Scientific Committee is composed of independent scientists acting on a voluntarily basis who advise the Board on scientific matters underpinning food safety and nutrition through the adoption and publication of scientific reports. The Scientific Committee may establish subcommittees in specific subject areas to develop its advice.

Within the FSAI there are five executive functional areas: (i) Corporate Affairs, (ii) Enforcement Policy, (iii) Audit, Incidents and Investigations, (iv) Regulatory Affairs and Compliance Building, and (v) Food Science and Standards. An important function of the Food Science and Standards functional area is the management and facilitation of the work of the FSAI Scientific Committee and its subcommittees.

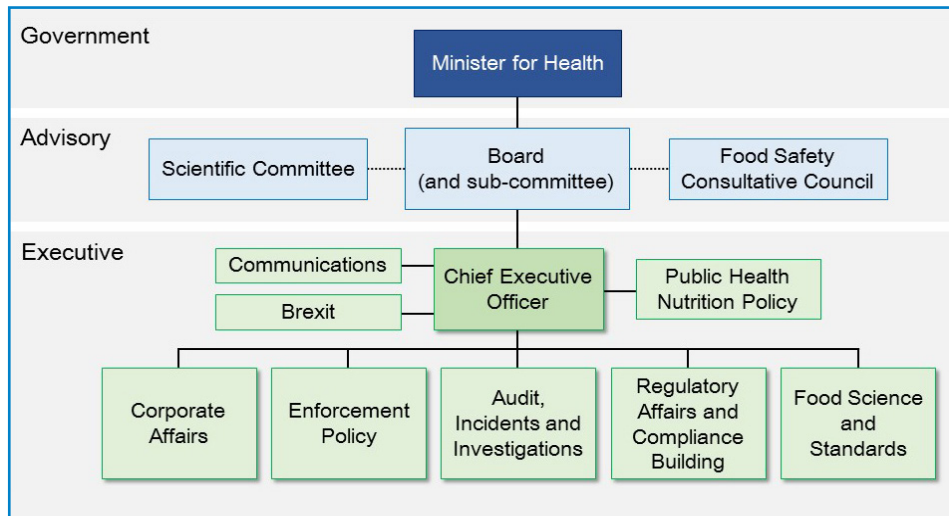


Figure 1. FSAI's organizational chart.

2. The FSAI Science Strategy 2020-2024

In June 2020, the FSAI published its second Science Strategy for the 2020-2024 period, which outlines how the Authority will achieve the scientific elements of the FSAI Corporate Strategy until 2024 (FSAI, 2020). The science strategy encompasses FSAI scientific work in the areas of risk assessment, risk management, science communication and regulation within a range of scientific disciplines such as microbiology, chemical safety, food science and technology, veterinary science, environmental health and public health nutrition.

The science strategy is designed to underpin the regulatory activities of the FSAI and articulate the scientific and technical expertise necessary to promote compliance by the food industry, enhance the enforcement activities of risk managers and official agencies and address the concerns of consumers with respect to food safety.

3. The functioning of the FSAI Scientific Committee

The functioning of the FSAI Scientific Committee is described in the FSAI Act, 1998 and stipulates that the members of the Scientific Committee are appointed by the Minister of Health in their individual capacities based on their *curriculum vitae* and expertise. The duration of the term is determined by the Minister and it is usually 5 years. The current Scientific Committee is composed of 15 members from a broad range of disciplines and its Chair is a member of the Board. It is the 5th Scientific Committee in the history of the FSAI, and its mandate runs from February 2021 until February 2026.

The FSAI Act establishes that the Scientific Committee shall advise the Board, where requested by it, on matters relating to

- scientific and technical questions relating to food safety and hygiene,
- the implementation and administration of food inspection services, and

- the nutritional value or content of food.

Those requests are referred to as 'Request for Advice' whereby the FSAI Executive on behalf of the Board contextualises the issue and lays down the specific question(s) that must be addressed by the Scientific Committee. These risk assessment questions (e.g., different risk assessment approaches and an assessment of the impact of each approach) will inform subsequent risk management decisions. The 'Request for Advice' may also specify a period within which the scientific advice/opinion shall be given by the Scientific Committee.

For the performance of its advisory role, the Scientific Committee establishes standing (existing for the lifetime of the Scientific Committee) and *ad hoc* (existing for the duration of a specific task) subcommittees where necessary. There are currently three standing subcommittees: Biological Safety, Chemical Safety and Public Health Nutrition, each of them with their own 'Terms of Reference'. To examine specific areas of interest or for requests that are outside the scope of the standing committees, *ad hoc* subcommittees are convened where the members appointed are experts who have a special knowledge and experience related to the question(s) asked. The Chair of a subcommittee must be a member of the Scientific Committee and each subcommittee can self-task within its terms of reference following consultation with the Scientific Committee.

The Scientific Committee is assisted by FSAI staff in an administrative and technical secretariat capacity. The Scientific Committee meets at least twice annually while the meeting frequency of the subcommittees varies depending on the work to be carried out and its progress. Subcommittee meetings are organised through their nominated Chair and assisted by an administrative and technical FSAI secretariat. The minutes of the meetings of the Scientific Committee are recorded, agreed, signed off and published on the FSAI website. The notes of the meetings of the subcommittees are not published but are subject to freedom of information requests, whereby any member of the public is entitled to access, to the greatest extent possible consistent with the public interest and the right to privacy, to information in the possession of public bodies.

Once the scientific advice/opinion is drafted by the subcommittees, it is discussed and debated before amendment, if necessary, and formal adoption by the Scientific Committee. Members of the Scientific Committee are tasked to interrogate and challenge draft advice that is outside their own area of expertise so that there is a sound basis for the advice provided. Following the formal adoption of the scientific advice, the Board will decide if it wishes to publish advice from the Scientific Committee at its discretion.

In brief, the Scientific Committee plays a vital role in providing scientific advice to the FSAI that ensures that the regulatory enforcement role of the FSAI has a sound scientific basis.

4. Scientific Opinions adopted by the FSAI Scientific Committee

Over the course of the FSAI's history, its four Scientific Committees have adopted a total of 48 scientific opinions or reports. These reports are published in English on the FSAI website (www.fsai.ie). Figure 2 illustrates the number of reports issued by topic and year.

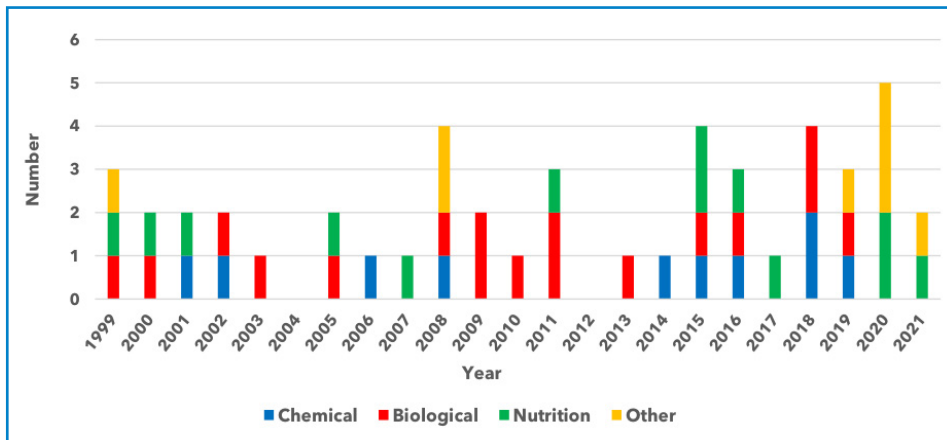


Figure 2. Number of Scientific Opinions issued between 1999 and 2021 by topic.

The following sections include a few examples of recent scientific reports performed by the FSAI Scientific Committee.

4.1 Chemical Safety Subcommittee

Risk Ranking Model for Chemical Contaminants in Food (FSAI, 2019a)

One aspect of the enforcement of food safety legislation in Ireland is the sampling and analysis of food products on the Irish market and the comparison of analytical results with legislative maximum levels. Within the Irish National Chemical Monitoring Programme, a broad range of parameters are analysed, for example, heavy metals, food processing contaminants, mycotoxins and other natural contaminants.

In 2019, the FSAI Scientific Committee was asked to consider what is the most appropriate risk ranking system for prioritising the selection of food and chemical analyte combinations for the annual official controls testing programme, and what information and data were required to develop and implement the risk ranking system. The implementation of a risk ranking approach would aid in the efficient and effective deployment of available resources, and shift focus to areas of greatest risk to Irish consumers.

This piece of work required a review of existing risk ranking systems, with the purpose of identifying the most suitable model for Ireland. The intended scope and coverage of the system was discussed, and benefits and limitations of including specific parameters above the recommended core criteria were highlighted. Consideration was given to the inclusion of parameters such as national food production (volumes), food import/export, regional characteristics, environmental factors and specific food processing factors/food handling techniques. It was recommended by the Scientific Committee that the FSAI should pilot the proposed model for a minimum period of 2 years, after which it should be presented to the Scientific Committee for review.

Total Diet Study 2014-2016: Assessment of dietary exposure to fluoride in adults and children in Ireland (FSAI, 2018a)

This report presents the findings of a total diet study on fluoride intake carried out in Ireland between 2014 and 2016 with the aim to evaluate possible risk, if any, to the health of children and adults arising from exposure to fluoride in foods and beverages, including fluoridated tap water. For this purpose, the most common foods in Ireland -based on national food consumption data- were analysed for fluoride, and dietary exposure to fluoride was then estimated for a representative population of adults (n= 1500), children aged 5-12 years (n= 594) and preschool children aged 1-4 years (n= 500).

Mean fluoride exposures in preschool children and children (0.023 and 0.017 mg/kg body weight/day, respectively) were lower than in adults (0.040 mg/kg b.w./day), all of which are below the adequate intake of 0.05 mg/kg b.w./day established by the European Food Safety Authority (EFSA) for caries protection. Adults were found to be predominantly exposed to fluoride via consumption of black tea (76 % of the total exposure), with tap water contributing 12 %. Tap water has been fluoridated in Ireland since the late 1960s and was the main contributor to fluoride intake in children (49 % in preschool children, 33 % in children aged 5-12 years), while tea was a significant contributor (29 %) in children aged 5-12 years.

The exposure estimates obtained were compared with tolerable upper intake levels (UL) for fluoride established by EFSA of 0.10 mg/kg b.w./day for children aged 1-8 years related to moderate dental fluorosis and 0.12 mg/kg b.w./day for children aged ≥ 9 years and adults, including pregnant and lactating women, related to adverse effects on bone. The results of the study showed that there is no appreciable risk of moderate dental fluorosis in children aged 1-8 years even if non-dietary sources of fluoride (e.g., toothpaste) are considered, no appreciable risk of adverse effects on bone in children aged 9-12 years and a low risk of adverse effects on bone in the adult population (fluoride intake only exceeded the UL in 1.6 % of adults) arising from fluoride intake from foods and beverages.

Based on the results of this study, the FSAI Scientific Committee concluded that there was no scientific basis for concerns about the safety of children and adults in Ireland from exposure to fluoride from foods and beverages.

4.2 Biological Safety Subcommittee

Advice on Shiga toxin-producing *Escherichia coli* (STEC) detection in food (FSAI, 2019b)

The evolving picture of human Shiga toxin-producing *Escherichia coli* (STEC) illness and changes in the methodology for STEC detection in clinical samples and in food has resulted in a lack of agreement across Europe on the risk posed and the appropriate risk-based action to be taken when STEC is detected in food. In 2014, the European Commission (EC) attempted to introduce a harmonised approach to assess and manage the risk of STEC in food, but EU Member States (MSs) were unable to reach an agreement and the EC suspended this work in 2016. A number of EU MSs have made their own risk assessments and policy decisions based on human epidemiology data and consumer practices relevant to their country, and some of these were summarised in this report.

Current Irish epidemiological data on STEC were reviewed in this report to assess the risk if STEC is detected in food in Ireland and the FSAI Scientific Committee concluded:

- When STEC is detected (i.e., culture isolation of an *E. coli* containing *stx* gene(s)) in a food, the risk of illness is dependent on the type of food (RTE and non-RTE foods), its likely final preparation prior to consumption and the vulnerability of the consumer to illness.
- At the present time, there is no scientific evidence to differentiate the potential risk of illness from STEC based on (i) the serogroup/serotype or (ii) the presence/absence of the *eae/aaiC* and *aggR* genes. Consequently, any STEC cultured from a food constitutes a potential risk of illness, although the risk posed is different depending on the food category as stated above.
- Based on current scientific evidence, although plausible, the loss and acquisition of an Stx-encoding phage are rare events under typical conditions of chilled food storage. Therefore, the detection of enteropathogenic *E. coli* or EPEC (possesses the *eae* gene but lacks the *stx* gene(s)) in food is not an indicator for the detection of STEC.
- There is currently no evidence to conclude that the presence of a *stx*-positive *Hafnia* strain in food poses a risk to human health.
- Public health risk cannot be assessed based on detection of *stx* gene(s) by molecular methods only (i.e., a positive PCR result/presumptive positive). However, where there is additional information that indicates a public health risk, a presumptive positive STEC (positive PCR only) may be taken as indicative of a risk to support an intervention.

It was acknowledged in the report that the advice provided, while based on current scientific knowledge and current Irish epidemiological information, may be revised in the future based on new scientific evidence.

An investigation of the most appropriate z-value to be used in calculating 'equivalent cooks' for beef burgers in food business establishments (FSAI, 2018b)

It is recommended that beef burgers are cooked to a minimum core temperature of 70 °C for at least two minutes or to a core temperature of no less than 75 °C to ensure the destruction of pathogens. However, in recent years, catering establishments in Ireland have started offering beef burgers prepared at core temperatures below 70 °C as it is considered that lower temperatures result in an improved flavour and texture that reflects the preference of modern consumers.

The calculation of an 'equivalent cook' (equivalent to 70 °C for 2 minutes) at lower (or higher) temperatures requires the use of a mathematical formula that uses the z-value of the target organism, which is usually *Listeria monocytogenes*, as it is one of the most thermal-resistant non-spore-forming foodborne bacterial pathogens. The z-value recommended for inactivation of *L. monocytogenes* is 7.5 °C. In 2007, the UK Advisory Committee on Microbiological Safety of Food (ACMSF) recommended using a z-value of 6.0 °C for calculating equivalent cooks when cooking burgers, based on heat inactivation data for STEC O157. When calculating equivalent cooks, these two z-values give different cooking time requirements at a given target temperature, thus the objective of this report

was to determine which z-value was more appropriate, in other words, would offer the greatest food safety protection.

The FSAI Scientific Committee concluded that a z-value of 6.0 °C was more appropriate as it would require longer cooking times for temperatures below 70 °C, while cooking times for temperatures above 70 °C were practically the same as those predicted using a z-value of 7.5 °C. This z-value of 6.0 °C is only appropriate for calculating equivalent cooks over the 60-75 °C range, and the corresponding cooking times were calculated. If alternative temperature-time combinations are to be employed, they must first be scientifically validated. It was also highlighted that an effective food safety management system including good hygiene practices and monitoring of cooking temperature is important in assuring the safety of beef burgers.

4.3 Public Health Nutrition Subcommittee

Scientific recommendations for food-based dietary guidelines for older adults in Ireland (FSAI, 2021a)

Older adults (≥65 years of age) are a diverse group and their nutritional needs are particularly varied due to their health status, physiological function and susceptibility to disease. In 2019 the Department of Health requested the FSAI Scientific Committee to provide an evidence-based report to underpin food-based dietary guidelines for older adults living in Ireland, outlining the nutritional issues related to ageing. For that purpose, older adults were classified in four groups in relation to their health status: (i) healthy person living independently, (ii) person with compromised mobility and/or with comorbidities and living independently, (iii) semi-independent person, and (iv) person dependent on residential care.

Dietary intakes for older adults in Ireland were explored using data from three contemporary Irish cohort studies, and macro- and micro-nutrients of public health concern for this age group were identified. These nutrients were then further examined to identify where nutrient goals or food-based dietary advice differ for older adults in comparison to the general adult population. Key reports from international bodies were also examined to identify goals for these nutrients. These goals were reviewed with reference to the dietary intakes of this age group as described in the three Irish cohort studies. Factors impacting on the dietary intakes of the four groups of older adults were explored.

The report acknowledged that for most nutrients examined, nutrient intake goals for older adults are the same as those for the general adult population. Nonetheless, increased requirements of specific nutrients in the older population were identified while key issues associated with ageing were highlighted. The report addressed those key issues and produced food-based dietary guidance for older adults and specific recommendations for relevant macro- and micronutrients. This report complements the 2016 'The Food Pyramid' report by the Department of Health.

The Safety of Vitamins and Minerals in Food Supplements - Establishing Tolerable Upper Intake Levels and a Risk Assessment Approach for Products Marketed in Ireland (Revision 2) (FSAI, 2019c)

Food supplements have been regulated in the EU since 2002 through Directive 2002/46/EC. However,

maximum safe levels of vitamins and minerals in food supplements are yet to be established in Europe. Vitamins and minerals can be used in the manufacture of food supplements to a maximum level at the discretion of the manufacturer. In the absence of EU maximum levels, the FSAI Scientific Committee was tasked to evaluate the safety of vitamins and minerals in food supplements in Ireland and to provide guidance to the food industry.

This report reviewed the ULs established by EFSA and the US Institute of Medicine (IOM) and recommended appropriate ULs for Irish population groups. For some micronutrients, no ULs were recommended as neither EFSA nor the IOM have established a UL, owing to lack of data. However, this does not mean that consuming excess amounts of these nutrients poses no risk(s). Data were also provided on highest intakes (the 95th percentile) of vitamins and minerals from sources other than food supplements estimated for Irish population groups in national food consumption surveys.

The report recommended a standard risk assessment approach for evaluating the safety of vitamins and minerals in food supplements in Ireland: when consumed according to manufacturer's instructions, the daily amount of a micronutrient from a food supplement as labelled added to the usual daily intake from food sources (i.e., from foods including fortified foods) of the highest consumers (i.e., the 95th percentile), should not exceed the UL for the population group(s) for whom the food supplement is intended. In line with EU guidance on tolerances around labelled values, the measured amount of micronutrient takes precedence over the declared amount when considering safety of the supplement. Therefore, the daily amount from the food supplement should be based on the measured amount in the product as purchased, not the amount declared on the label.

4.4 Ad-hoc Subcommittees

Information required for the risk assessment of undeclared food allergens in Ireland (FSAI, 2019d)

For individuals with a food allergy, avoidance of foods containing the relevant allergen is a key aspect of managing this condition. Some protection is offered to consumers with allergies through EU legislation that requires the declaration of 14 specified allergens when they are used as ingredients in prepacked and non-prepacked foods. When a food on the Irish market is discovered to contain any of the 14 allergens which is not declared as an ingredient, remedial action may be required by the relevant food business. The urgency and extent of any remedial action, e.g., re-labelling or product withdrawal/recall, can be informed by a risk assessment to be carried out by the food business and/or the FSAI, taken together with other pertinent factors.

This report provided scientific information to the FSAI which, with a case-by-case exposure assessment, would form the basis of a risk assessment in the event of an undeclared food allergen being detected in a food. This in turn would underpin proportionate risk management to protect public health.

Mycobacterium avium subsp. *paratuberculosis* and its links to Crohn's Disease (FSAI, 2021b)

Mycobacterium avium subsp. *paratuberculosis* (Map) is the causative agent of paratuberculosis or Johne's disease in cattle (JD). Similarities between JD in cattle and Crohn's Disease (CD), a type of inflammatory bowel disease, in humans have prompted speculation on a possible role for Map in

the pathogenesis of CD.

In 2000, the FSAI Scientific Committee reviewed the evidence of causality between Map and CD. The principal conclusion of that report was that the available data were inconclusive and a direct link between Map and CD could not be established. However, the report recommended that the Committee keep the issue under review. In 2008, the FSAI Scientific Committee conducted a more formal review of the scientific literature up to that point and adopted an opinion concluding that the balance of available evidence did not support a causal relationship between Map and the incidence of CD.

In 2020, an *ad-hoc* subcommittee of the FSAI Scientific Committee reviewed primary, peer-reviewed papers published in the scientific literature between 2009 and 2019 which referenced the putative link between Map and CD. While numerous studies provided evidence of an association between the presence of Map or human exposure to Map and the occurrence of CD, no new evidence had been published to substantiate the suggestion that this association is causal. A review of published papers on the efficacy of thermal pasteurisation at inactivating Map suggested that viable Map is unlikely to be found in milk that has been pasteurised at a time-temperature combination of at least 75 °C for 20 seconds. Finally, the Committee considered current gaps in knowledge which impact on the ability to assess the risk that Map poses to human health and the risk that humans could be exposed to Map present in food.

5. Current and future activities of the FSAI Scientific Committee

As indicated before, the new FSAI Scientific Committee was appointed by the Minister for Health in February this year and it is currently developing the work plan for its mandate. A significant number of proposals for scientific advice and risk assessment are being proposed. However, a timescale and priority are set for the provision of advice. Some of the agreed activities for the current Scientific Committee include:

- Review of the risk ranking model for chemical contaminants in food: Following the recommendation given in the report of 2019, the Scientific Committee is responsible for reviewing the model with a view to deliver a better risk-based approach and to focus resources efficiently and effectively.
- Risk ranking of Biological Hazards: Similar to the exercise completed for chemical contaminants, the Scientific Committee is tasked to advise FSAI on a risk ranking of microbiological hazards from foodborne sources in Ireland and to identify data gaps which, if filled, would enable a risk ranking with reduced uncertainty in the future.
- Safety concerns associated with cannabis edibles: The Scientific Committee will address the scientific evidence and medical information available regarding the adverse health effects associated with consuming cannabis edibles containing tetrahydrocannabinol (the principal psychoactive substance in cannabis) and will conclude on the level of risk associated with their consumption of cannabis edibles for different groups of the population using a quantitative risk assessment approach data allowing.

Conclusion

The FSAI is a science-based independent government agency dedicated to protecting the safety and interests of consumers in Ireland. The FSAI plays a significant role in raising compliance levels with food law throughout the food industry, taking the appropriate enforcement action, where necessary, by basing all its risk management decisions on science, evidence, and expertise. Access to the best available scientific expertise, information and robust data is achieved through the FSAI Scientific Committee, its scientific staff, and collaboration with scientists in Ireland and internationally. Throughout the history of the FSAI, its Scientific Committee and its subcommittees have proven crucial in assessing risks to consumers from food, which underpins strong risk management decisions and the development of policies that ultimately benefit public health.

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