Apple pomace improves gut health in Fisher rats independent of seed content
The mechanism behind the cholesterol lowering effects of apple pomace, a polyphenol- and fibre rich by-product in apple juice production, was investigated. Groups of male F344 rats were fed a control feed or the same feed with 2.1% or 6.5% dry apple pomace with or without seeds for 4 weeks. Effects on plasma cholesterol concentrations, excretion of bile acids, expression of genes involved in cholesterol- and bile acid synthesis, and other markers related to gut health were investigated. We found that pomace feeding decreased total-, LDL- and IDL-cholesterol concentrations compared to control. Higher production of SCFA, indicating elevated caecal fermentation, and increased excretion of total- and primary bile acids could explain the observed hypocholesterolemic effects of apple pomace, however, expression of selected genes involved in cholesterol and bile acid biosynthesis (Hmgcr and Cyp7a1) were not affected. We found no hepatotoxic or other effects of apple seeds. Altogether, our results indicate that apple pomace has beneficial effects on gut health, and that the cholesterol-lowering effect is linked to increased production of SCFA and excretion of bile acids. These effects are most likely linked to the fibre and other fruit constituents present in the pomace. Presence of apple seeds seems to impart no toxicity even at 6.5% pomace in the feed and seeds also had no influence on the biological effect of the pomace. In the future, apple pomace could potentially be used as a bioactive and possibly health promoting food ingredient.

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ISI indexed (2012): ISI indexed no
Critical review of methods for risk ranking of food related hazards, based on risks for human health

This study aimed to critically review methods for ranking risks related to food safety and dietary hazards on the basis of their anticipated human health impacts. A literature review was performed to identify and characterize methods for risk ranking from the fields of food, environmental science and socio-economic sciences. The review used a predefined search protocol, and covered the bibliographic databases Scopus, CAB Abstracts, Web of Sciences, and PubMed over the period 1993-2013. All references deemed relevant, on the basis of predefined evaluation criteria, were included in the review, and the risk ranking method characterized. The methods were then clustered - based on their characteristics - into eleven method categories. These categories included: risk assessment, comparative risk assessment, risk ratio method, scoring method, cost of illness, health adjusted life years, multi-criteria decision analysis, risk matrix, flow charts/decision trees, stated preference techniques and expert synthesis. Method categories were described by their characteristics, weaknesses and strengths, data resources, and fields of applications. It was concluded there is no single best method for risk ranking. The method to be used should be selected on the basis of risk manager/assessor requirements, data availability, and the characteristics of the method. Recommendations for future use and application are provided.

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Scopus rating (2015): SJR 1.941 SNIP 2.264 CiteScore 5.72
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Scopus rating (2014): SJR 2.041 SNIP 2.417 CiteScore 5.97
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Scopus rating (2013): SJR 2.072 SNIP 2.374 CiteScore 5.83
ISI indexed (2013): ISI indexed yes
BFI (2012): BFI-level 2
Scopus rating (2012): SJR 2.055 SNIP 2.684 CiteScore 5.73
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Investigating the risk-benefit balance of substituting red and processed meat with fish in a Danish diet

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Organisations: National Food Institute, Research Group for Risk-Benefit, Division of Risk Assessment and Nutrition, Ghent University
Authors: Thomsen, S. T. (Intern), Pires, S. M. (Intern), Devleesschauwer, B. (Ekstern), Poulsen, M. (Intern), Fagt, S. (Intern), Ygil, K. H. (Intern), Andersen, R. (Intern)
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Scopus rating (2016): CiteScore 3.96 SJR 1.351 SNIP 1.58
Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 1.202 SNIP 1.415 CiteScore 3.44
Web of Science (2015): Indexed yes
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 1.038 SNIP 1.369 CiteScore 3.12
Meeting the challenges in the development of risk-benefit assessment of foods

Background
Risk-benefit assessment (RBA) of foods aims to assess the combined negative and positive health effects associated with food intake. RBAs integrate chemical and microbiological risk assessment with risk and benefit assessment in nutrition.

Scope and Approach
Based on the past experiences and the methodological differences between the underlying research disciplines, this paper aims to describe the recent progress in RBAs, identifying the key challenges that need to be addressed for further development, and making suggestions for meeting these challenges.

Key Findings and Conclusions
Ten specific challenges are identified and discussed. They include the variety of different definitions and terminologies used in the underlying research disciplines, the differences between the “bottom-up” and the “top-down” approaches and the need for clear risk-benefit questions. The frequent lack of data and knowledge with their consequential uncertainties is
considered, as well as the imbalance in the level of scientific evidence associated with health risks and benefits. The challenges that are consequential to the need of considering substitution issues are discussed, as are those related to the inclusion of microbiological hazards. Further challenges include the choice of the integrative health metrics and the potential scope of RBAs, which may go beyond the health effect. Finally, the need for more practical applications of RBA is stressed. Suggestions for meeting the identified challenges include an increased interdisciplinary consensus, reconsideration of methodological approaches and health metrics based on a categorisation of risk-benefit questions, and the performance of case studies to experience the feasibility of the proposed approaches.

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Web of Science (2015): Indexed yes
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Scopus rating (2013): SJR 2.216 SNIP 2.653 CiteScore 4.83
ISI indexed (2013): ISI indexed yes
Web of Science (2013): Indexed yes
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Scopus rating (2012): SJR 2.048 SNIP 2.417 CiteScore 3.91
ISI indexed (2012): ISI indexed yes
Web of Science (2012): Indexed yes
BFI (2011): BFI-level 2
Scopus rating (2011): SJR 1.897 SNIP 2.675 CiteScore 3.81
ISI indexed (2011): ISI indexed yes
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Scopus rating (2010): SJR 1.763 SNIP 2.508
Web of Science (2010): Indexed yes
BFI (2009): BFI-level 2
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BFI (2008): BFI-level 2
Scopus rating (2008): SJR 1.75 SNIP 2.321
Web of Science (2008): Indexed yes
Scopus rating (2007): SJR 1.682 SNIP 2.279
Web of Science (2007): Indexed yes
Scopus rating (2006): SJR 1.17 SNIP 2.065
Use of Mathematical Optimization Models to Derive Healthy and Safe Fish Intake

Recommended fish intake differs substantially from observed fish intake. In Denmark, ∼15% of the population consumes the state-recommended fish intake. How much fish individuals eat varies greatly, and this variation cannot be captured by considering the fish intake of the average population. We developed a method intended to provide realistic and achievable personalized dietary recommendations based on an individual's body weight and current fish intake. The objective of the study was to propose specific fish intake levels for individuals that meet the recommendations for eicosapentaenoic acid, docosahexaenoic acid, and vitamin D without violating the permitted intake recommendations for methyl mercury, dioxins, and polychlorinated biphenyls. Two mathematical optimization models were developed that apply quadratic programming to model personalized recommended fish intake, fulfilling criteria on nutrients and contaminants, while simultaneously deviating as little as possible from observed individual intake. A recommended intake for 8 fish species was generated for each individual in a group of 3016 Danes (1552 women and 1464 men, aged 18-75 y), whose fish intakes and body weights were known from a national dietary survey. Individual, personal dietary recommendations were successfully modeled. Modeled fish intake levels were compared to observed fish intakes. For women, the average proposed increase in fish intake was 14 g/wk for lean fish and 63 g/wk for fatty fish; and for men these numbers were 12 and 55 g/wk, respectively. Using fish intake as an example, we show how quadratic programming models may be used to advise individual consumers how to optimize their diet, taking both benefits and risks into account. This approach has the potential to increase compliance with dietary guidelines by targeting the individual consumers and minimizing the need for large and ultimately unrealistic behavior changes.
Scientific Opinion on the safety of alginate-konjac-xanthan polysaccharide complex (PGX) as a novel food pursuant to Regulation (EC) No 258/97

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on alginate-konjac-xanthan polysaccharide complex (PGX) as a novel food (NF) submitted pursuant to Regulation (EC) No 258/97. The NF is an off-white granular powder composed of three non-starch polysaccharides: konjac glucomannan, xanthan gum and sodium alginate. The information provided on the composition,
the specifications, the batch-to-batch variability and the stability of the NF is sufficient and does not raise safety concerns. The production process is sufficiently described and does not raise concerns about the safety of the NF. The applicant intends to add the NF to a variety of foods as well as to market the NF in capsules. The recommended maximum daily intake of the NF from fortified foods and food supplements is 15 g. The target population proposed by the applicant is adults from 18 to 64 years of age. Considering the no observed adverse effect level of 1.8 g/kg body weight (bw) per day in a subchronic toxicity study with PGX and the highest mean and 95th percentile anticipated daily intake of NF from fortified foods, the margin of exposure (MoE) is 12 and 6, respectively, whereas the MoE for the NF from food supplements is 9. The Panel concludes that the safety of the novel food, PGX, for the intended uses and use levels as proposed by the applicant, has not been established.

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Scientific Opinion on the safety of cranberry extract powder as a novel food ingredient pursuant to Regulation (EC) No 258/97

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on ‘cranberry extract powder’ as a novel food (NF) submitted pursuant to Regulation (EC) No 258/97 of the European Parliament and of the Council. The NF contains about 55–60% proanthocyanidins (PACs). The Panel considers that the information provided on the composition, the specifications, batch-to-batch variability and stability of the NF is sufficient and does not raise safety concerns. Cranberry extract powder is produced from cranberry juice concentrate through an ethanolic extraction using an adsorptive resin column to retain the phenolic components. The Panel considers that the production process is sufficiently described and does not raise concerns about the safety of the novel food. The NF is intended to be added to beverages and yogurts to provide 80 mg PACs per serving. The target population is the adult general population. The mean and 95th percentile estimates for the all-user intakes from all proposed food-uses are 68 and 192 mg/day, respectively, for female adults, and 74 mg/day and 219 mg/day, respectively, for male adults. Taking into account the composition of the novel food and the intended use levels, the Panel considers that the consumption of the NF is not nutritionally disadvantageous. While no animal toxicological studies have been conducted on the NF, a number of human clinical studies have been conducted with cranberry products. Considering the composition, manufacturing process, intake, history of consumption of the source and human data, the Panel considers that the data provided do not give reasons for safety concerns. The Panel concludes that the cranberry extract powder is safe as a food ingredient at the proposed uses and use levels.

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Scientific opinion on the safety of proline-specific oligopeptidase as a novel food pursuant to Regulation (EC) No 258/97

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on proline-specific oligopeptidase (Tolerase® G) as a novel food ingredient submitted pursuant to Regulation (EC) No 258/97 of the European Parliament and of the Council, taking into account the comments and objections of a scientific nature raised by Member States. The novel food is an enzyme preparation of prolyl-oligopeptidase produced with a genetically modified Aspergillus niger self clone strain. The target population is the general adult population. The results from a bacterial reverse mutation test and of an in vitro chromosome aberration test did not indicate genotoxicity. The Panel considers that the reported effects observed in a 90-day rat study are treatment-related effects and can be attributed to the higher energy consumption by these animals. Taking into account the intended maximum use level for Tolerase® G, its daily consumption would correspond to 2,746 mg TOS/person or to 39.2 mg TOS/kg body weight (bw) per day, when considering a default body weight of 70 kg for an adult person. The margin between this value and the dose in the rats, which caused effects attributable to the excess energy intake, is approximately 45. Noting this margin, the Panel considers that it is unlikely that such effects would occur in human at the intended use levels. The Panel concludes that the NF, Tolerase® G, is safe for the intended use at the intended use level.

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Scientific Opinion on the safety of synthetic N-acetyl-D-neuraminic acid as a novel food pursuant to Regulation (EC) No 258/97

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on synthetic N-acetyl-d-neuraminic acid (NANA) as a novel food (NF) submitted pursuant to Regulation (EC) No 258/97. The information on the composition, the specifications, the batch-to-batch variability, stability and production process of the NF is sufficient and does not raise concerns about the safety of the NF. The NF is intended to be marketed as an ingredient in formulae and foods for infants and young children as well as an ingredient in a variety of foods and in food supplements for the general population. NANA is naturally present in human milk, in a bound and free form. The Margin of Exposure, which was based on the no-observed-adverse effect level (NOAEL) of 493 mg/kg body weight (bw) per day from a subchronic study and the anticipated daily intake of the NF, was considered to be sufficient for fortified foods for the general population and for food supplements for individuals above 10
years of age, as the anticipated daily intake was in the range of the exposure to free NANA from the consumption of early human milk, which is considered to be safe. The Panel concludes that the NF is safe when added to foods other than food supplements at the proposed uses and use levels for the general population; is safe in food supplements alone at the proposed uses and use levels for individuals above 10 years of age; is safe at the combined intake from fortified foods plus food supplements in individuals above 10 years of age; the safety of the NF is not established in food supplements alone at the proposed uses and use levels for individuals below 10 years of age.

Statement on the safety of EstroG-100™ as a novel food pursuant to Regulation (EC) No 258/97
Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to update its scientific opinion on the safety of EstroG-100™ as a novel food (NF) in the light of additional information submitted by the applicant. In its previous scientific opinion of 2016, the Panel concluded that EstroG-100™, which is a hot-water extract of a mixture of three herbal roots, is safe for the use in food supplements at the maximum intake level of 175 mg/day in post-menopausal women, which is lower than the maximum intake level proposed by the applicant (514 mg/day). The Panel reached its conclusions based on the effects of EstroG-100™ on liver and haematology as observed in several oral toxicity studies, the lack of information on liver and haematological parameters in human studies and the absence of chronic toxicity data. In view of the Panel's conclusion on the safety of EstroG-100™, the applicant has now provided additional information on haematological and liver parameters for the human intervention study with EstroG-100™ and historical control data related to the subchronic 90-day oral toxicity study with EstroG-100™. After assessing the additional information provided by the applicant, the Panel considers that the conclusion of the scientific opinion on the safety of EstroG-100™ does not need to be revised, and thus, the Panel reconfirms that the NF is safe for the use in food supplements at the maximum intake level of 175 mg/day in post-menopausal women.
Burden of disease of dietary exposure to acrylamide in Denmark

Acrylamide (AA) is a process-contaminant that potentially increases the risk of developing cancer in humans. AA is formed during heat treatment of starchy foods and detected in a wide range of commonly consumed products. Increased focus on risk ranking and prioritization of major causes of disease makes it relevant to estimate the impact that exposure to chemical contaminants and other hazards in food have on health. In this study, we estimated the burden of disease (BoD) caused by dietary exposure to AA, using disability adjusted life years (DALY) as health metric. We applied an exposure-based approach and proposed a model of three components: an exposure, health-outcome, and DALY-module. We estimated BoD using two approaches for estimating cancer risk based on toxicological data and two approaches for estimating DALY. In Denmark, 1.8 healthy life years per 100,000 inhabitants are lost each year due to exposure to AA through foods, as estimated by the most conservative approach. This result should be used to inform risk management decisions and for comparison with BoD of other food-borne hazards for prioritizing policies. However, our study shows that careful evaluation of methodological choices and assumptions used in BoD studies is necessary before use in policy making.

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Authors: Jakobsen, L. S. (Intern), Granby, K. (Intern), Knudsen, V. K. (Intern), Nauta, M. (Intern), Pires, S. M. (Intern), Poulsen, M. (Intern)
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Scopus rating (2014): SJR 1.038 SNIP 1.369 CiteScore 3.12
Web of Science (2014): Indexed yes
BFI (2013): BFI-level 1
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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016. Scientific opinion on the safety of fermented soybean extract NSK-SD® as a novel food pursuant to Regulation (EC) No 258/97

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the fermented soybean extract NSK-SD®, as a novel food (NF) submitted pursuant to Regulation (EC) No 258/97 of the European Parliament and of the Council, taking into account the comments and objections of a scientific nature raised by Member States. The NF is the fermented soybean extract NSK-SD®, which is standardised to a nattokinase enzyme activity of 20,000–28,000 fibrin degradation units/g. The information provided on the composition of the NF, the specifications, batch-to-batch variability and the stability is sufficient and does not raise safety concerns. The proposed maximum intake is 100 mg NSK-SD®/day as a food supplement. The target population proposed by the applicant is healthy men and women over the age of 35 years, excluding pregnant and lactating women. The Panel noted that nattokinase exhibits in vitro fibrinolytic activity and in vivo thrombolytic activity in animals when administered parenterally. However, the information provided with respect to absorption, distribution, metabolism and excretion of the NF does not allow conclusions to be drawn on the absorption of active nattokinase or any functional metabolites therefrom. A bacterial reverse mutation test did not show any indication of mutagenicity, and the NF was not clastogenic in an in vitro chromosome aberration assay. Taking into account the no observed adverse effect level (NOAEL) of 1,000 mg/kg body weight per day in the subchronic toxicity study in rats, and considering the proposed maximum intake level for the NF, the Panel concludes that the margin of exposure is sufficient. The Panel concludes that the NF, the fermented soybean extract NSK-SD®, is safe under the intended conditions of use as specified by the applicant.

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Authors: EFSA Journal
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Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283

Following the adoption of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, the European Commission requested EFSA to update and develop scientific and technical guidance for the preparation and presentation of applications for authorisation of novel foods. This guidance presents a common format for the organisation of the information to be presented in order to assist the applicant in preparing a well-structured application to demonstrate the safety of the novel food. The application should be comprehensive and complete. This guidance outlined the data needed for the safety assessments of novel foods. Requirements which should be covered in all applications relate to the description of the novel food, production process, compositional data, specification, proposed uses and use levels, and anticipated intake of the novel food. Further sections on the history of use of the novel food and/or its source, absorption, distribution, metabolism, excretion, nutritional information, toxicological information and allergenicity should be considered by the applicant by default. If not covered in the application, this should be justified. The applicant should integrate the data presented in the different sections to provide their overall considerations on how the information supports the safety of the novel food under the proposed conditions of use. Where potential health hazards have been identified, they should be discussed in relation to the anticipated intakes of the novel food and the proposed target populations. On the basis of the information provided, EFSA will assess the safety of the novel food under the proposed conditions of use.

Safety of UV-treated milk as a novel food pursuant to Regulation (EC) No 258/97

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on UV-treated milk as a novel food submitted pursuant to Regulation (EC) No 258/97.
taking into account the comments and objections of a scientific nature raised by Member States. The novel food is cow’s milk (whole, semi-skimmed or skimmed) to which a treatment with ultraviolet (UV) radiation is applied after pasteurisation in order to extend the shelf life of the milk. This treatment results in an increase in the vitamin D3 concentrations. The Panel considers that the provided compositional data, the specifications and the data from batch testing do not give rise to safety concerns. The data provided on the production process are sufficient and do not give rise to safety concerns. The target group is the general population with the exclusion of infants (up to 1 year of age). The Panel considers that it is unlikely that tolerable upper intake levels established by EFSA for children aged 1–10 years, adolescents and adults will be exceeded. The Panel considers that the novel food is not nutritionally disadvantageous. The data provided do not give rise to concerns with regard to the microbiological quality. The Panel considers that the risk of allergic reactions to the novel food is not dissimilar to that associated with conventional milk. The Panel concludes that the novel food, UV-treated milk, is safe under the intended conditions of use as specified by the applicant.

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Scientific opinion on the safety of synthetic L-ergothioneine (Ergoneine®) as a novel food pursuant to Regulation (EC) No 258/97
Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on synthetic l-ergothioneine, marketed as Ergoneine®, as a novel food submitted pursuant to Regulation (EC) No 258/97 of the European Parliament and of the Council. The novel food, synthetic l-ergothioneine, is produced by a one-pot patented manufacturing process. Chemically, l-ergothioneine is a derivative of thiolhistidine, and it is naturally present in a number of foodstuffs such as mushrooms, some varieties of black and red beans, offal and cereals. The production process for the novel food is sufficiently described and does not raise concerns about the safety of the novel food. The information on the composition, specifications, batch-to-batch variability and stability of the novel food is sufficient and does not raise safety concerns. The applicant intends to use the novel food in quantities of up to 5 mg per serving in alcohol-free beverages, cereal bars, milk, fresh dairy products and chocolate. The applicant also proposes to provide the novel food as a food supplement, with a daily dose of up to 30 mg/day for adults and 20 mg/day for children. The target population is children above 3 years of age and the general adult population, except pregnant and breastfeeding women. Considering the NOAEL of 800 mg/kg bw per day, which was based on two subchronic toxicity studies in rats, and the maximum estimated intake levels for l-ergothioneine from all sources, the Panel concludes that the margins of safety of 470 for adults (except pregnant and breastfeeding women) and of 216 for children above 3 years of age are sufficient. The Panel concludes that the novel food, synthetic l-ergothioneine (marketed as Ergoneine®), is safe under the intended conditions of use as specified by the applicant.

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Burden of disease estimates of cancer caused by dietary exposure to acrylamide: How methodological choices affect the outcome

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Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 1.281 SNIP 1.117 CiteScore 3.62
Web of Science (2015): Indexed yes
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 1.142 SNIP 1.154 CiteScore 3.45
Web of Science (2014): Indexed yes
BFI (2013): BFI-level 1
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ISI indexed (2013): ISI indexed yes
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BFI (2012): BFI-level 1
Scopus rating (2012): SJR 1.072 SNIP 1.148 CiteScore 3.41
ISI indexed (2012): ISI indexed yes
Web of Science (2012): Indexed yes
BFI (2011): BFI-level 1
Scopus rating (2011): SJR 1.133 SNIP 1.157 CiteScore 3.38
ISI indexed (2011): ISI indexed yes
Critical review of methodology and application of risk ranking for prioritisation of food and feed related issues, on the basis of the size of anticipated health impact

This study aimed to critically review methodologies for ranking of risks related to feed/food safety and nutritional hazards, on the basis of their anticipated human health impact. An extensive systematic literature review was performed to identify and characterize the available methodologies for risk ranking in the fields of feed and food safety and nutritional hazards, as well as the socio-economic field. Risk ranking methods from the environmental field were studied as well to determine whether approaches used in this field could also be applied for ranking human health risks related to feed and food safety and nutritional hazards. The review used a predefined search protocol. It covered the bibliographic databases Scopus, CAB Abstracts, Web of Sciences, and PubMed over the period 1993-2013. All references obtained were stored into an Endnote database and evaluated for their relevance. All references deemed to be relevant were studied in–depth so as to characterize the risk ranking method described. Characteristics of each method were stored in an Excel database. The methods for risk ranking were then grouped into method categories, which were described in general. These groups included: risk assessment, comparative risk assessment, risk ratio method, scoring method, cost of illness, DALY/QALY, willingness to pay, multi criteria decision analysis, risk matrix, flow charts/decision trees and expert judgment methods. Based on the characteristics of the individual methods and the method categories, an overarching framework was developed for selection of the appropriate method(s) that could be used for risk ranking of feed and food related hazards, on the basis of human health impact. This framework has the format of a decision tool, with which – given the characteristics of the risk ranking question at hand - the most appropriate method(s) can be selected. Application of this overall framework to several case studies showed it can be a useful tool for risk managers/assessors to select the most suitable method for risk ranking of feed/food and diet related hazards, on the basis of expected human health impact.

General information
State: Published
Organisations: National Food Institute, Research Group for Risk-Benefit, Division of Risk Assessment and Nutrition, Food and Environmental Research Agency, Newcastle University, Newcastle University, Wageningen University
EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific opinion on the safety of 2'-O-fucosyllactose as a novel food ingredient pursuant to Regulation (EC) No 258/97

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on 2'-O-fucosyllactose as a novel food ingredient (NFI) submitted pursuant to Regulation (EC) No 258/97 of the European Parliament and of the Council, taking into account the comments and objections of a scientific nature raised by Member States. 2'-O-fucosyllactose (2'-FL) is a synthetic trisaccharide, which is intended to be used in infant and follow-on formulae, foods for special medical purposes for infants and young children, and other foods for infants and young children, as well as in foods or food supplements for adults. The information provided on the potential mutagenicity of 2'-FL does not raise safety concerns as regards the genotoxicity of this NFI. Based on the observations from a sub-chronic 90-day toxicity study in rats, the Panel considers that the no observed adverse effect level is 2 000 mg/kg body weight per day. The applicant provided a double-blind, randomised, controlled clinical trial on the effects of 2'-FL consumed in combination with another oligosaccharide (lacto-N-neotetraose (LNNt)) in infants. The Panel concludes that 2'-FL is safe for infants (up to one year of age) when added to infant and follow-on formulae, in combination with LNNt, at concentrations up to 1.2 g/L of 2'-FL and up to 0.6 g/L of LNNt, at a ratio of 2:1 in the reconstituted formulae; is safe for young children (older than one year of age) when added to follow-on and young-child formulae, at concentrations up to 1.2 g/L of 2'-FL (alone or in combination with LNNt, at concentrations up to 0.6 g/L, at a ratio of 2:1). The Panel also concludes that 2'-FL is safe when added to other foods at the uses and use levels proposed by the applicant.

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on lacto-N-neotetraose as a novel food ingredient (NFI) submitted pursuant to Regulation (EC) No 258/97 of the European Parliament and of the Council, taking into account the comments and objections of a scientific nature raised by Member States. Lacto-N-neotetraose (LNnT) is a synthetic tetrasaccharide, which is intended to be used in infant and follow-on formulae, foods for special medical purposes for infants and young children and other foods for infants and young children, as well as in foods or food supplements for adults. The information provided on the potential mutagenicity of LNnT does not raise safety concerns as regards the genotoxicity of this NFI. Based on the observations from a sub-chronic 90-day toxicity study in rats, the Panel considers that the no observed adverse effect level is 2 500 mg/kg body weight per day. The applicant provided a double-blind, randomised, controlled clinical trial on the effects of LNnT consumed in combination with another oligosaccharide (2'-O-fucosyllactose (2'-FL)) in infants. The Panel concludes that LNnT is safe for infants (up to one year of age) when added to infant and follow-on formulae, in combination with 2'-FL, at concentrations up to 0.6 g/L of LNnT and up to 1.2 g/L of 2'-FL, at a ratio of 1:2 in the reconstituted formulae; is safe for young children (older than one year of age) when added to follow-on and young-child formulae, at concentrations up to 0.6 g/L of LNnT (alone or in combination with 2'-FL, at concentrations up to 1.2 g/L, at a ratio of 1:2). The Panel also concludes that LNnT is safe when added to other foods at the uses and use levels proposed by the applicant.

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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on the safety of UV-treated bread as a novel food

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) was asked to carry out the additional assessment for UV-treated bread as a novel food (NF) in the context of Regulation (EC) No 258/97, taking into account the comments and objections of a scientific nature raised by Member States. The NF is bread to which a treatment with UV radiation is applied after baking in order to convert ergosterol, which is present in bread as a result of yeast fermentation, to vitamin D2. The provided compositional data, the specifications (i.e. vitamin D2 content of 0.75–3 μg/100 g in the UV-treated bread, 1–5 g/100 g of yeast in the dough) and the data from batch testing do not give rise to safety concerns. The data provided on the production process are sufficient and do not give rise to safety concerns. The Panel considers that even if it is conservatively assumed that all consumed breads are UV-treated and contain the maximum proposed amount of 3 μg vitamin D2/100 g, it is highly unlikely that tolerable upper intake levels for vitamin D, established by EFSA for various age groups, will be exceeded. The NF is not nutritionally disadvantageous. Under certain conditions, UV treatment may result in reactions of biomolecules. However, the levels of potential reaction products that may be formed under the employed conditions are low compared with the reactions induced by the baking process. Therefore, the Panel considers that it is not necessary to perform additional analyses and that the absence of toxicological studies with the novel food is acceptable. The risk of allergic reactions to the NF is not dissimilar to that associated with conventional bread. The Panel considers that bread enriched with vitamin D2 through UV treatment is safe under the conditions of use as specified by the applicant.

General information
State: Published
EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Statement on the safety of lacto-N-neotetraose and 2'-O-fucosyllactose as novel food ingredients in food supplements for children

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on the safety of lacto-N-neotetraose and 2'-O-fucosyllactose as novel food ingredients in food supplements for children (excluding infants). In July 2015, the Panel concluded that LNnT and 2'-FL are safe for infants and for young children when added to infant, follow-on and young-child formulae under specific conditions of use; and for adults when added to foods at the uses and use levels proposed by the applicant, which include food supplements at a maximum intended daily intake of 1.5 g for LNnT and 3 g for 2'-FL. The applicant also intends to include LNnT and 2'-FL in food supplements for children, with maximum daily intake levels of 0.6 g for LNnT and 1.2 g for 2'-FL for toddlers (1–3 years of age), and maximum daily intake levels of 1.5 g for LNnT and 3 g for 2'-FL for children (4–18 years of age). In this scientific assessment, maximum daily intakes from food supplements for toddlers, children and teenagers are presented and two scenarios are calculated in which the maximum daily intakes from food supplements are added to the mean and 95th percentile intake estimates from all foods in which LNnT and 2'-FL are intended to be added. The Panel concludes that LNnT and 2'-FL are safe for the proposed use in food supplements at the maximum use levels proposed for toddlers (1–3 years of age) of 0.6 g/day for LNnT and 1.2 g/day for 2'-FL (alone or in combination) and for children (4–18 years of age) of 1.5 g for LNnT and 3 g for 2'-FL (alone or in combination). However, in children of 1-10 years of age the combined intakes from all foods in which the NFIs are intended to be added and from food supplements could result in intake levels which were reported to cause mild gastrointestinal symptoms in adults.
Helhedssyn på nødder: en risk-benefit vurdering

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Original language: Danish
Main Research Area: Technical/natural sciences
Electronic versions: N_dderapporten.pdf
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Source-ID: 115722593
Publication: Research › Report – Annual report year: 2015

Nødder kan være en del af en sund kost

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Organisations: National Food Institute, Division of Risk Assessment and Nutrition, Research Group for Risk-Benefit
Authors: Mejborn, H. (Intern), Olesen, P. T. (Intern), Jakobsen, L. S. (Intern), Poulsen, M. (Intern)
Pages: 24-27
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Original language: Danish
Source: PublicationPreSubmission
Source-ID: 117267980
Publication: Research - peer-review › Journal article – Annual report year: 2015

Scientific Opinion on the safety of ‘heat-treated milk products fermented with Bacteroides xylanisolvens DSM 23964’ as a novel food
Following a request from the European Commission, the EFSA NDA Panel was asked to carry out the additional assessment for ‘pasteurised milk products fermented with Bacteroides xylanisolvens DSM 23964’ as a novel food (NF) in the context of Regulation (EC) No 258/97. Pasteurised or ultra-high-temperature-treated milk is used for the fermentation process with B. xylanisolvens DSM 23964. After fermentation the product is heat treated for one hour at 75 °C to ensure the absence of viable B. xylanisolvens DSM 23964. The Panel considers the information provided on the identity and characterisation of B. xylanisolvens DSM 23964 to be sufficient. The production process encompasses standard techniques used by the dairy industry, is sufficiently described by the applicant and does not give rise to safety concerns. The Panel considers that the information provided on the production process and on the content of vitamins B2 and B12 and furosine in heat-treated fermented milk products does not give rise to concerns regarding disadvantageous nutritional effects. The Panel considers that the microbiological data provided do not give rise to safety concerns. The Panel also notes that a pilot study and a RCT over six weeks with 140 volunteers receiving daily doses of a spray-dried heat-treated fermented milk product containing intakes of up to 1 \(10^{12}\) inactivated bacterial cells of B. xylanisolvens DSM 23964 were provided. No clinical effects related to the treatment were observed in the two studies. Although no information has been provided to conclude on the risk of allergic reactions caused by the NF, the Panel considers that it is unlikely that its allergenic potential is dissimilar to that of other fermented dairy products. The Panel concludes that the NF ‘heat-treated
milk products fermented with B. xylanisolvens DSM 23964’ is safe for the proposed uses and at the proposed use levels.

Tissue content of vitamin D₃ and 25-hydroxy vitamin D₃ in minipigs after cutaneous synthesis, supplementation and deprivation of vitamin D₃

Information regarding the endogenous storages of vitamin D₃ after cutaneous vitamin D synthesis compared to oral vitamin D₃ supplementation is sparse. Furthermore, it is not known whether vitamin D₃ can be stored for later use during periods of shortages of vitamin D₃. To investigate the endogenous storages of vitamin D₃, two studies were carried out in Göttingen minipigs. In study 1, one group of minipigs (n=2) was daily exposed to UV light corresponding to 10–20min of midday sun and another group (n=2) of pigs were fed up to 60μg vitamin D₃/day corresponding to 3.7–4.4μg/kg body weight. Study 1 demonstrated that daily UV-exposure of minipigs stimulated the cutaneous synthesis of vitamin D₃ and resulted in increasing serum vitamin D₃ and 25-hydroxy vitamin D₃, but also carcasses containing vitamin D₃ and 25-hydroxy vitamin D₃. The vitamin D₃ content in adipose tissue from the UV-exposed minipigs was 150–260ng/g and the content was 90–150ng/g in the orally supplemented minipigs. In study 2, minipigs were UV-exposed daily for 49 days. Subsequently, one group (n=2) was fed a vitamin D-free diet and another group (n=2) was dosed daily with 13C-labeled vitamin D₃. The concentrations of vitamin D₃ and 25-hydroxy vitamin D₃ in serum and skin- and subcutaneous adipose tissue biopsies were repeatedly monitored. Vitamin D₃ and 25-hydroxy vitamin D₃ were eliminated from the skin and the adipose tissue after UV-exposure was ceased. Supplementation of 13C-vitamin D₃ did not seem to affect the decline in the endogenous vitamin D₃ in the adipose tissue formed during UV-exposure.

**General information**
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- **Organisations:** National Food Institute, Research Group for Risk-Benefit
- **Authors:** EFSA Journal
- **Number of pages:** 18
- **Publication date:** 2015

**Publication information**
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- **Publisher:** European Food Safety Authority
- **Original language:** English
- **Series:** The EFSA Journal
- **Volume:** 13(1)
- **Number:** 3956
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**Tissue content of vitamin D₃ and 25-hydroxy vitamin D₃ in minipigs after cutaneous synthesis, supplementation and deprivation of vitamin D₃**

**General information**
- **State:** Published
- **Organisations:** National Food Institute, Division of Food Chemistry, Research Group for Analytical Food Chemistry, Division of Toxicology and Risk Assessment, Research Group for Risk-Benefit, Research Group for Bioactives – Analysis and Application
- **Authors:** Burild, A. (Intern), Frandsen, H. L. (Intern), Poulsen, M. (Intern), Jakobsen, J. (Intern)
- **Number of pages:** 8
- **Pages:** 72-79
- **Publication date:** 2015
- **Main Research Area:** Technical/natural sciences

**Publication information**
- **Journal:** Steroids
- **Volume:** 98
- **ISSN (Print):** 0039-128X
- **Ratings:**
  - BFI (2018): BFI-level 1
  - Web of Science (2018): Indexed yes
  - BFI (2017): BFI-level 1
  - Scopus rating (2017): SNIP 0.996 SJR 0.904 CiteScore 2.53
  - Web of Science (2017): Indexed Yes
  - BFI (2016): BFI-level 1
Toxicological risk assessment of elemental gold following oral exposure to sheets and nanoparticles – A review

Elemental gold is used as a food coloring agent and in dental fillings. In addition, gold nanoparticles are gaining increasing attention due to their potential use as inert carriers for medical purposes. Although elemental gold is considered to be inert, there is evidence to suggest the release of gold ions from its surface. Elemental gold, or the released ions, is, to some extent, absorbed in the gastrointestinal tract. Gold is distributed to organs such as the liver, heart, kidneys and lungs. The main excretion route of absorbed gold is through urine. Data on the oral toxicity of elemental gold is limited. The acute toxicity of elemental gold seems to be low, as rats were unaffected by a single dose of 2000mg nanoparticles/kg of body weight. Information on repeated dose toxicity is very limited. Skin rashes have been reported in humans following the ingestion of liquors containing gold. In addition, gold released from dental restorations has been reported to increase the risk of developing gold hypersensitivity. Regarding genotoxicity, in vitro studies indicate that gold nanoparticles induce DNA damage in mammalian cells. In vivo, gold nanoparticles induce genotoxic effects in Drosophila melanogaster; however, genotoxicity studies in mammals are lacking. Overall, based on the literature and taking low human exposure into account, elemental gold via the oral route is not considered to pose a health concern to humans in general.

General information

State: Published
Organisations: National Food Institute, Division of Toxicology and Risk Assessment, Research Group for Molecular Toxicology, Research Group for Risk-Benefit, Division of Risk Assessment and Nutrition
Authors: Hadrup, N. (Intern), Sharma, A. K. (Intern), Poulsen, M. (Intern), Nielsen, E. E. (Intern)
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BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): SJR 0.812 SNIP 1.005 CiteScore 2.92
Web of Science (2017): Indexed Yes
BFI (2016): BFI-level 1
Scopus rating (2016): CiteScore 2.15 SJR 0.724 SNIP 0.92
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 0.734 SNIP 1.01 CiteScore 2.25
Web of Science (2015): Indexed yes
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 0.75 SNIP 1.089 CiteScore 2.13
Web of Science (2014): Indexed yes
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 0.83 SNIP 1.085 CiteScore 2.46
ISI indexed (2013): ISI indexed yes
BFI (2012): BFI-level 1
Scopus rating (2012): SJR 0.81 SNIP 1.135 CiteScore 2.38
ISI indexed (2012): ISI indexed yes
Web of Science (2012): Indexed yes
BFI (2011): BFI-level 1
Scopus rating (2011): SJR 0.865 SNIP 1.113 CiteScore 2.23
ISI indexed (2011): ISI indexed yes
Web of Science (2011): Indexed yes
BFI (2010): BFI-level 1
Scopus rating (2010): SJR 0.926 SNIP 1.193
Web of Science (2010): Indexed yes
BFI (2009): BFI-level 1
Scopus rating (2009): SJR 0.739 SNIP 1.089
Web of Science (2009): Indexed yes
BFI (2008): BFI-level 1
Scopus rating (2008): SJR 0.764 SNIP 1.234
Scopus rating (2007): SJR 0.878 SNIP 1.219
Web of Science (2007): Indexed yes
Scopus rating (2006): SJR 0.717 SNIP 1.066
Web of Science (2006): Indexed yes
Scopus rating (2005): SJR 0.686 SNIP 1.087
Scopus rating (2004): SJR 0.695 SNIP 1.08
Scopus rating (2003): SJR 0.608 SNIP 1.292
Scopus rating (2002): SJR 0.588 SNIP 1.012
Scopus rating (2001): SJR 0.597 SNIP 0.993
Scopus rating (2000): SJR 0.593 SNIP 1.159
Scopus rating (1999): SJR 0.511 SNIP 1.071
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Gold , Au Nanoparticle, Colloidal, Toxicity, Toxicology, Oral Elemental Metallic, Risk assessment
Burden of diseases estimates associated to different red meat cooking practices

The burden of disease estimate has been performed for diseases attributable to nutritional deficiency, foodborne pathogens, the environment, infection and other factors. However, the burden of disease estimate attributable to different food processing practices has not been investigated before. The aim of this study is to compare the burden of disease estimate attributable to red meat consumption processed using different cooking practices. The red meat cooking practices were categorized into three: (A) barbecuing/grilling; (B) frying/broiling and (C) roasting/baking. The associated endpoints, affected population, intake and dose–response data are obtained by literature survey. The selected endpoints are four types of cancer: colorectal, prostate, breast and pancreatic. The burden of disease per cooking practice, endpoint, sex and age is estimated in the Danish population, using disability adjusted life years (DALY) as a common health metric. The results reveal that the consumption of barbecued red meat is associated with the highest disease burden, followed by fried red meat and roasted red meat. The method used to quantify the difference in disease burden of different cooking practices can help to inform the consumer to make a choice on whether the benefit of a preferred cooking style is worth the associated health loss.

General information

State: Published
Organisations: National Food Institute, Division of Epidemiology and Microbial Genomics, Division of Toxicology and Risk Assessment
Authors: Berjia, F. L. (Intern), Poulsen, M. (Intern), Nauta, M. (Intern)
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Web of Science (2017): Indexed yes
BFI (2016): BFI-level 1
Scopus rating (2016): CiteScore 3.96 SJR 1.351 SNIP 1.58
Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 1.202 SNIP 1.415 CiteScore 3.44
Web of Science (2015): Indexed yes
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 1.038 SNIP 1.369 CiteScore 3.12
Web of Science (2014): Indexed yes
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 1.02 SNIP 1.506 CiteScore 3.26
ISI indexed (2013): ISI indexed yes
Web of Science (2013): Indexed yes
BFI (2012): BFI-level 1
Scopus rating (2012): SJR 1.126 SNIP 1.748 CiteScore 3.52
ISI indexed (2012): ISI indexed yes
Web of Science (2012): Indexed yes
BFI (2011): BFI-level 1
Scopus rating (2011): SJR 1.124 SNIP 1.58 CiteScore 3.36
ISI indexed (2011): ISI indexed yes
EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2014. Scientific Opinion on lipase from a genetically modified strain of Aspergillus oryzae (strain NZYM-FL)

The food enzyme considered in this opinion is a lipase (triacylglycerol lipase; EC 3.1.1.3) produced with a genetically modified strain of Aspergillus oryzae. The genetic modifications do not raise safety concern. The food enzyme contains neither the production organism nor recombinant DNA. The lipase is intended to be used in a number of food manufacturing processes, such as oils, fats and eggs processing. The dietary exposure was assessed on the basis of data retrieved from the EFSA Comprehensive European Food Consumption Database. The food enzyme did not induce gene mutations in bacteria nor chromosome aberrations in human lymphocytes. Therefore, there is no concern with respect to genotoxicity. The systemic toxicity was assessed by means of a 90-day subchronic oral toxicity study in rodents. A No Observed Adverse Effect Level was derived, which compared with the dietary exposure results in a sufficiently high Margin of Exposure. The allergenicity was evaluated by searching for similarity of the amino acid sequence to those of known allergens. The Panel considered that the likelihood of food allergic reactions to the enzyme is low and therefore does not raise safety concern. Based on the genetic modifications performed, the manufacturing process, the compositional and biochemical data provided and the toxicological studies, this food enzyme does not raise safety concern under the intended conditions of use.

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Authors: EFSA Journal
Number of pages: 15
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Place of publication: Parma, Italy
Publisher: European Food Safety Authority
Original language: English

The food enzyme considered in this opinion is a xylanase (endo-1,4-β-xylanase; EC 3.2.1.8) produced with a genetically modified strain of Aspergillus oryzae. The genetic modifications do not raise safety concern. The food enzyme contains neither the production organism nor recombinant DNA. The xylanase is intended to be used in a number of food manufacturing processes, such as starch processing, beverage alcohol (distilling), brewing, baking and other cereal based processes. The dietary exposure was assessed according to the Budget method. The food enzyme did not induce gene mutations in bacteria nor chromosome aberrations in human peripheral blood lymphocytes. Therefore, there is no concern with respect to genotoxicity. The systemic toxicity was assessed by means of a 90-day subchronic oral toxicity study in rodents. A No Observed Adverse Effect Level was derived, which compared with the dietary exposure results in a sufficiently high Margin of Exposure. The allergenicity was evaluated by searching for similarity of the amino acid sequence to those of known allergens. The Panel considered that the likelihood of food allergic reactions to the enzyme is low and therefore does not raise safety concern. Based on the genetic modifications performed, the manufacturing process, the compositional and biochemical data provided and the toxicological studies, this food enzyme does not raise safety concern under the intended conditions of use.

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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the extension of use for DHA and EPA-rich algal oil from Schizochytrium sp. as a Novel Food ingredient

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on an extension of use for docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA)-rich algal oil from Schizochytrium sp. as a novel food ingredient (NFI) in the context of Regulation (EC) No 258/97. The NFI is already authorised for use in a range of foodstuffs at specified maximum levels. The applicant requests an extension of use of the NFI in food supplements up to a maximum DHA and EPA content of 3 g per daily dose for the adult population, excluding pregnant and lactating women. In a previous opinion on the Tolerable Upper Intake Level of EPA, DHA and docosapentaenoic acid (DPA), the Panel concluded that supplemental intake of EPA and DHA combined at doses up to 5 g/day, does not give rise to safety concerns for adults. Based on estimations of high intake of DHA and
EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the safety of astaxanthin-rich ingredients (AstaREAL A1010 and AstaREAL L10) as novel food ingredients

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on the safety of astaxanthin-rich ingredients AstaREAL A1010 and AstaREAL L10 as novel food ingredients (NFIs) in the context of Regulation (EC) No 258/97. The NFIs are produced from astaxanthin-rich alga Haematococcus pluvialis. Astaxanthin content is 5.0–5.6 % in AstaREAL A1010 powder, 10.0–12.0 % in AstaREAL L10 oil and 2.5–2.7 % in AstaREAL L10 encapsulated oil. Sufficient information was provided regarding the composition, specification, manufacture and stability of the NFIs. The NFIs are intended to be used in fermented liquid dairy products, non-fermented liquid dairy products, fermented soya products and fruit drinks for healthy adults. The applicant recommends a maximum consumption of astaxanthin from the NFIs of 4 mg/day. Mean and high-level (95th percentile) daily intakes of 0.106 mg/kg bw and 0.256 mg/kg bw astaxanthin from the NFIs were estimated, based on European consumption data of the proposed food categories. The consumption of the NFIs is not considered to be nutritionally disadvantageous. There are no safety concerns regarding genotoxicity. There is no indication from the available toxicological data that the NFIs would be more toxic than astaxanthin. Therefore, the Panel bases the evaluation of the NFIs on the acceptable daily intake (ADI) of 0.034 mg/kg bw for astaxanthin derived by the FEEDAP Panel. The Panel notes that the maximum recommended intake of 4 mg astaxanthin per day (0.06 mg/kg bw) and the estimated mean intake based on the use levels in the proposed food categories (0.106 mg/kg bw per day) exceed the ADI by approximately two- and three-fold, respectively. The Panel therefore concludes that the safety of the NFIs at the proposed use and use levels has not been established.

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on the safety of “UV-treated baker’s yeast” (Lallemand SAS) as a novel food ingredient in the context of Regulation (EC) No 258/97, taking into account the comments and objections of a scientific nature raised by Member States. The novel food ingredient (NFI) is baker’s yeast treated with UV irradiation to induce the conversion of ergosterol to vitamin D2. The applicant intends to use the NFI during the production of yeast-leavened bread, rolls, fine pastry and food supplements. The Panel considers that the provided compositional data, the specification, the data from batch testing, data on the stability on the production process are sufficient and do not give rise to safety concerns. The Panel concludes that the data provided are sufficient and do not give rise to safety concerns. The applicant intends to use the NFI as an alternative source of vitamin D for food supplements and for fortification of yeast-leavened bread, rolls and fine pastry at maximum concentrations of 5 μg vitamin D2 per 100 g of these foods. The applicant provided combined intake estimates for these two food categories for “all subjects” and “consumers only”. The source for the production of the NFI is Saccharomyces cerevisiae, an organism with a long history of safe food use. Even if the NFI is used at the maximum intended use levels, which deliver 5 μg vitamin D/100 g bread, rolls and fine pastry, it is highly unlikely that Tolerable Upper Intake Levels as established by EFSA (EFSA NDA Panel, 2012) are exceeded. The Panel considers that UV-treated baker’s yeast exhibiting an enhanced content of vitamin D2 is safe under the intended conditions of use.
EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Statement on the safety of ‘Cetyl Myristoleate Complex’ as an ingredient in food supplements

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to update its opinion on the safety of ‘Cetyl Myristoleate Complex’ (CMC) as a novel food ingredient in the light of additional information submitted by the applicant. In its previous opinion of 2010, the Panel concluded that the safety of CMC as an ingredient in food supplements at an intake of 3.3 g per day has not been established. This conclusion was based on the considerations that in the absence of appropriate data on absorption, distribution, metabolism and excretion, the provided toxicological data were insufficient. In 2012, the Commission requested EFSA to review and update its opinion by taking into account a new subchronic 90-day oral toxicity study conducted with “Cetylated Fatty Acid Esters Powder 50 %” in mice. In its opinion of 2013, the Panel considered that a new 90-day study cannot serve as a reliable source of information supporting the absence of adverse effects of CMC. The dossier of this new mandate contains three new references which were not submitted and hence not considered in the previous assessments. The Panel notes that two references do not address the concerns expressed by the Panel in its previous assessments. The third reference provided is a report on an in vitro hydrolysis study demonstrating a low rate of hydrolysis of cetyl myristoleate and cetyl myristate. The Panel notes the low rate of hydrolysis of the two esters found in this in vitro hydrolysis study and therefore reiterates the need for adequate safety information on the unhydrolysed esters contained in CMC as expressed in its opinions of 2010 and 2013. The Panel concludes that, even after considering the newly submitted information, the safety of ‘Cetyl Myristoleate Complex’ has not been established.

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Publication: Commissioned - peer-review › Report – Annual report year: 2014

Finding the Optimum Scenario in Risk-benefit Assessment: An Example on Vitamin D
Background: In risk-benefit assessment of food and nutrients, several studies so far have focused on comparison of two scenarios to weigh the health effect against each other. One obvious next step is finding the optimum scenario that provides maximum net health gains. Aim: This paper aims to show a method for finding the optimum scenario that provides maximum net health gains. Methods: A multiple scenario simulation. The method is presented using vitamin D intake in Denmark as an example. In addition to the reference scenario, several alternative scenarios are simulated to detect the scenario that provides maximum net health gains. As a common health metric, Disability Adjusted Life Years (DALY) has been used to project the net health effect by using the QALIBRA (Quality of Life for Benefit Risk Assessment) software. Results: The method used in the vitamin D example shows that it is feasible to find an optimum scenario that provides maximum net health gain in health risk-benefit assessment of dietary exposure as expressed by serum vitamin D level. With regard to the vitamin D assessment, a considerable health gain is observed due to the reduction of risk of other cause mortality, fall and hip fractures when changing from the reference to the optimum scenario. Conclusion: The method allowed us to find the optimum serum level in the vitamin D example. Additional case studies are needed to further validate the applicability of the approach to other nutrients or foods, especially with regards to the uncertainty that is usually attending the data.

General information
Quantification of physiological levels of vitamin D$_3$ and 25-hydroxyvitamin D$_3$ in porcine fat and liver in subgram sample sizes

Most methods for the quantification of physiological levels of vitamin D3 and 25-hydroxyvitamin D3 are developed for food analysis where the sample size is not usually a critical parameter. In contrast, in life science studies sample sizes are often limited. A very sensitive liquid chromatography with tandem mass spectrometry method was developed to quantify vitamin D3 and 25-hydroxyvitamin D3 simultaneously in porcine tissues. A sample of 0.2–1 g was saponified followed by liquid–liquid extraction and normal-phase solid-phase extraction. The analytes were derivatized with 4-phenyl-1,2,4-triazoline-3,5-dione to improve the ionization efficiency by electrospray ionization. The method was validated in porcine liver and adipose tissue, and the accuracy was determined to be 72–97% for vitamin D3 and 91–124% for 25-hydroxyvitamin D3. The limit of quantification was
Vitamin D3 in Pigs: Distribution, Storage and Turnover under Various Input Conditions

Vitamin D3 is important for the mineralization of the skeleton to prevent the deficiency diseases rickets and osteoporosis, and to maintain a healthy skeleton throughout life.

Vitamin D3 is synthesized in the skin after exposure to the sun. Due to the low angle of the sun during wintertime at high latitudes, no or only a negligible amount of vitamin D3 is synthesized and the body needs to rely on its storages of vitamin D3, or dietary vitamin D3 in the form of vitamin D3 and 25-hydroxyvitamin D3. The information of the size of the storages of vitamin D3 in humans is sparse, but very low levels of vitamin D3 is found in tissues from animals fed physiologically relevant doses of vitamin D3. The natural synthesis of vitamin D3 might, however, influence on the storages of vitamin D3. The different inherent properties of the two forms of vitamin D3 might also affect the tissue distribution of vitamin D3 and 25-hydroxyvitamin D3 and how the distribution associates with serum 25-hydroxyvitamin D3.
To study the association between vitamin D₃ and 25-hydroxyvitamin D₃ in serum and tissue, two analytical methods were developed and validated.

The difference in tissue distribution of vitamin D₃ and 25-hydroxyvitamin D₃ after supplementation of vitamin D₃ and 25-hydroxyvitamin D₃ was investigated in slaughter pigs. Tissue 25-hydroxyvitamin D₃ was significantly higher in pigs fed 25-hydroxyvitamin D₃ compared to vitamin D₃, but vitamin D₃ in tissue was higher in the pigs fed vitamin D₃. The content of 25-hydroxyvitamin D₃ in the different tissues correlated with the serum 25-hydroxyvitamin D₃ level, but the correlation between the tissue content of vitamin D₃ and the serum 25-hydroxyvitamin D₃ concentration was dependent on the form of the ingested vitamin D₃.

Göttingen minipigs were used to investigate the endogenous storages of vitamin D₃ after UV-exposure to stimulate synthesis of vitamin D₃ and after oral supplementation of vitamin D₃. Furthermore, the minipigs were used to study the turnover of synthesized vitamin D₃ in skin and adipose tissue during vitamin D₃ shortages. Daily UV-exposure of minipigs stimulated the cutaneous synthesis of vitamin D₃. The results showed an increase in serum vitamin D₃ and 25-hydroxyvitamin D₃ but also tissues and organs contained vitamin D₃ and 25-hydroxyvitamin D₃. The vitamin D₃ content in adipose tissue from the UV-exposed minipigs was 150-260 ng/g while the content was 90-150 ng/g in the orally supplemented minipigs. Vitamin D₃ and 25-hydroxyvitamin D₃ declined from the skin and the adipose tissue after the UV-exposure had ceased.

A comprehensive pharmacokinetic-model was established to describe the relation between vitamin D₃ in tissue and vitamin D₃ and 25-hydroxyvitamin D₃ in serum by taking both synthesized and orally supplemented vitamin D₃ into account.

General information
State: Published
Organisations: National Food Institute, Division of Food Chemistry, Division of Toxicology and Risk Assessment
Authors: Burild, A. (Intern), Jakobsen, J. (Intern), Frandsen, H. L. (Intern), Poulsen, M. (Intern)
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A LC-MS metabolomics approach to investigate the effect of raw apple intake in the rat plasma metabolome
Fruit and vegetable consumption has been associated with several health benefits; however the mechanisms are largely unknown at the biochemical level. Our research aims to investigate whether plasma metabolome profiling can reflect biological effects after feeding rats with raw apple by using an untargeted UPLC–ESI–TOF–MS based metabolomics approach in both positive and negative mode. Eighty young male rats were randomised into groups receiving daily 0, 5 or 10 g fresh apple slices, respectively, for 13 weeks. During weeks 3–6 some of the animals were receiving 4 mg/ml 1,2-dimethylhydrazine dihydrochloride (DMH) once a week. Plasma samples were taken at the end of the intervention and among all groups, about half the animals were 12 h fasted. An initial ANOVA-simultaneous component analysis with a three-factor or two-factor design was employed in order to isolate potential metabolic variations related to the consumption of fresh apples. Partial least squares discriminant analysis was then applied in order to select discriminative features between plasma metabolites in control versus apple fed rats and partial least squares modelling to reveal possible dose response. The findings indicate that in laboratory rats apple feeding may alter the microbial amino acid fermentation, lowering toxic metabolites from amino acids metabolism and increasing metabolism into more protective products. It may also delay lipid and amino acid catabolism, gluconeogenesis, affect other features of the transition from the postprandial to the fasting state and affect steroid metabolism by suppressing the plasma level of stress corticosteroids, certain mineralocorticoids and oxidised bile acid metabolites. Several new hypotheses regarding the cause of health effects from apple intake can be generated from this study for further testing in humans.

General information
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Organisations: National Food Institute, Division of Toxicology and Risk Assessment, Sapienza University of Rome, University of Copenhagen
Authors: Rago, D. (Ekstern), Kristensen, M. (Intern), Gürdeniz, G. (Ekstern), Marini, F. (Ekstern), Poulsen, M. (Intern), Dragsted, L. O. (Ekstern)
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Publication date: 2013
Main Research Area: Technical/natural sciences
Publication information
Journal: Metabolomics
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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on Rooster Combs Extract

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to carry out the additional assessment for „Rooster Combs Extract” (RCE) as a food ingredient in the context of Regulation (EC) No 258/97, taking into account the comments and objections of a scientific nature raised by Member States. Rooster combs extract results from a production process involving enzymatic hydrolysis of rooster combs and subsequent filtration, concentration and precipitation steps. The principle constituents of RCE are the glycosaminoglycans hyaluronic acid, chondroitin sulphate A and dermatan sulphate. The applicant intends to add RCE to a number of dairy products with a recommended maximum intake of 80 mg RCE per portion and per day. The target population is the general population, with the exception of pregnant women, children and people with adverse reactions to sodium.
hyaluronate and/or avian protein. In the high intake scenario for “consumers only”, the highest daily intake would occur in adults in Belgium (0.788 g). The highest intake scenario for “all subjects” was estimated for adolescents in Denmark (0.427 g/day). The Panel notes that no adverse effects were observed at the highest tested dose of 600 mg/kg bw per day in a 90-day oral toxicity study in rats. Considering the nature, the natural occurrence and previous consumption of RCE constituents, the Panel is of the opinion that the margin between the intended as well as the estimated maximum possible intake of RCE in relation to the highest dose administered to rats without adverse effects in a subchronic oral toxicity study is sufficient. The Panel concludes that the novel food ingredient, Rooster Comb Extract, is safe under the proposed uses and use levels.

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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the safety of "coriander seed oil" as a Novel Food ingredient.
Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on “coriander seed oil (CSO)” as a novel food ingredient (NFI) in the context of Regulation (EC) No 258/97. Petroselinic acid (PA) is the major fatty acid in CSO. Conventional edible oil technologies are used to manufacture the NFI. The NFI is intended to be marketed as a food supplement for healthy adults, at a maximum level of 600 mg per day (i.e. 8.6 mg/kg bw per day for a 70 kg person), which would lead to significantly higher intakes of CSO and PA than current background intakes. There are no safety concerns regarding genotoxicity. In rats fed high amounts of CSO, increased liver weight, marked to severe fat infiltration in the liver, and lower tissue arachidonic acid concentrations were observed. In the same study, similar affects were observed when feeding other vegetable oils, although not as severe as that seen for CSO. The dose level of CSO was more than a thousand fold higher than the proposed use level. In a subchronic study using 150, 450 or 1 000 mg/kg bw per day of CSO, a treatment-related effect was observed on blood glucose concentrations of male rats. Although this effect was not accompanied by any toxicological findings, its biological relevance is unclear and therefore the Panel considers the dose level of 450 mg/kg bw per day to be the NOAEL in rats. This is more than 50 fold higher than the proposed use level. No treatment-related adverse effect was observed in one human study using the NFI at the proposed use level for six months. The Panel concludes that the novel food ingredient, CSO, is safe under the proposed uses and use levels.

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Authors: EFSA Publication
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Publication information
Place of publication: Parma, Italy
EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the safety of "Methyl Vinyl Ether-Maleic Anhydride Copolymer" (chewing gum base ingredient) as a Novel Food ingredient.

Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on the safety of "methyl vinyl ether-maleic anhydride copolymer (Gantrez SF)" as a novel food ingredient in the context of Regulation (EC) No 258/97. The novel food ingredient Gantrez SF is an anhydrous copolymer formed by the reaction of methyl vinyl ether (MVE) and maleic anhydride (MAN) under appropriate conditions. The Panel considers that the information provided on the specifications, stability and production process do not raise safety concerns. An estimated daily intake (EDI) for Gantrez SF associated with its use in chewing gum may be calculated based on the maximum concentration (2 %) of Gantrez SF in finished chewing gum, and on the level at which chewing gum is consumed. Based on data from the United Kingdom, a high intake estimate of 280 mg Gantrez SF per day was derived. The Panel notes that the NOAEL of 1.8 and 2.1 g/kg bw per day Gantrez SF for male and female rats, respectively, which was derived from a 90-day subchronic toxicity study, is about 500-fold above this conservative intake estimate. The Panel has no safety concerns regarding genotoxicity and the low molecular weight components. The Panel concludes that the novel food ingredient, methyl vinyl ether-maleic anhydride copolymer (Gantrez SF), is safe under the proposed uses and use levels.

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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the safety of * rapeseed protein isolate * as a Novel Food ingredient.
Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion on the safety of a “rapeseed protein isolate” (Isolexx™) as a novel food ingredient (NF) in the context of Regulation (EC) No 258/97. The NF is an aqueous extract with at least 90 % protein, isolated from rapeseed press cake originating from so-called canola varieties. The applicant intends to market the NF for the same food products, at similar concentrations and for corresponding purposes, as soy protein isolates. Total protein intake of “heavy” adult consumer may be estimated as the mean + 2 SD, i.e. 2.2 g/kg bw per day. The age group of 4 - 6 years is estimated to have the highest protein intake on a per kg bw basis with a mean and 95th percentile intake of up to 3 and up to 4.73 g/kg bw per day, respectively. A significant part of these estimated intakes could come from rapeseed protein. The Panel considers that the risk of sensitisation to rapeseed cannot be excluded and that it is likely that rapeseed trigger can allergic reactions in mustard allergic subjects. The biological value of rapeseed and soy protein, determined by the PDCAAS, appear to be similar. The Panel notes the source and nature of the novel food, the absence of a nutritional disadvantage at the proposed uses and use levels, the low concentrations of potentially adverse components in the NF, and the absence of toxicologically relevant effects in subchronic studies with rats conducted with rapeseed protein isolates with similar compositions. The Panel concludes that rapeseed protein isolate is safe under the proposed uses and use levels.
Compositional and toxicological analysis of a GM potato line with reduced α-solanine content – A 90-day feeding study in the Syrian Golden hamster

Steroidal glycoalkaloids (GAs) are toxins, produced by plants of the Solanaceae family. The potato plant (Solanum tuberosum L.) and its tubers predominantly contain the two GAs α-chaconine and α-solanine. These compounds are believed to act in synergy, and the degree of toxicity may therefore depend on their ratio in the potato. To determine the influence of α-solanine: α-chaconine ratio in potatoes on toxicity, a GM potato line (SGT 9-2) with reduced α-solanine content, and the parental control line (Desirée wild-type) having a traditional α-solanine: α-chaconine ratio were (1) studied for compositional similarity by analysing for a range of potato constituents, and (2) used in a 90-day feeding trial with the Syrian Golden hamster to study differential toxicity. The animal feeding study used diets with up to 60% freeze-dried potato powder from either line. Whilst data indicated some compositional differences between the GM line and its wildtype control these did not raise concerns related to nutritional value or safety. Results of the feeding trials showed a low number of significant differences between potato lines with different α-solanine: α-chaconine ratio but none were considered to raise safety concerns with regard to human (or animal) consumption.

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Organisations: National Food Institute, Division of Toxicology and Risk Assessment, The James Hutton Institute, Technische Universität München, United States Department of Agriculture
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BFI (2017): BFI-level 1
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Web of Science (2017): Indexed Yes
BFI (2016): BFI-level 1
Scopus rating (2016): CiteScore 2.15 SJR 0.724 SNIP 0.92
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 0.734 SNIP 1.01 CiteScore 2.25
Web of Science (2015): Indexed yes
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 0.75 SNIP 1.089 CiteScore 2.13
Web of Science (2014): Indexed yes
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 0.83 SNIP 1.085 CiteScore 2.46
ISI indexed (2013): ISI indexed yes
BFI (2012): BFI-level 1
Scopus rating (2012): SJR 0.81 SNIP 1.135 CiteScore 2.38
ISI indexed (2012): ISI indexed yes
Web of Science (2012): Indexed yes
BFI (2011): BFI-level 1
Scopus rating (2011): SJR 0.865 SNIP 1.113 CiteScore 2.23
ISI indexed (2011): ISI indexed yes
Web of Science (2011): Indexed yes
BFI (2010): BFI-level 1
Scopus rating (2010): SJR 0.926 SNIP 1.193
Web of Science (2010): Indexed yes
Risk-benefit assessment of cold-smoked salmon: microbial risk versus nutritional benefit

The objective of the study is to perform an integrated analysis of microbiological risks and nutritional benefits in a fish product, Cold Smoked Salmon (CSS).

Literature study identified the major health risks and benefits in connection with CSS consumption. The reduction of the risk of Coronary Heart Disease (CHD) mortality and stroke, as well as enhanced cognitive (IQ) development of unborns following maternal intake, are identified as the main health benefits of omega-3 fatty acid from CSS. Contrary, risk of meningitis, septicemia and abortion/stillborn are identified as a major health risk endpoints due to exposure to the pathogen L. monocytogenes. Two consumption scenarios were considered: a reference scenario (23g/day and 20g/day for man and woman respectively) and an alternative scenario (40g/day for both sexes). In order to evaluate and compare the risks and benefits, the Disability Adjusted Life Years (DALY) method has been used as a common metric. Results show that the overall health benefits outweigh the risk, foremost contributed by the effect of decreased CHD mortality and IQ increase. A sensitivity analysis indicated that this result was robust for the analyzed parameters, except the storage time: the adverse effect of consumption of CSS prevails over the beneficial effect if the storage time of CSS is increased from two weeks to five weeks or more, due to an increased risk of listeriosis. This study demonstrates how microbial risks can be integrated in risk-benefit assessment, and shows that a sensitivity analysis has an added value, even if the benefits largely outweigh the risk in the initial analysis.

General information

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Organisations: National Food Institute, Division of Epidemiology and Microbial Genomics, Division of Nutrition, Division of Toxicology and Risk Assessment, National Institute of Public Health and the Environment
Authors: Berjia, F. L. (Intern), Hoekstra, J. (Ekstern), Andersen, R. (Intern), Poulsen, M. (Intern), Nauta, M. (Intern)
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Daily intake of apples decrease total cholesterol

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Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): SNIP 1.057 SJR 1.317 CiteScore 2.78
Web of Science (2017): Indexed Yes
BFI (2016): BFI-level 1
Scopus rating (2016): SJR 1.215 SNIP 1.003 CiteScore 2.69
Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 1.074 SNIP 1.016 CiteScore 2.55
Web of Science (2015): Indexed yes
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 1.294 SNIP 1.096 CiteScore 2.64
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 0.957 SNIP 1.036 CiteScore 2.46
ISI indexed (2013): ISI indexed yes
Web of Science (2013): Indexed yes
BFI (2012): BFI-level 1
Scopus rating (2012): SJR 0.867 SNIP 0.89 CiteScore 2.35
ISI indexed (2012): ISI indexed yes
BFI (2011): BFI-level 1
Scopus rating (2011): SJR 0.889 SNIP 0.95 CiteScore 2.38
ISI indexed (2011): ISI indexed yes
Web of Science (2011): Indexed yes
BFI (2010): BFI-level 1
Scopus rating (2010): SJR 0.768 SNIP 0.834
BFI (2009): BFI-level 1
Scopus rating (2009): SJR 0.688 SNIP 0.898
Web of Science (2009): Indexed yes
BFI (2008): BFI-level 2
Scopus rating (2008): SJR 0.786 SNIP 0.785
Scopus rating (2007): SJR 0.697 SNIP 0.763
Web of Science (2007): Indexed yes
Regular consumption of fruits and vegetables is associated with reduced risks of certain cancers and other diseases in observational studies and animal models of human diseases. The aim of the present study was to investigate whether feeding of rats with whole raw apple has potentially chemopreventive properties by affecting markers of colon cancer. The end-point was preneoplastic changes in the colon known as aberrant crypt foci (ACF). Rats initiated with the colon carcinogen 1,2-dimethylhydrazine dihydrochloride (DMH) were given 0, 5, or 10 g apple/day for 13 wk. The group fed 5 g apple but not 10 g had a significantly lower number of ACF (P = 0.009) compared to the initiated control. DNA damage evaluated by the comet assay was significantly increased in leucocytes of DMH-treated animals (P = 0.021). No antigenotoxic effect of apple feeding was apparent in the colon. Apple feeding tended to lower DNA damage in the liver (P = 0.136 in DMH-initiated and P = 0.284 in noninitiated rats). Liver alanine aminotransferase was significantly increased in rats fed apples (P = 0.008 in DMH-initiated and P = 0.019 in noninitiated rats). In conclusion, feeding whole fresh apple may affect the occurrence of preneoplastic changes in the rat colon, but the effect was not gradual.

General information
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Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Research Institute of Pomology and Floriculture, University of Copenhagen
Authors: Poulsen, M. (Intern), Mortensen, A. (Intern), Binderup, M. (Intern), Langkilde, S. (Intern), Markowski, J. (Ekstern), Dragsted, L. O. (Ekstern)
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Scopus rating (2016): CiteScore 2.5 SJR 0.926 SNIP 0.829
BFI (2015): BFI-level 1
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Scopus rating (2014): SJR 0.926 SNIP 0.805 CiteScore 2.5
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Scopus rating (2013): SJR 1.061 SNIP 0.832 CiteScore 3.07
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BFI (2012): BFI-level 1
Effects of prebiotics on the infective potential of Listeria monocytogenes

The human gastrointestinal tract is colonized by a dense and complex community of bacteria. The intestinal microbiota has a large impact on the health of the host and the intestinal bacteria are roughly classified as either potential deleterious or potential beneficial bacteria. Several factors can affect the composition of the microbiota - among them prebiotics. Prebiotics are food ingredients that are non-digestible for the human body and therefore reach the large intestine in an intact form. In the large intestine the prebiotics selectively stimulate the growth of the beneficial rather than the harmful bacteria of the microbiota. Gastro-intestinal infections currently cause several hundred thousand reported cases of disease in the EU each year. Infections with the forborne pathogen Listeria monocytogenes are relatively rare, but it is one of the most severe infections in the industrialised countries with a mortality of about 30%. The gut has a very important function in defending the host against infections with ingested pathogenic bacteria and there is increasing evidence that prebiotics can help strengthen this defense. This is done through stimulation of beneficial intestinal bacteria that release bacteriocins toxic for the pathogens, lower the pH to a level that is unfavourable for pathogenic bacteria and compete with the pathogen for nutrients and mucosal adhesion sites in the intestine. However, besides the microbiota dependent mechanisms increasing evidence suggest that prebiotics exert their protective function against pathogens through microbiota independent mechanisms. This is thought to be done by blocking the pathogenic adhesion to intestinal cells, affecting the expression of virulence genes from the pathogen and by stimulating the immune system. In vivo evidence of the prebiotics effect against pathogenic enteric infections is scarce and I therefore investigated the effect of five non-digestible carbohydrates (putative prebiotics) on the resistance of guinea pigs to infection with three different strains of L. monocytogenes. Animals were fed a diet supplemented with either 10% xylooligosaccharides (XOS), galactooligosaccharides (GOS), inulin, apple pectin or polydextrose for three weeks before oral challenge with L. monocytogenes. XOS and GOS significantly improved resistance of guinea pigs to L. monocytogenes, while inulin and apple pectin decreased the resistance. No significant effect on resistance to L. monocytogenes was seen after feeding with polydextrose. To further explore the mechanisms behind these in vivo observations, microbiota independent effects of four of the carbohydrates (XOS, GOS, inulin and polydextrose) on the adhesive and infective potential of L. monocytogenes was investigated. Mixing L. monocytogenes with XOS just prior to infection decreased the adherence of two of the three strains of L. monocytogenes to the intestinal cell line Caco-2. Additionally, 2 hours incubation with XOS...
and subsequently washing of the bacteria decreased the adherence of all three strains of L. monocytogenes to Caco-2 cells. No effect on adhesion was seen for either GOS, inulin or polydextrose. Adherence to the intestinal epithelium is considered a very important step in the infection cycle for most of the pathogenic bacteria. Without adherence the pathogenic bacteria are rapidly eliminated from the intestine. The ability of the four carbohydrates to affect the expression of L. monocytogenes genes known to be involved in adherence to intestinal cells (inlA, lap, ami, lap, aut, fdpA, actA) was therefore investigated. It was found that expression of the adhesion genes was affected in a strain dependent manner by the presence of prebiotics in the growth media. In conclusion, these results show that different non-digestible carbohydrates can have entirely different effects on the in vivo infectivity of L. monocytogenes and that microbiota independent mechanisms might be involved. All the tested carbohydrates affected expression of adherence genes but only XOS affected the in vitro adhesion of L. monocytogenes to intestinal cell. This may suggest that different mechanisms are responsible for the observed in vivo effect of the different non-digestible carbohydrates. Mostly microbiota independent mechanisms were investigated in this project, but it is very likely that microbiota dependent mechanisms also are involved.

**General information**

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**Organisations:** Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment  
**Authors:** Ebersbach, T. (Intern), Poulsen, M. (Intern), Licht, T. R. (Intern)  
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**Effects of selected non-digestible dietary carbohydrates on the composition of the large intestinal microbiota and susceptibility to salmonella infections**

The mammalian intestinal tract is a complex ecosystem colonised by a high and diverse number of commensal bacterial. Bacteria colonising the intestinal tract have a profound impact on host health e.g. by acting as a barrier against colonisation by pathogens and by contributing to digestion of complex food components. In this regard there is a considerable interest in dietary components that can modulate the gut microbiota and potentially improve gut health. Some gut bacteria, known as probiotics, are believed to improve gut health upon ingestion, whereas non-digestible (ND) dietary carbohydrates, known as prebiotics, are food components aimed at selectively stimulating such beneficial bacteria already colonizing the intestinal tract. In this regard, prebiotics and other ND dietary carbohydrates may improve host resistance to intestinal infections by selectively modulating the composition of the gut microbiota or by stimulating the immune response. Salmonella is a genus of Gram-negative bacteria that are a major cause of food-borne illness globally. Several studies with probiotics have demonstrated protective effects against murine Salmonella infections, while studies with prebiotics have shown conflicting results. Therefore the aim of the present thesis was to investigate the effect of selected ND dietary carbohydrates on the large intestinal microbiota and susceptibility to Salmonella enterica serovar Typhimurium SL1344 infection in mice. The thesis contains an introduction to the digestive function of the gastrointestinal tract and the associated microbiota, followed by a description of dietary strategies for modulation of the intestinal microbiota with particular emphasis on effects on Salmonella infections. Subsequently, three manuscripts are presented based on the experimental studies performed. Results presented in Manuscript I demonstrated no in vivo protective effect of the investigated carbohydrates against the Salmonella infection. In contrast, two of the investigated substrates (fructo-oligosaccharides and xylo-oligosaccharides) demonstrated an adverse rather than a protective effect against the infection. Manuscript II investigated diet-induced changes in the large intestinal microbiota of mice exhibiting a reduced resistance to the Salmonella infection. Diets supplemented with fructo-oligosaccharides or xylo-oligosaccharides induced a number of microbial changes in the faecal microbiota including an increase in the Bacteroidetes phylum, the Bacteroides fragilis group and in Bifidobacterium spp., while reductions were observed in the Firmicutes phylum and the Clostridium cocoides group. The findings thus suggest that some microbial changes in the large intestine may increase the infectious potential of Salmonella. The last study, presented in Manuscript III, was performed during a research stay at CSIRO Food and Nutritional Sciences, Australia. In this study a two-stage continuous fermenter was used to determine if incubating human faeces with xylo-oligosaccharides (XOS) lowers faecal water genotoxicity induced by protein fermentation. XOS fermentation was seen to reduce faecal water genotoxicity in vessel 1, but to increase the genotoxicity in vessel 2. Butyrate concentrations were significantly elevated in both vessels and could be related to an increase in the C. cocoides group. Other microbial changes observed, including a reduction in Bifidobacterium spp. and sulphate-reducing bacteria, suggest that quantities of some bacterial species are related to changes in faecal water genotoxicity. Conclusively, the studies contribute to our knowledge of the effect of some ND dietary carbohydrates on the composition of the large intestinal microbiota and the effect such changes may have on the susceptibility to Salmonella infections or the risk of
An Onion Byproduct Affects Plasma Lipids in Healthy Rats
Onion may contribute to the health effects associated with high fruit and vegetable consumption. A considerable amount of onion production ends up as waste that might find use in foods. Onion byproduct has not yet been explored for potential health benefits. The aim of this study is to elucidate the safety and potential role of onion byproducts in affecting risk markers of cardiovascular disease (CVD). For that purpose, the effects of an onion byproduct, Allium cepa L. cepa 'Recas' (OBP), and its two derived fractions, an ethanolic extract (OE) and a residue (OR), on the distribution of plasma lipids and on factors affecting cholesterol metabolism in healthy rats have been investigated. The OBP or its fractions did not significantly reduce cholesterol or down-regulate hepatic 3-hydroxy-3-methylglutaryl-coenzyme A reductase (Hmgcr) gene expression. The OR even had the effect of increasing plasma triacylglycerides (TAG) and cholesterol in the very low density lipoprotein (VLDL-C) fraction. Neither total bile acids nor total primary or secondary bile acids were significantly affected by feeding rats the OBP or its fractions. Principal component analysis combining all markers revealed that the controls could be completely separated from OBP, OE, and OR groups in the scores plot and also that OE and OR groups were separated. Plasma lipids and bile acid excretion were the discriminating loading factors for separating OE and OR but also contributed to the separation of onion-fed animals and controls. It was concluded that the onion byproduct did not present significant beneficial effects on individual markers related to plasma lipid transport in this healthy rat model but that onion byproduct contains factors with the ability to modulate plasma lipids and lipoprotein levels.
plasma lipids, platelet aggregation, Onion byproduct, CVD risk factors, gene expression, bile acids

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Apple, Cherry, and Blackcurrant Increases Nuclear Factor Kappa B Activation in Liver of Transgenic Mice

Nuclear factor kappa B (NF-B) is essential in normal physiology, and several human disorders involve inappropriate regulation of NF-B. Diets dominated by plant-based foods protect against chronic diseases, and several food derived compounds have been identified as promising NF-B modulators. We investigated the effects of diets supplemented with apple, blackcurrant, or cherries on lipopolysaccharide (LPS)-induced NF-B activation in transgenic NF-B-luciferase mice. Whole body and organ specific NF-B activities were determined. The mice had ad libitum access to the respective experimental diets for 7 days. On Day 7, all mice were given an LPS-injection (2.5 mg/kg), and NF-B activation was monitored by in vivo imaging for 6 h. After imaging, blood samples were taken, the mice were euthanized, and ex vivo imaging of organs was performed. Compared to the control group, the apple and cherry groups had slightly higher whole-body NF-B activation at 4 h, and all 3 experimental groups had higher NF-B activation at 6 h. LPS-induced NF-B activation in liver was increased with all 3 experimental diets, but no effects were observed in other organs. Our findings indicate that high intakes of lyophilized fruits modulate in vivo NF-B signaling in the liver following LPS-induced stress; however, consequences of this NF-B modulation in hepatic tissue needs further investigation.
Assessing biosafety of GM plants containing lectins

The introduction of genetic engineering has already shown its benefits in transferring genes into crop plants and conferring resistance towards pests. Most of these crop plants on the market have been transformed with the cry genes from Bacillus species, conferring resistance towards certain insects. However, since the cry genes are not active against all insects, e.g. sap-sucking insects, other genes coding for proteins such as lectins show promise of complementing the cry genes for insect resistance. As with other novel plants, lectin-expressing plants will need to be assessed for their potential risks to human and animal health and the environment. The expressed lectin protein should be assessed on its own for potential toxicity and allergenicity as for any other new protein. Although not many lectins have been thoroughly tested for their toxicity, our evaluation suggests that most of the lectins that are potentially useful for insect resistance will pose no health risk in genetically modified (GM) plants. Since some lectins are known for their toxicity to humans, the insertion of lectin genes in food crop plants will have to be assessed carefully. It is expected that in some cases there will be a need to perform animal tests of such GM plants in order to eliminate any uncertainties about potential safety issues for these plants. A 90-day study designed and optimized for this purpose is suggested as one way to cope with these uncertainties.

General information
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Authors: Poulsen, M. (Intern), Pedersen, J. W. (Intern)
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Scopus rating (2016): SJR 0.257 SNIP 0.303 CiteScore 0.42
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Scopus rating (2015): SJR 0.284 SNIP 0.358 CiteScore 0.66
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 0.26 SNIP 0.325 CiteScore 0.56
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 0.238 SNIP 0.235 CiteScore 0.48
Certain dietary carbohydrates promote Listeria infection in a guinea pig model, while others prevent it

It has been proposed that dietary non-digestible carbohydrates can improve host resistance to intestinal infections by stimulating health-promoting bacteria in the gut. However, evidence from in vivo infection studies is scarce, particularly for gram-positive infections. We studied the effect of five non-digestible carbohydrates on the resistance of guinea pigs to Listeria monocytogenes infections. Animals were fed a diet supplemented with 10% xylooligosaccharides (XOS), galactooligosaccharides (GOS), inulin, apple pectin or polydextrose for three weeks before oral infection with a mixture of three different fluorescently labeled L monocytogenes strains. Colonisation of L. monocytogenes in the intestine was determined by quantification of L. monocytogenes in faecal, ileal and caecal samples while translocation was determined by quantification of L monocytogenes in mesenteric lymph nodes, spleen and liver. XOS and GOS significantly promote the growth of health-promoting bacteria, but also significantly increase the colonization of L. monocytogenes in the gut.
Effects of apples and specific apple components on the cecal environment of conventional rats: Role of apple pectin

Background: Our study was part of the large European project ISAFRUIT aiming to reveal the biological explanations for the epidemiologically well-established health effects of fruits. The objective was to identify effects of apple and apple product consumption on the composition of the cecal microbial community in rats, as well as on a number of cecal parameters, which may be influenced by a changed microbiota. Results: Principal Component Analysis (PCA) of cecal microbiota profiles obtained by PCR-DGGE targeting bacterial 16S rRNA genes showed an effect of whole apples in a long-term feeding study (14 weeks), while no effects of apple juice, puree or pomace on microbial composition in cecum were observed. Administration of either 0.33 or 3.3% apple pectin in the diet resulted in considerable changes in the
DGGE profiles. A 2-fold increase in the activity of beta-glucuronidase was observed in animals fed with pectin (7% in the diet) for four weeks, as compared to control animals (P <0.01). Additionally, the level of butyrate measured in these pectin-fed animal was more than double of the corresponding level in control animals (P <0.01). Sequencing revealed that DGGE bands, which were suppressed in pectin-fed rats, represented Gram-negative anaerobic rods belonging to the phylum Bacteroidetes, whereas bands that became more prominent represented mainly Gram-positive anaerobic rods belonging to the phylum Firmicutes, and specific species belonging to the Clostridium Cluster XIVa. Quantitative real-time PCR confirmed a lower amount of given Bacteroidetes species in the pectin-fed rats as well as in the apple-fed rats in the four-week study (P <0.05). Additionally, a more than four-fold increase in the amount of Clostridium coccoides (belonging to Cluster XIVa), as well as of genes encoding butyryl-coenzyme A CoA transferase, which is involved in butyrate production, was detected by quantitative PCR in fecal samples from the pectin-fed animals. Conclusions: Our findings show that consumption of apple pectin (7% in the diet) increases the population of butyrate- and beta-glucuronidase producing Clostridiales, and decreases the population of specific species within the Bacteroidetes group in the rat gut. Similar changes were not caused by consumption of whole apples, apple juice, puree or pomace.

General information
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Authors: Licht, T. R. (Intern), Hansen, M. (Intern), Bergström, A. (Intern), Poulsen, M. (Intern), Krath, B. (Intern), Markowski, J. (Ekstern), Dragsted, L. (Ekstern), Wilcks, A. (Intern)
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Web of Science (2015): Indexed yes
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Scopus rating (2014): SJR 1.519 SNIP 1.069 CiteScore 2.95
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ISI indexed (2011): ISI indexed yes
Web of Science (2011): Indexed yes
BFI (2010): BFI-level 1
Scopus rating (2010): SJR 1.433 SNIP 1.034
Web of Science (2010): Indexed yes
BFI (2009): BFI-level 1
Regular consumption of fruits and vegetables is associated with reduced risks of certain cancers, cardiovascular diseases, stroke, Alzheimer disease etc. In this project, we focused on apples as a model fruit for some of this research due to its high contents of soluble and insoluble fibers, flavonoids and phenolic acids and because of the high intakes of apples in northern parts of Europe. A series of 4-16 w rat feeding studies with fresh whole apples, dried apple, apple puree, clear and cloudy apple juices, apple pomace, and apple pectins have been conducted. A human cross-over dietary intervention study in 24 healthy volunteers with apple and apple products has also been performed. They supplemented a polyphenol and pectin restricted diet with whole apples, apple pomace, cloudy or clear apple juices or nothing for 4 weeks. Feeding rats with 10g apple/d reduced plasma total, HDL cholesterol, and VLDL cholesterol at 4w and 16w without significantly affecting cholesterol ratios, plasma triacylglycerols, or gastrointestinal transit times. Screening the genes coding for 16s RNA in the intestinal flora and applying multivariate statistics revealed significant changes in the flora related to feeding with apple or apple pectin. This was also reflected in changed gut flora enzymatic activities, whereas caecum short chain fatty acid concentrations were unaffected by feeding with all apple products, except high doses of apple pectins. In the human study the whole apple had the strongest hypocholesterolemic effect, followed by apple pomace and cloudy apple juice. The clear apple juice, which is free of cell wall components showed adverse effect on serum cholesterol concentration and the effect differed markedly compared to the other apple products. There was no effect on HDL-cholesterol, triacylglycerol, bile acid excretion, weight, waist-to-hip circumference or blood pressure. We conclude that the cholesterol-lowering effect of apples is most likely due to the content of soluble fibre in combination with other cell wall components.
NMR and interval PLS as reliable methods for determination of cholesterol in rodent lipoprotein fractions

Risk of cardiovascular disease is related to cholesterol distribution in different lipoprotein fractions. Lipoproteins in rodent model studies can only reliably be measured by time- and plasma-consuming fractionation. An alternative method to measure cholesterol distribution in the lipoprotein fractions in rat plasma is presented in this paper. Plasma from two rat studies (n = 68) was used in determining the lipoprotein profile by an established ultracentrifugation method and proton nuclear magnetic resonance (NMR) spectra of replicate samples was obtained. From the ultracentrifugation reference data and the NMR spectra, an interval partial least-square (iPLS) regression model to predict the amount of cholesterol in the different lipoprotein fractions was developed. The relative errors of the prediction models were between 12 and 33% and had correlation coefficients (r) between 0.96 and 0.84. The models were tested with an independent test set giving prediction errors between 19 and 46% and r between 0.96 and 0.76. Prediction of High, Low and Very Low Density Lipoprotein (HDL, LDL and VLDL) and total cholesterol was conducted in a study where rats had been supplemented with two doses of air-dried apple-powder. No significant difference in LDL, VLDL and total cholesterol was observed between the groups. The high apple-powder (20%) group had significantly lower HDL cholesterol (11%, P = 0.0452) than the control group. It is concluded that the iPLS approach yielded excellent regression models and thus univocal established chemometric analysis of NMR spectra of rat plasma as a strong and efficient way to quantify lipoprotein fractions in rat studies.
A 28-day repeat dose toxicity study of steroidal glycoalkaloids, alpha-solanine and alpha-chaconine in the Syrian Golden hamster

Glycoalkaloids alpha-solanine and alpha-chaconine are naturally present toxicants in the potato plant (Solanum tuberosum). Human intake of high doses of glycoalkaloids has led to acute intoxication, in severe cases coma and death. Previous studies have indicated that the ratio of alpha-solanine to alpha-chaconine may determine the degree and nature of the glycoalkaloid toxicity in potatoes, as the toxicity of the two alkaloids act synergistically. The aim of the present study was to investigate whether an altered ratio of alpha-solanine and alpha-chaconine would reduce the toxicity of the glycoalkaloids. The Syrian Golden hamster was given daily doses of alpha-solanine and alpha-chaconine by gavage for 28 days. Doses of up to 33.3 mg total glycoalkaloids/kg body weight were applied in ratios of 1:3.7 and 1:70 (alpha-solanine:alpha-chaconine). Administration of the highest doses of both ratios resulted in distended and fluid filled small intestines and stomach. Animals receiving the ratio with the reduced content of alpha-solanine were less affected compared to those receiving the other ratio. Gene expression profiling experiments were conducted using RNA from epithelial scrapings from the small intestines of the hamsters administered the highest doses of the glycoalkaloid treatments. In general, more differential gene expression was observed in the epithelial scrapings of the hamsters fed the ratio of 1:3.7. Mostly, pathways involved in lipid and energy metabolism were affected by the ratio of 1:3.7.
An exploratory NMR nutri-metabonomic investigation reveals dimethyl sulfone as a dietary biomarker for onion intake

**General information**

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Consejo Superior de Investigaciones Científicas, University of Copenhagen


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Effect of apple pectin on gut microbiota - qPCR in applied microbiology

This study was part of the large European project ISAFRUIT aiming to reveal the biological explanations for the epidemiologically well-established health effects of fruits. The objective was to identify effects of apple and apple product consumption on the composition of the cecal microbial community in rats, as well as on a number of cecal parameters, which could be influenced by a changed microbiota. Principal Component Analysis (PCA) of cecal microbiota profiles obtained by PCR-DGGE targeting bacterial 16S rRNA genes showed an effect of whole apples in a long-term feeding study (14 weeks), while no effects of apple juice, purée or pomace on microbial composition in cecum were observed.
Administration of pectin derived from apples resulted in considerable changes of these DGGE profiles. A 2-fold increase in the activity of beta-glucuronidase was observed in animals fed with pectin (7% in the diet) for four weeks, as compared to control animals (<P>.

**General information**

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**Organisations:** National Food Institute, Division of Microbiology and Risk Assessment, Division of Toxicology and Risk Assessment, University of Copenhagen  
**Authors:** Bergström, A. (Intern), Wilcks, A. (Intern), Poulsen, M. (Intern), Dragsted, L. O. (Ekstern), Licht, T. R. (Intern)  
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**Effect of apple pectin on gut microbiota - qPCR in applied microbiology**

This study was part of the large European project ISAFRUIT aiming to reveal the biological explanations for the epidemiologically well-established health effects of fruits. The objective was to identify effects of apple and apple product consumption on the composition of the cecal microbial community in rats, as well as on a number of cecal parameters, which could be influenced by a changed microbiota. Principal Component Analysis (PCA) of cecal microbiota profiles obtained by PCR-DGGE targeting bacterial 16S rRNA genes showed an effect of whole apples in a long-term feeding study (14 weeks), while no effects of apple juice, purée or pomace on microbial composition in cecum were observed. Administration of pectin derived from apples resulted in considerable changes of these DGGE profiles. A 2-fold increase in the activity of beta-glucuronidase was observed in animals fed with pectin (7% in the diet) for four weeks, as compared to control animals (<P>.

**General information**

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**Organisations:** National Food Institute, Division of Microbiology and Risk Assessment, Division of Toxicology and Risk Assessment, University of Copenhagen  
**Authors:** Bergström, A. (Intern), Wilcks, A. (Intern), Poulsen, M. (Intern), Dragsted, L. O. (Ekstern), Licht, T. R. (Intern)  
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**Effect of rapeseed oil derived plant sterol and stanol esters on atherosclerosis parameters in cholesterol challenged heterozygous Watanabe Heritable Hyperlipidemic rabbits**

Rapeseed oil (RSO) is a novel source of plant sterols, containing the unique brassicasterol in concentrations higher than allowed for plant sterol blends in food products in the European Union. Effects of RSO sterols and stanols on aortic atherosclerosis were studied in cholesterol-fed heterozygous Watanabe heritable hyperlipidaemic (Hh-WHHL) rabbits. Four groups (n 18 per group) received a cholesterol-added (2 g/kg) standard chow or this diet with added RSO stanol esters (17 g/kg), RSO stanol esters (34 g/kg) or RSO sterol esters (34 g/kg) for 18 weeks. Feeding RSO stanol esters increased plasma campestanol (<P>0·001) and sitostanol (<P>0·001) and aortic campestanol (<P>0·05) compared with controls. Feeding RSO sterol esters increased concentrations of plasma campesterol (<P>0·001), sitosterol (<P>0·001) and brassicasterol (<P>0·001) and aortic campesterol (<P>0·01). Significantly lower plasma cholesterol (<P>0·001) was recorded in the treated groups after 3 weeks and throughout the study. LDL-cholesterol was reduced 50 % in the high-dose RSO sterol ester (P <0·01) and high-dose RSO stanol ester (P <0·001) groups compared with controls. Atherosclerotic lesions were found in three rabbits in each of the RSO stanol ester groups and in one in the RSO sterol ester group. Aortic cholesterol was decreased in the treated groups (P <0·001) in response to lowering of plasma cholesterol induced by RSO sterol and stanol esters. In conclusion, RSO stanol and sterol esters with a high concentration of brassicasterol were well tolerated. They were hypocholesterolaemic and inhibited experimental atherosclerosis in cholesterol-fed Hh-WHHL rabbits. A significant uptake of plant sterols into the blood and incorporation of campesterol and campestanol into aortic tissue was recorded.

**General information**

**State:** Published  
**Organisations:** Division of Toxicology and Risk Assessment, National Food Institute, University of Bonn, Raisio Group
Effects of an onion by-product on bioactivity and safety markers in healthy rats

Onions are excellent sources of bioactive compounds including fructo-oligosaccharides (FOS) and polyphenols. An onion by-product was characterised in order to be developed as a potentially bioactive food ingredient. Our main aim was to investigate whether the potential health and safety effects of this onion by-product were shared by either of two derived fractions, an extract containing the onion FOS and polyphenols and a residue fraction containing mainly cell wall materials. We report here on the effects of feeding these products on markers of potential toxicity, protective enzymes and gut environment in healthy rats. Rats were fed during 4 weeks with a diet containing the products or a control feed balanced in carbohydrate. The onion by-product and the extract caused anaemia as expected in rodents for Allium products. No other toxicity was observed, including genotoxicity. Glutathione reductase (GR) and glutathione peroxidase (GPx1) activities in erythrocytes increased when rats were fed with the onion extract. Hepatic gene expression of Gr, Gpx1, catalase, 5-aminolevulinate synthase and NAD(P)H:quinone oxidoreductase was not altered in any group of the onion fed rats. By contrast, γ-glutamate cysteine ligase catalytic subunit gene expression was upregulated but only in rats given the onion residue. The onion by-products as well as the soluble and insoluble fractions had prebiotic effects as evidenced by decreased pH, increased butyrate production and altered gut microbiota enzyme activities. In conclusion, the onion by-products have no in vivo genotoxicity, may support in vivo antioxidative defence and alter the functionality of the rat gut microbiota.

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Scopus rating (2016): CiteScore 3.46 SJR 2.055 SNIP 1.535
Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 1.583 SNIP 1.442 CiteScore 3.52
GMO - hvad kan vi bruge det til?

General information
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Authors: Pedersen, J. W. (Intern), Poulsen, M. (Intern), Sørensen, I. K. (Intern)
Some putative prebiotics increase the severity of Salmonella enterica serovar Typhimurium infection in mice

Prebiotics are non-digestible food ingredients believed to beneficially affect host health by selectively stimulating the growth of the beneficial bacteria residing in the gut. Such beneficial bacteria have been reported to protect against pathogenic infections. However, contradicting results on prevention of Salmonella infections with prebiotics have been published. The aim of the present study was to examine whether S. Typhimurium SL1344 infection in mice could be prevented by administration of dietary carbohydrates with different structures and digestibility profiles. BALB/c mice were fed a diet containing 10% of either of the following carbohydrates: inulin, fructo-oligosaccharide, xylo-oligosaccharide, galacto-oligosaccharide, apple pectin, polydextrose or beta-glucan for three weeks prior to oral Salmonella challenge (10^7 CFU) and compared to mice fed a cornstarch-based control diet. RESULTS: The mice fed with diets containing fructo-oligosaccharide (FOS) or xylo-oligosaccharide (XOS) had significantly higher (P <0.01 and P <0.05) numbers of S. Typhimurium SL1344 in liver, spleen and mesenteric lymph nodes when compared to the mice fed with the cornstarch-based control diet. Significantly increased amounts (P <0.01) of Salmonella were detected in ileal and fecal contents of mice fed with diets supplemented with apple pectin, however these mice did not show significantly higher numbers of S. Typhimurium in liver, spleen and lymph nodes than animals from the control group (P <0.20). The acute-phase protein haptoglobin was a good marker for translocation of S. Typhimurium in mice. In accordance with the increased counts of Salmonella in the organs, serum concentrations of haptoglobin were significantly increased in the mice fed with FOS or XOS (P <0.001). Caecum weight was increased in the mice fed with FOS (P <0.01), XOS (P <0.01), or polydextrose (P <0.001), and caecal pH was reduced in the mice fed with polydextrose (P <0.001). In vitro fermentation in monocultures revealed that S. Typhimurium SL1344 is capable of fermenting FOS, beta-glucan and GOS with a corresponding decline in pH. CONCLUSION: Supplementing a cornstarch-based rodent diet with 10% FOS or XOS was found to increase the translocation of S. Typhimurium SL1344 to internal organs in mice, while 10% apple pectin was found to increase the numbers of S. Typhimurium in intestinal content and feces.
Spis frugt og bliv sundere

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, University of Copenhagen
Authors: Dragsted, L. O. (Ekstern), Poulsen, M. (Intern)
The Use of Transcriptomics to Elucidate the Genome Wide Impact of Unsaturated Fatty Acids

General information
State: Published
Organisations: Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment, University of Copenhagen
Pages: 54-54
Publication date: 2009
Main Research Area: Technical/natural sciences

Publication information
Journal: Annals of Nutrition and Metabolism
Volume: 55
Issue number: Suppl. 1
ISSN (Print): 0250-6807
Ratings:
- BFI (2018): BFI-level 1
- Web of Science (2018): Indexed yes
- BFI (2017): BFI-level 1
- Scopus rating (2017): SJR 1.057 SNIP 1.317 CiteScore 2.78
- Web of Science (2017): Indexed Yes
- BFI (2016): BFI-level 1
- Scopus rating (2016): SJR 1.215 SNIP 1.003 CiteScore 2.69
- Web of Science (2016): Indexed yes
- BFI (2015): BFI-level 1
- Scopus rating (2015): SJR 1.074 SNIP 1.016 CiteScore 2.55
- Web of Science (2015): Indexed yes
- BFI (2014): BFI-level 1
- Scopus rating (2014): SJR 1.294 SNIP 1.096 CiteScore 2.64
- BFI (2013): BFI-level 1
- Scopus rating (2013): SJR 0.957 SNIP 1.036 CiteScore 2.46
- ISI indexed (2013): ISI indexed yes
- Web of Science (2013): Indexed yes
- BFI (2012): BFI-level 1
- Scopus rating (2012): SJR 0.867 SNIP 0.89 CiteScore 2.35
- ISI indexed (2012): ISI indexed yes
- BFI (2011): BFI-level 1
- Scopus rating (2011): SJR 0.889 SNIP 0.95 CiteScore 2.38
- ISI indexed (2011): ISI indexed yes
- Web of Science (2011): Indexed yes
Acute toxicity of high doses of the glycoalkaloids, alpha-solanine and alpha-chaconine, in the Syrian Golden hamster

Sprouted, stressed, or spoiled potato tubers have reportedly led to human acute intoxication, coma, and death when consumed in high amounts. These effects have been attributed to glycoalkaloids (GAs), primarily alpha-solanine and alpha-chaconine, naturally present in all potatoes. The level of GAs in potato tubers has previously been shown to increase substantially as a result of improper handling and postharvest storage. A short-term study was performed to investigate the dose-response profile of alpha-solanine and alpha-chaconine alone or in combination, administered daily by oral gavage to Syrian Golden hamsters. Daily doses of 100 mg of alpha-solanine [kg body weight (BW)](-1) induced death in two of four hamsters within 4 days, when administered by gavage to female Syrian hamsters. Doses of 100 mg of alpha-chaconine alone or alpha-solanine and alpha-chaconine combined in a ratio of 1:2.5, in doses of 75 or 100 mg (kg BW)(-1), induced death in one of four hamsters within the same period. Animals dosed with alpha-solanine alone or in combination with alpha-chaconine suffered from fluid-filled and dilated small intestines. The GA administration had no effect on acetyl cholinesterase (AChE) or butyryl cholinesterase (BuChE) activity in plasma or brain. Liquid chromatography-mass spectrometry-based metabolomics showed that there was a specific accumulation of alpha-chaconine in the liver tissues. In addition, metabolomics gave direct evidence of glycolytic metabolism of the GA with the beta(1), beta(2), and gamma-GAs detected in the urine and, to a lesser extent, the feces. Doses from 75 mg (kg BW)(-1) of alpha-chaconine, alpha-solanine, or the two compounds combined were potentially lethal within 4-5 days in the Syrian Golden hamster. However, the cause of death in these studies could not be established. No synergistic effects of alpha-solanine combined with alpha-chaconine were evident.

General information
State: Published
Organisations: National Food Institute, Division of Toxicology and Risk Assessment
Authors: Langkilde, S. (Intern), Schrøder, M. (Intern), Stewart, D. (Ekstern), Meyer, O. A. (Intern), Conner, S. (Ekstern), Davies, H. (Ekstern), Poulsen, M. (Intern)
Pages: 8753-8760
Publication date: 2008
Main Research Area: Technical/natural sciences

Publication information
Journal: Journal of Agricultural and Food Chemistry
Volume: 56
Issue number: 18
ISSN (Print): 0021-8561
Ratings:
BFI (2018): BFI-level 2
Web of Science (2018): Indexed yes
Effect of apple consumption on aberrant crypt foci, an intermediate colon cancer biomarker - an example of research activities within ISAFRUIT project

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Center for Systems Microbiology, Department of Systems Biology
Publication date: 2008

Publication information
Publisher: Wydawnictwo SGGW
ISBN (Print): 978-83-7244-959-7
Original language: English
Main Research Area: Technical/natural sciences
Source: orbit
Source-ID: 233495
Publication: Research - peer-review › Book – Annual report year: 2008

Effect of apple pectin consumption on the rat caecal microbiota

General information
State: Published
Organisations: Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment, University of Copenhagen
Publication date: 2008

Publication information
Original language: English
Main Research Area: Technical/natural sciences
Source: orbit
Source-ID: 250181
Publication: Research › Sound/Visual production (digital) – Annual report year: 2008

Health benefits of increased fruit intake - integrating observational studies with experimental studies on fruit health and nutrigenomics

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Danish Cancer Society, Research Institute of Pomology and Floriculture, University of Copenhagen
Authors: Dragsted, L. O. (Ekstern), Tjonneland, A. (Ekstern), Ravn-Haren, G. (Intern), Kristensen, M. (Intern), Poulsen, M. (Intern), Plocharski, W. (Ekstern), Bügel, S. (Ekstern)
Pages: 55-69
Publication date: 2008

Publication information
Journal: Scripta Horticulturae
Volume: 8
ISSN (Print): 1813-9205
Original language: English
Links:
Source: orbit
Source-ID: 245831
Publication: Research - peer-review › Journal article – Annual report year: 2008
Immunotoxicological studies of genetically modified rice expressing PHA-E lectin or Bt toxin in Wistar rats

As part of the SAFOTEST project the immunomodulating effect of Cry1Ab protein from Bacillus thuringiensis (Bt) and PHA-E lectin from kidney bean (Phaseolus vulgaris erythroagglutinin) was examined in 28- and 90-day feeding studies in Wistar rats. PHA-E lectin was chosen as positive control. Rats were fed control rice, transgenic rice expressing Cry I Ab protein or PHA-E lectin, or transgenic rice spiked with the purified recombinant protein. Total immunoglobulin levels, mitogen-induced cell proliferation, T-dependent antibody response to sheep red blood cells and the antigen-specific antibody response in serum were examined at the end of the studies. A dose-dependent increase in mesenteric lymph node weight and total immunoglobulin A was seen when feeding PHA-E transgenic rice alone or spiked with 0.1% purified PHA-E lectin for 90 days indicating a local effect of PHA-E in the intestine. No adverse effects of Cry1Ab protein were found. An anti-PHA-E and anti-Cry I Ab antibody response was induced both after inhalation (control groups) and after inhalation/ingestion (groups fed recombinant protein alone or together with transgenic rice). In conclusion, only PHA-E lectin was found to have an immunomodulating effect when feeding rats for 90 days with approximately 70 mg PHA-E/kg bodyweight per day. As both PHA-E lectin and Cry1Ab protein were capable of inducing an antigen-specific antibody response it is important to make careful considerations when designing future animal studies to avoid intake of proteins from the other groups by inhalation as well as to examine the sensitization and elicitation potential of 'foreign' proteins before introduction to the world market. (C) 2007 Elsevier Ireland Ltd. All rights reserved.

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Authors: Kroghsbo, S. (Intern), Madsen, C. B. (Intern), Poulsen, M. (Intern), Schrøder, M. (Intern), Kvist, P. H. (Ekstern), Taylor, M. (Ekstern), Gatehouse, A. (Ekstern), Shu, Q. (Ekstern), Knudsen, L. B. (Ekstern)
Pages: 24-34
Publication date: 2008
Main Research Area: Technical/natural sciences

Publication information
Journal: Toxicology
Volume: 245
Issue number: 1-2
ISSN (Print): 0300-483X
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): SNIP 0.978 SJR 1.1 CiteScore 3.39
Web of Science (2017): Indexed Yes
BFI (2016): BFI-level 1
Scopus rating (2016): SJR 1.468 SNIP 1.198 CiteScore 3.91
Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 1.345 SNIP 1.262 CiteScore 3.7
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 1.23 SNIP 1.256 CiteScore 3.39
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 1.239 SNIP 1.443 CiteScore 3.9
ISI indexed (2013): ISI indexed yes
BFI (2012): BFI-level 1
Scopus rating (2012): SJR 1.303 SNIP 1.361 CiteScore 3.79
ISI indexed (2012): ISI indexed yes
Web of Science (2012): Indexed yes
BFI (2011): BFI-level 1
Scopus rating (2011): SJR 1.273 SNIP 1.348 CiteScore 3.75
ISI indexed (2011): ISI indexed yes
BFI (2010): BFI-level 1
Scopus rating (2010): SJR 1.218 SNIP 1.166
Web of Science (2010): Indexed yes
BFI (2009): BFI-level 1
Prebiotics for prevention of Salmonella infections

General information
State: Published
Organisations: Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment
Authors: Petersen, A. (Intern), Wilcks, A. (Intern), Poulsen, M. (Intern), Licht, T. R. (Intern)
Publication date: 2008
Event: Abstract from 6th Joint INRA-RRI Symposium on Gut Microbiome, Functionality, Interaction with the host and Impact on the environment, Clermont-Ferrand, France.
Main Research Area: Technical/natural sciences
Source: orbit
Source-ID: 234133
Publication: Research - peer-review › Conference abstract for conference – Annual report year: 2008

Prebiotics for prevention of Salmonella infections

General information
State: Published
Organisations: Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment
Authors: Petersen, A. (Intern), Wilcks, A. (Intern), Poulsen, M. (Intern), Licht, T. R. (Intern)
Publication date: 2008
Event: Poster session presented at 6th Joint INRA-RRI Symposium on Gut Microbiome, Functionality, Interaction with the host and Impact on the environment, Clermont-Ferrand, France.
Main Research Area: Technical/natural sciences
Source: orbit
Source-ID: 234134
Publication: Research › Poster – Annual report year: 2008

Prebiotics for Prevention of Salmonella Infections
Prebiotics for Prevention of Salmonella Infections

General information
State: Published
Organisations: Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment
Authors: Petersen, A. (Intern), Lahtinen, S. (Ekstern), Poulsen, M. (Intern), Wilcks, A. (Intern), Licht, T. R. (Intern)
Publication date: 2008
Event: Abstract from 2nd ASM Conference on Beneficial Microbes, San Diego, CA, United States.
Main Research Area: Technical/natural sciences
Source: orbit
Source-ID: 234125
Publication: Research - peer-review › Conference abstract for conference – Annual report year: 2008

Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Authors: EFSA Publication
Pages: S1-S1
Publication date: 2008
Main Research Area: Technical/natural sciences

Publication information
Journal: Food and Chemical Toxicology
Volume: 46
ISSN (Print): 0278-6915
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): CiteScore 3.99 SJR 1.144 SNIP 1.427
Web of Science (2017): Indexed yes
BFI (2016): BFI-level 1
Scopus rating (2016): CiteScore 3.96 SJR 1.351 SNIP 1.58
Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 1.202 SNIP 1.415 CiteScore 3.44
Web of Science (2015): Indexed yes
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 1.038 SNIP 1.369 CiteScore 3.12
Web of Science (2014): Indexed yes
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 1.02 SNIP 1.506 CiteScore 3.26
ISI indexed (2013): ISI indexed yes
Web of Science (2013): Indexed yes
BFI (2012): BFI-level 1
Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Pages: S2-S70
Publication date: 2008
Main Research Area: Technical/natural sciences

Publication information
Journal: Food and Chemical Toxicology
Volume: 46
ISSN (Print): 0278-6915
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
A 90-day safety study in Wistar rats fed genetically modified rice expressing snowdrop lectin Galanthus nivalis (GNA)

Genetically modified plants expressing insecticidal traits offer a new strategy for crop protection, but at the same time present a challenge in terms of food safety assessment. The present 90-day feeding study was designed to assess the safety of a rice variety expressing the snowdrop Galanthus nivalis lectin (GNA lectin), and forms part of a EU-funded project where the objective has been to develop and validate sensitive and specific methods to assess the safety of genetically modified foods. Male and female Wistar rats were given a purified diet containing either 60% genetically modified or parental rice for 90 days. This corresponds to a mean daily GNA lectin intake of approximately 58 and 67 mg/kg body weight for males and females, respectively. Prior to the animal study comprehensive analytical characterization of both rice materials was performed. The chemical analyses showed a number of statistically significant differences, with the majority being within the ranges reported in the literature. In the animal study a range of clinical, biological, immunological, microbiological and pathological parameters were examined. A number of significant differences were seen between groups fed the two diets, but none of them were considered to be adverse. In conclusion, the design of the present animal study did not enable us to conclude on the safety of the GM food. Additional group(s) where the expressed gene products have been spiked to the diet should be included in order to be able to distinguish whether the observed effects were due to the GNA lectin per se or to secondary changes in the GM rice.

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Microbiology and Risk Assessment
Pages: 350-363
Publication date: 2007
Main Research Area: Technical/natural sciences

Publication information
Journal: Food and Chemical Toxicology
Volume: 45
Issue number: 3
ISSN (Print): 0278-6915
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): CiteScore 3.99 SJR 1.144 SNIP 1.427
Web of Science (2017): Indexed yes
BFI (2016): BFI-level 1
Scopus rating (2016): CiteScore 3.96 SJR 1.351 SNIP 1.58
Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 1.202 SNIP 1.415 CiteScore 3.44
Web of Science (2015): Indexed yes
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 1.038 SNIP 1.369 CiteScore 3.12
Web of Science (2014): Indexed yes
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 1.02 SNIP 1.506 CiteScore 3.26
ISI indexed (2013): ISI indexed yes
Web of Science (2013): Indexed yes
BFI (2012): BFI-level 1
Scopus rating (2012): SJR 1.126 SNIP 1.748 CiteScore 3.52
ISI indexed (2012): ISI indexed yes
Web of Science (2012): Indexed yes
BFI (2011): BFI-level 1
Scopus rating (2011): SJR 1.124 SNIP 1.58 CiteScore 3.36
ISI indexed (2011): ISI indexed yes
A 90-day safety study of genetically modified rice expressing Cry1Ab protein (Bacillus thuringiensis toxin) in Wistar rats

An animal model for safety assessment of genetically modified foods was tested as part of the SAFOTEST project. In a 90-day feeding study on Wistar rats, the transgenic KMD1 rice expressing Cry1Ab protein was compared to its non-transgenic parental wild type, Xiushui 11. The KMD1 rice contained 15 mg Bt toxin/kg and based on the average feed consumption the daily intake was 0.54 mg Bt toxin/kg body weight. No adverse effects on animal behaviour or weight gain were observed during the study. Blood samples collected one week prior to sacrifice were analyzed and compared for standard haematological and biochemical parameters. A few parameters were significantly different, but all within the normal reference intervals for rats of this breed and age and not in relation to any other findings, thus not considered treatment related. Upon sacrifice a large number of organs were weighed, macroscopic and histopathological examinations were performed with only minor changes to report. The aim of the study was to use a known animal model in performance of safety assessment of a GM crop, in this case KMD1 rice. The results show no adverse or toxic effects of KMD1 rice when tested in the design used in this 90-day study. Nevertheless the experiences from this study lead to the overall conclusion that safety assessment for unintended effects of a GM crop cannot be done without additional test group(s).

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Microbiology and Risk Assessment
Pages: 339-349
Publication date: 2007
Main Research Area: Technical/natural sciences
Apples and pectin change the rat ceacal microbiota

General information
State: Published
Organisations: Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment
Authors: Wilcks, A. (Intern), Poulsen, M. (Intern), Madsen, B. (Ekstern), Dragsted, L. O. (Ekstern), Licht, T. R. (Intern)
Publication date: 2007
Event: Poster session presented at XXX International Congress on Microbial Ecology and Disease Joint with the 4th Probiotics, Prebiotics and New Foods, Rome, Italy.
Main Research Area: Technical/natural sciences
Links:
http://www.somed.nu
Source: orbit
Source-ID: 245270
Publication: Research › Poster – Annual report year: 2007

Apples and pectin change the rat ceacal microbiota

General information
State: Published
Organisations: Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment, Technical University of Denmark
Publication date: 2007
Event: Abstract from The 4th Probiotics, Prebiotics & New Foods, XXX Somed Meeting, Rome, Italy.
Main Research Area: Technical/natural sciences
Source: orbit
Source-ID: 247778
Publication: Research › Conference abstract for conference – Annual report year: 2007

Apples and pectin change the rat ceacal microbiota

General information
State: Published
Organisations: Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment, Technical University of Denmark
Publication date: 2007
Event: Abstract from 5th Symposium on Food Microbiology, Helsingør, Denmark.
Main Research Area: Technical/natural sciences
Source: orbit
Source-ID: 247777
Publication: Research › Conference abstract for conference – Annual report year: 2007

Apples and pectin change the rat ceacal microbiota

General information
State: Published
Organisations: Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment, Technical University of Denmark
Publication date: 2007
Event: Abstract from The Second ISAFRUIT General Assembly, Bologna, Italy.
**Comparative safety testing of genetically modified foods in a 90-day rat feeding study design allowing the distinction between primary and secondary effects of the new genetic event**

This article discusses the wider experiences regarding the usefulness of the 90-day rat feeding study for the testing of whole foods from genetically modified (GM) plant based on data from a recent EU-project [Poulsen, M., Schroder, M., Wilcks, A., Kroghsbo, S., Lindecrona, R.H., Miller, A., Frenzel, T., Danier, J., Rychlik, M., Shu, Q., Emami, K., Taylor, M., Gatehouse, A., Engell-K. H., Knudsen, I., 2007a. Safety testing of GM-rice expressing PHA-E lectin using a new animal test design. Food Chem. Toxicol. 45, 364-377; Poulsen, M., Kroghsbo, S., Schroder, M., Wilcks, A., Jacobsen, H., Miller, A., Frenzel, T., Danier, J., Rychlik, M., Shu, Q., Emami, K., Sudhakar, D., Gatehouse, A., Engell-K. H., Knudsen, I., 2007b. A 90-day safety in Wistar rats fed genetically modified rice expressing snowdrop lectin Galanthus nivalis (GNA). Food Chem. Toxicol. 45, 350-363; Schroder, M., Poulsen, M., Wilcks, A., Kroghsbo, S., Miller, A., Frenzel, T., Danier, J., Rychlik, M., Shu, Q., Emami, K., Gatehouse, A., Shu, Q., Engell-K. H., Knudsen, I., 2007. A 90-day safety study of genetically modified rice expressing Cry1Ab protein (Bacillus thuringiensis toxin) in Wistar rats. Food Chem. Toxicol. 45, 339-349]. The overall objective of the project has been to develop and validate the scientific methodology necessary for assessing the safety of foods from genetically modified plants in accordance with the present EU regulation. The safety assessment in the project is combining the results of the 90-day rat feeding study on the GM food with and without spiking with the pure novel gene product, before the hazard characterisation is concluded. The results demonstrated the ability of the 90-day rat feeding study to detect the biological/toxicological effects of the new gene product in the GM food. The authors consider on this basis that the 90-day, rodent feeding study with one high dose level and a dietary design based upon compositional data on the GM food and toxicity data on the gene product is sensitive and specific enough to verify the presence/absence of the biological/nutritional/toxicological effects of the novel gene insert and further by the use of spiking able to separate potentially unintended effects of the novel gene product from other unintended effects at the level of intake defined in the test and within the remit of the test. Recommendations for further work necessary in the field are given.

**General information**

State: Published

Organisations: Division of Toxicology and Risk Assessment, National Food Institute

Authors: Knudsen, I. (Ekstern), Poulsen, M. (Intern)

Pages: 53-62

Publication date: 2007

Main Research Area: Technical/natural sciences

**Publication information**

Journal: Regulatory Toxicology and Pharmacology

Volume: 49

Issue number: 1

ISSN (Print): 0273-2300

Ratings:

BFI (2018): BFI-level 1

Web of Science (2018): Indexed yes

BFI (2017): BFI-level 1

Scopus rating (2017): SJR 0.812 SNIP 1.005 CiteScore 2.92

Web of Science (2017): Indexed Yes

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**Apples and pectin change the rat ceacal microbiota**

**General information**

State: Published

Organisations: Division of Microbiology and Risk Assessment, National Food Institute, Division of Toxicology and Risk Assessment, Technical University of Denmark


Publication date: 2007

Event: Poster session presented at 5th Symposium on Food Microbiology, Helsingør, Denmark.

Main Research Area: Technical/natural sciences
Increased plant sterol and stanol levels in brain of Watanabe rabbits fed rapeseed oil derived plant sterol or stanol esters

Foods containing plant sterol or stanol esters can be beneficial in lowering LDL-cholesterol concentration, a major risk factor for CVD. The present study examined whether high dietary intake of rapeseed oil (RSO) derived plant sterol and stanol esters is associated with increased levels of these components in brain tissue of homozygous and heterozygous Watanabe rabbits, an animal model for familial hypercholesterolemia. Homozygous animals received either a standard diet, RSO stanol or RSO sterol ester while heterozygous animals were additionally fed with 2 g cholesterol/kg to the respective diet form for 120 d (n 9 for each group). Concentrations of cholesterol, its precursor lathosterol, plant sterols and stanols in brain and additionally in liver and plasma were determined by highly sensitive GC-MS. High-dose intake of RSO derived plant sterols and stanols resulted in increased levels of these components in plasma and liver. In brain a limited uptake of plant sterols and stanols was proven, indicating that these compounds passed the blood-brain barrier.
and may be retained in the brain tissue of Watanabe rabbits. Plant stanol ester feeding lowered plant sterol levels in brain, liver, and plasma. Cholesterol synthesis in brain, indicated by lathosterol, a local surrogate cholesterol synthesis marker, does not seem to be affected by plant sterol or stanol ester feeding. We conclude that high dose intake of plant sterol and stanol esters in Watanabe rabbits results in elevated concentrations of these components not only in the periphery but also in the central nervous system.

**General information**
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Pages: 890-899
Publication date: 2007
Main Research Area: Technical/natural sciences

**Publication information**
Journal: The British Journal of Nutrition
Volume: 98
Issue number: 5
ISSN (Print): 0007-1145
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): SNIP 1.555 SJR 1.756 CiteScore 3.65
Web of Science (2017): Indexed yes
BFI (2016): BFI-level 1
Scopus rating (2016): CiteScore 3.46 SJR 2.055 SNIP 1.535
Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 1.583 SNIP 1.442 CiteScore 3.52
Web of Science (2015): Indexed yes
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 1.532 SNIP 1.273 CiteScore 3.18
Web of Science (2014): Indexed yes
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 2.746 SNIP 2.479 CiteScore 3.61
ISI indexed (2013): ISI indexed yes
Web of Science (2013): Indexed yes
BFI (2012): BFI-level 1
Scopus rating (2012): SJR 2.308 SNIP 2.427 CiteScore 3.12
ISI indexed (2012): ISI indexed yes
Web of Science (2012): Indexed yes
BFI (2011): BFI-level 1
Scopus rating (2011): SJR 2.085 SNIP 1.649 CiteScore 3.13
ISI indexed (2011): ISI indexed yes
Web of Science (2011): Indexed yes
BFI (2010): BFI-level 1
Scopus rating (2010): SJR 1.236 SNIP 1.253
Web of Science (2010): Indexed yes
BFI (2009): BFI-level 1
Scopus rating (2009): SJR 0.627 SNIP 0.572
Web of Science (2009): Indexed yes
BFI (2008): BFI-level 2
Scopus rating (2008): SJR 0.966 SNIP 1.2
Web of Science (2008): Indexed yes
Scopus rating (2007): SJR 0.987 SNIP 1.255
Phytosterols, Brain cholesterol, LDL receptor, Hypercholesterolemia, Atherosclerosis

DOIs:
10.1017/S0007114507756532

ISAFRUIT health research: Integrating experimental and observational studies on fruit and health with nutrigenomics

Prebiotics for prevention of Salmonella infections

Prebiotics for Prevention of Salmonella Infections
Safety testing of GM-rice expressing PHA-E lectin using a new animal test design

The 90-day animal study is the core study for the safety assessment of genetically modified foods in the SAFOTEST project. The model compound tested in the 90-day study was a rice variety expressing the kidney bean Phaseolus vulgaris lectin agglutinin E-form (PHA-E lectin). Female Wistar rats were given a nutritionally balanced purified diet with 60% parental rice, 60% PHA-E rice or 60% PHA-E rice spiked with 0.1% recombinant PHA-E lectin for 90 days. This corresponded to a mean daily PHA-E lectin intake of approximately 0, 30 and 100 mg/kg body weight for each group, respectively. The spiking was used to increase the specificity and to demonstrate the sensitivity of the study. A range of biological, biochemical, microbiological and pathological parameters were examined and significant differences in weight of small intestine, stomach and pancreas and plasma biochemistry were seen between groups. Included in this paper are also data from the molecular characterisation and chemical analysis of the PHA-E rice, from the construction and production of the PHA-E lectin, and from the preceding 28-day in vivo study where the toxicity of the pure PHA-E lectin was determined. In conclusion, the combined use of information from the compositional analysis, the 28-day study and the characterisation of the PHA-E rice and the PHA-E lectin has improved the design of the 90-day study. The spiking procedure has facilitated the interpretation of the results of the study and transferred it into a valuable tool for the future safety testing of genetically modified foods.
Carbohydrate digestibility predicts colon carcinogenesis in azoxymethane-treated rats

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Technical University of Denmark
Pages: 163-170
Publication date: 2006
Main Research Area: Technical/natural sciences

Publication information
Journal: Nutrition and Cancer
Volume: 55
Issue number: 2
ISSN (Print): 0163-5581
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes

Original language: English
spiking, animal study, GMO, genetically modified rice, PHA-E lectin, SAFOTEST, safety assessment
DOIs:
10.1016/j.fct.2006.09.003
Source: orbit
Source-ID: 214379
Publication: Research - peer-review › Journal article – Annual report year: 2007
Dietary carbohydrate source influences molecular fingerprints of the rat faecal microbiota

Background: A study was designed to elucidate effects of selected carbohydrates on composition and activity of the intestinal microbiota. Five groups of eight rats were fed a western type diet containing cornstarch (reference group), sucrose, potato starch, inulin (a long-chained fructan) or oligofructose (a short-chained fructan). Fructans are, opposite sucrose and starches, not digestible by mammalian gut enzymes, but are known to be fermentable by specific bacteria in the large intestine. Results: Animals fed with diets containing potato starch, or either of the fructans had a significantly (p < 0.05) higher caecal weight and lower caecal pH when compared to the reference group, indicating increased fermentation. Selective cultivation from faeces revealed a higher amount of lactic acid bacteria cultivable on Rogosa agar in these animals. Additionally, the fructan groups had a lower amount of coliform bacteria in faeces. In the inulin and
oligosaccharide groups, higher levels of butyrate and propionate, respectively, were measured. Principal Component Analysis of profiles of the faecal microbiota obtained by Denaturing Gradient Gel Electrophoresis (DGGE) of PCR amplified bacterial 16S rRNA genes as well as of Reverse Transcriptase-PCR amplified bacterial 16S rRNA resulted in different phylogenetic profiles for each of the five animal groups as revealed by Principal Component Analysis (PCA) of band patterns. Conclusion: Even though sucrose and cornstarch are both easily digestible and are not expected to reach the large intestine, the DGGE band patterns obtained indicated that these carbohydrates indeed affected the composition of bacteria in the large gut. Also the two fructans resulted in completely different molecular fingerprints of the faecal microbiota, indicating that even though they are chemically similar, different intestinal bacteria ferment them. Comparison of DNA-based and RNA-based profiles suggested that two species within the phylum Bacteroidetes were not abundant in numbers but had a particularly high ribosome content in the animals fed with inulin.
Effects of Short- and Long-Chain Fructans on Large Intestinal Physiology and Development of Preneoplastic Lesions in Rats

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Authors: Poulsen, M. (Intern)
Number of pages: 904
Pages: 781-799
Publication date: 2005

Host publication information
Title of host publication: Handbook of carbohydrate engineering
Volume: Chapter 26
Publisher: Taylor & Francis
ISBN (Print): 15-74-44472-7
Main Research Area: Technical/natural sciences
Source: orbit
Source-ID: 247556
Publication: Research › Book chapter – Annual report year: 2005

Assessment of the safety of foods derived from genetically modified (GM) crops
This paper provides guidance on how to assess the safety of foods derived from genetically modified crops (GM crops); it summarises conclusions and recommendations of Working Group I of the ENTRANSFOOD project. The paper provides an approach for adapting the test strategy to the characteristics of the modified crop and the introduced trait, and assessing potential unintended effects from the genetic modification. The proposed approach to safety assessment starts with the comparison of the new GM crop with a traditional counterpart that is generally accepted as safe based on a history of human food use (the concept of substantial equivalence). This case-focused approach ensures that foods derived from GM crops that have passed this extensive test-regime are as safe and nutritious as currently consumed plant-derived foods. The approach is suitable for current and future GM crops with more complex modifications. First, the paper reviews test methods developed for the risk assessment of chemicals, including food additives and pesticides, discussing which of these methods are suitable for the assessment of recombinant proteins and whole foods. Second, the paper presents a systematic approach to combine test methods for the safety assessment of foods derived from a specific GM crop. Third, the paper provides an overview on developments in this area that may prove of use in the safety assessment of GM crops, and recommendations for research priorities. It is concluded that the combination of existing test methods provides a sound test-regime to assess the safety of GM crops. Advances in our understanding of molecular biology, biochemistry, and nutrition may in future allow further improvement of test methods that will over time render the safety assessment of foods even more effective and informative.

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Technical University of Denmark
Effects of sucrose and cornstarch on 2-amino-3-methylimidazo[4,5-f]quinoline (IQ)-induced colon and liver carcinogenesis in F344 rats

The purpose of the present study was to compare the effect of sucrose and cornstarch on colon and liver carcinogenesis induced by 0.02% of the food-borne carcinogen 2-amino-3-methylimidazo [4,5-f]quinoline (IQ) in the feed. Male F344 rats were allocated to four groups. Two groups were fed diets high in either cornstarch (68%) or sucrose (34% sucrose/34% cornstarch) and were initiated with IQ. The remaining two groups received the same two diets but did not receive any IQ. In both liver and colon, administration of IQ resulted in a higher level of DNA adducts. In animals not dosed with IQ, sucrose increased the adduct level in both organs but to a lower level than IQ. However, simultaneous administration of IQ and sucrose did not further increase the adduct level. Both IQ and sucrose increased the expression of the DNA-repair enzyme ERCC1 in the liver. In the colon, the number of large and medium aberrant crypt foci (ACF) of the group fed IQ and cornstarch was significantly higher than that in the other groups. There was no statistically significant difference in any tumour incidence in IQ dosed-animals fed either cornstarch or sucrose. In conclusion, no difference in effect on liver carcinogenesis was seen between sucrose and cornstarch-based diets, however, the number of tumours per animal tended to be slightly higher in the rats fed cornstarch (P = 0.08). Cornstarch enhanced ACF development induced by IQ when compared to sucrose whereas due to a low intestinal tumour incidence no correlation to diet and tumour incidence could be established.

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Technical University of Denmark
Pages: 17-24
Publication date: 2004
Main Research Area: Technical/natural sciences

Publication information
Journal: Cancer Letters
Volume: 209
Issue number: 1
ISSN (Print): 0304-3835
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): SNIP 1.284 SJR 2.35 CiteScore 6.26
Web of Science (2017): Indexed Yes
BFI (2016): BFI-level 1
Scopus rating (2016): CiteScore 6.26 SJR 2.372 SNIP 1.229
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 2.362 SNIP 1.224 CiteScore 5.77
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 2.245 SNIP 1.261 CiteScore 5.29
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 1.98 SNIP 1.188 CiteScore 4.93
ISI indexed (2013): ISI indexed yes
Web of Science (2013): Indexed yes
New methods for the safety testing of transgenic food

Background This project proposal deals with the development of a sensitive and specific animal test which is necessary for safety analysis of genetically modified plants according to the Opinion of the Scientific Committee for Food on the assessment of novel foods. The test will be based on the OECD 90 day rodent study supplemented with sensitive and specific markers for potential toxicity of the products encode by the inserted genes in the tested food item, the use of a semisynthetic diet with interchangeable constituents and the extensive use of initial chemical and in-vitro testing for guiding the precise design of the animal study. The genetically modified food plants to be used for this test development will be 3 transgenic rice varieties (2 types of lectins and the Bt toxin). Objectives The overall objective of this project is to develop and validate the scientific methodology which is necessary for assessing the safety of foods from genetically modified plants in accordance with the EU Regulation 258/97 of 27 January 1997 concerning novel foods and novel food ingredients. The project is designed to meet the urgent need for a sensitive and specific testing strategy for GM foods in a scientifically valid and economically feasible manner. The specific objectives are to: improve the sensitivity and specificity of standard OECD guideline toxicity tests towards detection of specific chemical entities in the GM food matrix by the measurement of additional biological endpoints based on prior knowledge. improve the quality of this prior knowledge through precise information regarding the gene construct, its site of insertion and the chemical and toxicological characteristics of the gene product based upon chemical analytical studies and short term in vivo and in vitro studies. improve the quality of this prior knowledge through precise information regarding unintended secondary changes in the GM food item, which may alter the nutritional-toxicological properties of that food. (expected) Results and achievements The results of the project will be evaluated at a final workshop and the recommendations will be used to guide future test requirement for the safety assessment of genetically modified food plant within EU and worldwide.
Effects of dietary antioxidants and 2-amino-3-methylimidazo[4,5-f]-quinoline (IQ) on preneoplastic lesions and on oxidative damage, hormonal status, and detoxification capacity in the rat

The potential beneficial or adverse affect of prolonged dietary administration of moderate to high doses (1-100 mg/kg diet) of the antioxidants, lycopene, quercetin and resveratrol or a mixture of lycopene and quercetin was investigated in male F344 rats. Selected markers for toxicity and defense mechanisms were assayed in blood, liver and colon and the impact of the antioxidant administrations on putative preneoplastic changes in liver and colon was assessed. The dietary carcinogen, 2-amino-3-methylimidazo[4,5-f]quinoline (IQ) (200 mg/kg diet) served as a pro-oxidant, genotoxicity and general toxicity control. IQ increased the levels of protein and DNA oxidation products in plasma, the area of glutathione S-transferase-placental form positive (GST-P) foci in the liver as well as the number of colonic aberrant crypt foci (ACF). All antioxidants and the antioxidant combination significantly increased the level of lymphocytic DNA damage, to an extent comparable with the effect induced by IQ. In contrast to the control group where no GST-P foci were detected, GST-P foci were detected in animals exposed to quercetin, lycopene and the combination of the two. However, the increase in the volume of GST-P foci did not reach statistical significance. The present results indicate that moderate to high doses of common dietary antioxidants can damage lymphocyte DNA and induce low levels of preneoplastic liver lesions in experimental animals. Long-term exposure to moderate to high doses of antioxidants may thus via pro-oxidative mechanisms modulate carcinogenesis.
Subchronic oral toxicity study on the three flavouring substances: octan-3-ol, 2-methylcrotonic acid and oct-3-yl 2-methylcrotonate in Wistar rats

Groups of 10 male and 10 female rats were administered 0, 25, 100 or 400 mg octan-3-ol/kg body weight per day, 77 mg 2-methylcrotonic acid/kg body weight per day or 163 mg oct-3-yl 2-methylcrotonate/kg body weight per day by gavage for 90 days. Relative liver weights of high-dose octan-3-ol males, and males and females dosed with oct-3-yl 2-methylcrotonate were significantly greater than those of the control. In male and female rats dosed with the highest level of octan-3-ol and in male rats dosed with 2-methylcrotonic acid, incidences of bile duct proliferation were increased. In the kidneys of males dosed with mid- and high level of octan-3-ol and oct-3-yl 2-methylcrotonate, tubular karyomegaly and desquamation of tubular epithelial cells were observed. Based on increased liver weight and microscopic evaluation of the liver and kidney, a no-observed-effect level (NOEL) of 25 mg/kg for octan-3-ol in rats was established. The histopathological evaluation of the liver of rats dosed with oct-3-yl 2-methylcrotonate revealed lesions corresponding to the lesions seen in rats dosed mid-dose with octan-3-ol. This observation is in accordance with the general assumption that oct-3-yl 2-methylcrotonate is completely hydrolysed to octan-3-ol and 2-methylcrotonic acid. However, when comparing the liver histopathology of oct-3-yl 2-methylcrotonate and 2-methylcrotonic acid and the kidney lesions of all three substances, conflicting results were seen and the present study does not allow the conclusion to be drawn that oct-3-yl 2-methylcrotonate and structurally-related esters are completely hydrolysed, at least under the conditions of the present study. (C) 2003 Elsevier Science Ltd. All rights reserved.

General information
The safety assessment of Novel Foods and concepts to determine their safety in use

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Pages: S3-S32
Publication date: 2003
Main Research Area: Technical/natural sciences

Publication information
Journal: International Journal of Food Sciences and Nutrition
Volume: 54
ISSN (Print): 0963-7486
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): SNIP 0.761 SJR 0.733 CiteScore 2.17
Web of Science (2017): Indexed Yes
BFI (2016): BFI-level 1
Scopus rating (2016): SJR 0.592 SNIP 0.671 CiteScore 1.61
Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 0.521 SNIP 0.664 CiteScore 1.58
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 0.493 SNIP 0.712 CiteScore 1.41
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 0.496 SNIP 0.678 CiteScore 1.48
ISI indexed (2013): ISI indexed yes
BFI (2012): BFI-level 1
Scopus rating (2012): SJR 0.51 SNIP 0.739 CiteScore 1.26
ISI indexed (2012): ISI indexed yes
BFI (2011): BFI-level 1
Scopus rating (2011): SJR 0.539 SNIP 0.776 CiteScore 1.32
ISI indexed (2011): ISI indexed yes
BFI (2010): BFI-level 1
Scopus rating (2010): SJR 0.431 SNIP 0.461
BFI (2009): BFI-level 1
Scopus rating (2009): SJR 0.505 SNIP 0.769
Different effects of short- and long-chained fructans on large intestinal physiology and carcinogen-induced aberrant crypt foci in rats

Inulin-type fructans, which are nondigestible carbohydrates, have been shown to modulate the number of induced preneoplastic lesions in the colon as well as the colonic microflora in laboratory animals. The present study was designed to investigate the effect of a short- and long-chained inulin-type fructan on 1,2-dimethylhydrazine dihydrochloride-induced aberrant crypt foci (ACF) in the rat colon. In addition, the present study investigated the influence of chain length, dietary level (5% or 15%), and duration of feeding (5 or 10 wk) on the following intestinal parameters supposed to be involved in the development of ACF: microflora, short-chain fatty acids, pH, and cell proliferation. A 3-wk pretreatment period with both fructans was included. Feeding the long-chained fructan (5% or 15%) significantly inhibited the numbers of small and total ACF after 5 and 10 wk. The short-chained fructan (15%) inhibited the number of small and total ACF after 5 and 10 wk but significantly increased the numbers of medium and large ACF after 10 wk. In conclusion, the effect on ACF outcome was influenced by the chain length of the fructans.

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Authors: Poulsen, M. (Intern), Molck, A. (Ekstern), Jacobsen, B. L. (Ekstern)
Pages: 194-205
Publication date: 2002
Main Research Area: Technical/natural sciences

Publication information
Journal: Nutrition and Cancer-an International Journal
Volume: 42
Issue number: 2
ISSN (Print): 0163-5581
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): SNIP 0.698 SJR 0.745 CiteScore 2.4
Web of Science (2017): Indexed yes
BFI (2016): BFI-level 1
Scopus rating (2016): CiteScore 2.5 SJR 0.926 SNIP 0.829
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 0.98 SNIP 0.809 CiteScore 2.36
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 0.926 SNIP 0.805 CiteScore 2.5
BFI (2013): BFI-level 1
Effect of a long-chained fructan Raftiline HP on blood lipids and spontaneous atherosclerosis in low density receptor knockout mice

The effect of a long-chained fructan Raftiline HP on spontaneous hypercholesterolemia and atherosclerosis was studied in 40 LDLR-/- male mice receiving isocaloric, balanced in fat content, purified diets with 0 or 10% Raftiline HP, for 16 weeks. The feed intake was comparable (3.9 v. 3.8 g/day) but the terminal body weight was lower in the Raftiline HP group (36 v. 32g, p

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Authors: Mortensen, A. (Intern), Poulsen, M. (Intern), Frandsen, H. L. (Intern)
Pages: 473-480
Publication date: 2002
Main Research Area: Technical/natural sciences

Publication information
Journal: Nutrition Research
Volume: 22
Issue number: 4
ISSN (Print): 0271-5317
Ratings:
BFI (2018): BFI-level 1
Immunotoxicity of nucleic acid reduced BioProtein - a bacterial derived single cell protein - in Wistar rats

BioProtein is a single cell protein produced by a mixed methanotrophic and heterotrophic bacteria culture using natural gas as energy source, which has been approved for animal feed. BioProtein contains a large amount of nucleic acids making the product less suitable for human consumption, therefore, a nucleic acid reduced variant (NABP) has been developed by the manufacturer. The purpose of the present study was to establish the safety of NABP in a subchronic toxicity rat study. Groups of 10 male and 10 female Wistar rats were fed diets containing 0, 6, 12 or 24% NABP for 13 weeks. Feeding NABP induced a humoral immune response and proliferation of phagocytic cell lines, mainly
macrophages. The humoral response involved induction of NABP specific IgM and IgG. The proliferation of phagocytic cells involved increase of the white blood cell count of all dosed female groups. Males showed the same tendency, although, not statistically significant (P = 0.09). The subsets of cells identified as neutrophils and eosinophils were increased and lymphocytes decreased. The histopathological examination revealed histiocytosis and accumulation of foamy macrophages in the mesenteric lymph nodes, hyperplasia of Kupffer cells in the liver, increased granulopoiesis in spleen and bone marrow, and infiltration of lamina propria of the large intestine with eosinophilic granulocytes. The most consistent and pronounced changes were observed in the highest dose group, but even at the lowest dose level some of the changes were present. Accordingly, a no-observed-effect level could not be established based on this study. (C) 2002 Elsevier Science Ireland Ltd. All rights reserved.

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Department of Systems Biology, Technical University of Denmark
Authors: Mølck, A. (Ekstern), Poulsen, M. (Intern), Christensen, H. R. (Intern), Lauridsen, S. (Ekstern), Madsen, C. B. (Intern)
Pages: 183-200
Publication date: 2002
Main Research Area: Technical/natural sciences

Publication information
Journal: Toxicology
Volume: 174
Issue number: 3
ISSN (Print): 0300-483X
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): SNIP 0.978 SJR 1.1 CiteScore 3.39
Web of Science (2017): Indexed Yes
BFI (2016): BFI-level 1
Scopus rating (2016): SJR 1.468 SNIP 1.198 CiteScore 3.91
Web of Science (2016): Indexed yes
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 1.345 SNIP 1.262 CiteScore 3.7
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 1.23 SNIP 1.256 CiteScore 3.39
BFI (2013): BFI-level 1
Scopus rating (2013): SJR 1.239 SNIP 1.443 CiteScore 3.9
ISI indexed (2013): ISI indexed yes
BFI (2012): BFI-level 1
Scopus rating (2012): SJR 1.303 SNIP 1.361 CiteScore 3.79
ISI indexed (2012): ISI indexed yes
Web of Science (2012): Indexed yes
BFI (2011): BFI-level 1
Scopus rating (2011): SJR 1.273 SNIP 1.348 CiteScore 3.75
ISI indexed (2011): ISI indexed yes
BFI (2010): BFI-level 1
Scopus rating (2010): SJR 1.218 SNIP 1.166
Web of Science (2010): Indexed yes
BFI (2009): BFI-level 1
Scopus rating (2009): SJR 1.159 SNIP 1.182
BFI (2008): BFI-level 2
Scopus rating (2008): SJR 1.01 SNIP 1.206
Web of Science (2008): Indexed yes
Scopus rating (2007): SJR 1.053 SNIP 1.262
Scopus rating (2006): SJR 1.034 SNIP 1.344
The combination of 1α, 25(OH)2 – Vitamin D3, calcium and acetylsalicyclic acid affects azoxymethane-induced aberrant crypt foci and colorectal tumours in rats

Effects of 1alpha,25(OH)(2)-vitamin D(3) and acetylsalicylic acid at various dietary levels of calcium (CaCO(3)) on development of aberrant crypt foci (ACF) and tumours in colon were examined in groups of 16 male F344 rats initiated with azoxymethane and observed for 16 weeks. Calcium was the most potent modulator of ACF development. The total number of ACF increased with low calcium and decreased with high calcium. The number of large ACF decreased with any addition of calcium, acetylsalicylic acid and 1alpha,25(OH)(2)-vitamin D(3). High levels of calcium alone or in combination with 1alpha,25(OH)(2)-vitamin D(3) increased the incidence of tumour-bearing animals. 1alpha,25(OH)(2)-vitamin D(3) and acetylsalicylic acid at 5,000 ppm calcium increased the incidence as well.

General information
State: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Technical University of Denmark
Authors: Mølck, A. (Ekstern), Poulsen, M. (Intern), Meyer, O. A. (Intern)
Pages: 19-28
Publication date: 2002
Main Research Area: Technical/natural sciences

Publication information
Journal: Cancer Letters
Volume: 186
Issue number: 1
ISSN (Print): 0304-3835
Ratings:
BFI (2018): BFI-level 1
Web of Science (2018): Indexed yes
BFI (2017): BFI-level 1
Scopus rating (2017): SNIP 1.284 SJR 2.35 CiteScore 6.26
Web of Science (2017): Indexed Yes
BFI (2016): BFI-level 1
Scopus rating (2016): CiteScore 6.26 SJR 2.372 SNIP 1.229
BFI (2015): BFI-level 1
Scopus rating (2015): SJR 2.362 SNIP 1.224 CiteScore 5.77
BFI (2014): BFI-level 1
Scopus rating (2014): SJR 2.245 SNIP 1.261 CiteScore 5.29
BFI (2013): BFI-level 1
Effect of dietary antioxidants and 2-amino-3-methylimidazo[4,5-f]quinoline (IQ) on biomarkers for redox and hormonal status and enzyme detoxification capacity in blood and major organs of male F344 rats

General information
State: Published
Organisations: National Food Institute, Division of Toxicology and Risk Assessment, Technical University of Denmark
Authors: Breinholt, V. (Ekstern), Molck, A. (Ekstern), Daneshvar, B. (Ekstern), Svendsen, G. (Ekstern), Vinggaard, A. (Intern), Poulsen, M. (Intern), Lauridsen, S. (Ekstern), Dragsted, L. O. (Ekstern)
Pages: 93-93
Publication date: 2001
Main Research Area: Technical/natural sciences

Publication information
Journal: Toxicology
Volume: 164
Issue number: 1-3
ISSN (Print): 0300-483X
Ratings:
Guidelines and conditions for use of health claims in Denmark

General information
The influence of simple sugars and starch given during pre- or post-initiation on aberrant crypt foci in rat colon

The aim of the present study was to investigate the enhancing effect of dietary sugar on the development of aberrant crypt foci (ACF) in male F344 rats initiated with azoxymethane (AOM). The potential role of sugar as either a co-initiator or a promoter was investigated by giving diets high in sucrose and dextrin (61%) during either the pre-initiation, the initiation, and/or the post initiation stage of the ACF development. The colonic cell proliferation, activity of colonic phase II enzymes, and a biomarker of lipid peroxidation were additionally examined in order to obtain information on the specific mechanisms involved in the suggested effect of sucrose and dextrin on ACF development. The number of large sized and the total number of ACF were significantly increased by feeding sucrose and dextrin in the post-initiation period. No positive association between colonic cell proliferation and ACF was seen. The level of oxidative stress in the cytosol from the proximal colon and colonic glutathione transferase and quinone reductase was not affected by the sugar treatments. The overall results from this study show that sucrose and dextrin enhance the number of preneoplastic lesions in AOM-initiated rats, and act primarily as promoters in the development of ACF.
Safety evaluation of fructans

General information
State: Published
Organisations: Division of Nutrition, National Food Institute, Division of Toxicology and Risk Assessment
Authors: Knudsen, I. (Ekstern), Andersen, R. (Intern), Mejborn, H. (Intern), Poulsen, M. (Intern), Andersson, C. (Ekstern), Gudmundsdóttir, E. (Ekstern), Hallikainen, A. (Ekstern), Mælck, A. (Ekstern), Paulsen, J. E. (Ekstern)
Publication date: 2000
Lack of histological cerebellar changes in Wistar rats given pulegone for 28 days. Comparison of immersion and perfusion tissue fixation

Pulegone was given orally by gavage to groups of 28 SPF Wistar rats at dosage levels of 0 or 160 mg/kg body weight per day for 28 days. Clinically treated animals showed slackness, depression, decreased food consumption, and body weight. The loss of body weight was accompanied by a marked decrease in plasma creatinine. In contrast to earlier results, this study did not reveal occurrence of cyst-like spaces in the white matter of cerebellum using either perfusion or immersion tissue fixation techniques. Pulegone increased plasma alkaline phosphatase and relative liver weight indicating an adverse effect on the liver.
Scopus rating (2011): SJR 1.133 SNIP 1.157 CiteScore 3.38
ISI indexed (2011): ISI indexed yes
Web of Science (2011): Indexed yes
BFI (2010): BFI-level 1
Scopus rating (2010): SJR 1.233 SNIP 1.15
BFI (2009): BFI-level 1
Scopus rating (2009): SJR 1.09 SNIP 1.202
Web of Science (2009): Indexed yes
BFI (2008): BFI-level 2
Scopus rating (2008): SJR 1.02 SNIP 1.053
Web of Science (2008): Indexed yes
Scopus rating (2007): SJR 0.951 SNIP 1.211
Web of Science (2007): Indexed yes
Scopus rating (2006): SJR 1.018 SNIP 1.277
Web of Science (2006): Indexed yes
Scopus rating (2005): SJR 1.006 SNIP 1.109
Web of Science (2005): Indexed yes
Scopus rating (2004): SJR 1.007 SNIP 1.13
Web of Science (2004): Indexed yes
Scopus rating (2003): SJR 0.806 SNIP 0.949
Web of Science (2003): Indexed yes
Scopus rating (2002): SJR 0.6 SNIP 0.91
Scopus rating (2001): SJR 0.625 SNIP 0.734
Web of Science (2001): Indexed yes
Scopus rating (2000): SJR 0.336 SNIP 0.582
Scopus rating (1999): SJR 0.346 SNIP 0.511
Original language: English
toxicity, neuropathy, pulegone, fixation techniques, rats
DOIs:
10.1016/S0378-4274(98)00029-0
Source: orbit
Source-ID: 231085
Publication: Research - peer-review › Journal article – Annual report year: 1998

Projects:

**Novel methods to quantify health in benefit risk assessment. A case study on fish**

National Food Institute
Period: 01/02/2016 → 31/01/2019
Number of participants: 4
Phd Student:
Perssson, Inez Maria (Intern)
Supervisor:
Pires, Sara Monteiro (Intern)
Poulsen, Morten (Intern)
Main Supervisor:
Nauta, Maarten (Intern)

**Financing sources**
Source: Internal funding (public)
Name of research programme: Samfinansieret - Andet
Project: PhD

**Risk-benefit assessment of whole diet**

National Food Institute
Period: 01/01/2016 → 31/12/2018
Number of participants: 5
Phd Student:
Thomsen, Sofie Theresa (Intern)
Supervisor:
Pires, Sara Monteiro (Intern)
Pires, Sara Monteiro (Intern)
Poulsen, Morten (Intern)
Main Supervisor:
Andersen, Rikke (Intern)

Financing sources
Source: Internal funding (public)
Name of research programme: Samfinansieret - Andet
Project: PhD

Assessment of developmental toxicity of a perfluorinated compound in rats - with focus on endocrine disruption and mixture effects

National Food Institute
Period: 01/12/2014 → 21/06/2018
Number of participants: 7
Phd Student:
Ramhøj, Louise (Intern)
Supervisor:
Hass, Ulla (Intern)
Madsen, Charlotte Bernhard (Intern)
Main Supervisor:
Petersen, Marta Axelstad (Intern)
Examiner:
Poulsen, Morten (Intern)
Hougaard, Karin Sørig (Ekstern)
Kortenkamp, Andreas (Ekstern)

Financing sources
Source: Internal funding (public)
Name of research programme: Samfinansieret - Andet
Project: PhD

Helhedssyn på nødder

National Food Institute
Division of Nutrition
Division of Toxicology and Risk Assessment
Division of Food Chemistry
Period: 10/04/2014 → ...
Number of participants: 4
Project participant:
Mejborn, Heddie (Intern)
Poulsen, Morten (Intern)
Olesen, Pelle Thonning (Intern)
Jørgensen, Kevin (Intern)

Development of models for assessing the disease burden for chemical compounds and nutritional factors in the Danish population
The overall aim of the project is to estimate the burden of foodborne disease in Denmark due to chemicals and suboptimal diets. Specifically it is investigated how existing toxicological and epidemiological data on chemicals and nutritional factors can be utilized in the quantitative estimation of burden of disease. Exposure to acrylamide through foods and low consumption of fruits and vegetables will be used as case-studies
Development of models for assessing the disease burden from chemical compounds and nutritional factors in the Danish population

National Food Institute
Period: 15/12/2012 → 05/12/2017
Number of participants: 7
PhD Student:
Jakobsen, Lea Sletting (Intern)
Supervisor:
Nauta, Maarten (Intern)
Pires, Sara Monteiro (Intern)
Main Supervisor:
Poulsen, Morten (Intern)
Examiner:
Nielsen, Elsa Ebbesen (Intern)
Devlesschauwer, Brecht (Ekstern)
Petersen, Kim (Ekstern)

Financing sources
Source: Internal funding (public)
Name of research programme: Institut stipendie (DTU)
Project: PhD

Risk-benefit assessment of functional foods – Focus on vitamin D metabolism
This PhD study represents one of five PhD projects within the Mobility stipend entitled: An Integrated approach to risk-benefit assessment of the human health effects of food and food contaminants.

The aim of this project is to study the vitamin D metabolism if vitamin D is synthesized in the skin by UV B exposure and if fed by feeding vitamin D. The animal model is the mini-pigs.

For measurement specific LC-MS/MS methods will be developed and validated for vitamin D metabolites in plasma and in food i.e. organs, meat and fat.

National Food Institute
Division of Food Chemistry
Division of Toxicology and Risk Assessment
Period: 01/12/2010 → 30/11/2014
Number of participants: 4
Acronym: Vitamin D Metabolism
Contact person:
Burild, Anders (Intern)
Jakobsen, Jette (Intern)
Project participant:
Poulsen, Morten (Intern)
Frandsen, Henrik Lauritz (Intern)
Project
Risk-benefit analyser af funktionelle fødevarer – Fokus på D-vitamin
National Food Institute
Division of Food Chemistry
Division of Toxicology and Risk Assessment
Department of Energy Conversion and Storage
Mixed Conductors
Period: 01/12/2010 → 30/11/2014
Number of participants: 4
Project participant:
Burild, Anders (Intern)
Poulsen, Morten (Intern)
Frandsen, Henrik Lund (Intern)
Project Manager, organisational:
Jakobsen, Jette (Intern)

Betydningen af genotyper for D-vitaminstatus
National Food Institute
Period: 01/09/2010 → 15/12/2015
Number of participants: 9
Phd Student:
Nissen, Ioanna (Intern)
Supervisor:
Andersen, Elisabeth Wreford (Intern)
Ravn-Haren, Gitte (Intern)
Vogel, Ulla Birgitte (Intern)
Wulf, Hans Christian (Ekstern)
Main Supervisor:
Andersen, Rikke (Intern)
Examiner:
Poulsen, Morten (Intern)
Linneberg, Allan (Ekstern)
Meyer, Haakon E. (Ekstern)

Financing sources
Source: Internal funding (public)
Name of research programme: Forskningsrådsfinansiering
Project: PhD

Prebiotics for Prevention of Listeria Infections
National Food Institute
Period: 01/04/2007 → 22/09/2010
Number of participants: 6
Phd Student:
Ebersbach, Tine (Intern)
Supervisor:
Poulsen, Morten (Intern)
Main Supervisor:
Licht, Tine Rask (Intern)
Examiner:
Gram, Lone (Intern)
Ingmer, Hanne (Ekstern)
Rastall, Robert (Ekstern)

Financing sources
Prebiotics for Prevention of Salmonella Infections

National Food Institute
Period: 01/04/2007 → 25/08/2010
Number of participants: 5
Phd Student:
Petersen, Anne (Intern)
Supervisor:
Poulsen, Morten (Intern)
Main Supervisor:
Licht, Tine Rask (Intern)
Examiner:
Aabo, Søren (Intern)
Kleerebezem, Michiel (Ekstern)

Financing sources
Source: Internal funding (public)
Name of research programme: Forskningsrådsfinansiering
Project: PhD

Prebiotics for Prevention of Gastrointestinal Infections

National Food Institute
Department of Systems Biology
Period: 01/01/2007 → 01/09/2011
Number of participants: 7
Acronym: PreGI
Project participant:
Wilcks, Andrea (Intern)
Bergström, Anders (Intern)
Andersen, Jens Bo (Intern)
Poulsen, Morten (Intern)
Project Manager, organisational:
Licht, Tine Rask (Intern)
Frøkiær, Hanne (Intern)
Pedersen, Susanne Brix (Intern)

Financing sources
Source: Forskningsrådene - Andre
Name of research programme: Forskningsrådene - Andre
Amount: 8,500,000.00 Danish Kroner
Project

PreGI - Prebiotics for Prevention of Gut Infections

There is increasing evidence that (i) intestinal beneficial bacteria are selectively stimulated by ingestion of specific (prebiotic) carbohydrates, and that (ii) beneficial bacteria ingested as probiotics are capable of suppression of bacterial pathogens in the gut. The idea of this project is to utilize existing animal models to identify dietary (prebiotic) carbohydrates that inhibit infection with selected pathogenic bacterial challengers. Carbohydrates with the best potential for pathogen inhibition will then be further studied with respect to effects on beneficial gut bacteria, production of short-chain fatty acids (SCFAs), and immune modulation in the host animals. Visualization of pathogenic challengers as well as of prebiotic-stimulated beneficial species in the intestinal environment will reveal whether an observed inhibition of a given pathogen results e.g. from competition for adhesion sites. The results obtained will be analyzed in a multivariate approach, in order to determine which of the above-mentioned factors have important impact on the anti-pathogen effect of prebiotics.

Division of Microbiology and Risk Assessment
Quantitative risk assessment strategies for novel foods

The overall objective of this project is to develop and validate the scientific methodology, which is necessary for quantitative risk assessment of second generation of novel foods to be marketed in EU. The project is designed to address both the risk assessment (including hazard identification, hazard characterization, exposure assessment and risk characterization) and the risk/benefit equation. The project addresses the scientific challenge of developing state of the art approaches to assess the safety, nutritional adequacy and efficacy of novel foods in a comprehensive and interlinked set of studies. The novel approaches deployed will be tested on three model examples which are either already on, or may be introduced to, the market. The models selected are (i) genetically modified (GM) and conventionally bred potato tubers with altered content and balance of inherent toxicants (glycoalkaloids), (ii) a conventionally bred rice mutated line low in an anti-nutritional constituent (phytic acid), and (iii) functional food ingredients of natural origin (phytosterol and phytostanol esters). The proposed methodology takes us beyond the current state of the art since it aims at: Deploying precise genomic and non-targeted profiling approaches for comprehensive characterisation of the novel foods as the primary basis for subsequent in-vitro and in-vivo studies Performing sensitive in-vitro studies supported by profiling approaches to identify early biomarkers of toxicity and efficacy as additional tools for designing tailored in-vivo studies Introducing a de-minimis diet for sensitive in-vivo studies, supported by profiling approaches and addressing safety, nutritional adequacy, and efficacy in a common approach Conducting exposure assessment by innovative probabilistic techniques based on recipe databases on tailored software code Combining the outcomes of hazard/efficacy assessment, exposure assessment in a risk-benefit analysis Taking into account whether the risk/benefit evaluation carried out will sufficiently address the problems with the respective foods as understood by the general public Summarising the results of the project in an appropriate form for subsequent communication to the wider stakeholder audience The project is coordinated by the National Food Institute, Division of Toxicology and Risk Assessment.
Fruit and its impact on human health and well-being
Period: 29 Jan 2009
Morten Poulsen (Speaker)
National Food Institute
Division of Toxicology and Risk Assessment

Description
Place: Årslev, Denmark

Related external organisation

Unknown external organisation
Activity: Talks and presentations › Conference presentations

Press clippings:

Om mikrobølgeovne og hvad der sker med mad, der opvarmes i en mikrobølgeovn
Morten Poulsen
27/09/2016

Subject
Mikrobølgeovne
National Food Institute, Research Group for Risk-Benefit

Media contribution (1)

Om mikrobølgeovne og hvad der sker med mad, der opvarmes i en mikrobølgeovn
27/09/2016
DR P1 Videnskabens Verden, Radio
Ida Kellemann
Morten Poulsen
National Food Institute, Research Group for Risk-Benefit
Press / Media

Mikrobølgeovne, myter, sundhed
Morten Poulsen
18/03/2015

Subject
Mikrobølgeovne, myter, sundhed
National Food Institute, Division of Toxicology and Risk Assessment

Media contribution (1)

Mikrobølgeovne, myter, sundhed
18/03/2015
journaliststuderende - freelance, Web
Mathias Meier
Morten Poulsen
National Food Institute, Division of Toxicology and Risk Assessment
Press / Media

Bestrålning, bakterier, sikkerhed, sundhed
Morten Poulsen
25/08/2014

Subject
Bestrålning, bakterier, sikkerhed, sundhed
National Food Institute, Division of Toxicology and Risk Assessment

Media contribution (1)
Bestrålning, bakterier, sikkerhed, sundhed
25/08/2014
BT, Print
Emilie Maarbjerg Mørk
Morten Poulsen
National Food Institute, Division of Toxicology and Risk Assessment
Press / Media

Mikrobølgeovne, mad, sikkerhed, sundhed
Morten Poulsen
06/08/2014

Subject
Mikrobølgeovne, mad, sikkerhed, sundhed

Som svar på en bekymret læsers spørgsmål – en slags brevkasse
National Food Institute, Division of Toxicology and Risk Assessment

Media contribution (1)

Mikrobølgeovne, mad, sikkerhed, sundhed
06/08/2014
videnskab.dk, Web
Anne Ringgaard
Morten Poulsen
National Food Institute, Division of Toxicology and Risk Assessment
Press / Media

Mad tilberedt i mikrobølgeovn giver ikke kræft
Morten Poulsen
18/02/2014
National Food Institute, Division of Toxicology and Risk Assessment

Media contribution (1)

Mad tilberedt i mikrobølgeovn giver ikke kræft
18/02/2014
Ingeniøren, Print
Mie Stage
Morten Poulsen
National Food Institute, Division of Toxicology and Risk Assessment
Press / Media

GMO
Morten Poulsen
19/09/2012
National Food Institute, Division of Toxicology and Risk Assessment

Media contribution (1)

GMO
19/09/2012
National Public Radio, Radio
Dan Charles
Morten Poulsen
National Food Institute, Division of Toxicology and Risk Assessment
Press / Media

Tilberedning af mad i mikrobølgeovn er uden risiko
Morten Poulsen
30/09/2010
National Food Institute, Division of Toxicology and Risk Assessment
Tilberedning af mad i mikrobølgeovn er uden risiko
30/09/2010
Television
Morten Poulsen
National Food Institute, Division of Toxicology and Risk Assessment
Press / Media

Mikrobølgeovne, stråler og sikkerhed
Morten Poulsen
01/01/2010
National Food Institute, Division of Toxicology and Risk Assessment

Mikrobølgeovne, stråler og sikkerhed
01/01/2010
Print
Morten Poulsen
National Food Institute, Division of Toxicology and Risk Assessment
Press / Media