

Insights

Issue 5: July 2022

Special diets – providing for universal consumer needs

Welcome to the fifth edition of *LGC Assure Insights*, a free digital newsletter to support your food safety management journey. The four previous editions of the newsletter have covered diverse topics from *Listeria monocytogenes*, allergens, sustainability and food fraud, so if you missed any of them [signup here to receive future editions here](#).

In this edition I have brought together insights about foods for special diets, a somewhat eclectic mix of products with a common aim to fulfil a specific



dietary need such as allergy or intolerance, sports nutrition, supplements including vitamins and minerals, and food for special medical purposes. But let's start with a customary overview of some of the issues and incidents happening across the world.

LGC ASSURE Insights is different from other news sources as it combines otherwise unpublished food safety management data held across the *LGC ASSURE* Network of companies with real-time events to provide an unparalleled view of current and emerging issues and trends. And, of course, it is free.

EU alerts and notifications – a year of increased fraud and contamination events

The European Union Alert Cooperation Network (ACN) allows member states to share information on risks in food, food contact material or feed, issues that do not present a risk and on suspected fraud through the Rapid Alert System for Food and Feed (RASFF).

The 2021 annual report from the ACN highlighted 4,607 RASFF notifications, 2,290 non-compliance notifications and 407 fraud notifications during the year. Notifications increased against 2020 by 19.6% for food and 3.5% for feed. The top three countries were Turkey, India and China and the top three hazards were pesticides, *Salmonella* spp. and aflatoxins. Non-compliance notifications were dominated by pesticides and accounted for 15% of all notifications. Dietetic food, food supplements and fortified food were the next highest foods receiving notifications due to unauthorised health claims, substances or novel foods and incomplete ingredient information. Of the 407 fraud notifications, 114 were reportedly due to the illegal movement of pets with the main food category being fish and fish products.

Food recall highlights of the month

Microbiological contamination events were a prominent feature of recalls in the last month particularly in the USA with *Listeria monocytogenes* in [cheese](#), [crabmeat](#), [prepared salad](#), [ice-cream](#) and [onions](#), *Salmonella* spp. in the obligatory peanut butter containing products ([1](#), [2](#), [3](#)) but, interestingly, also in [protein powder](#) and [fresh pet food](#).

[Protein bars](#) were recalled due to the presence of *E. coli*. A recall due to an unidentified cause of gastrointestinal illness and potential liver function issues after consumption of a [lentil and leek crumble](#) was also reported although this may actually be due to a reaction to a [novel ingredient](#). Microbiological recalls in other countries included:

- *Listeria monocytogenes* in [hot smoked trout fillets](#) (UK), [soft cheese](#) (Germany), [liver sausage](#) (Israel) and [salmon pate](#) (Australia)

- *Salmonella* spp. in [cooked chicken](#) (UK), [curry powder](#) (Germany), [tahini](#) and [tahini containing products](#) (Germany)
- norovirus associated with [spot prawns](#) (Canada) and [raspberry gelato](#) (Canada).

Allergen recalls included [ice cream](#) due to undeclared peanuts as a result of the use of an incorrect lid, [lentil soup](#) due to the presence of wheat gluten caused by the wrong packaging being used for the product and [chocolate truffles](#) labelled as vegan and dairy free but containing milk due to cross-contamination in the factory.

The inadvertent use of a whey-derived ingredient resulted in a recall of a [protein powder](#) due to undeclared milk. There was a recall of [fried fish balls](#) due to undeclared egg because the formulation of the product had been changed to include eggs but the labelling had not been updated.

Chemical alerts included the recall of [smoked clams](#) due to the presence of per- and polyfluoroalkyl substances (PFAS), [organic corn chips](#) due to contamination with tropane alkaloids, [apricot seeds](#) containing high levels of cyanide, a prohibited dye in [sumac](#) and ethylene oxide in [ice cream](#).

Foreign body recalls resulted from the presence of glass in [breaded chicken products](#) and [bamboo shoots](#), metal in [bread rolls](#) and plastic in [cookies](#).

Food for special diets

The first point to note when introducing the topic of special diets is that it is an exceptionally ill-defined area except for a subset of foods for special medical purposes.

Codex, in its 1985 Standard on the [Labelling of and Claims for Prepackaged Food for Special Dietary Uses](#) stated that “Foods for Special Dietary Uses are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist”.

The US FDA defines foods for special dietary use in the [Code of Federal Regulations](#) as “Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological

or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight; Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood; Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property”.

In the EU, [Regulation \(EU\) No 609/2013](#) on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control defines food for special medical purposes as “food specially processed or formulated and intended for the dietary management of



patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone”.

Beyond legislation

These days foods for special diets are generally considered to include a much wider variety than those cited in legislation. It includes those where nutrition or a medical need is the key driver together with those where lifestyle dictates the choice such as in sports foods and drinks. Vegan, vegetarian and allergen ‘free’ foods i.e. those produced without wheat, milk, nuts, eggs, and other allergens are also covered.

Supplements including vitamins and minerals and foods fortified with them are also included on some lists of foods for special diets. In a recent guidance document produced by the International Special Dietary Foods Industries (ISDI) on [Food for Special Dietary Needs](#), the following broad food groups were cited:

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- infant formula
 - follow-up formula
 - complementary foods
 - foods for special medical purposes
 - meal replacement and total diet replacement
 - gluten-free food
 - low-sodium food
 - sports food
 - other food for special dietary uses (not otherwise defined).

All of these food groups with the exception of sports foods and other foods have published Codex standards managed through the [Codex Committee on Nutrition and Foods for Special Dietary Uses \(CCNFSDU\)](#).

It should be noted that in its 2016 review of [Food Intended for Sportspeople](#), the European Commission considered sports foods to be outside of the remit of Regulation (EU) No 609/2013 (see above) and therefore not a food for special medical purposes.

It is what it says on the packet

No matter what different groups define as a food for special diets, it is essential that they are formulated to the defined nutritional profile and labelled as stated in the respective legislation (detailed above). Where specific legislation does not exist they must be [labelled in a way that meets the legislative norms](#) especially where any [nutrition or health claims](#) are made. And, of course all products must be free from any contaminant that may invalidate their intended use i.e. allergens for free-from products, [banned substances for sports foods and supplements](#), etc.

The standards and legislation generally provide information on these criteria and a useful summary of considerations are detailed in the [ISDI guidance document](#). The importance of manufacturing foods for special diets to the exacting principles specified cannot be overstated as the health, livelihood and sometimes life of the consumers of these products is dependent on meeting such standards.

An example of this is in elite sport where a professional athlete's entire career and possibly health may be at risk due to the inadvertent consumption of a sports food, drink or supplement contaminated with banned substances. [Advice on the heightened risks for athletes from such products](#) advocates either not consuming them at all or only using products that are subject to

[certified third party assurance schemes](#) designed to ensure that the standards of manufacture and final product verification result in a product that does not contain any banned substance. Schemes such as Informed exist to provide certified assurance at a [manufacturing level](#) and also at an [ingredient](#) and/or [product level](#). Extensive testing for a suite of banned substances delivers a high level of confidence in compliance to required standards. These schemes also provide links to online searchable databases that have been developed to provide athletes with real-time access to the certification status of the product prior to consumption.

It is a well-trodden path in each of these newsletters that accredited voluntary third party assurance (vTPA) schemes such as the BRCGS Global Standard Food Safety ([Issue 9 August 2022](#)) play an important role in helping a food business demonstrate its ability to consistently meet high standards of food safety in the production of its products. Whilst vTPA schemes like BRCGS deliver additional independent assurance regarding safety, there are also specific schemes that focus on single issue assurance that are of particular relevance when considering food for special diets. For example, schemes exist for accredited certification of [gluten-free](#) and [plant-based](#) food manufacturers and for [sports foods producers](#).

You will have read in previous editions of this newsletter about the importance of verification and how it offers assurances that the controls in place during manufacture have delivered a compliant product. Delivering and maintaining the correct concentration of nutrients and micronutrients in foods for special diets during production can be a challenge. Analysis can support the establishment of effective formulation and shelf life strategies. The use of [accredited laboratories](#) using suitable [reference materials](#) to develop and validate a site's methods is essential to be confident in such critical analysis.

Similarly, [analytical testing](#) can be an important element in the assurance of allergen-free products as part of raw material assurance programmes, cross-contamination risk assessment and end product verification. Many of these considerations in relation to manufacturing controls and analysis were covered in LGC ASSURE Insights, Issue 2 - please do have a look back for more detail.

Foods for special diets is unquestionably a complex topic but given the significant growth of this sector

in recent years, it is one that merits close attention in terms of food safety assurance. I hope that this has given you some useful insight. Look out for the next edition of LGC ASSURE Insights due at the end of August.

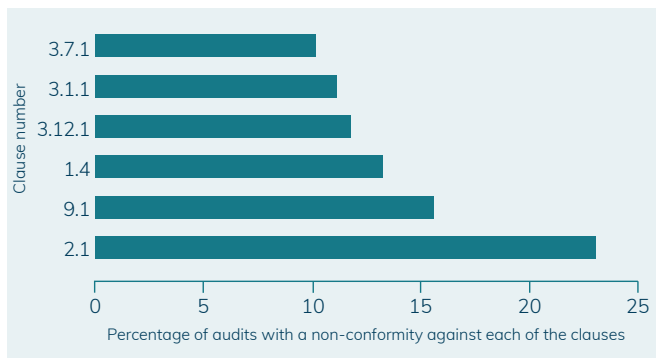


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Special diets in practice

The most commonly occurring non-conformities from audits against the Gluten-Free Certification Program (GFCP) are illustrated in graph 1. The data show that it is important for sites manufacturing products for special diets to ensure:

- that foundational food safety activities continue to operate effectively
- good manufacturing practices are extended into all the specific activities required for the manufacture of the products for the special diet
- the site fully addresses any additional controls specifically needed for the special diet products.



Graph 1: BRCGS Gluten-Free Certification Program - most common non-conformities.

Looking at the data in graph 1:

- The most common non-conformities arise from clause 2.1 (HACCP pre-requisites). Having an effective HACCP plan is fundamental to safe food production, including sites working with gluten-free products.
- The non-conformities against internal audits (clause 9.1) highlight the need to expand good manufacturing practices to include activities that

are associated with the special diet – in this case expanding the internal audit program to meet the additional needs of the GFCP.

- There are two clauses relating to training (1.4 and 3.1.1) which appear in this list. These clauses require companies to appoint a team leader for the gluten-free management system and of a training programme for employees. Controls specifically related to gluten-free products must be covered in training and staff have to understand the significance of the product to the consumer.

Contaminated supplements: the threat to athletes

The majority of athletes use supplements to help with recovery and their performance. All athletes need to make sure the products they are recommended and provided with are safe to use. Doping scandals, whether intake was intentional or not, have ruined careers, programs, lives and reputations.

For example when a marathon runner collapsed and died after competition analysis found they had taken a supplement containing DMAA. This, in combination with extreme physical exertion, caused acute cardiac failure. A boxer who won an Olympic Gold medal was a favourite in his division, only to find himself facing a potential ban of up to four years even if he proved the supplement he consumed was unintentionally contaminated.

In 2016, LGC carried out a survey assessing 67 supplements commonly available in the Australian market. Supplement products were purchased from a range of internet sites and retail stores and all products were analysed. The analysis used LGC's ISO/IEC17025 accredited nutritional supplement screen, utilising the diagnostic techniques of liquid chromatography mass spectrometry (LC-MS/MS) and gas chromatography mass spectrometry (GC-MS/MS).

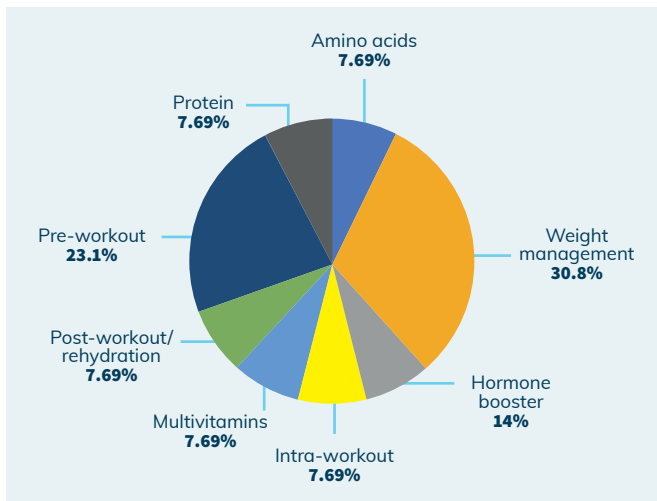
All the products were screened for a wide range of substances prohibited within sport (see table 1), including anabolic agents (exogenous and endogenous), Beta-2 agonists, diuretics, and stimulants.

Of the 67 products tested, 13 (19%) showed evidence for one or more substances which would be considered prohibited within sport. The findings also failed to meet the acceptance criteria for the Informed Sport/Informed Choice testing

programmes. The most common substance found was the stimulant 1,3-dimethylbutylamine (also known as AMP Citrate) which was identified in 7 products (10%). The results were limited to two compound classes, anabolic steroids (25%) and stimulants (75%).

| Analyte identified | Type |
|------------------------------|----------------|
| 1,3-dimethylbutylamine | Stimulant |
| Methamphetamine | Stimulant |
| Methylephedrine | Stimulant |
| Methylhexaneamine | Stimulant |
| Nopseudoephedrine | Stimulant |
| Oxilofrine | Stimulant |
| Selegiline | Stimulant |
| Strychnine | Stimulant |
| 1,4-androstadiene-3,17-dione | Anabolic Agent |
| 5(6)-androstene-3,17-dione | Anabolic Agent |
| DHEA | Anabolic Agent |

Table 1: Identified banned analytes.



Graph 2: Distribution of indications by function.

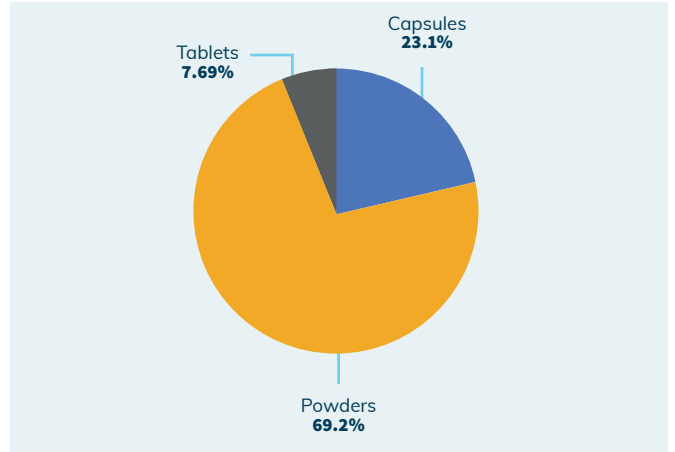


Table 3: Distribution of screening indications by product formulation

Whilst most findings were within the low parts per billion (ppb) two were identified with significantly elevated levels; both at mgg-1 concentrations. One product contained the prohibited stimulant 1,3-dimethylbutylamine and the other the prohibited stimulant methylhexaneamine.

There was no reference to either compound in the declarations/ingredient claims for either product and based on the estimated concentrations observed, contamination or deliberate adulteration could not be ruled out.

“I took a recommended supplement to combat inflammation. Unfortunately this supplement contained an ingredient that was on the NFL’s banned substance list.” This professional American football player is estimated to have lost \$3.4m during his suspension.



The presence of unlabelled stimulants at such elevated levels not only poses a significant risk of an athlete failing a doping test, but also has the potential to cause serious health problems. This is why it is vital that athletes who are subject to routine doping control ensure they only use products which have been subject to appropriate quality control/testing programs such as Informed Sport.



Newsworthy

Inaugural report on UK food standards cautions of challenges ahead
(UK) FSA, June 2022

2022 State Food Enacted Legislation
(USA), Food Safety News, 18 July 2022

FSSAI issues draft norms related to nutraceuticals, special dietary food (India), F&B News, 12 July 2022

Warnings about honey with ingredients that are not disclosed, including ED drugs
Food Safety News, 13 July 2022

When it comes to food safety 'organic' can be a risky business
Real Clear Science, 18 July 2022

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