Annex A to TOX/2020/39

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Allergen risk assessment for adventitious contamination of soya in wheat flour milled and consumed in the UK

Secretariat

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1. Statement of Purpose

FSA needs to revisit its evidence base regarding adventitious contamination of soya in wheat flour and grist to inform its risk management position on this issue. This will help to inform both FSA’s handling of incidents involving adventitious contamination of soya and the advice that FSA provides more widely to industry regarding reference doses and action levels for contamination of soya in wheat flour.

A risk assessment is required to understand the risk to the allergic population associated with soya in wheat flour milled and consumed in the UK. In particular, this needs to take into account up-to-date industry data on prevalence/levels of soya contamination, the potential impact of processing and heat treatment on allergenicity of soya and the applicability of current reference doses to adventitious soya in wheat flour.

Currently, industry is using an action level of 236 mg/kg of soya protein in raw wheat flour and it is understood that below this level, advisory statements for soya contamination in the wheat flour may not be communicated to food business in receipt e.g. on the product specification. Decisions on whether to use advisory statements for adventitious contamination of wheat flour with soya at the raw ingredient level is currently informed by industry due diligence monitoring against this action level.

Ultimately, information on the risk of unintentional allergen presence due to cross-contamination informs decision on precautionary allergen statements throughout the supply chain and labelling on the final product. Precautionary allergen labelling (PAL) on final products is used as a risk management measure to warn against the inadvertent consumption of unintentionally present allergens, which are not ingredients, by sensitive consumers and enable a variety of safe and nutritious food choices for the allergic consumer. Precautionary allergen labelling should only be used if the risk of allergen cross-contamination is real and cannot be removed, in order to prevent unnecessarily restricting the availability of food to sensitive individuals.

The aim of this risk assessment is to look at the appropriateness and feasibility of a set action level for use by businesses selling raw ingredients intended for further processing.

2. Hazard Identification

Allergens in Soybean

Soybeans and products thereof are recognised as a common cause of food allergies and thus are included on the EU1169/2011 annex II list of declarable allergens.

Soybean (soy seed) (*Glycine max*) is an edible legume belonging to the *Fabaceae* family. The seed contains 20% oil and approximately 35-40% proteins, of which at least 33-38 IgE- reactive proteins have been suggested as allergens. Among those, 8 allergens are officially registered on the World Health Organisation/International Union of Immunological Societies (WHO/IUIS) Allergen Nomenclature Subcommittee (Appendix table 1). The clinical relevance of different soya allergens can vary depending on the allergic individual but certain proteins such as Gly m 4, 5, 6 and 8 have been demonstrated as good markers for predicting clinical relevance (Kattan & Sampson. 2015). In addition, the papain protease protein, Gly m Bd 30k, is thought to be an immunodominant and clinically relevant allergen despite it being estimated to only make up 1% of total soybean seed protein (Wilson 2008; Jeong et al. 2013; Tsai et al. 2017).

3. Hazard Characterisation

Uses of Wheat Flour

Wheat flour is a widely used primary commodity and its consumption is widespread across the world. There are various types of wheat flour, each with different properties that are utilised for different food products. It is commonly used as the primary ingredient in bakery products such as bread, pastry, cookies and cakes, different wheat flours being blended to confer properties specific for particular products.

Wheat flour is often fortified with other high protein-based flours and commonly includes the addition of soya flour and when used as such, is required to be declared as an allergenic ingredient. These and other products that contain intentionally added soya are therefore out of scope of this risk assessment.

Uses of Soybean

Consumption of soya is widespread in Asia and the USA and has increased in Europe in recent years. In vegetarian cuisine soy is consumed as soy oil, soya flour, soymilk, soy drinks, soya flakes or as fermented soybean products such as Miso, Okara, soy sauce (Tamari, Shoyu), tempeh or tofu.

Soya products are also used in the food industry for technological reasons as texturizers, emulsifiers and protein fillers; it is a low cost protein source and may be part of a wide variety of processed foods such as meat products, sausages, bakery goods, chocolate or breakfast cereals. This makes it a good candidate for use as an improver in wheat flour based products.

Prevalence of soya allergy

Soya allergy is mainly reported in young children compared to adults, and it is also reported that children often develop tolerance or ‘grow-out’ of soya allergy (Savage et al. 2010). The exact prevalence of soya allergy is unknown in the UK. The population based EuroPrevall birth cohort study has confirmed a cumulative incidence of IgE-mediated reactions to soya of 0.1% (0.0 - 0.4%) in children up to the age of 2 years (Grimshaw et al. 2016). A meta-analysis of European studies by Nwaru et al (2014) demonstrated a rate of 0.3% (0.1 – 0.4%) food challenge verified soya allergy prevalence. Previous studies also generally support this estimation (Kattan et al. 2011; Roehr et al. 2004; Young et al. 1994; Bock. 1987). Adult data on confirmed food allergy are too limited to estimate prevalence for this section of the population.

Severity of reactions to soya

Soybean-induced allergic symptoms span the typical range of all IgE-mediated reactions and thus can range from skin, gastrointestinal, or respiratory tract reactions up to anaphylaxis leading to death although severe reactions appear to be rarer than for some other food allergies (Sicherer et al. 2000a; 2000b) and tend to be towards less processed forms of soya.

Reported symptoms in response to soya flour material are, oral allergy syndrome, angioedema, dyspnea, dysphagia, emesis, decrease in blood pressure, urticaria, nausea, gastrointestinal pain, dysphonia, tightness of throat or chest, blisters of the oral mucosa, pruritus, flush, conjunctivitis and laryngeal edema (Ballmer-Weber et al. 2007). Exercise-induced anaphylactic reaction to soya has also been reported (Adachi et al. 2009).

Due to similarities of structure of soybean allergens with other allergens, cross-reactive allergies are possible, particularly in those with birch pollen and/or other legume allergies (Mittag et al. 2004; Cabanillas et al 2018). A study (DeSwert et al. 2012) looking at secondary allergy to soybean (with cross-reactivity from a primary allergy to birch pollen) found that of the 15 participants with birch pollen allergy, eight were also allergic to soya. All eight had acute symptoms, and three of them showed chronic (long-term) symptoms.

Adventitious contamination of wheat flour with soybean

The adventitious contamination of wheat flour with soya is known to occur due to the manner by which soybean and other grains, such as wheat, are grown, harvested, stored and transported, leading to detectable level of soya in raw wheat flour. The United States Department of Agriculture (USDA) Grain Inspection Handbook allows up to 10% of other grains with established standards to be present in wheat which includes soybeans (USDA 2004). As part of long-standing agricultural practices, it's common for cereal grains, oil seeds and pulses to be grown near one another and are often harvested, handled, stored and transported using the same equipment and infrastructure making it difficult to eliminate low levels of cross-contamination via agricultural co-mingling.

With respect to UK wheat only, storage and transportation are identified as the contamination risk areas due to soya not being grown in the UK. The Codex

Committee of Food Hygiene have been developing a Code of Practice on food allergen management for food business operators, which at the November 2019 meeting was agreed to be sent to the final stage 8 (adoption and publication). It lays out ways in which all allergens should be managed from farm to fork. Within this code of practice, and most relevant to this paper, it identifies the 4 stages mentioned above and identifies the following factors contributing to exposure:

- inadequate or ineffective cleaning of containers, including reusable bags, and transport vehicles;
- inadvertent inclusion of foreign particulates (e.g. grains, nuts or seeds);
- inadequate physical separation or storage of commodities with different allergen profiles; and
- inadequate or a lack of employee training and awareness on managing food allergens.

It should be noted that wheat flour is widely used in food products which already contain soya-based ingredients; in these cases, soya contamination is not of concern as allergic consumers would already avoid such products. However, there are products which do not contain soya ingredients and consideration will need to be given to the level of risk associated with adventitious soya contamination in such cases.

Incidence of allergic reactions to soya and specifically associated with wheat products

The occurrence of allergic reactions to soya associated specifically with soya contamination of wheat products has not been reported**.** In the 2013 paper by Remington et al, it was suggested that the high number of reactions predicted using their quantitative approach would be unlikely to pass unnoticed if true (2850 predicted reactions per day in the USA). **It should be noted that there is currently no systematic way of reporting allergic reactions to food so absence of evidence in this case cannot be assumed to indicate evidence of absence**. The FSA is currently in the process of developing a mechanism for reporting of reactions involving food allergens that will enable such data to be gathered in future.

Terms used in allergen risk assessment

When looking at hazard characterisation and risk levels for allergens in food, it is important to explain the meaning of different terms used in this context.

- Eliciting dose (ED): the dose (mg) predicted to provoke reactions in a defined proportion of the allergic population. E.g. ED_{01} equals the dose predicted to provoke a reaction in 1% of the at-risk allergic population. ED_{05} is the dose predicted to provoke a reaction in 5% of the at-risk allergic population. These are derived through dose distribution modelling of minimum eliciting doses (individual thresholds) from oral food challenges in allergic individuals

- Reference dose: an acceptably low eliciting dose level (mg) e.g. ED_{01}, ED_{05} (95th percentile Lowest CI) chosen as a health-based intake limit per eating occasion.
- Reference amount: the maximum amount of food eaten in a typical eating occasion
- Action level: The allergen protein concentration (mg/kg) in food as consumed that can be present in a food without it being an issue for the defined proportion of allergic individuals concerned, as defined by the selected reference dose based on specified conditions of exposure (e.g. serving/portion size, consumption amounts, inclusion levels), above which action is warranted to mitigate the risk to the allergic population

Application of levels

A risk assessment was conducted by the FSA in September 2014 (Appendix E) utilising the conclusions from a 2013 published paper from Remington et al the Food Allergy Research & Resource Program (FARRP), which used a probabilistic approach. An action level was given of 236 mg/kg soya protein which was based on a 30 g reference amount which equated to a dose of 7.1 mg soya protein in a single eating portion. However, since then, there has been wide acceptance for the use of population eliciting doses (EDp), in deterministic risk assessment of allergens in final products (meaning those intended for presentation to the consumer).

The most widely accepted eliciting dose and reference values also come from FARRP (and others) and are adopted into the Voluntary Incidental Trace Allergen Labelling (VITAL) system created by the Allergen Bureau and widely accepted as suitable reference dose levels amongst industry and regulators (Taylor et al. 2014; Remington et al. 2020). The previous ED for soya, published in 2014, was based on a 5% eliciting dose level (ED_{05}) at 1.0 mg (based on the 95^{th} percentile lower confidence interval) and was utilised by FSA for the risk assessment of levels in final products for food incidents. Sufficient data were not available at the time to derive a robust ED_{01}.

Updated eliciting dose levels for various allergens, in-line with those under the EU 1169/2011 annex II list of allergens, were recently published in March 2020 (but released in VITAL 3.0 in September 2019) which gave an ED_{01} and ED_{05} (where only 1% and 5% of the soy allergic population would be predicted to experience any objective allergic reaction) for soy protein of 0.5 mg and 10 mg respectively. These levels are based on data from challenges with soy flour and soymilk. In the interest of proportionately protecting the allergic consumer, the FSA utilises ED_{01} levels (where available) as suitable reference doses, where applicable, for determining the risk posed by levels in a final product. This is also in-line with the approach recommended by the VITAL Scientific Expert Panel.

Although it is clear how to assess the risk of a final product, there are **uncertainties** around how industry should best apply references doses at the raw/bulk ingredient/product level, and specifically soya in wheat. This is partly due to variation in the level of inclusion of wheat flour in final products, consumption amounts for the different final products, and the potential effects of processing on the allergenicity and detectability of soya and therefore, the suitability of suggesting an indicative reference amount and action level for flour in general in place of tailored calculations for every product the ingredient/flour is used in.

Effect of processing on soya allergenic proteins

The risk assessments performed by industry when deciding on the use of an action level(s) should consider the final destination of the wheat flour and the extent and type of processing involved until the point of consumption by the final consumer. However, there are uncertainties around the effect of processing commonly applied to wheat flour-based products on the allergenicity and detectability of soya proteins. It is important to state that changes to allergenicity are not necessarily the same as changes to detectability. Processing can impact on detection whilst leaving a protein still able to elicit reactions.

Almost all food products containing wheat flour are submitted to thermal treatments (baking, boiling, roasting, autoclaving, microwave heating, etc.) during their industrial production or cooking at home, therefore, if adventitious soya is present in the flour, it be subject to this processing also. Thermal treatment of food proteins is known to cause different modifications and conformational changes that may affect the epitope binding of allergens and therefore capacity to elicit an allergic reaction by either enhancement (exposing or creating new epitopes) or reduction (loss of epitope) (Verhoeckx et al. 2015).

Overall, there is evidence to suggest that the typical processing of wheat flour (thermal and pressure) could reduce the detectability and allergenicity of major soya allergens and thus could reduce the risk to the allergic population but the extent to which this may occur is subject to various factors, in particular temperature and duration, and there is no robust evidence to suggest the risk could be eliminated completely through processing alone. (Amigo-Benavent et al. 2008; Wilson et al. 2008; Gomaa & Boye. 2013; Verhoeckx et al. 2015; Cabanillas et al. 2017; Costa et al. 2017; Xi and He. 2018; Villa et al. 2020).

4. Exposure Assessment

Industry perform due diligence testing for soya in wheat flour to monitor these levels. The National Association of British and Irish Flour Millers (NABIM) provided the most recent data submitted by their members for the period between September 2015 and May 2020 which includes 369 test results. The results of testing range between below the LOD of the tests used (analytical zero) to 1100.7 mg/kg soya protein and included flours, eithers solely or combined, from the UK, Germany, France, Russia, Australia, Canada, and the US. The majority of those with higher levels of soya contamination tended to be those from non-EU origin or combined with non-EU wheat flour. However, there was a small proportion of solely UK and solely EU origin flour with what could be deemed as high levels of soya contamination, suggesting the issue is not entirely limited to non-EU wheat flour.

FSA's exposure assessments for allergen incidents where there is unintentional presence of an allergen due to cross-contamination in a final product to be presented to the final consumer take into account the level(s) detected, the likely consumption amounts of the product and the most appropriate population reference dose for the allergen.

As part of best practise for effective allergen management, industry take into account these factors in risk assessments for their own products and to decide what information they provide on this risk to their customer(s) and whether they would apply precautionary statements based on evidence relating to their specifics products.

Wheat flour is a versatile primary commodity and is used in different foods at different levels, each undergoing varying levels and types of processing. Practically, reference amounts and action levels should be determined by industry on a case-by-case dependant on the different scenarios of usage for their flours.

Some products will contain soya as an intentional ingredient, requiring allergen ingredient declarations and thus are out of scope of this risk assessment

UK Flour Miller Soya Contamination Due Diligence Testing Data

NABIM provided soya due diligence monitoring data gathered from their member companies since 2015 till present (2020). Details of this testing can be found in appendix B and further breakdown of average results by year and origin can be found in appendix C and D respectively.

The following calculations take into account the due diligence testing data gathered between 2015 and 2020, provided by NABIM, and are for illustrative purposes to demonstrate the proportion of flour sampled that could produce objective symptoms in the allergic population if present and consumed in the final product if certain example reference amounts are used to arrive at an action level for the raw flour.

Example exposure calculations assuming different reference amounts/consumption levels in g of contaminated wheat flour:

- General calculation used: Detection Result (mg soy protein/g wheat flour) x Reference amount (g) = Exposure dose (mg soy protein). The number of wheat flour samples which, using this approach, would equate to a soy protein amount in mg above the ED_{01} but not the ED_{05}, and above the ED_{05}, and all samples above the ED_{01} are presented. Theoretical action levels are then back calculated using the ED_{01} (0.5 mg) and ED_{05} (10 mg) for soya protein divided by the reference amount (g), to give mg soy protein/g wheat flour level, then converted it into mg soy flour /kg wheat flour levels (x1000).

- Using the ED_{01} and ED_{05} reference dose for soya of 0.5 mg and 10 mg soya protein respectively and a consumption equivalent of **80 g** quantity of flour,

157/367 (43%) flours sampled would be predicted (based on the ED values) to produce objective symptoms in between 1% - 5% of the allergic population and 18/367 (5%) would present a risk to greater than 5% of the allergic population. **In total 175/367 (48%) would be above the ED_{01} of 0.5 mg soy protein**
    - **Effective action level of 6.3 mg soy protein/kg flour (ppm) at ED_{01}**
    - **Effective action level of 126 mg soy protein/kg flour(ppm) at ED_{05}**

- Using the ED_{01} and ED_{05} reference dose for soya of 0.5 mg and 10 mg soya protein respectively and a consumption equivalent of **50 g** quantity of flour, 148/367 (40%) flours sampled would be predicted to produce objective symptoms in between 1% - 5% of the allergic population and 5/367 (1%) would present a risk to greater than 5% of the allergic population. **In total 153/367 (42%) would be above the ED_{01} of 0.5 mg**
    - **Effective action level of 10 mg soy protein/kg flour (ppm) at ED_{01}**
    - **Effective action level of 200 mg soy protein /kg flour (ppm) at ED_{05}**

- Using the ED01 and ED05 reference dose for soya of 0.5 mg and 10 mg soya protein respectively and consumption equivalent of **30 g** quantity of flour, 118/367 (32%) flours sampled would be predicted to produce objective symptoms in between 1% - 5% of the allergic population and 1/367 (0.3%) would present a risk to greater than 5% of the allergic population. **In total 119/367 (32%) would be above the ED_{01} of 0.5mg**
    - **Effective action level of 16.7mg soy protein/kg flour (ppm) at ED_{01}**
    - **Effective action level of 334mg soy protein/kg flour (ppm) at ED_{05}**

Solely UK origin Flour:

- Using the ED_{01} and ED_{05} refence dose of 0.5 mg and 10 mg of soya protein respectively and consumption equivalent of **50 g** quantity of flour, **12/146 (8%)** of solely UK flours sampled would be predicted to produce objective symptoms in between 1% - 5% of the allergic population but **none would pose a risk to greater than 5%.**

*percentages rounded to nearest whole number.

The calculations above assume no reduction in detectable soya protein levels or allergenicity from the raw ingredient to the final product (decrease exposure) given the variability and uncertainty associated with the extent to which this may occur. The calculations also do not factor in other potential sources of contamination of soya from other final product ingredients (increase exposure) or take into account that some of the products may have soya-containing ingredients deliberately added as part of the recipe.

Reference amounts for wheat-based products

Information provided by the Nabim states that an average slice of white bread weighs 46-54g per slice (thin/thick). According to data in the recipes database

(NDNS, 2008-2016), wheat flour makes up between 50 and 60% of white bread. This was also seen to be similar for wholemeal bread. Therefore, it can be assumed that the reference amount of 30 g of flour equates to approximately 1 slice of medium thickness bread, 50 g of flour to approximately 1.5 slices of thickly sliced bread and 80 g of flour to approximately 3 slices of thinly sliced bread.

Furthermore, the Nabim also gives information that a plain biscuit would weigh approximately 40 g when baked, while according to the recipes database (NDNS, 2008-2016) a plain digestive biscuit would be approximately 60% wheat flour. Similarly, it can be assumed that 30 g of wheat flour would approximately equate to than one and one quarter of an average sized biscuit, 50 g of wheat flour to about two biscuits and 80 g of wheat flour to slightly more than three biscuits.

Another example is a Danish pastry/croissant, Nabim have suggested that the average weight would be circa 70 – 120 g. According to the recipes database (NDNS, 2008 – 2016) a Danish pastry or croissant would be made up of between 35 and 45% wheat flour. Therefore, 30 g of wheat flour would be about one small Danish pastry or croissant, 50 g would be about one large Danish pastry or croissant and 80 g would be approximately one small and one large pastry combined.

Table 1 shows the acute consumption of wheat flour across multiple food groups for infants 4 – 18 months), toddlers (1.5 – 3 years), young children (4 – 10 years), children (11 – 18 years), adults (19 - 64 years) and the elderly (65+ years). Consumption data from the Diet and Nutrition Survey of Infants and Young Children (DNSIYC), 2011 was used for infants, while for all other age groups data was from the National Diet and Nutrition Survey (NDNS), 2008 – 2016.

Table 1: Acute (eating occasion) consumption of wheat flour in g/ person *

Age groups	Minimum	Median	Mean	75th percentile	Maximum	Percentage consumers (%)****
Infants (4-18 months) **	0.22	35	39	54	150	93.7
Toddlers (1.5-3years) ***	2.1	70	72	89	210	99.9
4 – 10 years***	8.4	100	110	128	480	99.8
11 – 18 years***	1.1	120	130	166	470	99.9
19 – 64 years***	0.15	110	120	152	450	99.3
65 + years***	0.10	96	100	127	320	99.8

*rounded to 2 s.f.. ** consumer-based acute consumption data from DNSIYC (2011) ***consumer-based acute consumption data from NDNS (2008-2016)

**** Percentage consumers is based on a ratio of the number of consumers compared to the number of respondents in the population group (age group) from the DNSIYC or NDNS surveys

(not rounded to 2 s.f.)

The acute consumption data for wheat flour in Table 1 shows that all age groups are on average likely to exceed 30 g of wheat flour per eating occasion per day, those from age 1.5 years and above are likely to exceed 50 g of wheat flour per eating occasion on average and those from age 4 years and above are likely to exceed 80 g per eating occasion The highest contributor to wheat flour consumption was from bread, followed by pasta, pastry, cakes and biscuits and other. These data do not exclude products that may have soya as an intentional ingredient.

Tables 2 and 3 show the soya protein intake which were derived using data provided by the NABIM from the most recent due diligence testing for soya in wheat flour (September 2015 – May 2020) and the consumption data for wheat flour in Table 1.

There were 369 test results provided by the NABIM by NABIM member companies, and according to the NABIM ‘different companies use different test kits or commercial laboratories to test their flours for soya. As such, there was variation in how results were reported, with some reporting soya flour and some soya protein. Where soya flour was reported, this was almost always where a Neogen Veratox ELISA kit had been used. The manufacturer instructions state that to convert a soya flour result to soya protein, it should be multiplied by 0.515 (51.5%). This conversion was carried out on results reported as soya flour.’ As such, all results were reported as soya protein. Furthermore, the NABIM stated that ‘there is variation in the LOD of different soya testing methods. Where a result was below the LOD, the middle bound was used (LOD*0.5) to generate a result that can be analysed statistically. Where a test method gives a range of detection, the mid-point was used (e.g. >10 to <25, converted to 17.5 ppm).’

For the exposure assessment, the average of the 369 test results was taken to give the mean concentration of soya protein in wheat flour (29 mg/kg wheat flour rounded to 2 s.f.) and the maximum concentration recorded (1100 mg/kg wheat flour rounded to 2 s.f.) was used.

Table 2: Acute exposure to soya protein from wheat flour (mg/person/) using the mean concentration from the Nabim data (29 mg/kg)*

Age groups	Minimum	Median	Mean	75th percentile	Maximum	Percentage consumers (%)****
Infants (4-18 months) **	0.0063	1.0	1.1	1.5	4.5	93.7
Toddlers (1.5-3years) ***	0.061	2.0	2.1	2.6	5.9	99.9

4 – 10 years***	0.24	3.0	3.1	3.7	14	99.8
11 – 18 years***	0.032	3.6	3.6	4.8	13	99.9
19 – 64 years***	0.0043	3.3	3.5	4.4	13	99.3
65 + years***	0.0028	2.8	3.0	3.7	9.3	99.8

*rounded to 2 s.f.. ** consumer-based acute consumption data from DNSIYC (2011) ***consumer-based acute consumption data from NDNS (2008-2016)

****Percentage consumers is based on a ratio of the number of consumers compared to the number of respondents in the population group (age group) from the DNSIYC or NDNS surveys (not rounded to 2 s.f.)

Table 3: Acute exposure to soya protein from wheat flour (mg/person/) using the maximum concentration from the Nabim data (1100 mg/kg)*

Age groups	Minimum	Median	Mean	75th percentile	Maximum	Percentage consumers (%)****
Infants (4-18 months) **	0.24	39	42	59	170	93.7
Toddlers (1.5-3years) ***	2.3	77	79	98	230	99.9
4 – 10 years***	9.3	110	120	140	530	99.8
11 – 18 years***	1.2	140	150	180	510	99.9
19 – 64 years***	0.16	130	140	170	500	99.3
65 + years***	0.11	110	110	140	350	99.8

*rounded to 2 s.f.. ** consumer-based acute consumption data from DNSIYC (2011) ***consumer-based acute consumption data from NDNS (2008-2016)

**** Percentage consumers is based on a ratio of the number of consumers compared to the number of respondents in the population group (age group) from the DNSIYC or NDNS surveys (not rounded to 2 s.f.)

Table 2 demonstrates that, at the average level of soya protein in wheat flour based on due diligence testing from the NABIM member companies over the past 5 years, all consumers, except those eating very small amounts of wheat flour products (minimum), would exceed the ED_{01} reference dose for soya of 0.5 mg. However, it also shows that average consumers (mean and median) would not exceed the ED_{05} reference dose for soya of 10 mg soya protein for all age groups. Similarly, high level consumers (75th percentile) would not exceed the ED_{05}, although maximum level consumers between the ages of 4 and 64 years would exceed this.

Furthermore, Table 3 illustrates that at the maximum level of soya protein in wheat flour based on due diligence testing from the NABIM member companies over the past 5 years that all consumers, except those eating very small amounts of wheat flour products (minimum) would exceed both the ED_{01} and ED_{05} reference dose for soya of 0.5 mg and 10 mg soya protein respectively for all age groups.

It should be noted however that the maximum from the NABIM data of 1100 mg of soya protein per kg of wheat flour is higher than other values from the due diligence testing by a large margin. For example, the second highest value from this data is 318 mg/kg. Therefore, this maximum level of soya protein may give an overestimation of exposure and it is very difficult to draw conclusions about general risk management of the issue from such an extreme value.

Finally, Table 4 shows the percentage of consumers in each age group who (based on acute consumption data) are consuming ≥ the reference amounts of 30 g, 50 g and 80 g wheat flour per day.

Table 4: Percentage of consumers consuming ≥ the reference amounts of wheat flour per day based on acute consumption (%)*

Age groups	≥30g	≥50g	≥80g
Infants (4-18 months) **	54	27	6.5
Toddlers (1.5-3 years) ***	94	78	35
4 – 10 years***	99	94	75
11 – 18 years***	99	96	83
19 – 64 years***	97	92	76
65 + years***	98	92	67

*rounded to 2 s.f.. ** calculated from consumer-based acute consumption data from DNSIYC (2011)
***calculated from consumer-based acute consumption data from NDNS (2008-2016)

Table 4 demonstrates that as the reference amount increases there are fewer consumers exceeding it. It supports that older age groups are more likely than younger age groups to eat more than the reference amounts.

It is important to note that the acute consumption values are derived from a distribution of the highest consumption in one sitting that occurs over the 4 day food diary for each wheat flour consumer in the NDNS and DNSIYC surveys, however an average is taken from that distribution for each of the age groups described. Therefore, we have considered minimum, mean, 75th percentile and maximum values to look at average and high-level data. The median has also been included to give an idea how skewed the data are, which is deemed to be low. An allergic reaction tends to occur following consumption of a meal or food in one eating occasion, the consumption data presented is the highest amounts consumed in one sitting throughout one day over the recording period so may not reflect the exact situation for an allergic consumer. However, these data are useful to give an estimation of the likely level of exceedance of the reference amounts of wheat flour in different age groups.

As mentioned, the minimum, mean, median, maximum and 75th percentile consumption data has been considered in order to take into account low, mid, high- and maximum-level consumption of wheat flour. Furthermore, the exposure of consumers to soya protein from wheat flour has been considered in order to demonstrate the likelihood of each group exceeding the ED_{01} and ED_{05} reference dose for soya of 0.5 mg and 10 mg soya protein respectively. Finally, the comparison of the reference amounts of wheat flour to wheat flour containing products demonstrates that the 97.5th and maximum consumption amounts are conservative but are indicators of high level consumers of flour, while mean and median acute consumption data are more in line with what one would expect somebody to eat in one sitting. Collectively, this data gives a more realistic view of the risk than if considered separately.

To FSA's knowledge, there are no data available in relation to testing results for different final products made using wheat flour with known levels of soya protein. These data could provide support or challenge to the hypothesis that processing reduces the detectable levels of soya protein that would be expected in flour-based final product as sold to the consumer and therefore pose a lower risk to the soya allergic population than currently estimated. However, previous studies have supported this occurrence in various food matrices (Amigo-Benavent et al. 2008; Gomaa & Boye. 2013).

5. Risk Characterisation

The prevalence of soya allergy in the UK population is mostly unknown but some prevalence data is available that suggests 0.1 – 0.4% of children up until the age of 2 years have soya allergy, for adults it is unknown but likely to be less. There is currently no UK surveillance system to further estimate the prevalence in the population of reactions to soya or the severity of those allergic reactions.

Wheat flour milled in the UK contains adventitious soya contamination arising from cross contamination in the field (for non-UK wheat) or later in the process such as during milling or transport. There are different concentrations of adventitious soya in wheat flour found in industry sampling data.

- UK flour millers are currently using an action level of 236mg/kg, and sampling data indicates that only 1% of wheat flour is over this level and results in UK flour millers communicating a risk of soya contamination to their customers.
- However, using the most up to date published eliciting doses to inform action levels would mean that, if using the ED01 as the reference dose, 32-48% or

more of flours would be over this limit, depending on the reference amount in final products.

This current application of a set action level at the raw ingredient supply level may be hindering communication of risk through the supply chain and the ultimate decision on communicating risk to the final consumer via a precautionary allergen statement e.g. 'may contain'.

Wheat flour is most often consumed as a cooked end product such as biscuit, bread or cake. During this process the concentration of soya in the flour will be diluted with other ingredients and there is considerable variability between different end products as to that dilution factor. The raw food mixture may be diluted to a level below the action level.

Thermal processing of the raw mixture to provide the cooked end product may degrade some soybean allergens to varying degrees. However, there is a significant data gap in the reduction factor to be applied to allergenicity that could be used in a risk assessment given the variability of cooking time and temperatures between different product types and a lack of basic information of thermal rate of decay and soya allergen reduction. This effect cannot currently be simply quantified.

Estimate of the number of UK allergic reactions using each action level

Due to lack of prevalence data for adults, and the variability between final products for the proportion of wheat flour contained over the different action levels discussed, and the lack of quantitative data on the reduction brought about by thermal processing of end products, it is not possible to arrive at an estimate of the number of reactions expected for the different action levels at this time.

Consumption data shows that higher reference amounts than have been demonstrated here may be more suitable which would increase the amount of flours requiring application of precautionary statements.

Ultimately, information on the risk of unintentional allergen presence due to cross-contamination informs decision on precautionary allergen statements throughout the supply chain and labelling on the final product. Precautionary allergen labelling (PAL) is used as a risk management measure to warn against the inadvertent consumption of unintentionally present allergens, which are not ingredients, by sensitive consumers and enable a variety of safe and nutritious food choices for the allergic consumer. Precautionary allergen labelling should only be used if the risk of allergen cross-contamination is real and cannot be removed, in order to prevent unnecessarily restricting the availability of food to sensitive individuals. The proportion of soya allergic consumers who would not consume food products labelled for soya is not known. The evidence regarding which consumers are most likely to adhere to PAL statements is mixed. While some studies report those with more severe allergies or those with a child with allergies are more likely to be cautious regarding products with PAL (Cornelisse-Vermaat et al. 2007; Ben-Shoshan et al. 2012; Cochrane et al. 2013; DunnGalvin et al. 2019), other studies report no significant differences in adherence to PAL based on consumer characteristics (Noimark et al. 2009; Barnett et al. 2011; Zurzolo et al. 2013).

Estimating the severity of reactions

Severity of reactions to soya are mixed but tend to be less severe when compared to outcomes from other food allergies and data on incidence of reactions in the UK and knowledge of their exact trigger is lacking. It is assumed that the level of severe reactions is unlikely to be high, otherwise more reactions being reported via hospitalisations or in the case literature would be expected. However, absence of evidence is not necessarily evidence of absence. Eliciting dose levels have been developed to enable predictions of the proportion of the allergic population who would be expected to experience adverse reactions to different dose levels.

Key Messages/Conclusions

- The use of a set allergen action level to inform decision on risk communication of soya contamination in wheat flour by food businesses selling raw/bulk product intended for further processing is not appropriate due to variation in the level of inclusion in final products, consumption amounts, and the potential effects of processing on the allergenicity and detectability of soya
- This current application of a set action level at the raw ingredient supply level may be hindering communication of risk through the supply chain and the ultimate decision on communicating risk to the final consumer via a precautionary allergen statement e.g. ‘may contain’.
- Risk management considerations need to be explored including business to business communication of robust quantitative cross contact information throughout the supply chain to the final product producer. Other sources of soya contamination in the supply chain should be assessed and communicated at each stage in the supply chain

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7. Appendices

A. Table 1: WHO/IUIS registered soybean allergens (adapted from Cabanillas et al. 2017) http://www.allergen.org/search.php?Species=Glycine%20max

Super family	Protein family	Allergen name(s)
Prolamin	Hydrophobic, soybean hull protein	Gly m 1
Scorpion, toxin-like, knottin	Defensin	Gly m 2
Profilin	Profilin	Gly m 3
Bet v 1-like	Bet v 1 family	Gly m 4
Cupin	7s globulin	Gly m 5
Cupin	11s globulin	Gly m 6
Unspecified	Seed biotinylated protein	Gly m 7
Prolamin	2s albumin	Gly m 8

B. NABIM UK Flour Miller soya contamination in wheat flour due diligence testing

As per information provided:

- 367 separate sampling results submitted to NABIM by member companies between September 2015 till May 2020 where provided

- Different member companies used different test kits or commercial laboratories to test their flours for soya. As such, there was variation in how results were reported, with some reporting soya flour and some in soya protein.

Year sampled	Mean Soya protein inc <LOD (ppm)	Medium Soya protein inc <LOD (ppm)	Results range inc <LOD (ppm soya protein)	Total Number of results (n)	Number of results <LOD
2011	49.62	2.5 (<LOD)	2.5 - 710	29	14
2013	12.45	1.25 (<LOD)	1.25 – 156	45	31
2014	13.02	8.15	0.01 – 113.1	81	34
2015	31.88	0.6 (<LOD)	0.6 - 307	22	16
2016	39.83	12.5	0.0 - 1100.7	83	35
2017	18.19	8.0	0.6 - 185	48	20
2018	30.30	12.9	0.6 - 142	31	11
2019	35.68	4.4	0.6 - 318.8	109	47
2020	49.38	36.9	0.6 - 128.8	8	3
No year given	7.18	0.6 (<LOD)	0.6 - 123	66	42

- Where soya flour was reported, this was almost always where a Neogen Veratox ELISA kit had been used. The manufacturer instructions state that to convert the results for soya flour into soya protein, it should be multiplied by 0.515 (51.5%). This conversion was applied to all results using this kit as per manufacturers instructions, but it should be noted that the level of soya protein may vary dependant on the source of soya protein contamination.
- This conversion was carried out by Nabim on the results reported as soya flour, thus all results provided by Nabim are reported as soya protein.
- There was also variation in the reported limit of detection (LOD) of different soya testing methods used. Where a result was below the LOD, the middle bound (LOD*0.5) was used to generate a result that can be analysed statistically. Where a test method gives a range of detection, the mid-point was used (e.g. >10 to <25, converted to 17.5ppm).

C. Due diligence testing data by year. Includes results submitted in before 2014 and 2015 – 2020 collated results submitted in 2020. <LOD results included as per in appendix B.

D. Due diligence testing data by country(ies) origin 2015 –2020.

Mean result by country/countries of origin	Mean soya protein Inc <LOD) (ppm)	Results range (ppm soya protein)	Number of test results (n)
Australian	0.6	NA	1
Australian/French	0.6	NA	1
Canadian	56.7	0.0 - 301.1	67
Canadian / German	136.6	0.6 - 1100.7	12
Canadian / German / UK	11.7	4.6 - 17.5	4
Canadian / UK	49.8	0.0 - 318.8	52
Canadian / US / UK	76.4	53.6 - 100.9	3
French	9.5	0.6 - 61.8	20
German	14.4	0.6 - 72.1	15
German / French	2.6	NA	1
German / UK	3.0	0.6 - 18.9	22
German / US / UK	52.6	NA	1
Russian	3.4	0.6 - 12.5	8
Russian / UK	0.6	0.6	2
UK	4.2	0.0 - 114.0	146
US	153.8	0.6 - 307	2
US / UK	82.3	2.6 - 170	10

E. 2014 Risk assessment and recommendations– Soya in Flour

Risk assessment - Soya in flour.

1. **Uses**

Soy (soybean) (*Glycine max)* is an edible legume belonging to the *Fabaceae* family. The seed contains around 20% oil and 38-40% protein.

Consumption of soy, widespread in Asia and the USA, has increased in Europe during the past years particularly. In vegetarian cuisine soy is consumed as soy oil, soy flour, soymilk, soy drinks, soy flakes or as fermented soybean products such as Miso, Okara, soy sauce (Tamari, Shoyu), tempeh or tofu.

Soy products are also used in the food industry for technological reasons as texturizers, emulsifiers and protein fillers; it is a good and cheap protein source and may be part of a wide variety of processed foods such as meat products, sausages, bakery goods, chocolate or breakfast cereals.

2. **Allergens in soya**

The main storage proteins in soybean are glycinin (11S) and β-conglycinin (7S), which account for about 70% of the total seed protein.

3. **Prevalence**

Higher levels in children than in adults – children tend to outgrow their soy allergy by the age of 7. The prevalence of soya allergy is not as common as some of the other allergens in the EU Regulatory list.

4. **Clinical reactions & symptoms**

Symptoms of soy allergy are generally mild. Severe and/or fatal anaphylaxis reactions to soy and soy containing foods seem to be rare.

More severe reactions are reported in individuals with multiple allergies specifically those with a peanut allergy. Some cross reactions to soya protein in those with birch pollen, legume and/or bovine casein allergies.

5. **How processing affects allergenicity of soya**

Heat – there is evidence that allergenicity is reduced with heat treatment (80 -120°C for 60mins). High hydrostatic pressure, natural or induced fermentation also reduced allergenicity of soya protein

Detection of soya protein is affected significantly by processing.

6. **Thresholds**

- **Remington et al** (2013) Food and Chemical Toxicology – published research on soya contamination of wheat in the US (soya protein was reported in flour between 1.6-236 mg/kg).
- Survey was performed in 2010. Using contamination data and probabilistic risk modelling.
- The paper reported no reactions in soya allergic individuals at a dose of 88 mg soya protein. Using the principles of toxicology, a 10-fold safety factor to the 88 mg ‘threshold’ was applied to give a maximum dose of ~8.8 mg soya protein.
- For example, soya protein contamination was found in concentration up to 236 mg/kg in wheat flour. 236 mg / 1000 g x 30 g equates to a dose of 7.1 mg soya protein in a single eating portion.
- No published data of an objective (observed) allergic reaction at <7.1 mg/kg soya protein; therefore, no precautionary allergen labelling required.

7. **Current and available advice on soya contamination in wheat**

Health Canada – advises that soya allergic consumers should not avoid wheat products. The levels of cross contamination and the likelihood of experiencing an allergic reaction following the consumption of soya contamination wheat product is remote.

8. Results from NABIM surveys

Between 2009-2014, 174 samples of flour were taken and tested from UK milling companies. 89 of the 174 samples tested positive for the presence of soya protein. No samples were taken during 2010 and 2012.

For a number of the samples, soya was detected but the level was not quantified and therefore it was not possible to define the upper limit of contamination. i.e. '>5 mg/kg' or '>25 mg/kg'.

As part of the 2011 and 2013 surveys, NABIM also examined the flour for the presence of other allergens – lupin, mustard as well as soya. These results were not shared. It was not clear whether samples were also analysed for lupin and mustard for 2009 and 2014 samples.

On reviewing the raw data, non-EU flour had higher levels of soya but these were generally "tolerable levels" of contamination. There were two spikes in 2011 where two samples had results of 370mg/kg 710mg/kg; both samples originated from the USA.

[Note: 'non UK' and 'EU' include blends with UK and non-UK flours.]

Year	Samples (n)	Reporting Range	Comments
2009	**19**	**All - LOD - >5 mg/kg**	
	2	UK - <LOD	No positives found
	14 *(5)*	EU – <LOD - > 5mg/kg *(>5 mg/kg)*	5/14 samples positive
	3 *(1)*	Non-UK <LOD- > 5mg/kg *(>5 mg/kg)*	1/3 samples positive
2011	**29** **(15)**	**All <2.5 – 710 mg/kg** **(2.5-710 mg/kg)**	
	10 *(2)*	UK <2.5 – 55 mg/kg *(5.1-55 mg/kg)*	2/10 samples positive
	9 *(3)*	EU <2.5- 25 mg/kg *(2.5-25 mg/kg)*	3/9 samples positive
	10	Non –UK 8-710 mg/kg	All samples positive
2013	**45** *(14)*	**All <2.5 – 156 mg/kg** *(3.1-156 mg/kg)*	14/45 samples positive
	34 *(5)*	UK <2.5 – 21.5 mg/kg *(5.1-21.5 mg/kg)*	5/34 samples positive
	5 *(4)*	EU <2.5 – 61 mg/kg *(3.1-61 mg/kg)*	4/5 samples positive

	6 *(5)*	Non-UK <2.5 – 156 mg/kg *(21-156 mg/kg)*	5/6 samples positive
2014	**81** ***(53)***	**All <LOD -113.1 mg/kg** ***(0.01-113.1 mg/kg)***	LOD vary from <1.25, <2.5, <10, <25 and <LOD. 53/81 samples positive
	36 *(20)*	UK <LOD -113.1 mg/kg *(0.02-113.1 mg/kg)*	20/36 samples positive
	19 *(13)*	EU <1.25 – 75.8 mg/kg *(0.02-75.8 mg/kg)*	13/19 samples positive
	19 *(15)*	Non-UK <1.25 – 55.4 *(0.02-55.4 mg/kg)*	15/19 samples positive
	7 *(5)*	Unknown 0.01 – 15.7 mg/kg *(12.2->25 mg/kg)*	5/7 samples positive

9. Discussion.

Wheat flour is widely used in food products which already contain soya-based ingredients; in these cases, the soya contamination is not of concern as allergic consumers would avoid such products. However, there are products which do not contain soya ingredients and consideration will need to be given on the level of risk in such cases.

It should also be noted that soya protein is vulnerable to processing, clinical thresholds data from soya allergic patients are obtained through the consumption of soya challenge material which has undergone very little processing. On initial review the levels in the flours may seem high enough to elicit reactions in soya allergic patients; however, foods using flour require processing (cooking) before it is consumed therefore affecting the allergenicity and bioavailability of the soya protein.

To date the FSA has not received any reports from clinicians, food allergy charities or from food incidents which indicate that soya allergic consumers are suffering from frequent bouts of unexplained (idiopathic) allergic reactions.

In January 2013, Health Canada issued advice on soya allergy and the soya contamination of cereals. Health Canada consulted with patient associations and was not made aware of any reports of adverse reactions in soya allergic consumers due to the low level of soya in wheat. Health Canada determined that exposure was not likely to represent a health risk for soya allergic consumers and advised the food industry that precautionary allergen labelling for soya was not required and would unduly restrict food choices.

Based on the data from the Remington et al (2013) paper levels of soya at <236mg/kg would not require precautionary allergen labelling. Using the data from NABIM, only two samples of 174 (370 and 710 mg/kg) breached this bench mark. Both samples were taken during 2011 and were from the USA.

10. Conclusion

On the basis on the available evidence – precautionary allergen labelling would not be required where there is contamination below 236mg/kg of soya protein. The data from NABIM revealed that only two out of 174 (370 and 710 mg/kg) flour samples breached this bench mark. Both samples were taken during 2011 and were from the USA.

Higher levels of soya in flour will need to be considered on a case by case basis, consideration will need to be given on the end use of the flour and whether soya ingredients will be added in the finished food stuff thereby negating the concerns surrounding soya contamination.