# SA HEALTH SUBMISSION ON -

## A1186 – Soy Leghemoglobin in meat analogue products

September 2020

SA Health welcomes the opportunity to provide comment on A1186 – Soy Leghemoglobin in meat analogue products.

The proposed drafting is overly prescriptive, lengthy and difficult to interpret. This is a concern for enforcement purposes.

SA Health is of the view that the Application draft amendment does not provide any regulatory certainty for enforcement purposes if it is assessed only as a Genetically Modified (GM) food and nutritive substance and not also as a food additive. SA Health support the decision to expand the assessment beyond a GM food only.

1. It would be more appropriate for the soy leghemoglobin to be assessed as a Food additive as it has a **technological function** as described by the applicant in the application. In section 2.1.2 (page 2 of supporting document 1 of A1186 report) states "The applicant indicates the primary purpose of adding soy leghemoglobin to meat analogue products is to replicate the flavour and aroma of myoglobin'. This is clearly the technological function of a Flavouring of leghemoglobin as listed in schedule 14 of the Food Standards Code. Schedule 14 describes a flavouring as intense preparations which are added to foods to impart taste or odour, which are used in small amounts and are not intended to be consumed alone, but do not include herbs, spices and substances which have an exclusively sweet, sour or salt taste. Soy leghemoglobin proposed use meets this definition, in that it imparts flavour, is used in small amounts, and is not intended to be consumed alone.
2. Soy leghemoglobin is a US FDA recognised GRAS flavouring substance. So by reference, soy leghemoglobin is a permitted flavouring substance in Australia and New Zealand if listed in references defined in the Food Standards Code.

   In Standard 1.1.2 - Definitions used throughout the Code:

   ***permitted flavouring substance*** means any of the following:

   (a) a substance that is listed in at least one of the following publications:
   - (i) Generally Recognised as Safe (GRAS) lists of flavouring substances published by the Flavour and Extract Manufacturers' Association of the United States from 1960 to 2018 (edition 28);
   - (ii) Chemically-defined flavouring substances, Council of Europe, November 2000;
   - (iii) Annex I of Council Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances [2012] OJ L267/1;
   - (iv) 21 CFR § 172.515;

   (b) a *flavouring substance obtained by physical, microbiological, enzymatic or chemical processes from material of vegetable or animal origin either in its

raw state or after processing by traditional preparation process including drying, roasting and fermentation;

(c) a flavouring substance that is obtained by synthetic means and which is identical to one of the substances described in paragraph (b).

3. Soy leghemoglobin as a flavouring substance will be permitted to be added to food at GMP levels (ie greater than 0.8%) which is not consistent with the 0.8% level proposed for its addition as a novel food. It will be impossible for State and Territory jurisdictions to enforce a 0.8% level, as the manufacture may claim that the soy leghemoglobin is being added as a flavouring substance not as a nutritive substance. So the level of soy leghemoglobin may easily exceed the limit of 0.8% and present a public health and safety issue.
4. It is important that leghemoglobin be assessed as a food additive so that the technological justification for its addition to food is determined. There is potential for leghemoglobin to be added to food not in accordance with Good Manufacturing Practice (GMP) which food additives are subject to by regulation.
5. Any permission for the addition of leghemoglobin to a meat analogue should also consider the "carry over" of the additive to another food. Could the leghemoglobin be found in mixed meat products such as a mixture of sausage meat and meat analogue containing leghemoglobin by carry over?
6. The drafting unit of 0.8% level for soy leghemoglobin is not consistent with mg/kg units used elsewhere in the Code for maximum permitted levels.
7. If soy leghemoglobin is used at a very low level (for example 0.05%) which may not be a nutritionally significant contribution to the diet of an individual, is it really being used as a nutritive substance? If soy leghemoglobin is an expensive ingredient, then there will be the tendency for a meat analogue manufacturer to use a minimum level to reduce cost of the product. This could be deceptive to consumers it they believe that they are receiving the iron equivalent of consuming meat.
8. The proposed drafting states -

   - For the purposes of subsection (1), soy leghemoglobin must not be present in a meat analogue product in its raw state at a concentration greater than 0.8%.

   If a meat analogue product is cooked, then this level does not apply as it is not in the raw state. It is assumed that the meat analogue products will be sold cooked. The enforcement of a soy leghemoglobin level in a cooked product is not possible using this proposed regulation.

*9.* The inclusion of a specification for soy leghemoglobin preparation is not required. It contains mainly quality parameters specific to the applicant's production method. These quality parameters (appearance, solids, ash, moisture etc) do not serve to protect public health and safety. The specification is restrictive to innovation and trade. The parameters are not required to define the nutritive substance which has been given a separate definition to the specification in the drafting. Also the microbiological specifications if required to protect public health and safety should be included in the microbiological standard in the Code to draft consistently. Otherwise

there will be too many vertical standards created in the Code and it will be cumbersome to navigate. The assessment report for Application A1186 has not done a microbiology report examining the parameters listed in the specification for *E. coli, Salmonella spp.* or *Listeria* that scientifically justifies their inclusion in a standard.

**S3—42 Specification for a soy leghemoglobin preparation**

***Note*** Subsections S26—3(5) and (7) require a soy leghemoglobin preparation to comply with the specifications set out in this section.

For a soy leghemoglobin preparation, the specifications are the following:

(a) soy leghemoglobin protein—maximum 9.0%;

(b) soy leghemoglobin protein purity—minimum 65%;

(c) appearance—dark red concentrated liquid;

(d) solids— maximum 26%;

(e) fat—maximum 2.0%;

(f) carbohydrate—maximum 6.0%;

(g) pH—5-10;

(h) moisture—maximum 90%;

(i) ash—maximum 4.0%;

(j) lead—maximum 0.4 mg/kg;

(k) arsenic—maximum 0.05 mg/kg;

(l) mercury—maximum 0.05 mg/kg;

(m) cadmium—maximum 0.2 mg/kg;

(n) microbiological:

(i) *Escherichia coli*—negative to test;

(ii) *Salmonella spp*.—negative to test;

(iii) Listeria monocytogenes—negative to test.

10. ‘Meat analogue product’ is not defined in the proposed drafting. This would make enforcement of the standard difficult to interpret. There is also in the drafting the term ‘Analogues derived from legumes’ which is not defined. It is not clear what the difference between the two terms means for enforcement purposes or if they are interchangeable in meaning.

11. It is unclear from the proposed drafting whether permission is being provided for “soy leghemoglobin” or “soy leghemoglobin preparation”. Using the two terms makes interpretation of the regulation confusing.