



Submission: Application A1186: Soy leghemoglobin in meat analogue products

Many thanks for the opportunity to comment on FSANZ's proposal to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of soy leghemoglobin (SLH) in the form of LegH Prep in meat analogue products (including the Impossible™ Burger, meatballs, sausages, and as fillings in buns and dumplings). We believe there is insufficient evidence to support the safety of this product and that FSANZ should reject Impossible Foods' application.

Impossible Foods' SLH is derived from a strain of genetically modified (GM) *Pichia pastoris* yeast. SLH in its natural state exists in the roots of soy beans and has thus far never been an integral part of the human diet. Consequently, GMO-derived SLH has no history of safe use as a foodstuff. Therefore, consumer safety following consumption of GMO-derived SLH cannot be assured. Given the potential for harm, FSANZ must enforce stronger safety standards for this product.

The lack of independent safety assessments leaves the government and public without critical scientific data about the direct and indirect health consequences from the GMO-derived SLH.

All products derived from genetic engineering require regulation and assessment for their potential health and environmental impacts.

FSANZ has supplied insufficient evidence to support its conclusion that SLH is safe. Contrary to FSANZ's assertion that none of the 17 proteins produced by the GM yeast are significantly similar to known toxins or allergens, Impossible Foods' supporting documents state that a number of the proteins produced show similarities to known toxins and allergens (Appendix 8 – pp. 8-11). Such a finding should prompt further investigation to ensure public health and safety, but they are recklessly dismissed as insignificant.

Furthermore, some research suggests that heme iron may contribute to an increased risk of colon cancer and other health problems that have been associated with red meat consumption. It's still unknown whether the heme iron from soy leghemoglobin may pose that same risk.¹

Inadequate safety study: Strong third-party scientific studies must be required

The 28-day feeding study where laboratory rats were fed the GMO-derived SLH², and which Impossible Foods commissioned, was inadequate to address questions of safety, as it covered too short a study period and had too small a sample size to ensure adequate statistical power. After the US Food and Drug Administration told Impossible Foods that their 2014 submission did not "point to a general recognition of safety,"³ and after Impossible Foods withdrew their 2014 GRAS application,⁴ Impossible Foods proposed a 90-day feeding study,⁵ a standard length of time for sub-chronic testing for toxicity in rats.

As Michael Antoniou, PhD and Claire Robinson note in an article discussing the study, “the shorter the duration of a study, the less likely it is to find health effects such as organ damage, which take time to show up.”⁶ It is therefore unclear why Impossible Foods disregarded the 90-day feeding study proposal and standard scientific procedure and only conducted a 28-day feeding study. No claims of long-term safety from the consumption of its product can be made on the basis of this inadequate short term study.

The small sample size of the study is a major limitation. There were only 20 rats in each of the 4 test groups (10 rats per sex per group).⁷ This impedes researchers’ ability to draw statistically significant conclusions about the health consequences of small physiological changes, which would require long-term studies with significantly larger numbers of animals.

Despite the shortcomings of the study design, a number of statistically significant physiological differences were observed between some of the controls, and test groups fed the GMO-derived SLH. “Rats fed the genetically modified (GM) yeast-derived SLH developed unexplained changes in weight gain, changes in the blood that can indicate the onset of inflammation or kidney disease, and possible signs of anemia.”⁸ Statistically significant findings such as these should signal that more thorough long-term studies are needed to fully evaluate the safety of this product, especially when it is widespread in the human food supply, unlabelled and untraceable.

However, FSANZ has not required long-term safety assessments and data. And without presenting experimental evidence, Impossible Foods dismissed the statistically significant effects found in their study as “non-adverse,”⁹ which ignores the norms of sound scientific practice.

Not only is the GMO-derived SLH a liability for FSANZ, it may be potentially hazardous and risky for consumers. Without clear long-term, independent data sets and safety assessments, FSANZ cannot know whether there could be adverse reactions to the GMO-derived SLH in the intermediate to long-term in the human population.

Conclusion

FSANZ has full authority to require independent safety assessments for ingredients derived from genetic engineering, particularly those that are new to the human diet and have no established history of safe use such as the GMO-derived SLH. FSANZ should not deem Impossible Food’s GMO-derived SLH safe on the basis of inadequate scientific evidence.

Impossible Food’s application to use GMO-derived SLH in the Australian and New Zealand food chain, should be declined and the substance should not be approved for sale.

¹ Bastide, N.M *et al.* (2015) A central role for heme iron in colon carcinogenesis associated with red meat intake. *Cancer Res.* **75**(5):870-9. doi: 10.1158/0008-5472.CAN-14-2554
<https://www.ncbi.nlm.nih.gov/pubmed/25592152>

² Impossible Foods, Inc. GRAS notification for soy leghemoglobin protein preparation derived from *Pichia pastoris*: GRAS Notice (GRN) No. 737. October 2017. <https://www.fda.gov/media/124351/download>

³ Impossible Foods FOIA documents. 2017. “FDA’s Evaluation of the Notifier’s Response to FDA’s Questions.” Page 26. Retrieved from https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/2017/08/072717_Impossible_Burger_FOIA_documents.pdf

⁴ Impossible Foods FOIA documents. 2017. Page 28. Retrieved from https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/2017/08/072717_Impossible_Burger_FOIA_documents.pdf

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- ⁵ Impossible Foods FOIA documents. 2017. Page 30. Retrieved from https://1bps6437gg8c169i0y1drtgz-wpengine.netdna-ssl.com/wp-content/uploads/2017/08/072717_Impossible_Burger_FOIA_documents.pdf
- ⁶ <https://www.gmoscience.org/rat-feeding-studies-suggest-the-impossible-burger-may-not-be-safe-to-eat/>
- ⁷ Impossible Foods, Inc. GRAS notification for soy leghemoglobin protein preparation derived from *Pichia pastoris*: GRAS Notice (GRN) No. 737. October 2017. <https://www.fda.gov/media/124351/download>
- ⁸ *Ibid.*
- ⁹ *Ibid.*