

This is a provisional English translation of an excerpt from the original full report.

Risk Assessment Report

BLAD protein extracted from the germinated seeds of sweet *Lupinus albus* (Exempted Substances)

Food Safety Commission of Japan (FSCJ)
January 2024

ABSTRACT

The FSCJ conducted a risk assessment of BLAD¹ protein extracted from the germinated seeds of sweet *Lupinus albus* (CAS No. 1219521-95-5) (hereinafter referred to as “BLAD”), a fungicide, based on submitted documents. The purpose of the assessment was to provide the FSCJ’s opinion on whether BLAD could be designated by the Minister of Health, Labour and Welfare as an Exempted Substance², defined as having no adverse effects on human health, in accordance with Article 13, paragraph (3) of the Food Sanitation Act (Act No. 233 of 1947).

The median lethal dose (LD₅₀) of BLAD in the acute toxicity study in rats was greater than 5,000 mg/kg bw, and the no-observed-adverse-effect level (NOAEL) in the 90-day subacute toxicity study in rats was 500 mg/kg bw per day. Biologically significant genotoxicity was not observed.

BLAD is a component of naturally-occurring seed storage proteins. Even when used as a pesticide, it is expected to be rapidly degraded in the environment by microorganisms, resulting in its low residue levels in agricultural products. Furthermore, even if ingested, it is rapidly degraded by proteolytic enzymes such as trypsin present in the intestinal tract of animals; therefore its absorption of BLAD is considered to be extremely low.

Regarding the allergenicity of BLAD, considering comprehensively that residue levels in agricultural products are low when used as a pesticide within the prescribed usage standards, that it is rapidly

¹ BLAD is an acronym of the Portuguese words “banda de *Lupinus albus* doce”, meaning [electrophoresis] “band from sweet *Lupinus albus*”.

² On May 29, 2006, the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods, which is a system that prohibits distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. Exempted Substances are defined by the MHLW as substances having no apparent risk to cause damage to human health, based on the provision of Article 13, paragraph (3) of the Food Sanitation Act.

degraded by proteolytic enzymes such as trypsin, and that no allergic reactions have been reported in its history of use overseas, it is considered unlikely to induce allergic reactions in humans.

However, if new information becomes available in the future, further evaluation may be necessary; therefore, it is important to continue collecting relevant information.

Based on the above, the FSCJ concluded that BLAD, when used in accordance with its intended usage as a pesticide, is unlikely to pose a risk to human health through residues in food. This conclusion is made on the premise that impurities in the technical material are controlled within the limits specified by relevant standards.