

Customer Communication Sheet

CCS-02-060514



Legal Status of NaProLup Products

(more detailed description and argumentation)

Preliminary Remark

NaProFood's raw materials origin from Australia (**Lupinus angustifolius**) and from Chile and France (**Lupinus albus**).

(1) In Europe, lupins of the **Lupinus albus** variety ("white lupins") and products thereof have traditionally and significantly been used for human consumption in the Mediterranean countries (Italy, Spain, Portugal, Greece) prior to May 1997 (see (6)).

(2) In Australia, lupins breeding and cultivation have been concentrated on the species **Lupinus angustifolius** ("the narrow leaved lupin").

(3) In Oct. 1990, the Grain Pool of Western Australia (GPWA), which is – among others – a raw material supplier of NaProFood, requested food safety clearance from the relevant UK authorities for the seeds of *Lupinus angustifolius* for their use in the production of lupin based food products. This submission has been completed through additional studies (commissioned by GPWA) during 1991 to 1994.

(4) Evaluation of this submission has been performed by the UK Advisory Committee on Novel Foods and Processes (ACNFP). Based on this, the UK Ministry of Agriculture, Fisheries and Food (MAFF) has declared on June 24th, 1996, that

"... there are no objections to the seeds of the narrow leaved lupin (Lupinus angustifolius) being used as food as described in your (i.e. GPWA's) submission to the Committee."

(5) ACNFP statement in 1996 expresses that

"... lupins have been used elsewhere in the world (i.e. not in the UK) as a human and animal food for many centuries."

Since this is especially valid for several European countries (which can be proved from literature), ACNFP's statement implies that lupins and products thereof are not regarded as Novel Foods according to 258/97 EEC.

(6) To NaProFood's best knowledge, there is no comparable official statement available for *Lupinus albus* and products thereof which indicates their Food Regulatory Status within the European Union. This legal situation also applies to most of traditional food and food ingredients in Europe. However, we have received an additional information from the UK Food Standards Agency (FSA) in June 2003 which clearly indicates that

*" Lupin species (i.e. **Lupinus albus** and *Lupinus angustifolius*) are not considered to be novel foods as they have a significant history of consumption in the EU prior to May 1997. However, approval to derived products would only cover products produced using conventional food manufacturing processes... ."*

(7) The FSA statement provides a clear definition of Novel Processes ("*... including any steps that intentionally modify the properties of the native constituents of the lupin ...*") which will clearly not apply to NaProFood's manufacturing processes.

(8) Finally, NaProFood states that all European countries have to regard any food as a traditional food if it is regarded as "traditional" in at least one European country.

From these facts it is evident, that NaProLup products are regarded as conventional food ingredients according to European food legislation.

At the same time NaProFood states that FDA approval for lupins and products thereof is presently not available.