



Federal Office of Consumer Protection and Food Safety
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Borut Poje

Only via e-mail:

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Tatjana Drewitz
Referentin

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YOUR REFERENCE
YOUR MESSAGE FROM 12.10.2021

OUR REFERENCE 111.11050.0.364923
(please indicate in reply)

DATE 25.10.2021

Registrierung des Lebensmittels für besondere medizinische Zwecke

Dear Mr. Poje,

Thank you for your e-mail.

With regard to your inquiry I would like to forward the following information to you:

Enforcement of food law regulations lies with the federal states (Bundesländer). The federal states, their supreme food control authorities and subordinate food control offices, perform random tests to check whether food products are in conformity with the food law. Addresses and information on the competent federal authorities can be found here:

www.bvl.bund.de/lebensmittelueberwachungDerBundeslaender

Please take note that the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit - BVL) is not the competent authority for verifying and certifying compliance of products with food law regulations and their marketability in Germany or the EU.

Food business operators at all stages of production, processing and distribution are primarily responsible for ensuring that their activities are carried out in compliance with food legislation. For that purpose, they shall maintain of a system of own controls.

Subject to another opinion of the competent federal authorities, I can give you the following information:

When a Food for Special Medical Purposes (FSMP) in line with Article 2 (2) (g) Regulation (EU) No 609/2013 is placed on the market for the first time according to Article 9 of the Delegated Regulation (EU) 2016/128 the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product [...]. In Germany the competent authority is the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit - BVL).

More information about the notification procedure you will find under the following link (only available in German):

http://www.bvl.bund.de/DE/01_Lebensmittel/04_AntragstellerUnternehmen/02_DiaetetischeLM/04_AnzeigeVerf/lm_diaetLM_anzVerf_node.html

You have notified the BVL of the placing on the market of the product you mentioned. Afterwards, you have received a confirmation of receipt, which you can save or print.

The notification is filed under file number 111.11152.0.0123(2021). Please indicate this in all correspondence.

Another document will not be issued by the BVL.

The product can be placed on the market as soon as the notification is submitted to the BVL, provided that all relevant food law requirements are met.

I would like to point out that this is only a notification. The BVL is not the competent authority for verifying and certifying compliance of the notified FSMP with food law regulations. The BVL does not carry out a legal evaluation of the received notifications of FSMP. It is therefore not intended to issue a certificate of marketability as a condition for the marketing of FSMP. The BVL forwards the notifications to the state authority responsible for food control. They are the competent authorities to decide whether or not a FSMP complies with the legal requirements and can be placed on the market in Germany.

Every food business operator is responsible for ensuring that his products comply with the requirements of food law and, therefore, carry out own internal inspections on his own responsibility. A legal evaluation of the products by the authorities or by BVL before placing the products on the market is, however, not provided by law.

If you have further questions regarding notification procedure, please don't hesitate to contact me. However, please understand that the BVL cannot provide comprehensive legal advice in individual cases.

For further questions, please contact a food chemistry expert sworn in by the Chamber of Industry and Commerce (IHK). Addresses can be obtained from the local IHK or via <http://svv.ihk.de/svvmain.asp>.

In addition, you can contact the food (counter sampling) experts approved by the federal states. A list of the counter sample experts can be found on the BVL website at: www.bvl.bund.de/gegenprobensachverstaendige

Legal advice from lawyers specialized in food law is recommended. Appropriate contacts can be found through the local bar associations, which provide a lawyer search service. A list of the respective bar associations can be found on the website of the Federal Bar Association: <http://www.brak.de/fuer-verbraucher/anwaltssuche/>

You can also search for a lawyer within the EU using the following link: https://ejustice.europa.eu/content_find_a_lawyer-334-de.do

I hope this information is of assistance to you.

Yours sincerely,
On behalf of BVL

signed
Tatjana Drewitz

This letter is computer-generated, no signature is required.