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Anzeige von Lebensmitteln für besondere medizinische Zwecke und von Säuglingsanfangsnahrung durch den Hersteller oder Einführer Entgegennahme

Heruntergeladen am 05.07.2025

<https://fimportal.de/xzufi-services/102889164/B100019>

Modul	Sachverhalt
Leistungsschlüssel	99118034261000
Leistungsbezeichnung I	Anzeige von Lebensmitteln für besondere medizinische Zwecke und von Säuglingsanfangsnahrung durch den Hersteller oder Einführer Entgegennahme
Leistungsbezeichnung II	Foodstuffs for special medical purposes, infant formulae and certain follow-on formulae for sale in Germany
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	fachlich freigegeben (gold)
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	

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Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Produkt- und Stoffzulassung (2120200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	06.06.2023
Fachlich freigegen durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32013R0609 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32016R0128 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32016R0127 https://www.gesetze-im-internet.de/lmbvw/_3.html
Teaser	If you wish to market food for certain consumer groups requiring special protection, such as sick people or infants, in Germany, you must notify the Federal Office of Consumer Protection and Food Safety (BVL).
Volltext	The following foods must meet certain legal requirements for food safety and consumer protection. This applies not only to production or declaration, but also when you make the product available for sale or use: - Foods for special medical purposes, so-called balanced diets, for use under medical supervision. They cover all or part of the nutritional requirements of sick people when this is not possible with conventional foods. - Infant formula and - certain follow-on formulas. In the following cases, please send a notification to the Federal Office of Consumer Protection and Food Safety (BVL): Initial notification: You must notify the BVL at the latest when you first redistribute the product on the German market or offer it for use or sale. You must

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submit a separate notification for each product.

Notification of change: Notify the BVL, for example, if the already notified product - has a changed recipe, - you change the consumption recommendations or - your company has a new address.

Second notification: You must also send a notification if the product - is already registered in another EU member state and - you wish to place the product on the market in Germany for the first time.

The BVL will forward your information to the competent authorities in the federal states and to the Federal Ministry of Food and Agriculture. The competent authorities of the federal states monitor compliance with the legal requirements. As a company, you are responsible for implementing these requirements. The BVL does not assess the marketability of the products, i.e. the extent to which they comply with food law regulations. Therefore, the BVL cannot confirm whether your product complies with the food law regulations within the scope of the notification. No approval or authorization is granted following the submission of the notification of a food for special medical purposes, an infant formula or certain follow-on formulas.

Erforderliche Unterlagen

- Sample of the label in German to be used for the product
- Proof of suitability
- If there are several pack sizes or flavors, please submit all corresponding product labels.
- Authorization if you are notifying the product on behalf of the responsible food business operator
- If you have already notified your product in another EU Member State, the following documents are optional: Confirmation of the first notification as a copy German or English translation of the confirmation, if applicable

Voraussetzungen

- You are planning to launch foods for special medical purposes, infant formula or certain follow-on formulas on the German market.

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Kosten	Abgabe: Es fallen keine Kosten an There are no costs.
Verfahrensablauf	You can submit the notification online via the federal portal: • Call up the online form on the federal portal verwaltung.bund.de. This will guide you step by step through the necessary information. • Complete the form, upload the required documents and submit the notification online. • You will receive a confirmation of receipt.
Bearbeitungsdauer	Duration: 0.5 hours Processing is completed once the notification form has been sent or confirmation of receipt has been received.
Frist	You must make the notification at the latest when you make the product available for sale or use in Germany.
weiterführende Informationen	https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/04_AntragstellerUnternehmen/02_DiaetetischeLM/04_AnzeigeVerf/Im_diaetLM_anzVerf_node.html https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/04_AntragstellerUnternehmen/02_DiaetetischeLM/01_Ueberblick/Im_diaetLM_ueberblick_node.html
Hinweise	The following information is available: The confirmation of receipt of the notification does not constitute a certificate as to whether the product is marketable. The marketability of the product (e.g. labeling) is not checked in the notification. A notification does not replace the individual obligation to comply with food law regulations.
Rechtsbehelf	none
Kurztext	• Notification of foods for special medical purposes, infant formulae and certain follow-on formulae by the manufacturer or importer Receipt • Companies notify the Federal Office of Consumer Protection and Food Safety (BVL) of the making available for sale or use of: Foods for special medical purposes, so-called balanced diets, and infant formulae and certain follow-on formulae

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- Initial notification must be made at the latest when companies offer the products on the German market for the first time or distribute them further
- Notification of changes: Companies notify changes to products that have already been notified, for example changed recipe, new instructions for consumption or new company address.
- Second notification is required if the product is already registered in another EU Member State and is to be placed on the market in Germany for the first time
- Notification can only be made online
- Companies send a sample of the label in German and further information (such as proof of suitability)
- BVL forwards information to the competent food control authorities of the federal states and to the Federal Ministry of Food and Agriculture
- The content of the information and documents is not checked
- This is not an authorization
- Responsible: Federal Office of Consumer Protection and Food Safety (BVL)

Ansprechpunkt

Zuständige Stelle

Formulare

Forms available: No Written form required: No
Informal application possible: No Personal appearance necessary: No Online services available: Yes

Ursprungsportal

Anzeige von Lebensmitteln für besondere medizinische Zwecke und von Säuglingsanfangsnahrung durch den Hersteller oder Einführer Entgegennahme, Anzeige von Lebensmitteln für besondere medizinische Zwecke und von Säuglingsanfangsnahrung durch den Hersteller oder Einführer Entgegennahme