

Knowledge Empowers Business – Forum 2025

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Registration of food supplements, food products and cosmetics in the Custom Union of the Eurasian Economic Union.

Collisions of regulations and strategies of entering new markets in scope of product registration.

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Located in the heart of Siberia

Full service company since 1996

Development → Manufacturing → Promotion

- **2 laboratories and a 16-person R&D team providing 160 studies monthly**
- **3 production buildings equipped with 18 types of production lines**
- **Representative offices in 29 countries**

For over 27 years, we have been developing and producing products for an active and healthy lifestyle. We use only high-quality certified raw materials from global companies, as well as environmentally friendly ingredients from Siberian farmers.

Our key areas:

- **Food supplements**
- **Cosmetics**
- **Sports and Functional nutrition**
- **Perfumes and Children's products**

Part 1. Product registration in Russia and the Custom Union of EAEU

Dietary supplement registration

Food → Specialized Food Products → Biologically active supplements

Definition:

Biologically active supplements - Natural and/or identical to natural biologically active substances as well as probiotic microorganisms intended to be consumed together with food or introduced into the content of food products;

! Require **state registration** before they can be manufactured, import and sale. This process ensures the product's safety and compliance with regulations.

Dietary Supplements.
Regulatory frames

The **Customs Union of the Eurasian Economic Union (or EAEU Customs Union)** is a trade bloc of 5 post-Soviet states:

Russian Federation

The Republic of Belarus

The Republic of Kazakhstan

Kyrgyzstan

Armenia

- Establishes a common external tariff, eliminating customs duties and economic restrictions among member states.
- **!** Certificate of State registration obtained in any country of the Customs Union has the same legal power and recognized by other countries of the Union.

Dietary Supplements.
Regulatory frames

Regulatory base:

- **Technical Regulations of the Customs Union 021/2011, "On Food Safety,"** is a key document outlining the requirements for food products, including dietary supplements.
- **Technical Regulations of the Customs Union TR CU 022/2011 "Food products in terms of their labeling"**, sets mandatory requirements for labeling food products circulating within the Eurasian Economic Union (EAEU).

Dietary Supplements.
Regulatory frames

Competent authorities responsible for state registration in the member states

- **Russian Federation**

the Federal Service for Supervision of Consumer Rights Protection and Human Welfare (**Rospotrebnadzor**)

- **Republic of Armenia**

Food Safety Inspection Body of the Republic of Armenia (authorized body in the field of safety of food products and goods in contact with food products)

- **Republic of Belarus**

Ministry of Health Republic of Belarus

- **Republic of Kazakhstan**

Committee for Sanitary and Epidemiological Control of the Ministry of Health of the Republic of Kazakhstan

- **Kyrgyz Republic**

Ministry of Health of Kyrgyz Republic

Dietary Supplements. Regulatory frames

Who Can Register Dietary Supplements

- **Legal entities in the EAEU:** Only companies officially registered in one of the Eurasian Economic Union member states.
- Foreign manufacturers without a local presence need to engage a representative or partner within the EAEU.

Certificate of State Registration

Valid period - indefinitely

- Proves the product harmless for consumers
- Free circulation of the product within Russia and all Customs-Union states



**Dietary Supplements.
Regulatory frames**

When Is Registration of Dietary Supplements Possible?

- ❖ Absence of therapeutic claims
 - ❖ Supplemental function
 - ❖ Compliant advertising
 - ❖ Permitted composition

**Dietary supplements.
Registration Process**

Registration Process

Steps:

- Dossier Preparation
- Testing and Analysis
- Submission to the Authority
- Certificate Issuance

Timeline for Processing:

- **Laboratory analyses:** 1 to several weeks
- **Expert conclusion (within authority review):** 4 to 6 weeks
- **Official registration:** about 1 month

What is required for registration

1) Application form with the attached documents:

- legalized Power of Attorney from the applicant to the representative;
- certified copies of the Manufacturer's Authorizations for all manufacturing sites involved in manufacturing process issued by the competent authorities of countries-manufacturers (*if available*);
- certified copies of HACCP (and GMP – is available) Certificates for all manufacturing sites involved in manufacturing process;
- certified copies of documents according to which a food supplement is produced (*standards, technical conditions, regulations, technological instructions, manufacturing process, specifications, recipes, information on the composition*);
- declaration of the manufacturer about the presence of GMO, nanomaterials, hormones, pesticides in food supplement;

- certified copy of instruction for use or summary of product characteristics (*composition, product form, description, shelf-life, storage conditions, etc.*);
- certified copy of Certificate of Analysis or Quality Certificate or Material Safety Data Sheet
- a copy of the document from the authorized health authorities (other state authorized bodies) of the country of origin, confirming safety and allowing free circulation of the product in the territory of the state of the manufacturer, certified in accordance with the legislation of the Party where state registration is conducted, or the manufacturer's notification of no need for such a document;
- proposed mockups for the Russian market;
- testing reports (hygienic certificates), scientific reports, expert opinions;

2) Samples of food supplement for conducting the required studies.

**Dietary supplements.
Registration Process**

What testing covers:

- ❑ Microbiological purity (bacteria, yeast, mold)
- ❑ Levels of toxic metals and other hazardous elements
- ❑ Residues of pesticide compounds
- ❑ Concentrations of naturally occurring radionuclides
- ❑ Active substances declared in a product's formula

You can choose accredited test centers or laboratory that holds a valid license.

**Dietary supplements.
Registration Process**

Labelling and claims

The Technical Regulation of the Customs Union TR CU 022/2011 “On food products in terms of labelling” – basic regulation for labeling of food supplements. It lays out labeling criteria and guidelines for the use of nutrition and health claims.

“Chestny Znak” (Honest Sign) system

This system uses unique digital codes (Data Matrix) applied to product packaging, allowing for the tracking of the product from manufacturer to consumer and verifying its authenticity



**Dietary supplements.
Registration Process**

Reasons for Potential Refusals:

- ❖ Mismatch between product content and declared documentation
- ❖ Presence of banned ingredients
- ❖ Incorrect classification
- ❖ Documentation errors

**Dietary supplements.
Registration Process**

How to Simplify the Documentation Process

- Consult specialized experts
- Keep track of current regulations
- Ensure proper translations

Food Products Declaration

Food Products Declaration

Definition:

Food products – products of animal, plant, microbiological, mineral, artificial or biotechnological origin in natural, treated or processed form intended for consumption by human as food, including specialized food products, drinking water filled in bottles, drinking mineral water, alcohol-containing (including beer and products manufactured on the basis of beer) and alcohol-free beverages, biologically active dietary supplements, chewing gum, ferments and starter cultures of micro-organisms, yeast, food additives and flavourants, as well as food (edible) raw materials.

Food Products Declaration

Food products subject to **certification for compliance** with the requirements of the technical regulations of the Customs Union.

A Declaration of conformity is a key document you get as a result of the declaration.

- Required for products put into circulation in the territory of the Customs Union.
- Issued by a certification body accredited by competent authorities.
- Validity period - 1, 3, 5 years, depending on product type.



Regulation base for food products:

- **TR TS 021/2011** **Technical Regulations On Food Safety**
- TR TS 023/2011 Requirements for juices
- TR TS 027/2012 Requirements for children's and medical nutrition, drinking water, products for pregnant women, athletes, as well as dietary additives
- TR TS 034/2013 Requirements for meat and products derived from it
- TR TS 033/2011 Requirements for quality and safety of milk and its products, as well as milk-based infant nutrition
- TR TS 024/2011 Requirements for oil and fat products, as well as plant fats
- TR TS 015/2011 Requirements for grain for animal feeding and food use. In the case of grain storage, the declaration is provided
- TR TS 029/2012 Requirements for food additives

Food Products Declaration

Stages of the Food Product Declaration:

- Stage 1: Development of the technical documentation for a product subject to certification;
- Stage 2: Production of an experimental batch of products and laboratory testing;
- Stage 3: Preparation of documents and filing an online application for declaration;
- Stage 4: Obtaining the Declaration of conformity. The documents is issued electronically and included to the official register of declarations.

Food Products Declaration**A typical documentation kit is as follows:**

- ❑ Registration data of the applicant and extracts from the registers;
- ❑ Product description;
- ❑ Laboratory tests of samples
- ❑ Copies of the technical documentation on which the product is manufactured and references to standards to which it must comply;
- ❑ Labeling sample;
- ❑ Supply contract (for imported goods).

The test includes:

- Safety examination for correspondence to Technical regulation of the Custom Union (microbiology, toxicology, heavy metals, radionuclides, pesticides)
- Physical and chemical parameters

Perfumery and Cosmetics Registration

Perfumery and Cosmetic products subject to state registration or self-declaration (notification), depending of product type

Basic regulation:

Technical Regulation TR CU 009/2011 on the safety of perfumery and cosmetic products

State Registration

Registration is mandatory for higher-risk products.

- ❖ Ensures the safety and hygiene of specific cosmetic products before they can be sold in Russia and the Customs Union.
- ❖ Certificate of State registration is valid for an indefinite period.
- **Process:**
 - Submitting documents to authorized registration body
 - Samples testing in an accredited laboratory
- ❖ Products sold in the Customs Union should be produced according to Good Manufacturing Practices (**GMP**).

Declaration of Conformity

- ❖ A self-declaration (notification) that the cosmetic product meets the requirements of the Technical Regulation TR CU 009/2011 on the safety of perfumery and cosmetic products.
- ❖ Declaration of conformity can be valid for a period of 1, 3, 5, or 7 years
- **Process:**
 - Testing the product in an accredited laboratory
 - Submitting the results along with other required documentation to a designated certification body.
- ❖ Any claims made about the product's safety or effectiveness must be substantiated.

List of cosmetic products requiring State registration

Perfumery and Cosmetics Registration

- The following types of perfumery and cosmetic products are subject to the state registration:
- Perfumery and cosmetic products for sunless tanning.
- Perfumery and cosmetic products for skin lightening (whitening).
- Permanent cosmetics.
- Intimate cosmetics.
- Exfoliating products.
- Fluoride-containing oral care products with a mass fraction of fluorides greater than 0.15% (0.05% for liquid oral care products).
- Teeth whitening products containing hydrogen peroxide or other components that produce hydrogen peroxide, including carbamide peroxide and zinc peroxide, with a concentration of hydrogen peroxide (as an ingredient or product) of 0.1% to 6.0%.
- Perfumery and cosmetic products for individual skin protection from harmful workplace exposures.
- Children's cosmetics.
- Perfumery and cosmetic products for chemical hair dying, lightening and highlighting.
- Perfumery and cosmetic products for chemical hair waving and straightening.
- Perfumery and cosmetic products produced with nanomaterials.
- Perfumery and cosmetic products for hair removal.

Part 2. Collisions of regulations and strategies of entering new markets in scope of product registration

- ❖ Research of local regulation Is the most important step before entering foreign market!
- ❖ Find a good professional partner!

List of questions exporters should pay attention to:

- 1) What category the product is belong to?
- 2) What list of documents is required for product registration?
- 3) Are there any specific certificates required?
- 4) What is allowed limits for safety parameters? Are they corresponded to the limits adopted in your country?
- 5) What ingredients are allowed to use?

The most significant challenges within registration process in the new markets:

- ❖ Communication!
- ❖ Changing of registration rules and regulation

Reasons:

- Corruption
- Counterfeit and poor-quality products
- Harmonization of legislation with regional association or economic blocs

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