

Translation from Bulgarian

Appendix No. 2 to the Procedure of service provision at the request of the food operators with the Department of Food Control to the Regional Directorate of Food Safety

REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE AND FOOD
BULGARIAN AGENCY OF FOOD SAFETY
REGIONAL DIRECTORATE OF FOOD SAFETY - VARNA

STATEMENT

Today, 20.04.2017, we

1. Dr. Rosina Diyanova Baleva - Simeonova - inspector
2. Snezhana Georgieva Nenova - senior inspector

working with the Regional Directorate of Food Safety - Varna

performed an inspection in respect of an Application filed by a food operator concerning a consultation in accordance with Art. 3, Para 5 of the Bulgarian Agency of Food Safety Act with Ref. No. 1799 of 18.04.2017

regarding the following product: T8 Blend

Address: Town of Burgas, Municipality of Burgas,

40 Perushtitsa str., flat 1, tel. 0894329110,

of the company: Vivali EU EOOD

in the presence of Tatyana Vasilyovna Makrushina

Findings of the inspection:

According to the documents enclosed to the file for the food non-alcoholic concentrate T8 - Blend, developed by Vilavi EU OOD, it is evident that the product you intend to place on the Bulgarian market is a food non-alcoholic concentrate. Vilavi EU OOD may sell the aforementioned product on the Bulgarian market, labeled in Bulgarian and its writing shall be in accordance with REGULATION (EU) No. 1169/2011 of the European Parliament and of the Council of 25.10.2011 on the provision of food information to consumers, for amendment of Regulation (EC) No. 1924/2006 and (EC) No. 1925/2006 of the of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Commission Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5EC and Regulation (EC) No. 608/2004 of the Commission.

According to the Additional regulations of the Food Act, Para 1, it. 71, food supplements are the foods, intended to supplement the regular diet and being concentrated sources of vitamins, minerals and other substances with nutritional or physiological effect, used on their own or in combination and placed on the market in dozed forms such as capsules, tablets, pills, etc. being in the form of powder, ampoules with fluid and other similar liquid or powder forms, intended to be taken in previously dozed small quantities.



Recommendations: To be translated the label of the aforementioned product in Bulgarian according to REGULATION (EU) No. 1169/2011

Conclusion: It does not fall under the competence of the Regional Directorate of Food Safety to make a statement for a certain product by deciding whether it is a food supplement or juice. That shall be determined by the producer himself.

The inspection is performed by: 1.....
2.

Person, present at the inspection: Atroshenko, *signed*
Affixed the stamp of the Regional Directorate of Food Safety

I, the undersigned Antoaneta Lyubenova Dimitrova certify the true translation made by me from Bulgarian into English of the attached document. The translation consists of 2 pages.

Translator: *Antoaneta Lyubenova Dimitrova*



„СТЕДИ ПРЕВОДИ” ЕООД

11, Tsar Osvoboditel Blvd., 9000 Varna, Bulgaria
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Translation from Bulgarian

REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE, FOODS AND FORESTS
BULGARIAN FOOD SAFETY AGENCY
REGIONAL FOOD SAFETY DIRECTORATE OF VARNA

Outgoing No. KX-2888/04.07.2018

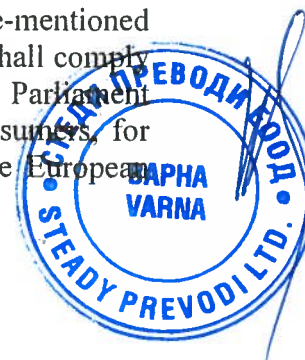
To: Trofima Atroshenko
Authorized representative of
VILAVI EU EOOD
Flat 1, block 40, Perushtitsa Str.
Burgas

Subject: Notification for food supplement market launch filed in the Regional Food Safety Directorate of Varna, incoming No. 2888/25.06.2018, <<T8 – Stone>>

Dear Mr. Atroshenko,

Food supplements are only launched on the market if they comply with *Ordinance No. 47 dated 28.12.2004 on the Requirements on Food Supplements*, published in the State Gazette, issue 5/14.01.2005, as amended and published in the State Gazette, issue 44/2007, as amended and published in the State Gazette, issue 90/16.10.2010 and pursuant to Art. 4 of the same, producers and traders who are to launch supplements on the market in the Republic of Bulgaria for the first time, before its launch, shall notify the respective Regional Food Safety Directorate as per their seat and if they do not have such on the territory of the Republic of Bulgaria – shall notify a Regional Food Safety Directorate at their choice. In this respect, the seat of the company you represent is located in an area controlled by the Regional Food Safety Directorate of Burgas and therefore you shall submit the notification to the Regional Food Safety Directorate of Burgas. No sample label has been enclosed to the above notification, as required. The regimen is a notification and not a registration and an immediate and full responsibility for labelling and compliance of food supplements with the requirements of the current legislation shall have their producer or importer.

In accordance with the documentation enclosed to the file for non-alcoholic food concentrate, *T8 - Stone*, developed by Vilavi EU OOD, it is clear that the product you want to launch on the Bulgarian market is a non-alcoholic food concentrate designed for in-house preparation of soft drink by dilution in normal or mineral water, as well as to be a raw material for production of soft drinks. Based on the above, Vilavi EU OOD can sell the above-mentioned product on the Bulgarian market, labelled in Bulgarian, and the text on the label shall comply with the requirements of REGULATION (EU) No. 1169/2011 of the European Parliament and of the Council of 25.10.2011 on the provision of food information to consumers, for amendment of Regulation (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European



Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Commission Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Regulation (EC) No. 608/2004 of the Commission.

Regards,

Dr. Zlatina Dimova, *signed*

Head of the Regional Food Safety Directorate of Varna

Stamped

19 Sofroniy Vrachanski Str., 9000 Varna
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MINISTRY OF AGRICULTURE, FOODS AND FORESTS
BULGARIAN FOOD SAFETY AGENCY
REGIONAL FOOD SAFETY DIRECTORATE OF VARNA

Outgoing No. KX-1126/17.03.2017

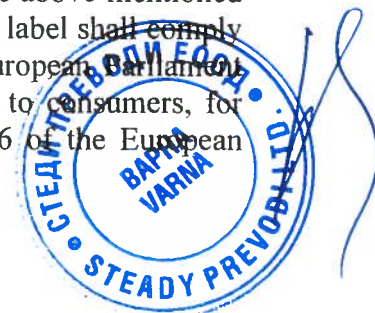
To: Trofima Atroshenko
Authorized representative of
VILAVI EU EOOD
Flat 1, block 40, Perushtitsa Str.
Burgas

Subject: Notification for food supplement market launch filed in the Regional Food Safety Directorate of Varna, incoming No. 1126/10.03.2017, <<T8 – EXTRA>>

Dear Mr. Atroshenko,

Food supplements are only launched on the market if they comply with *Ordinance No. 47 dated 28.12.2004 on the Requirements on Food Supplements*, published in the State Gazette, issue 5/14.01.2005, as amended and published in the State Gazette, issue 44/2007, as amended and published in the State Gazette, issue 90/16.10.2010 and pursuant to Art. 4 of the same, producers and traders who are to launch supplements on the market in the Republic of Bulgaria for the first time, before its launch, shall notify the respective Regional Food Safety Directorate as per their seat and if they do not have such on the territory of the Republic of Bulgaria – shall notify a Regional Food Safety Directorate at their choice. In this respect, the seat of the company you represent is located in an area controlled by the Regional Food Safety Directorate of Burgas and therefore you shall submit the notification to the Regional Food Safety Directorate of Burgas. No sample label has been enclosed to the above notification, as required. The regimen is a notification and not a registration and an immediate and full responsibility for labelling and compliance of food supplements with the requirements of the current legislation shall have their producer or importer.

In accordance with the documentation enclosed to the file for non-alcoholic food concentrate, *T8 - Extract*, developed by Vilavi EU OOD, it is clear that the product you want to launch on the Bulgarian market is a non-alcoholic food concentrate designed for in-house preparation of soft drink by dilution in normal or mineral water, as well as to be a raw material for production of soft drinks. Based on the above, Vilavi EU OOD can sell the above-mentioned product on the Bulgarian market, labelled in Bulgarian, and the text on the label shall comply with the requirements of REGULATION (EU) No. 1169/2011 of the European Parliament and of the Council of 25.10.2011 on the provision of food information to consumers, for amendment of Regulation (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European



Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Commission Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Regulation (EC) No. 608/2004 of the Commission.

Regards,

Dr. Zlatina Dimova, signed

Head of the Regional Food Safety Directorate of Varna

Stamped

For the Head: Dr. K. Marinova

Head of the Food Control Department

Substitution Ordinance: РД 11-442

Dated 08.03.2017

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