Food supplements in Romania – interview with Toma Barbarasa*

Agnieszka: W: The food supplement sector is regulated at the EU level by the Directive no. 2002/46 *on the approximation of the laws of the Member States relating to food supplements.* In Poland, the provisions of this Directive have been implemented in the horizontal *Act on food and nutrition safety* of 25 August 2006 as well as in the implementing regulation adopted by the Minister of Health that encompasses the composition and the labeling of food supplements only. What laws are applicable to the food supplements in Romania? Did the Romanian legislator provide for any specific solutions, or maybe – as it is in Poland - the domestic provisions mainly constitute a "true copy" of the Directive's provisions?

T.B.: Similarly to Poland, the Romanian legislator implemented Directive no. 2002/46 by Order no. 1069/2007 adopted by the Ministry of Health for the approval of Norms on food supplements ("**Order 1069/2007**"). The Norms regulate food supplements containing only vitamins and/or minerals.

As regards food supplements containing other nutrients, the Romanian authorities have adopted the following regulations:

a) Order no. 244/2005 adopted by the Ministry of Agriculture, Forests and Rural Development together with the Ministry of Health on the processing and marketing of medicinal and aromatic plants used as such, partially processed or processed in the form of supplements ("**Order 244/2005**");
b) Order no. 1228/2005 adopted by the Ministry of Agriculture, Forests and Rural Development for the approval of the Technical Norms regarding the marketing of pre-dosed food supplements of animal and vegetal origin and / or mixtures thereof with vitamins, minerals and other nutrients ("**Order 1228/2005**" and together with Order 244/2005, the "**Orders**").

The Orders cover food supplements containing other nutrients (e.g. extracts, amino acids, hive products) apart from vitamins and minerals or any combinations thereof. These are subject to notification to the Food Bioresources Institute or to the competent Public Health Regional Centres.

Agnieszka: Are there any differences in introducing in the market the supplements with vitamins/minerals and those with plant substances? What is the procedure for placing supplements on the market in Romania? Is their notification or authorisation required?

Toma: Yes, there are quite significant differences. While supplements with vitamins and/or minerals are subject to a simple label notification (together with a specific form) submitted to the Ministry of Health before placing them on the market, supplements containing botanicals and/or other nutrients than vitamins and/or minerals need to be registered before one may market them in Romania. To this end, a complete dossier with documents (e.g. technical data sheets for all ingredients, for the finished product and for the

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packaging, technological flow chart, proposed label) as well as a product sample need to be submitted to the Food Bioresources Institute or to the competent Public Health Regional Centres.

Agnieszka: We have heard about the controversial draft of the food supplement act, which has been held unconstitutional by the Romanian President. Could you tell us more about it? What exactly is the project about and why was it considered contrary to the Constitution?

Toma: The draft law on food supplements (PL-x no. 468/2012 - the "**Draft Law**") was initiated in September 2012, yet it was already rejected by the Senate by November 2012. Nevertheless, the Chamber of Deputies (the other legislative chamber which forms the Romanian Parliament, together with the Senate) adopted the Draft Law in October 2020 with significant amendments compared to the initial version.

The updated Draft Law (i) establishes the Ministry of Health as the only competent authority in the food supplements' industry (compared to the initial version which included also the Anti-doping National Agency and the Ministry of Agriculture and Rural Development), (ii) regulates the general conditions under which food supplements may be marketed based on Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in another EU Member State and (iii) sets specific rules for the labelling and marketing of food supplements.

As the Draft Law adopted by the Chamber of Deputies contains significant amendments compared to its initial version which were not analysed and debated by the first Parliamentary Chamber (in this case, the Senate), the Draft Law was considered unconstitutional by the Romanian President, as it breaches the bicameralism principle. Consequently, the Romanian President challenged the Draft Law to the Constitutional Court. On December 16, 2020, the Constitutional Court rejected the President's challenge and ruled that the Draft Law observes the Romanian Constitution.

Agnieszka: What are those specific rules for the labelling and marketing of food supplements provided in the Draft Law? Is there any novelty as compared to the rules set out in the directive no. 2002/46 and/or the regulation (EU) 2019/515?

Toma: Essentially, the Draft Law designates the Ministry of Health as the only competent authority for regulating food supplements (irrespective of their composition) which is significantly different from the current status as the Food Bioresources Institute and the competent Public Health Regional Centres are now responsible for the notification of supplements containing other nutrients than vitamins and/or minerals. Furthermore, the Draft Law stipulates that in case of supplements which contain other nutrients than vitamins and/or minerals, a technical endorsement shall be provided by a Technical Committee before the product is notified.

Considering the majority of supplements on the market contain other nutrients than vitamins and/or minerals, the above amendments could lead to difficult situations in practice (e.g. delays and longer notification duration) as the Technical Committee is an entity which comprises various members from different ministries, academic bodies and institutes. The Committee has a supervisory role and is responsible for assessing technical and scientific issues (e.g. use of non-permitted claims and/or ingredients) which arise from the notification of food supplements. Nevertheless, the Committee could be perceived as rather bureaucratic given that difficulties arose in the past due to its infrequent meetings.

Another issue is that the Draft Law does not make any reference to the update or repealing of the Orders or to the relationship between the Draft Law's sanctioning rules by reference to other sanctioning rules already

applicable for public health protection. Consequently, this may lead to the parallel application of different legislations.

Moreover, the Draft Law does not provide specific technical rules as regards the future notification procedure. Although it is specified the Ministry of Health shall elaborate methodological norms for the application of the Draft Law within 90 days from its entry into force, in practice, the authorities rarely observe such short terms. Consequently, this could lead to delays and/or unclear legal frameworks for food operators.

In terms of labelling, the Draft Law contains less mandatory information than the current in-force rules, yet it introduces sanctions for specific breaches. Precisely, non-compliant labelling or advertising of supplements is sanctioned with an administrative fine ranging from RON 3,000 to RON 10,000 (approx. EUR 615 to EUR 2,055) and temporary marketing prohibition until remedy thereof while marketing of supplements in lack of the mandatory notification certificate or containing non-permitted ingredients is sanctioned with an administrative fine ranging from RON 13,000 to RON 15,000 (approx. EUR 2,670 to EUR 3,080) and permanent marketing prohibition.

Agnieszka.: Currently, at the EU level, an intensive preparatory work with regard to more restrictive regulation on food supplements is underway. It is planned, inter alia, to define the maximum levels of vitamins and minerals and to initiate the procedure under the art. 8 of regulation no 1925/2006 against many components of food supplements, including hydroxyanthracene derivatives (HAD) present in the plant preparations (the latter applies to products having aloe, senna or rhubarb in their composition), monacolins in red yeast rice, green tea catechins, alpha-lipoic acid, fennel tea or Garcinia cambogia. Will these new regulations have a major impact on the Romanian food supplement market?

Toma: Indeed, there is a tendency of EU Member States to regulate the food supplements industry more strictly and Romania follows this trend. A good example to this end is the above mentioned Draft Law, although the outcome is still subject to intense debates. There are generally no maximum levels of vitamins and minerals set at national level, but the Romanian authorities usually follow the recommendations of EFSA as well as of the competent authorities in other EU Member States. Considering there is much interest in the industry with approx. 150 new food supplements (products containing more than vitamins and minerals) marketed each month, I consider the new regulations (both at EU and national level) shall definitely have a major impact on the Romanian market.

Agnieszka: For years, the issue concerning the application of the so-called "botanicals" has been unsolved. There is no harmonization as regards the rules governing the authorization of these substances for use in food production as well as the rules enabling to set their acceptable limits. Also, the approach towards this issue varies between the Member States. Does a list (more or less formal) of plant ingredients that may be used or are prohibited to use in food supplements exist in Romania? We do not have such lists in Poland, although there have been some proposals for their establishment.

Toma: I agree, the various regulations on "botanicals" at EU Member States' level clearly evidence the differences between local rules and practices and the difficulties to have a unitary approach in this matter. In Romania, Order 244/2005 (defined above) regulates the use of botanicals in food supplements and includes a positive and negative list of herbs and plants as well as a positive list of cultivated and wild

mushrooms. Additionally to the existing lists, there are certain plants but also fungi and lichens which have been specifically permitted or prohibitted based on Opinions of a Technical Committee competent to rule thereof.

Moreover, Order 288/2005 (defined above) provides specific rules on the approval of food supplements containing animal or herbal products (extracts), or in combination with vitamins and minerals.

Based on the above, in practice it is very interesting but also challenging at times to analyse if certain botanicals are permitted or not and this is usually performed on a case-by-case basis. In case of botanicals which are not covered by the Romanian legislation, the competent authority usually follows the BELFRIT (Belgium, France and Italy cooperation project) common list on permitted botanicals.

Agnieszka: There is no doubt that the issues regarding the health claims and the plant ingredients are inter-related. Are Romanian producers allowed to use the health claims included on the EU pending list and if yes – on what terms?

Toma: Indeed, plant ingredients and corresponding health claims are closely related, especially since marketing teams usually want to use health claims related to the ingredients used in the marketed products.

Romanian producers as well as EU food business operators are generally permitted to use health claims included in the EU pending list as long as they observe the general principles and specific conditions provided under Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. Moreover, the Romanian wordings used for the health claims need to reflect as much as possible the wordings provided in the pending list.

Agnieszka: And finally, a question that may be of particular interest to Polish entrepreneurs. If a Polish producers would like to introduce their supplement to the Romanian market, what should they start with and what should they remember?

Toma: Good question, since I have noticed a high interest of Polish manufacturers and operators to introduce food supplements on the Romanian market which I consider a very good thing.

Firstly, the most important aspect is to determine the legal category under which the product falls based on its composition, since this triggers different applicable rules.

Secondly, the complete and up-to-date technical documentation, together with the proposed label and product sample should be timely prepared and available as this can lead to delays in the notification process.

Thirdly, although the notification duration is not officially long (10 to 30 days (depending on the product composition) from submission of complete documentation), a longer duration should be practically considered, as there are hindrances which sometimes occur (e.g. authority overwork, informatic system crashes). The Covid-19 pandemic has also affected the authorities' activity.

To this end, a good consultant might prove helpful as there are a lot of legal and practical aspects which need to be taken into account, especially since the Draft Law will probably enter into force in its current form.

Thank you very much for this interview 😊