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# HEALTH CLAIMS, PRECAUTIONS AND WARNINGS ON OMEGA-3 FATTY ACID FOOD SUPPLEMENTS

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### **INTRODUCTION & AIM**

Health claims listed on the labels of food supplements contain voluntary information that should facilitate **consumers' choices**, while mandatory precautions and warnings are intended to safeguard **consumers' well-being**. Consumers' interest in health has fueled the expansion of the market of **omega-3 fatty acid (w-3-FA) supplements**.

The study focused on the evaluation of the regulatory compliance of health claims and mandatory statements on the labels of w-3-FA supplements.

#### **RESULTS & DISCUSSION**

### METHOD

A cross-sectional study - **regulatory compliance** of w-3-FA supplements in terms of labelled:

health claims - according to the EU register of health claims
 mandatory statements – according to the EU regulations

**97 supplements** included in the study were produced in numerous European countries and marketed in Serbia, whose regulatory framework is harmonized with the one in the EU, but in contrast requires the premarket registration of food supplements.

Intake of w-3-FA was calculated based on the labelled content of w-3-FA

and recommended use of the supplement. > 76 out of 97 supplements - verbal health claims - the active substance  $\geq$  68 supplements - w-3-FA claims  $\rightarrow$  59 compliant with regulations CONCLUSION (31 - single claim, 28 - multiple ones; 107 claims in total) (Fig.1). Along with questionable consumer understanding of health promotion > The intake of w-3-FA - not always appropriate to support the given claims, the volume and severity of misleading claims is posing claims (one supplement provided only 6% of the required dose) (Fig.2). considerable concerns for public health, urging stricter control of > The majority of the supplements contained mandatory statements supplement labeling. (Fig.3), and some of them warnings and precautions (Fig.4). 14(1) (b) necessary for the normal growth and EFA contributes to the maintenance of normal ALA Adults development of children UValid blood cholesterol levels (a) 13(1) contributes to the maintenance of normal ALA in the mother, it contributes to the normal Not valid cholesterol levels in the blood Children development of the brain of the fetus : (g) in the mother, it contributes to the normal Not enough data in the mother, it contributes to the normal development of the brain of fetuses and... Pregnant and nursing development of the eye of the fetus : (q) 14(1) (b) DHA in the mother, it contributes to the normal women development of the eye of the fetus and... contributes to the normal visual development Adults, children of infants up to 12 months of age (f) contributes to the normal visual development DHA of infants up to 12 months of age contributes to maintaining normal levels of Adults, children, triglycerides in the blood (e) contributes to the maintenance of normal pregnant and nursing levels of triglycerides in the blood (a) contributes to the maintenance of normal women contributes to the maintenance of normal vision (d) DHA vision contributes to the maintenance of normal contributes to the maintenance of normal brain function (d) brain function 13(1) contribute to the maintenance of normal contribute to the maintenance of normal blood pressure (c) blood pressure (a) EPA/DHA **EPA+DHA** contribute to maintaining a normal level of contribute to maintaining a normal level of triglycerides in the blood (b) triglycerides in the blood (a) contribute to the maintenance of normal contribute to the maintenance of normal heart function (a) heart function

0 5 10 15 20 25 30 35 40 45

Number of claims

**Figure 1.** Authorized health claims referring to omega-3 fatty acids listed on supplement labels, categorized by the type of fatty acid and the regulation article to which the claim pertains (Article 13(1) – general claims and Article 14(1)(b) – claims related to children's health, displayed by target population groups.

Note: <sup>(a)</sup> Usage restriction: The statement will not be used for food intended for children.



0 5 10 15 20 25 30 35 40 45

Number of claims

Figure 2. Validity assessment of claims based on ω-3-FA intake from supplements in relation to the intake requirements for foods bearing omega-3 claims. Notes:
(a) A food that is at least a source of omega-3 fatty acids (at least 0.3 g of ALA per 100 g and per 100 kcal, or at least 40 mg of the combined EPA and DHA per 100 g and per 100 kcal).
(b) A food that provides a daily intake of 2 g of EPA and DHA
(c) A food that provides a daily intake of 3 g of EPA and DHA
(d) Food that contains at least 40 mg of DHA per 100 g and per 100 kcal
(e) Food that provides a daily intake of 2 g of DHA and contains DHA in combination with EPA
(f) Food must contain at least 0.3% of its total fatty acids as DHA
(g) Food that provides a daily intake of at least 200 mg of DHA



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