

### **Food Supplements Europe Comments on the proposed maximum limits (MLs) for 3-MCPD, 3-MCPD esters and glycidyl esters in “food supplements containing special fatty acids”**

Food Supplements Europe would like to thank the Commission for providing the opportunity to comment on the newly proposed MLs for 3-MCPD, 3-MCPD esters and glycidyl esters in “food supplements containing special fatty acids”. The following MLs are proposed:

- Glycidyl esters: 400 µg/kg
- Sum of 3-MCPD and 3-MCPD esters (expressed as 3-MCPD): 750 µ/kg

Based on information provided by our membership and the Global Organization for EPA and DHA Omega-3s (GOED), representing the supply chain of fish and marine oils, we consider that these newly proposed levels are not consistent with the MLs already established for these contaminants for fish oils and oils from other marine organisms in Commission Regulation (EU) 2020/1322 of 23 Sept 2020 amending Regulation (EC) No. 1881/2006 as regards maximum levels of 3-monochloropropanediol (3-MCPD), 3-MCPD fatty esters and glycidyl fatty acid esters in certain foods.

These oils are used as such in food supplements, are not diluted by the food supplement composition, nor is there further formation of glycidyl esters, 3-MCPD and 3MCPD esters during manufacturing. Even when using compliant oils, most food supplements will therefore exceed the newly proposed MLs

We therefore propose that the Commission does not proceed with these MLs but that, as is the case today, the MLs already established for the raw materials also apply to food supplements. The level permissible in the final product should therefore be calculated on the basis of the percentage of the oils used in the final product composition. The setting of MLs for end-products would increase considerably the burden for analysis and monitoring, while not offering any additional safety for consumers.

We hope the Commission can take on board our proposal.

More clarification is provided in the annex to this letter.

We remain available for further clarification should this be required.

## Annex

This annex provides more detailed information on the relationship between the proposed maximum limits (MLs) for glycidyl esters (GE), 3-MCPD and 3-MCPD esters in food supplements and the limits already established for fish oils and oils from other marine organisms.

The below information is collected from the membership of Food Supplements Europe and from GOED, the Global Organization for EPA and DHA Omega-3s.

- Food supplements Europe represents manufacturers and sellers of food supplements and food supplement raw materials in Europe. Our membership covers both small and larger companies, through national associations and direct company membership.
- GOED represents the worldwide eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 industry. GOED's 160+ members represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands. GOED's members supply EPA and DHA for food supplements in the EU.

From the input received, it becomes clear that there is considerable concern that the omega-3 industry may not be capable of meeting the new MLs proposed for the category 'food supplements containing special fatty acids'.

For the following reasons, we propose that the Commission not proceed with adopting the proposed MLs for food supplements containing special fatty acids given that the MLs already established for the raw materials (oils) also apply to food supplements:

1. Commission Regulation (EU) 2020/1322 of 23 Sept 2020 amending Regulation (EC) No. 1881/2006 as regards maximum levels of 3-monochloropropanediol (3-MCPD), 3-MCPD fatty esters and glycidyl fatty acid esters in certain foods already establishes MLs for fish oils and oils from other marine organisms.

However, the proposed MLs for supplements under the category "food supplements containing special fatty acids" are considerably stricter than those already set for fish and marine oils: 400 µg/kg for GE (expressed as glycidol) and 750 µg/kg for the sum of 3-MCPD and 3-MCPD esters (expressed as 3-MCPD), compared to 1000 µg/kg for GE and 2500 µg/kg for the sum of 3-MCPD and 3-MCPD esters in Commission Regulation (EU) 2020/1322.

This means that the proposed MLs for a food supplement containing fish oil, are set to 40 % for GE and 30 % for 3-MCPD in the food supplement, as compared to the levels permitted for fish oils. This is a significant reduction.

2. Food supplements supplying oils and fats exist under a number of forms:
  - Gelatin soft-gel capsules containing approx. 65 to 75% of the total weight of oil.
  - Syrup-type products containing approx. 25-40% of oil.
  - Instant powder products containing approx. 10-45 % of oil.
  - Liquid fish oil supplements containing up to 98% of oil.

If oil is used that complies with the maximum limits set in Commission Regulation (EU) 2020/1322 of 23 Sept 2020 amending Regulation (EC) No. 1881/2006 as regards maximum levels of 3-monochloropropanediol (3-MCPD), 3-MCPD fatty esters and glycidyl fatty acid esters in certain foods, in most of these cases the proposed MLs for the food supplement cannot be met.

3. From occurrence data collected from GOED members, most products comply with the current already established MLs. However, it is estimated that approximately 17% of products will not be in compliance with the GE ML of 400 µg/kg, and approximately 45% of products will not be able to comply with a ML of 750 µg/kg for 3-MCPD esters. GOED's internal data from producers and brands include occurrence data collected over several years, and these numbers may be an overestimation since refiners have improved their processing conditions over the past years. However, even the largest producer in the world of refined anchovy fish oils, an ingredient oil from which the majority of European fish oil supplements and omega-3 concentrates are made, currently produces refined anchovy oil with an average 3-MCPD ester content of 760 µg/kg. Achieving this level was already a major improvement compared to the situation before process mitigation was undertaken, and likely paints a realistic picture of the level of 3-MCPD in fish oils today. Hence, the proposed MLs are too stringent, in particular for 3-MCPD.
4. GOED sought further clarification by making a request to EFSA for public access to its contaminants database (PAD 2020/031; March 11, 2021) to determine the occurrence data on which authorities rely for making decisions for the proposals of MLs. This information was made available by EFSA's Legal and Assurance Services on July 2, 2021 and in the accompanying letter EFSA explained that "information about the category 'Formulations containing special fatty acids (e.g. Omega-3, essential fatty acids)' is provided in the F04 ingredient facet of the sampMathCode data element, and that no further information is provided for this category." From reviewing the data in the EFSA database, it was observed that all 15 entries for EPA/DHA-containing supplements for which data were available for 3-MPCD esters met the ML of 2500 µg/kg (0% non-compliance), and 12 of the 14 EPA/DHA supplements for which data were available for GE met the ML of 1000 µg/kg (14.3% non-compliance). These numbers are in line with GOED's internal data. There was a larger number of entries (n=108) for which it was not clear if the reported levels were for GE or for 3-MCPD esters (i.e. column "PARAMTEXT" specifies N\_A). In this case, if it is assumed that all should need to meet the more stringent limit of maximum 1000 µg/kg, only 3.4% of samples would be out of compliance against the current MLs.

If compliance against the newly proposed MLs is calculated, the EFSA contaminant database for GE and 3-MCPD esters shows that 21.4% of tested products for which 3-MCPD levels are available do not meet the proposed ML of 400 µg/kg for GE, and 6.7% of supplements for which 3-MCPD levels are available do not meet the proposed ML of 750 µg/kg for the sum of 3-MCPD and 3-MCPD esters (expressed as 3-MCPD). For those samples for which it is not clear if the levels correspond to 3-MCPD or GE, non-compliance with a ML of 400 µg/kg is 24.6%.

The above is confirmed by data gathered by Food Supplements Europe from its membership. For most food supplements containing EPA, DHA and other essential fatty acids the proposed limits would not allow to use oils complying with the current established MLs.

5. Food supplements are consumed in small measured quantities, typically 250 mg to 1 gram per day. This also results in low absolute intakes of GE, 3-MCPD esters and 3-MCPD. Because the MLs are expressed per unit of weight (per kg) and not per daily amount which would make more sense for food supplements, the absolute intake of these contaminants from food supplements is not considered.
6. For these types of food supplements containing fish oil, and omega-3 EPA/DHA oils from other marine organisms (e.g. krill, roe, and calanus oils), there is no dilution of the EPA/DHA-containing omega-3 ingredient oil to what is present in the supplement form. Therefore, the MLs that were adopted for fish and marine oils in Commission Regulation (EU) 2020/1322 should be applicable for the category "food supplements containing special fatty acids," at least when applicable to EPA and DHA (and other long-chain polyunsaturated fatty acids like docosapentaenoic acid omega-3). It does not make sense

to set different MLs for the ingredient oils and for those same oils present in the corresponding marketed supplements.

On the contrary, if different levels will apply depending on whether the product is packed in a bottle as food ingredient (2500 µg/kg) or as food supplement (750 µg/kg), this will create confusion as to what level applies. It is also not logical since paradoxically the use as food supplement would be in the range of 0.25-1 g/day while bottled oils can be used without a restriction.

For the above reasons, Food Supplements Europe and GOED stress that the limits for fish oils in food supplements, which are taken in small doses (a few grams daily at most, but usually in the order of 250 mg to 1 gram a day), were already quite demanding and were set in the same range as vegetable oils, which are ingested in much larger volumes by consumers. A further reduction in MLs for fish oils when used as food supplements is not reasonable given the very low intake of these foodstuffs and is not consistent with the limits that already exist for fish oils within Regulation (EC) No 1881/2006 as amended.

In addition, imposing specific limits for both the raw materials and the finished products imposes additional costs for monitoring and analytical verification of both raw materials and final products, which does not add to the level of consumer protection already ensured by the current MLs of the raw materials. The necessity of such would need to be justified and the impact on businesses assessed.

## Food Supplements Europe – January 2022