

# Are over-the-counter fish oil supplements safe, effective and accurate with labelling? Analysis of 10 New Zealand fish oil supplements

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## ABSTRACT

**AIM:** Fish oil supplements are regulated in New Zealand under the Dietary Supplement Regulations (Section 42, Food Act 1981) and therefore are not subject to the same level of scrutiny and regulations as medicines. We investigated accuracy of labelling, stated health benefits of fish oil supplements sold in New Zealand, and risks relating to possible mercury content.

**METHOD:** The amounts of omega-3 fatty acids contained per capsule were determined by an independent laboratory using gas chromatography on 10 of the most popular over-the-counter fish oil supplements sold in New Zealand and were compared with amounts stated on product labels. Information on doses recommended to achieve a specific health benefit were taken from the 10 labels as well as the company websites. These recommended doses were compared with published recommended doses identified as being effective in those health areas stipulated on the labels, based on either systematic reviews, meta-analyses and/or consensus statements. Mercury was analysed by an independent laboratory using inductively coupled plasma mass spectrometry.

**RESULTS:** The actual amounts of EPA and DHA per capsule in 90% of the over-the-counter fish oil supplements analysed were within 10% of the amount stated on the product labels. Only one product was greater than 10% below the stated dose on the label. All products suggested benefit across heart, brain and joint health and all but two products stated a range of capsules required to achieve that health benefit (eg, 2–6 capsules). Based on the *maximum* number of capsules recommended (which ranged from 3–6 capsules), only three products would likely confer the dose identified as optimal for achieving a health benefit across all three health areas. Only two products recommended doses that would likely confer a health benefit both at the minimum and maximum number of capsules. More products would likely benefit brain and heart health than joint health. Mercury was not detected in any sample.

**CONCLUSIONS:** It is reassuring that the doses of 90% of the products were accurate and that mercury was not detected in any sample; however, less than a third of the supplements would likely confer all the health benefits stated, even at the highest recommended daily doses. This paper has highlighted the ongoing challenges associated with the regulation of “health claims” associated with dietary supplements in New Zealand. Indeed, the literature on health effects is contradictory at best. Clearer definitions of the types of health statements that can be made and the research necessary to support them requires regulatory clarification.

Fish oil supplements are among the most popular dietary supplements on the global market, with use having increased dramatically over the last decade.<sup>1,2</sup> In a biochemical context, the omega-3 fatty acids, docosahexaenoic acid

(DHA) and eicosapentaenoic acid (EPA), play crucial roles in brain development, cell signalling and gene regulation;<sup>3-5</sup> they are essential (ie, required in the diet) fatty acids (EFAs) because they are not biosynthesised in human cells.<sup>5</sup>

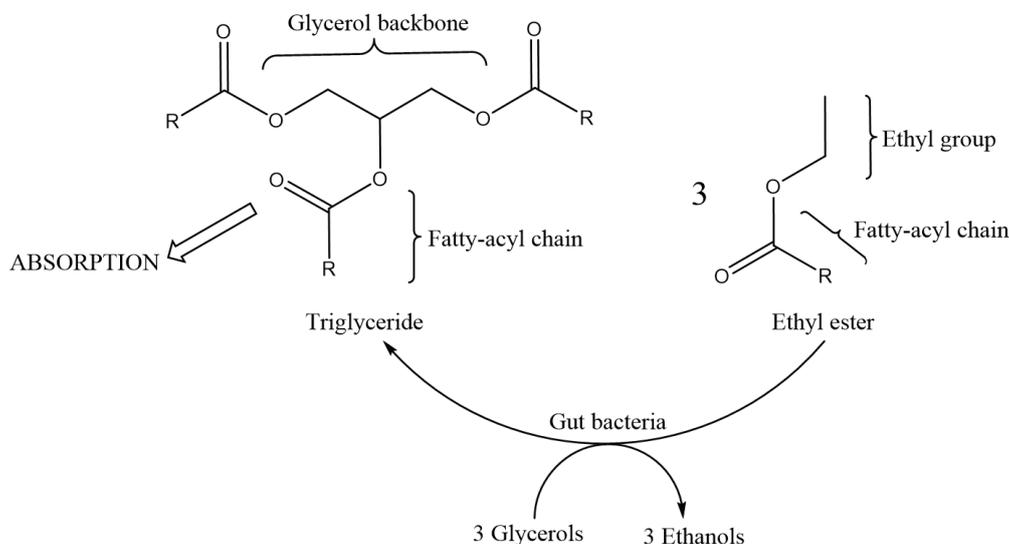
There has been an enormous body of research exploring the health benefits (note that “health benefit” is not being used with any legal or regulatory meaning) of EFAs for both physical and mental health. There have been hundreds of clinical trials, reviews and meta-analyses documenting the potential benefits of omega-3 fatty acids in medical conditions, including treatment of migraine,<sup>6</sup> cardiovascular health post-myocardial infarction,<sup>7</sup> rheumatoid arthritis,<sup>8</sup> post-operative immune function<sup>9</sup> and treating type 2 diabetes.<sup>10</sup> Other studies have shown no clinical benefit, such as in the treatment of postoperative arrhythmias,<sup>11</sup> postoperative atrial fibrillation,<sup>12</sup> dementia<sup>13</sup> or acute lung injury.<sup>14</sup>

Research over the last decade demonstrating the importance of fish oil for mental health and supplementing the diet with EFAs has emerged as a promising therapy for the management/treatment of psychiatric disorders, both as a monotherapy and as adjunct to medications, to reduce the risk of developing psychosis,<sup>15</sup> treat attention-deficit/hyperactivity disorder (ADHD),<sup>16</sup> anxiety,<sup>17</sup> and assist with the management of mood disorders.<sup>18–20</sup> On the other hand, no effects have been observed for the treatment of symptoms associated with autism<sup>21</sup> and tics.<sup>22</sup>

Fish oil supplements in New Zealand are regulated by the Dietary Supplement Regulations 1985 under the Food Act 2014. As part of these regulations as well as the Consumers Guarantees Act 1993, supplements must be true to label. However, a study published in 2015 indicated that many fish oil supplements sold in New Zealand did not contain the amounts of active ingredients stated on labels (only 3 of 32 brands tested contained label amounts of omega-3 fatty acids),<sup>23</sup> raising concern that supplements are poorly regulated in New Zealand.<sup>24</sup> Further, the majority of the fish oil supplements (83%) analysed by Albert et al<sup>23</sup> exceeded recommended oxidation levels, meaning they were highly oxidised, likely due to the oxidative susceptibility of double bonds in the fatty acid chain. The implication for consumers is that the *actual* daily intakes may be too small to confer health benefits.

In considering health benefits, the form of the EFAs is important. In fish oil supplements, the omega-3 fatty acids are either as triglycerides or ethyl esters (Figure 1). Ethyl esters are more common probably because they are cheaper to produce.<sup>25</sup> Following a refinement process, the fatty acids may be present as free fatty acids, ethyl esters or re-esterified triglycerides, which leads to

**Figure 1:** Conversion of omega fatty acid ethyl esters to triglycerides by gut bacteria.



Triglycerides are well absorbed in the gut, but ethyl esters are poorly absorbed.

For high omega fatty acid supplements: R = omega fatty acid (eg, ALA); the R groups in a tryglyceride might be different (eg, ALA, DHA).

questions about the quality and bioavailability of this highly refined and ostensibly synthetic product.

EFA ethyl esters are manufactured by trans-esterification of natural EFA triglycerides. The resulting ethyl esters are distilled at low pressure (molecular distillation) to enhance the omega-3 ethyl ester content by removing short chain fatty acid ethyl esters. However, research has shown that EFA ethyl esters are less well absorbed than natural EFA triglycerides, as they must be reconverted to triglycerides to enable intestinal absorption.<sup>25,26</sup> Poor absorption has important implications for the bioavailability of fatty acids derived from fish oil and supplement effectiveness.

In addition to *actual* EPA and DHA capsule content, whether the consumed dose will confer a stated health benefit is important and has not been systematically researched for accuracy. Labels on fish oil supplements typically provide information on the recommended daily dose to give a health benefit. The most common benefits on labels of fish oil supplements are improved heart, joint and brain health—DHA and EPA doses are particularly important for these health benefits. By law, the label cannot stipulate a *therapeutic claim* (as that would make it a medicine) and therefore, interpretation of the intention of the stated health benefit is obscured. However, the only way to learn about potential health benefits and optimal doses would be through published clinical trials, systematic reviews and meta-analyses.

EPA and DHA doses used in clinical trials vary considerably with concomitant effect discrepancies; however, published recommendations have been made on optimal doses for conferring benefit for specific health conditions. For example, a 2017 meta-analysis<sup>27</sup> and 2018 review<sup>7</sup> identified 1.0g/day EFAs (EPA+DHA) as more likely to be helpful for improving cardiovascular health post-myocardial infarction (MI). Two meta-analyses have identified that ingestion of EFAs (EPA+DHA) at a dose  $\geq 2.7$ –3.0g/day is more effective in improving painful and/or tender joints compared with  $< 2.7$ g/day.<sup>8,28</sup> For brain health, the greatest amount of positive evidence is for mood disorders and ADHD.<sup>29</sup> A 2019 consensus paper identified that the optimal dose for the treatment of

depression should be 1–2g of net EPA daily, from either pure EPA or an EPA/DHA (>2:1) formula.<sup>30</sup> A 2018 meta-analysis concluded that the dose of EPA should be  $\geq 0.5$ g/day to be most likely to confer benefit for the management of ADHD symptoms.<sup>16</sup>

In addition to health benefits, it is also important to consider health risks. In the case of fish oil consumption, the most significant toxicological risk relates to organic mercury (eg, methyl mercury— $\text{CH}_3\text{Hg}^+$ ) contamination—organic mercury is neurotoxic and lipid soluble and so concentrates up the food chain particularly into oily fish.<sup>31</sup> Oily fish species (eg, sardines, pilchards) are often used for fish oil manufacture.

We are aware of only one study that investigated mercury in over-the-counter fish oil supplements.<sup>32</sup> Analysis by cold vapor atomic absorption spectrometry revealed that all five supplements studied contained insignificant amounts of mercury with levels ranging from  $< 6\mu\text{g/L}$  to  $12\mu\text{g/L}$ .<sup>32</sup> However, it is the form of mercury that is toxicologically important. Organic mercury (eg,  $\text{CH}_3\text{Hg}^+$ ) is far more toxic than inorganic mercury ( $\text{Hg}^+$  or  $\text{Hg}^{2+}$ ) because it forms a cysteine complex which mimics methionine and crosses the blood brain barrier.<sup>33</sup> Inorganic mercury is less neurotoxic as it is unable to efficiently cross the blood brain barrier.<sup>34</sup>

The aims of the current research were to investigate whether the EPA and DHA content of the top 10 dietary fish oil supplements sold over-the-counter in New Zealand are accurate (as determined through analysis of fatty acid composition), contain low mercury levels, and whether the recommended daily doses for a health benefit are consistent with the doses determined to be effective based on meta-analyses, systematic reviews and/or consensus statements.

## Methods

### Selection of the top 10 fish oil supplements sold in New Zealand

A fish oil dietary supplement for the purpose of this study was defined as any product consumed orally that was labelled ‘fish oil’, ‘odourless fish oil’ or ‘omega-3 fish oil supplement’ and contained EPA and DHA from the bodies of deep-water fish (ie, sardines, pilchards, anchovies, mackerel, tuna) or farmed salmon. Marine oils from

alternative sources (eg, krill, calamari, algae) were omitted due to their compositional differences. Similarly, plant sources of omega-3 (eg, flax, chia seeds, walnuts, rapeseed) fell outside the scope of the current study.

All fish oil supplements that were available over-the-counter in supermarkets, pharmacies and health stores in New Zealand were eligible for inclusion in the study; however, we asked for assistance from local companies (Foodstuffs New Zealand Ltd, Progressive Enterprises Ltd, Green Cross Health Ltd, and Health 2000 Retail Ltd) to determine the top 10 best sellers based on sales information from these companies. Fish oil supplements were purchased over-the-counter from stores owned and operated by Foodstuffs New Zealand Ltd and Green Cross Health Ltd, including Life Pharmacy, Amcal, and PAK'n SAVE supermarket. Products with a use by date between 15 and 35 months from the date of purchase were selected.

The ingredients and recommended daily dosage to confer health benefits for each supplement were recorded, including the batch number and country of origin. Possible health benefits were based on the label statements as well as statements on the manufacturers' New Zealand websites, and the range in the number of capsules recommended for each health benefit was noted. These stated health benefits and doses were confirmed as up-to-date as of 24 November 2019.

### Collection, storage and analysis of fish oil samples

Fish oil supplements were purchased in April 2015, they were stored in the dark at <math><30^{\circ}\text{C}</math> to minimise oxidative and light-induced changes. Three capsules from each fish oil package were analysed within three months of purchase. The samples were coded so that the analyst did not know the product identity.

### Analysis of fish oil supplement samples for omega-3 fatty acids

The contents of three fish oil capsules were pooled and an aliquot analysed by gas liquid chromatography (GLC) for EPA and DHA using AOAC Official Method 991.39<sup>35</sup> byASUREQuality Ltd, Auckland, a New Zealand Good Laboratory Practice

(GLP) accredited laboratory approved by International Accreditation New Zealand (IANZ). This accreditation denotes that the analytical methodology has been validated to determine between sample and within sample analytical variability, and that all quantitative laboratory equipment (eg, balances) is regularly calibrated in accordance with approved Standard Operating Procedures and that readings (eg, mass) variability is within pre-defined acceptable limits.

In brief: approximately 0.025g of fish oil from each capsule was accurately weighed into a glass vial containing 25mg hexacosanoic acid (C23:0) methyl or ethyl ester (internal standard) in 2,2,4-trimethylpentane. Samples were derivatised to methyl esters, separated on a capillary GLC column, and peaks detected by a flame ionisation. GLC peaks were identified using EPA and DHA authentic standards; retention times were expressed relative to the internal standard for identification purposes. Peak areas were used to determine EPA and DHA concentrations. Results were expressed as amount (mg) of EPA and DHA per capsule (ie, taking account of different fish oil weights per capsule for different products). Individual samples were analysed (ie, no replicates); however, each batch of analyses included at least one sample in duplicate to check within sample variability. All duplicate samples analysed fell within ASUREQualities repeatability criteria.

### Analysis of mercury in fish oil supplement samples

Mercury was determined by inductively coupled plasma mass spectrometry (ICP-MS) by Hill Laboratories Ltd (GLP accredited, IANZ approved). The American Public Health Association (APHA) Standard Method 3125B was used.<sup>36</sup> In brief: fish oil samples were acid digested (nitric acid + hydrochloric acid, 85°C, 1 h) and the acid extract analysed directly by ICP-MS.

## Results

### Top 10 over-the-counter fish oil supplements sold in New Zealand

The top 10 fish oil supplements sold in New Zealand were identified (brand names are not reported here for commercial reasons) and purchased.

## Analysis of omega-3 fatty acids in the top 10 fish oil supplement samples

The analytical laboratory (ASUREQuality) carried out in batch and between batch replicates of samples to determine analytical variability. Their results are as follows: repeatability  $\pm 5\%$ , reproducibility  $\pm 12\%$ , and uncertainty of measurement  $\pm 7.2\%$ . The limit of detection of the analytical method is 6mg/100g, and the limit of quantification is 10mg/100g.

Table 1 shows the label amounts of EPA and DHA and the actual amounts based on our analyses. The percentage differences between actual amount and label amount of EPA and DHA range from 2.8% above the label amount to 11.1% below the label amount for EPA, and no difference to 12.5%

below the label amount for DHA. All fish oil supplements analysed contained greater amounts of EPA than DHA. Using 10% as an accepted range of error (this also accounts for the analytical method's uncertainty of measurement of 7.2%, and is consistent with TGA regulations on standards for capsules and tablets that state they must be above 90% of the stated content);<sup>37</sup> using this definition, 90% of the products were true to label in terms of capsule EPA and DHA content.

## Recommended daily doses of the 10 supplements for conferring a health benefit

To determine whether doses contained within the supplements are comparable to those doses identified in the published literature as most likely to achieve a health benefit, we calculated the doses of EPA

**Table 1:** Doses (label and actual) of 10 supplements (brands) sold in New Zealand and daily doses for health benefit based on label recommendations.

Brand	EPA Label mg/cpsl	EPA Actual mg/cpsl	EPA Label-Actual Diff <sup>1</sup> %	DHA Label mg/cpsl	DHA Actual mg/cpsl	DHA Label-Actual Diff <sup>1</sup> %	Label recommended daily dose for health effects			Total recommended dose range <sup>2</sup> mg			
							Heart	Joint	Brain	Heart EPA+DHA	Joint EPA+DHA	Brain (mood) EPA only	Brain (ADHD) EPA only
1	180	181	+0.6	120	114	-5.0	1-3	1-3	1-3	300-900 <sup>3</sup>	300-900	180-540	180-540
2	180	184	+2.2	120	119	-0.8	3-6	6	3-6	900-1,800	1,800	540-1,080	540-1,080
3	270	273	+1.1	180	171	-5.0	2-4	4	2-4	900-1,800	1,800	540-810	540-810
4	270	266	-1.7	180	174	-3.3	1-3	1-3	1-3	450-1,350	450-1,350	270-810	270-810
5	180	177	-1.7	120	118	-1.7	1-3	1-3	1-3	300-900	300-900	180-540	180-540
6	360	352	-2.2	240	228	-5.0	3	5	3	1,800	3,000	1,080	1,080
7	275	281	+2.0	185	175	-5.3	1-3	1-3	1-3	460-1,380	460-1,380	275-825	275-825
8	360	320	-11.1	240	210	-12.5	1-3	1-3	1-3	600-1,800	600-1,800	360-1,080	360-1,080
9	270	278	+2.8	180	171	-5.0	2-4	6	2-6	900-1,800	2,700	540-1,620	540-1,620
10	360	360	0.0	240	240	0.0	3	5	3	1,800	3,000	1,080	1,080
Number of products likely to be effective for health benefit based on published recommended doses.										2/10 (lower) to 8/10 (upper)	3/10	2/10 (lower) to 5/10 (upper)	5/10 (lower) to 10/10 (upper)

**BOLD:** Doses likely to be effective based on comparison with published recommendations on dose across heart ( $\geq 1\text{g EPA+DHA}^{7,27}$ ), joint ( $\geq 2.7\text{g EPA+DHA}^{8,28}$ ) and brain ( $\geq 1\text{g EPA for mood}^{30}$  and  $\geq 500\text{mg EPA for ADHD}^{16}$ ). Actual amounts have been rounded to the nearest whole number.

Grey boxes identify those two products that recommend a daily dose within the same ranges as those identified as effective in the published literature across heart, joint and brain.

<sup>1</sup>(Label-Actual)/Label x 100%

<sup>2</sup>Label dose x number of capsules recommended. Range based on number of capsules recommended on product labels.

<sup>3</sup>Example: (180mg+120mg)x3=900mg

Abbreviations: cpsl = capsule, diff = difference

and DHA based on the number of capsules recommended. The daily dose was determined by using both the lowest and the highest recommended daily dose given on the specific labels (eg, if the label stated take 2–4 capsules for brain health, we used two capsules and four capsules as the daily lowest and highest number of capsules for ‘brain’ respectively) and was calculated based on *label* content of omega-3 fatty acids per capsule. EPA dose alone was also calculated as EPA dose alone is relevant for supporting symptoms associated with mood and ADHD.

The health benefits stipulated across the 10 supplements were similar, with all of them reporting promotion of heart health, joint health and brain function on the labels and/or manufacturer websites. Stated benefits varied from “assists in the maintenance of healthy brain function” to “helps during times of stress and emotional upset” to “keeping your heart healthy” to “easing many kinds of inflammation, including joint swelling and stiffness”. As of 24 November 2019, none of the labels or company websites referred to specific research that supported the stated health benefit; however, this is not a regulatory requirement for dietary supplements.

All products taken at the *highest* recommended daily dose contained more than 500mg of EPA and as such could support symptoms associated with ADHD,<sup>16</sup> 50% of them taken at this highest dose would contain the minimal dose ( $\geq 1$ g EPA)<sup>30</sup> identified for supporting mood, 80% of the products had doses comparable to the recommended dose for heart health ( $\geq 1$ g EPA+DHA),<sup>7,27</sup> and 30% contained the optimal dose for assisting with joint health ( $\geq 2.7$ g EPA+DHA).<sup>8,28</sup> Based on the *lowest* recommended daily doses, 50% were in the range necessary to confer a benefit for symptoms associated with ADHD, 20% were in the dose range for heart health and mood, and 30% were in the dose range for joints. At the highest recommended dose, three (Brands 6, 9 and 10) of the products (30%) would confer a health benefit across all three areas of function. Only two products (Brands 6 and 10—Table 1) recommended doses that matched research doses identified as necessary in order to confer a health benefit both at the minimum and maximum number of capsules (Table 1).

## Amounts of mercury in fish oil supplements

Measurement of mercury showed no mercury above the limit of detection (LoD); 0.010 mg/kg; ie, not detected. Therefore, the mercury levels were below WHO provisional tolerable weekly intakes.<sup>38</sup>

## Discussion

### Label vs *actual* content of omega-3 fatty acids in fish oil supplements

The *actual* amounts of EPA and DHA per capsule in all but one of the over-the-counter fish oil supplements analysed were within 10% (which takes account of the analytical uncertainty of measurement of  $\pm 7.2\%$ ) of the amount stated on the product labels. A single product had EPA/DHA doses greater than 10% below the stated dose on the label. Only one sample was analysed per product; therefore, it is not possible to determine within brand variance.

These results are not consistent with the results of Albert et al,<sup>23</sup> in that 90% of the products were true to label versus 10% of those tested by Albert et al.<sup>23</sup> This also means that there was likely very much less oxidation in our samples (although we did not measure it). It is possible that in the intervening year since the Albert et al<sup>23</sup> study was published, the industry addressed the labelling issues. It is also possible that the popular brands that we studied were not on the shelf for as long as other less popular brands that might have been included in the Albert et al study,<sup>23</sup> allowing for less time for oxidation to occur. Indeed, two more recent studies<sup>39,40</sup> showed that Australian and New Zealand fish oil products *did* meet the stated doses on their labels for EPA and DHA content, and were not oxidised, although the methodology used has been challenged.<sup>41</sup>

It is possible that omega-3 fatty acids might be lower than those stipulated on the labels because unsaturated fatty acids are vulnerable to oxidation due to the double bonds in the fatty acyl chain<sup>23</sup> which can undergo an ultra violet light catalysed oxidative free radical reaction. Indeed Albert et al<sup>23</sup> explained the discrepancy between label and actual omega-3 fatty acid levels in their study by the presence of oxidation products. In addition, the legislation requires data from a pooled sample of

20 capsules, whereas we analysed three individual capsules from the same purchased container. Bearing this in mind, in our study we found only one product (Brand 8; Table 1) with marginally lower EPA and DHA than stated on the label and therefore we do not think it necessary to consider the toxicological implication of unsaturated fatty acid oxidation products in the context of the top 10 fish oil supplements sold in New Zealand.

### Health benefits

We investigated whether the recommended doses on labels of these 10 over-the-counter supplements are in line with the amounts shown to provide optimal health benefits based on research. Based on the *highest* recommended daily doses, the doses of all 10 products are within the ranges used in clinical studies that have been effective in treatment of symptoms associated with ADHD ( $\geq 0.5$ g EPA<sup>16</sup>) but only half contained doses recommended for supporting mood ( $\geq 1$ g EPA<sup>30</sup>). Eighty percent of products sampled used doses recommended for support of cardiovascular health (1g EPA+DHA/day<sup>7,27</sup>) whereas 30% contained the dose identified to be of benefit for joint health ( $\geq 2.7$ –3g EPA+DHA<sup>8,28</sup>). However, for the *lowest* recommended daily dose, 50% would be adequate for ADHD, 20% for cardiovascular health and mood, and 30% for joints. Therefore, in order for the consumer to increase the opportunity for a health benefit to occur, it would be best to consume at least the highest number of capsules recommended, albeit in some cases, this would mean taking up to six fish oil capsules per day.

In interpreting these health benefits, it is important to note based on the published literature we reviewed and cited that there is large variability in doses and measures used in clinical research across the conditions investigated. It is important to recognise that the conditions studied (heart, joint, brain) cover myriad health problems and therefore it is difficult to identify optimal effective doses for specific disorders. Indeed, it is equally difficult to define the broad disorders covered; for example ‘joint’ could refer to osteo- or rheumatoid arthritis or other non-arthritis disorders, ‘heart’ could mean prevention of cardiovascular infarction, lowering high

blood pressure, modifying cholesterol levels, and ‘brain’ could mean improved cognitive function or mood or reduce anxiety.

Therefore, this aspect of our discussion is indicative and not definitive. Further, the samples range from children to adults and a dose that may confer a health benefit for an adult may not necessarily apply for children and vice versa.

Even the results on a specific dose are mixed with some studies showing benefit and others not. For example, a 2017 meta-analysis<sup>42</sup> did not find a significant benefit of a dose  $\geq 2.6$ g/day for assisting with the reduction of arthritic symptoms, but the authors admit significant discrepancies between the individual studies used in their analysis. Further, their analysis showed that EFAs are effective in pain reduction in rheumatoid arthritis, but not in osteoarthritis.<sup>42</sup> A much higher dose may be required to be effective in the management of hypertension,<sup>43</sup> highlighting the difficulty in determining effects and effective doses. There is also disagreement on overall health benefits across meta-analyses; for example, a 2018 meta-analysis identified that omega-3 capsules do not reduce heart disease, stroke or death,<sup>44</sup> while a 2019 meta-analysis identified that marine omega-3 supplementation *does* lower risk of myocardial infarction and other cardiovascular outcomes.<sup>45</sup> What is clear is that the EFA/health benefits interface is a minefield of conjecture.

The effective dose of  $\geq 0.5$ g EPA for ADHD symptoms does not reflect the fact that many of the studies have included DHA in their formulae which may also be important.<sup>16</sup> Further, the positive effect of EFAs for ADHD has only been observed for parent ratings not ratings by teachers.<sup>29</sup> Lower doses than those identified in the literature as optimal *may* confer a benefit, although the opportunity for benefit diminishes the further the dose is away from that identified as optimal. However, one observation that is consistent across all three health areas we explored (brain, heart, joint) is that there appears to be a linear dose-response relationship between omega-3 supplementation and outcome. As such, the doses we identified through the literature appear reasonable targets to optimise the opportunity of a health effect to occur.

Importantly, the doses used in the research were at least of the same magnitude as those recommended in the daily doses of the over-the-counter supplements we studied. Previously, we found that B vitamin doses from over-the-counter products are significantly below the therapeutic doses used in clinical studies for the treatment of mental health conditions in children.<sup>46</sup> It is reassuring that this is not the case for EFAs.

This research highlights the challenges of labelling for supplement manufacturers in terms of health benefits and exposes that the law as it stands, encourages vague statements that are very difficult to substantiate and tie to any specific clinical literature. The most common and simplest way to determine whether a product has conferred a health benefit is to study people who have a disease and then track whether that disease improves following supplement consumption. A “health benefit” could relate to prevention of a disease developing, reduction of mild symptoms or improvement in those with no disease or symptoms. Definitive efficacy studies for prevention are very challenging to conduct and to verify proof of an effect. Investigations of healthy populations typically result in null effects due to participants having no room for improvement. As a result of this difficulty, the interpretation that a health benefit results from research on people with symptoms is reasonable. Further, the field is moving so quickly such that health benefits observed in early trials are not always replicated in later trials, making it a challenge

to keep up with the research underpinning the statements and leaving it open for dispute as to what constitutes a reasonable health benefit. Better regulation of “health claims” for dietary supplements and the research necessary to support these statements is clearly overdue.<sup>24</sup> A starting point could be for manufacturers to list on labels and websites the source of the evidence to support any stated health benefit.

### Risks

Our studies showed that mercury levels in fish oil supplements analysed were <0.010mg/kg (ie, LoD). Thus, there is no or negligible risk of mercury toxicity from over-the-counter fish oil supplements.

## Conclusion

This study suggests that the majority of the 10 most popular fish oil supplements sold in New Zealand are true to label based on dose but mixed in terms of potential health benefits they might confer. Overall, if *maximum* recommended daily doses of supplements are taken (as recommended on the label), most products may confer health benefits for brain and heart health, but probably not joint health. In this respect, only two products were true to label *and* would likely confer a health benefit across heart, joint and brain across *both* minimum and maximum daily dose. However, mercury was not found in any of the samples analysed which suggests that the risk of mercury toxicity is negligible and therefore, while they may not all confer a health benefit, they are safe to consume.

**Competing interests:**

Nil.

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