MORLIFE SUBMISSION IN RESPONSE TO PROPOSED CLARIFICATION THAT CERTAIN SPORTS SUPPLEMENTS ARE THERAPEUTIC GOODS

Executive Summary

A. We **strongly oppose** the implementation of the *Therapeutic Goods (Declared Goods) Order 2020* (**Draft Order**) in its current form.

B. The Draft Order would restrict the sale of foods that are making compliant health claims and foods that contain permitted food ingredients.

C. Any increase in regulatory certainty arising from the Draft Order would come at the expense of higher burdens placed upon industry and lower product accessibility for consumers.

D. The Draft Order would capture the vast majority of sports supplements on the market, even if they do not present a safety risk and are fully compliant with food regulations.

E. The Draft Order should **not** capture products that make permitted health claims, as such products do not present a risk to public safety.

F. The Draft Order would have a damaging effect on our business, which would be reflected throughout the sports supplement industry and the Australian economy in general.

G. The Draft Order would go against the interests of consumers who use functional foods to support their nutrition improvement wellness model by forcing these products into a therapeutic framework.

Our detailed submission is as follows:

1. Please indicate your level of support for the TGA's proposal to declare that certain sports supplements are therapeutic goods.

1.1 We do not support the Draft Order in its current form. While we do support aspects of the Draft Order, we believe that its overall effect would create unwarranted disruption within the industry, as it would capture many products that are appropriately classified and regulated as foods.

1.2 In particular, we believe that the Draft Order would require the relabelling and/or reclassification of functional food products that do not present any safety risk and are fully compliant with food regulations.

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1.3 This is in large part attributable to its treatment of claims that are listed in Schedule 4 of the *Australia New Zealand Food Standards Code* (**Food Standards Code**) as therapeutic claims.

Aspects of the Draft Order that we support

1.4 We only support those aspects of the Draft Order that would cause the following products to be regulated as therapeutic goods:

- A product containing a substance that is listed on the Poisons Standard;
- A product containing a substance that is listed on the WADA Prohibited List;
- A product containing β-methylphenylethylamine, dendrobium, methylliberine or N-phenethyl dimethylamine; and
- A product containing a substance that is equivalent to any of the substances identified above.

It is worth noting that a food product would likely be prohibited under current food regulation from containing any of the substances referred to above, and could therefore be subject to enforcement action irrespective of whether it is classified as a food or a therapeutic good.

Aspects of the Draft Order that we do not support

1.5 We strongly oppose the view that the claims listed in the Draft Order ought to trigger classification of products as therapeutic goods. We provide further detail on this issue below.

1.6 We believe that many of the examples provided in the Draft Order are more appropriately regulated as health claims and as such are expressly permitted under the Food Standards Code on behalf of food products. These claims do not present a safety risk and their classification as therapeutic claims would cause considerable confusion and disruption throughout the food industry.

1.7 If such claims were regulated as therapeutic claims, this would severely inhibit the ability for functional foods to communicate to consumers the functions that they are performing. This would cause food manufacturers to be deliberately obtuse in their marketing and would significantly restrict the flow of information to consumers, negatively impacting consumer choice and access to functional products.

1.8 Approved health claims for foods assist consumers in their quest for health and wellness, an objective which should not be undermined. Indeed, classifying a food product as a therapeutic good would deter consumers from using such products to improve wellness, as consumers would be more likely to regard them as “medicines” that are used to treat illness.

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1.9 In addition, we disagree with the automatic classification of products containing substances that are permitted in Schedule 29 of the Food Standards Code in higher amounts than is permitted under Schedule 29. Whilst we do not oppose the maximum limits within Schedule 29 and believe that all food products should observe these limits, we believe that a food product that exceeds these limits is more appropriately regulated as a non-compliant food, rather than as a therapeutic good. This particular concern can be addressed through existing regulation and enforcement. The Draft Order would only add regulatory burden and confusion rather than serve the purpose of observing the Schedule 29 limits.

2. What impact would the proposed declaration have on the availability and choice of sports supplements for consumers?

2.1 The Draft Order would significantly reduce the availability of and consumer access to "sports supplement" products. [redacted] estimates that up to 60-80 percent of existing sports supplement products would be impacted by the Draft Order.

2.2 To the extent that it restricts the sale of products containing substances on the Poisons Standard or WADA Prohibited List, we support the Draft Order. However, we believe that the Draft Order would have a disproportionate effect and would also apply to many compliant foods that present no safety risk.

2.3 Such products would face the burdensome choice of either:

- Relabelling and/or reformulating, which would restrict the flow of information between businesses and consumers and potentially cause major consumer confusion; or
- Seeking registration as a therapeutic good, which may or may not be commercially feasible depending on other product offerings and whether the product is already manufactured in a TGA-approved facility.

2.4 Either option would involve significant cost and would likely cause many sports food providers to either reduce their product offerings or go out of business altogether. This would significantly limit the availability and choice of sports supplements for consumers and would have a negative effect on the Australian economy in general.

The Draft Order would restrict products making compliant health claims

2.5 Standard 1.2.7 of the Food Standards Code sets out a precise regulatory framework that specifies when a food is eligible to make a health claim as well as the content of any health claim. Schedule 4 of the Food Standards Code lists many pre-approved health claims that are permitted to be made on behalf of food products provided that any conditions for use are met.

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2.6 Many of the pre-approved health claims listed in the Food Standards Code are equivalent to the claims that are listed in the Draft Order as examples of therapeutic claims. In particular, claims about "gaining muscle", "increasing mental focus", "increasing metabolism", "increasing stamina" and "losing weight or fat" directly correlate with health claims listed in Schedule 4. Claims about preparing for workout and recovering from workout also meet the Food Standards Code definition of a health claim and may be made on behalf of food subject to a self-substantiation process.

2.7 The Draft Order would regard many foods making health claims (that are pre-approved under the Food Standards Code) as therapeutic goods solely on the basis of these claims. The fact that the Draft Order does not limit the definition of a therapeutic claim to the examples given means that it could in fact capture other claims that would be regulated as health claims under the Food Standards Code.

2.8 Many functional foods make claims that would be regarded as therapeutic claims under the Draft Order. Such claims are intended to communicate the functional nature of the product to consumers and are common for these types of products throughout Australia and the rest of the world. Consumers would not understand such claims as implying that the product is intended for therapeutic use. These products do not present a safety risk, yet the Draft Order would restrict consumer access to them.

2.9 Classifying such products as therapeutic goods could turn consumers away from sports supplements and other functional foods as they would be seen as medicine. Consumers would not seek these products out as they would not perceive themselves as being sick. Such classification would hamper consumers' quest for greater wellness.

The Draft Order would restrict products containing substances that are permitted in foods

2.10 Sections S29-18 and S29-19 of Schedule 29 of the Food Standards Code set out substances that may be used as nutritive substances in formulated supplementary sports foods. Each of the substances listed in Schedule 29 has been specifically assessed as being safe for use in food.

2.11 If a food contains substances that are permitted by Schedule 29 in amounts that exceed the relevant maximum permitted level specified in Schedule 29, that food would be in breach of the Food Standards Code. However, the Draft Order would classify foods that as therapeutic goods.

2.12 Whilst we agree that a product that contains a nutritive substance in higher than permitted levels should be regarded as non-compliant, we do not believe that such a product should be classified as a therapeutic good simply for containing a substance that has been specifically considered as appropriate for use in food.

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2.13 Classifying a product as a therapeutic good when all of its ingredients are expressly permitted in food would impose a significant restriction on the use of food ingredients in food products. As discussed in more detail below, such a product would not necessarily present a safety risk, and therefore this restriction would not be based on product safety grounds.

3. Would the proposed declaration provide greater clarity for industry as to whether their goods should be marketed as foods or medicines?

3.1 We believe that the Draft Order represents a significant regulatory overreach and would disproportionately classify many compliant food products as therapeutic goods. As such, any purported clarity would not come about; indeed, the opposite is more likely to result. Any changes brought about by the Draft Order would also come at the expense of higher burdens placed upon industry and lower product accessibility for consumers.

3.2 We believe that the Draft Order is likely to create significant **confusion** when it comes to its treatment of product claims. The broad definition of a health claim in the Food Standards Code and therapeutic use in the *Therapeutic Goods Act* means that there is the potential for these definitions to overlap, causing some degree of uncertainty.

3.3 As identified above, virtually all of the claims listed as examples in the Draft Order meet the definition of a health claim under the Food Standards Code. Many of these claims are in fact equivalent to health claims that are pre-approved for use on behalf of food in Schedule 4 of the Food Standards Code.

3.4 The fact that these claims are listed as examples of therapeutic claims in the Draft Order only serves to further blur the line between a health claim and a representation of therapeutic use. Indeed, the Draft Order indicates that a claim that is expressly permitted to be used on behalf of food may be a therapeutic claim that prevents a product from being a food. This is likely to cause chaos among the food industry, who would no longer be able to rely on the fact that a health claim is pre-approved in the Food Standards Code as guaranteeing that they are able to make that claim.

3.5 The restrictions on substances that may be present in a product and the format that a product may take found in Column 2 of the table at Part 2 of the Draft Order are clear. However, as outlined above, the application of the Draft Order to substances in Schedule 29 of the Food Standards Code would serve only to clarify that products that are most appropriately regulated as foods should be classified as therapeutic goods.

3.6 The fact that the Draft Order would impact the sale of many food products currently on the market, yet would exist entirely separately to the Food Standards Code and would not be directly referenced in anywhere in the food legislative framework, would create further confusion.

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4. Are you aware of goods on the market that would not be captured by the proposed order but should be?

4.1 As it stands, the Draft Order would capture the vast majority of sports supplements on the market, even if they do not present a safety risk and are only marketed and formulated in compliance with food regulations. We believe that the Draft Order could be seen to capture other food products, and accordingly must be limited dramatically so as to not capture any more products on the market. As discussed elsewhere in this submission, we in fact believe that the Draft Order should be modified so as to reduce its scope.

4.2 It is worth noting that the Draft Order would not apply to imported products that have been purchased for personal use. We believe that the restriction of products on the Australian market under the Draft Order would cause consumers to turn in droves to buy products non-compliant and potentially unsafe products online from overseas. This Draft Order would therefore significantly damage the Australian sports supplement industry.

5. Are you aware of goods on the market that would be captured by the proposed declaration but should not be?

5.1 In its current form, the Draft Order would capture products that make health claims that are permitted under the Food Standards Code and products that contain substances permitted by Schedule 29 but exceed the maximum permitted levels. We believe that such products are adequately regulated under Australia's food laws and should not be captured by the Draft Order. Regulating these products as therapeutic goods would not address any safety risk, nor would it enhance public safety.

The Draft Order should not capture products that make permitted health claims

5.2 As discussed above, the vast majority of the examples of therapeutic claims given in the Draft Order are in fact equivalent to health claims that are expressly permitted by the Food Standards Code. The regulation of health claims under the Food Standards Code is extensive and any claim made on behalf of food that falls outside of these regulations amounts to a clear breach of the Food Standards Code.

5.3 Claims about muscle mass, stamina, workout and similar matters are commonly made on behalf of food products. They are used by functional foods to communicate the nature of the product to consumers. Neither the food industry nor end consumers understand these claims as implying that a product has some therapeutic benefit. In particular, cartoon imagery of a bicep is in line with imagery on many food products and is very unlikely to be taken by a consumer to mean that the product is a medicine.

5.4 It is difficult to see how a consumer could perceive such claims in a way that would cause them to misuse the product in such a way that would create a safety risk. By regulating such claims as representations of therapeutic use, the Draft Order

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therefore does not address any safety risk. Indeed, it would limit the ability of food products to explain their functional nature to consumers, which could in itself create a safety risk.

5.5 Instead, the Draft Order would reclassify products for making claims that are currently adequately regulated by the Food Standards Code. This would in fact reduce regulatory certainty as it would create the paradoxical effect that the same claim could be expressly permitted by the Food Standards Code, yet also amount to a representation of therapeutic use.

The Draft Order should not capture products that contain permitted food substances

5.6 The Draft Order would capture food products that contain an isolated substance that is permitted by Sections 29-18 and 29-19 of Schedule 29 at a level that is higher than the maximum limit permitted by those sections.

5.7 As indicated above, the substances listed in Schedule 29 of the Food Standards Code have been specifically assessed as safe to use in food. Any food that contains an isolated substance in excess of the maximum limit is clearly in breach of the Food Standards Code and is a non-compliant food.

5.8 The Food Standards Code permits food products to contain any food as an ingredient. Many functional foods contain botanical, fungal or other wholefood ingredients that are expressly permitted for use in food and have been used safely in food for a long time. These ingredients may naturally contain the substances listed in Schedule 29 at many times the relevant maximum permitted level; however, as these substances are naturally occurring and have not been isolated and added to the product, the Schedule 29 limits do not apply. These products do not present a safety risk.

5.9 We therefore believe that the regulation of products that contain a Schedule 29 substance in higher levels than the maximum permitted amount under the Draft Order would not address a specific safety concern. Such products are currently adequately regulated under Australia's food framework. This regulation would also not recognise that functional foods may be naturally rich in the substances listed in Schedule 29 without any fortification.

6. What impact would the proposed declaration, if made, have on your business?

6.1 If the Draft Order were to pass into law in its current form, it would drastically impact the way that our business operates. We would have to reconsider our current product offering which may include:

- Obtaining TGA registration;
- Reformulating and/or relabelling food products; or
- A combination of both.

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6.2 We are also considering whether we would have to move part of our operations overseas to be able to provide a product offering that meets consumers' demands. Any of these options would cause significant disruption and would involve substantial cost.

6.3 In addition to the impacts on our business, [redacted] estimates that the sports supplements sector is currently worth approximately $1.1 billion in direct product sales. The Draft Order would throw this sector into chaos and would likely cause a large number of firms to exit the market. This would have a negative impact on competition, consumer choice and the Australian economy generally.

6.4 The costs that would result from implementation of the Draft Order would include but not be limited to: discarding existing product packaging; registering our premises with the TGA; and registering individual products with the TGA. These costs are not necessary to enhance consumer safety. The total costs would virtually kill our existing business, especially in the current economic climate.

7. Please provide any other comments related to the consultation.

7.1 In addition to the comments above, it is worth noting that the implementation of the Draft Order in its current form would represent a severe increase in regulatory "red tape" for the food industry.

7.2 Food manufacturers would face a much higher regulatory burden as they would have to consult an entirely new legislative instrument that exists completely separately to the Food Standards Code and is enforced by a different regulator in the TGA. As detailed above, the Draft Order has the potential to capture many products that do not present a risk to public health and safety.

7.3 These products would face significant additional regulatory oversight and barriers to entering the market. Similar regulatory systems are not in place in other parts of the world, and in this sense this over-regulation would serve to make Australian products less competitive.

7.4 The Draft Order would also go against consumer interest by effectively taking away the products they routinely use and are familiar with. Prices for these products would increase to reflect re-categorisation, and consumers seeking to maintain a diet-based wellness approach would be confused and dissatisfied with the image of these products being framed as medicines.

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