To: Food Standards ANZ
Via email: submissions@foodstandards.gov.au

Submission for Proposal P1056 – Caffeine Review

Company: ATP Science Pty Ltd

Contact Details:

[redacted]

Submission authorised by [redacted]

1. **Do you consider there are risks to consumers from caffeine in the current market environment, under the current regulations? Please provide any evidence or relevant examples in detail to assist FSANZ in its assessment?**

   No, ATP Science does not believe there are risks to consumers from caffeine in the current environment. Caffeine is generally thought to be safe in moderate amounts (i.e., ≤ 400 mg per day) in healthy adults[1]and thus products recommending up to 400mg of caffeine daily for adults should not pose a problem for most people. Caffeine has a half-life of around 3-7 hours[2i] thus caffeine can be consumed throughout the day without toxicity.

   People who are caffeine sensitive have clear access to labels to indicate the amount of caffeine in relevant products. Individuals who have suffered with caffeine toxicity have taken very large dosages (i.e., teaspoons, or multiple grams equating to up to 50 cups of coffee), which is not reflective of the caffeine dosages currently seen in FSSF products.

   It is widely known that people regularly consume multiple FCBs in a day, exceeding 200mg per day, and often back-to-back. In some cases, users are adding caffeinated pre-workouts to ready-to-drink FCBs without ill effect.

2. **Do you have any thoughts on FSANZ's preferred option that if caffeine is prohibited to be added to all foods apart from cola-type drinks, FCBs and FSSF, that a premarket assessment is then required to add caffeine to any other food? If not, are there other approaches that would better address the problem?**

   No, ATP Science does not believe a pre-market assessment is required to add caffeine to any other food. As caffeine is considered safe in most adults up to 400mg per day, then including a statement of caffeine level on the label should be sufficient. Individuals can make their own informed decisions on the usage of these caffeine-containing products.

3. **Do you foresee any compliance or enforcement issues with the preferred approach of expressly permitting total caffeine in FSSF at a maximum one-day quantity of 200 mg, whilst expressly prohibiting the addition of caffeine to all foods apart from cola-type drinks and FCBs?**

   At the submission level, a 'preferred approach' should not exist as this review must be approached with an open mind and should be determined by evidence and science.

   The United States Food and Drug Administration (FDA), Health Canada and the European Food Safety Authority (EFSA) have all determined that a total daily intake of 400 mg of caffeine is unlikely pose a risk of serious harm to the general population of adults unless pregnant. If a woman is pregnant, the maximum caffeine consumed should be 200 mg/day. These levels align with the previously quoted level in the medical literature of 400mg per day.

   500mg of caffeine is currently commonly found in Australian manufactured and sold pre-workout drinks if they are double scooped. If this dose is problematic, evidence should already exist of this because these levels are widely consumed by people who attend gyms and use these products to enhance performance. In short, if the level was truly a problem there would already have been a host of adverse effect reports on pre-workouts.

   A reduction in caffeine per serve will simply see gym goers taking more scoops to reach their desired caffeine levels, and as such will then be ingesting more of the other active ingredients in the product which may be more adverse than the caffeine dose. As already mentioned, the rate of deaths from caffeine toxicity has been linked to megadoses of caffeine nearing the equivalent of 50 cups of coffee.

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[1] Willson C. The clinical toxicology of caffeine: A review and case study. Toxicol Rep. 2018 Nov 3;5:1140-1152. doi: 10.1016/j.toxrep.2018.11.002. PMID: 30505695; PMCID: PMC6247400.

[2] Temple JL, Bernard C, Lipshultz SE, Czachor JD, Westphal JA, Mestre MA. The Safety of Ingested Caffeine: A Comprehensive Review. Front Psychiatry. 2017 May 26;8:80. doi: 10.3389/fpsyt.2017.00080. PMID: 28603504; PMCID: PMC5445139.

4. Are there other supporting measures that FSANZ should consider, whether regulatory or non-regulatory?

FSANZ should consider the caffeine at a daily allowance of 400mg/day in FSSF products. If the level is reduced to 200mg/day, consumers will seek higher levels of caffeine and directly import American pre-workouts off E-bay, i-herb, or sites like www.bodybuilding.com.

This not only harms Australian businesses, but exposes more Australians to pre-workout products with undisclosed amount of caffeine and other stimulants. If an individual wants a higher caffeine product, they are easily accessible on-line. This poses higher risk to the consumer as there is no ability to police every individual purchase or product, and imported products may include other banned substances. For example, in the USA the average dose is 500mg of caffeine in pre-workouts, and Starbucks Reserve Nitro Cold Brew coffee has 400mg of coffee per serve.

Alternatively, as previously mentioned, they will simply take more scoops of the product and thereby ingest increased amounts of the other actives. Decreasing the daily amount will make no material difference to consumer usage, and possibly cause other unexpected, and undesirable, results.

5. Can you share any further knowledge of current research about?
a. the health effects of caffeine,
b. global developments in caffeinated food products, or
c. regulatory approaches being taken in comparable markets?

Caffeine is the most widely consumed psychostimulant in the world. It is estimated, that caffeine is being consumed by more than 80% of the world's and up to 89% of the United States population. It has been consumed for thousands of years and as the European and American regulators state, doses of 400mg are unlikely to be harmful. It seems counter intuitive for Australian regulators to defy the medical literature and other health authorities and restrict caffeine to levels that are unlikely to have the desired effect, which begins significantly at 250mg. This will drive consumers off-shore, which has less regulation that Australian markets because if the 'preferred' maximum level of 200mg is adopted, it will not deliver the effects consumers are seeking.

It makes much more sense to restrict daily levels to 400mg/serve once daily and clearly label the levels to inform consumers. This level simply matches what one serve of caffeinated pre-workout drinks are currently consumed and absent of significant reported toxicities; this level should be adopted.

Relevant literature that supports the safety of caffeine at 400mg/serve in workouts includes:

(a) https://nutricartel.com/products/crack-reloaded-pre-workout?variant=43072149356786&aff=4
(b) https://ascsupplements.com/pages/jefe-ltd-v2-liftvault?aff=5
(c) Heckman M.A., Weil J., Gonzalez de Mejia E. Caffeine (1, 3, 7-trimethylxanthine) in foods: a comprehensive review on consumption, functionality, safety, and regulatory matters. J. Food Sci. 2010;75:R77–R87.
(d) Verster J.C., Koenig J. Caffeine intake and its sources: a review of national representative studies. Crit. Rev. Food Sci. Nutr. 2018;58:1250–1259.
(e) Heckman M.A., Weil J., Gonzalez de Mejia E. Caffeine (1, 3, 7-trimethylxanthine) in foods: a comprehensive review on consumption, functionality, safety, and regulatory matters. J. Food Sci. 2010;75:R77–R87.
(f) Smith A. Effects of caffeine on human behavior. Food Chem. Toxicol. 2002;40:1243–1255.
(g) Wilson C. The clinical toxicology of caffeine: A review and case study. Toxicol Rep. 2018 Nov 3;5:1140-1152. doi: 10.1016/j.toxrep.2018.11.002. PMID: 30505695; PMCID: PMC6247400.
(h) Temple JL, Bernard C, Lipshultz SE, Czachor JD, Westphal JA, Mestre MA. The Safety of Ingested Caffeine: A Comprehensive Review. Front Psychiatry. 2017 May 26;8:80. doi: 10.3389/fpsyt.2017.00080. PMID: 28603504; PMCID: PMC5445139.

6. **In the medium term, does your company have any plans to expand the number of SKUs that contain caffeine? What would be the nature of those SKUs?**

   ATP Science had new product development in progress that would contain caffeine. These products would be formulated as pre-workouts to assist adults with their sporting endeavours. There is also potential to introduce nootropic style powdered beverages for the computer gaming enthusiast.

7. **Do the current regulations around caffeine, in particular, where cola-type drinks and FCBs are concerned, allow for your future product development needs? If not please explain why not and what regulation you think would be more suitable?**

   ATP Science does not believe the current regulations allow for future product development needs. We would recommend there be a separate sports nutrition caffeinated supplement category legislated by FSANZ. This would enable the development of high-quality pre-workouts both in powdered and ready-to-drink formats that would be safe for the targeted adult consumer.

8. **Beyond the mandated labelling imposed by the Code, is there any current or planned industry led mitigation measures to reduce consumers' exposure to caffeine?**

   There is no current plan for industry led mitigation to reduce exposure to caffeine. Caffeine is currently identified on FSSF labels, and the target adult audience is already well versed and educated in caffeine usage.

9. **Will your company be prepared to help develop non-regulatory measures to monitor and manage the number of food products that contain caffeine?**

   ATP Science would be prepared to help develop non-regulatory measures to manage food products containing caffeine. We strongly believe in industry lead, government aligned codes of conduct guidelines.

10. **For product developers considering the addition of plant or other extracts containing caffeine, do you consider these would meet the definition of a novel food and therefore require a pre-market safety assessment?**

    ATP Science does not believe caffeine containing plant extracts are a novel food. The plant materials used have years of safety data, have GRAS status and are widely used across the globe. There is also numerous scientific and medical studies on most plant products that are used by the FSSF industry that further demonstrates their safety in human consumption.

    So long at the total product caffeine is listed on the product label then individual consumers may make their own judgement. The consumers of FSSF products are a sophisticated market who understand the nature of ingredients, understand caffeine levels and have specific aims in mind when using these products.

11. **How many SKUs will be affected by the proposed changes, for either FSSF or other foods, or both?**

    ATP Science currently has 10 SKUs that would be impacted, and had designs on a further 10 SKUs. However, industry wide the effects would be very significant as caffeinated pre-workouts make up to 40% of the sports supplement market.

12. If your business has any SKUs affected then

a) **What is the nature of those products**
b) **What action will you take in response to the regulation (i.e., withdraw, reformulate, update labels)**

The nature of ATP Science's products are Formulated Supplementary Sports Foods, designed for adult athletes and sportspeople. Our action will depend on how reasonable the changes in the regulation are. We would need to assess the changes to determine our response. It should be noted that withdrawal from the market from Australian manufacturers would not be beneficial to Australian industry as it would simply provide more space for imported products. Imported products are likely to have a higher degree of consumer risk due to lower-quality products (i.e., from China) or products with banned substances (i.e., from USA or Europe).

13. What will be the cost of the above actions (be specifics as possible and separate cost by type i.e., reformulation, re-labelling, write off etc).

Withdrawal from the market would cost us approximately $500,000 in finished product and raw material write offs. There would be a minimum of $1 Million in lost revenue per annum (this is a conservative estimate).

Reformulation and subsequent re-labelling would cost approximately $75,000 to reformulate, $30,000 to relabel and over $100,000 in material write offs. There would also be a further spend of $500,000 on marketing, sampling and promotion goods and deals to re-establish the reformulated products in the market.

We believe these costs are significant strain on a medium-sized Australian business particularly in the current economic climate. It could almost be considered negligent of FSANZ to impose this on Australian businesses.

14. For any of your existing SKUs likely to be affected, how long do those SKUs take to be sold

We would expect a run-out period of at least 6-9 months. Even so, a residual balance of obsolete packaging, labelling and unique raw ingredients would need to be written off.

15. To what extent to you agree that there are relatively few general foods (i.e., not FSSF) that contain added caffeine that would be impacted, and currently sold in Au & NZ

ATP Science does not believe there are many general foods that contain added caffeine outside of FSSF and FCB. However, there are a huge number of caffeinated products delivered from overseas. Individuals can order easily products from America, Asia or Europe from the convenience of their phone and have the product delivered at a reasonable cost. This further harms Australian businesses who will be unable to compete due to unnecessary caffeine restriction in products. With easy access to alternative imported products, the general consumer will not be protected by this regulation.

16. Are there any unintended consequences of the proposal

Yes, the regulation is specifically and exclusively legislating against Australian products, whilst giving more opportunity to overseas imported products. It is our strong opinion that caffeinated pre-workouts and drinks should only sold to adults. They should be free to make their own decisions as long as the product contains less than 600mg of caffeine, which is the level that the TGA has considered to be a therapeutic dose level. Labels should be clearly labelled for consumer education.

The regulation would negatively affect Australian manufacturing and there would be potential job losses due to reduced revenue. Conversely it would benefit overseas companies with more imports in the market and increased unregulated, black market of 'back yard' produced products.

17. How effective do you believe each of the proposed options would be in achieving the objectives of the proposal and why? Consider risks of over-consumption of caffeine for sensitive sub-populations.

ATP Science does not believe the options will be effective at all. At ATP Science we feel strongly in industry and government collaboration. If the regulation is over-bearing or non-sensical, consumers will switch to overseas products or create their own products in non-regulated ways (i.e., taking a pre-workout with a NoDoz tablets). Individuals may also seek illegal drugs such as amphetamines to gain the highs and performance gains, that they were previously able to get with reasonable, and safe, doses of caffeine.

18. Do you have any other comments on the benefits or costs of the proposed options?

ATP Science believes the costs to industry would lead to loss of employment and drive consumers to higher caffeine overseas products. Consumers may also seek easily available black market, illegal or more dangerous products. If the labels are clearer, individuals can make their own informed choices. Education and visible warnings need to be the focus, indicated a maximum level of 600mg and suggesting a daily limit.

Fatal caffeine doses are typically 8 times these levels (Ref: Kerrigan S, Lindsey T. Fatal caffeine overdose: two case reports. Forensic Sci Int. 2005 Oct 4;153(1):67-9. doi: 10.1016/j.forsciint.2005.04.016. PMID: 15935584.), and as clearly outlined in Page 14 of your proposal document the life-threatening dose is 5-10g, with the lowest lethal dose recorded at 3g (possibly in a caffeine sensitive individual).

ATP Science believe Option One (Status Quo) is the preferred option for Australian businesses and consumers, as there is no overwhelming risk within the current market for educated adult users.

Option Two is acceptable for manufacturers and consumers as it will drive an overall uptake in caffeine usage. Option 3 is unacceptable for manufacturers and consumers. It would come a high direct and indirect cost to Australian businesses and their employees as need to make costly overhaul of products and see reduced revenue. Option 3 is also pointless; it will pose an impost on manufacturers whilst consumers will simply purchase imports to avoid the regulation – thereby negating the effect of FSANZ's proposed reform.