September 24, 2020

F-Factor
65 East 55th Street, Floor 27
New York, NY 10022

Re: Toxicological and Risk Assessment of F-Factor Fiber/Protein Powders and Bars

This letter summarizes the work conducted by CTEH®, LLC (CTEH) in response to a request by F-Factor to conduct a toxicological and risk assessment of F-Factor Fiber/Protein Powders and Bars.

Please feel free to contact us by phone at (501)-801-8500 or via e-mail at ddrechsel@cteh.com or mlumpkin@cteh.com if you have any questions.

Thank you,

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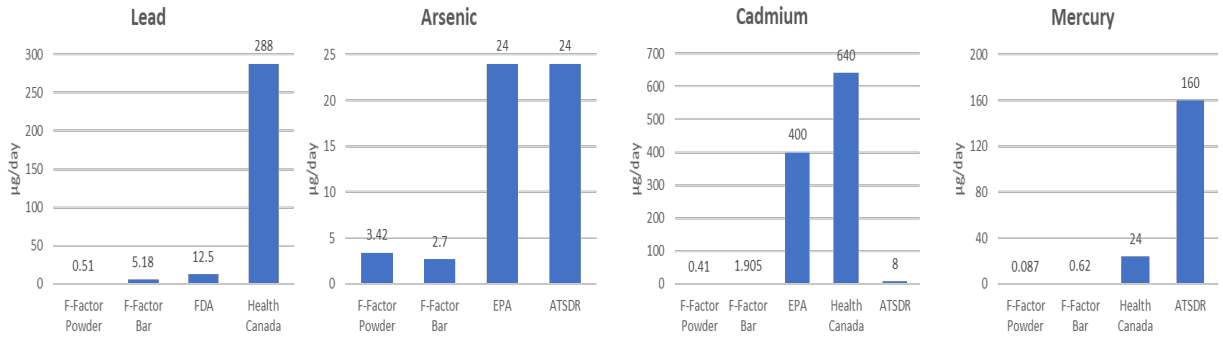
Executive Summary

At the request of F-Factor, CTEH, LLC (CTEH) conducted an independent evaluation of F-Factor Fiber/Protein Powder and Bar products. The evaluation was conducted in two phases: 1) hazard evaluation of ingredients in F-Factor Fiber/Protein Powders and Bars, and 2) risk analysis for any ingredients identified as a potential safety concern to consumers. The evaluation focused on toxicological effects, or adverse disruptions (permanent or transient) of normal physiological function associated with exposure to a substance or chemical. Such effects are distinct from intolerances often observed with foods, which are characterized by a natural physiological response to a substance that leads to an acute adverse effect that resolves without pathological damage.

The majority of ingredients present in F-Factor Fiber/Protein Powders and Bars were identified as low potential safety concern to consumers. This is based on a history or recognition of safe use in foods and dietary supplements. Ingredients containing dietary soluble fiber and lactose were identified that may cause potential intolerance issues in certain people (e.g. individuals who do not typically consume enough daily fiber or have lactose intolerance). However, these ingredients do not present a toxicological concern at levels present in F-Factor Fiber/Protein Powders and Bars. An increase in fiber intake from eating F-Factor Fiber/Protein Powders and Bars was identified as a potential cause of unpleasant gas or bloating in some people contributing to temporary gastrointestinal distress. Such effects are commonly seen in a diet containing high levels of soluble fiber or when dietary fiber consumption is suddenly increased. These temporary effects are expected to resolve as a person's gut becomes accustomed to the increased level of fiber intake.

Three ingredients were identified as possible concerns due to the potential presence of heavy metals that occur naturally in rice- and cocoa-derived ingredients. Regulatory agencies including the US FDA, US EPA and Health Canada have established tolerable intake levels for heavy metals which represent a level below which it is unlikely that adverse health effects will occur. The risk analysis demonstrated that metal intake resulting from consumption of F-Factor Fiber/Protein Powders and Bars was from 2 to 1,500-times less than any tolerable intake levels for heavy metals of concern.



In summary, common reports of adverse events including gastrointestinal upset and allergy (e.g. rash, hives) are likely caused by normal physiological reaction to increased intake of dietary fiber or allergens

in certain individuals. There is no evidence that F-Factor Fiber/Protein Powders and Bars pose a toxicological risk to consumers. Reports of adverse effects not related to dietary fiber intake or allergy are likely co-incidental events that are typically also observed with foods and ingredients, such as vitamin C supplements, with a history of safe use.

Introduction

F-Factor Fiber/Protein Powder and Bar products are intended to be used as part of the F-Factor Diet that encourages consumption of lean protein and low-calorie high-fiber carbohydrates. While not intended to replace eating lean protein, fruits, and vegetables, the powder and bar products are intended to provide a source of fiber and protein to meet the dietary recommendations of the F-Factor Diet (https://www.ffactor.com/what-is-f-factor/).

It is our understanding that since the beginning of August 2020, an increase in the number of adverse events, compared to previous months, has been reported to F-Factor by consumers using F-Factor Fiber/Protein Powders and Bars. In response, F-Factor requested that CTEH perform an assessment of the F-Factor Fiber/Protein Powders and Bars and constituent ingredients at issue to identify any potential toxicological or safety concerns from consumer use of these products.

Methodology

Review of Product Complaints

Product complaint logs dating from 2018 through September 10, 2020 were provided to CTEH by F-Factor. Complaints were reviewed for those related to an adverse health event and categorized by reported symptoms.

Hazard Evaluation

The initial step of the assessment was to conduct a hazard evaluation of individual ingredients of F-Factor Fiber/Protein Powders and Bars. A health hazard evaluation considers innate properties of a substance that may result in adverse effects on the body under certain consumption conditions. However, it does not inform the likelihood of the occurrence of an adverse effect. Product formulation sheets and ingredient specification sheets were provided to CTEH by F-Factor and were reviewed to develop a list of ingredients present in six varieties of F-Factor Fiber/Protein products, including three powders and three bars:

1) F-Factor 20/20 Fiber/Protein Powder – Unflavored
2) F-Factor 20/20 Fiber/Protein Powder – Chocolate Flavor
3) F-Factor 20/20 Fiber/Protein Powder – Vanilla Flavor

4) F-Factor Fiber/Protein Bar – Chocolate Brownie
5) F-Factor Fiber/Protein Bar – Blueberry
6) F-Factor Fiber/Protein Bar – Peanut Butter

Ingredient-specific data were reviewed where available from a variety of scientific and regulatory sources including peer-reviewed scientific studies identified by searching PubMed and Google Scholar, and databases or compendiums developed by US Food and Drug Administration (US FDA), US Environmental Protection Agency (US EPA), Agency for Toxic Substances and Disease Registry (ATSDR), Health Canada, European Food Safety Authority (EFSA), and World Health Organization (WHO). Regulatory data were reviewed to determine any applicable standards to limit exposure, while a toxicological evaluation was performed to identify disruptions of normal physiological function (i.e. toxicity) associated with exposure to the identified ingredient. While intolerances and hypersensitivities to food (e.g. lactose intolerance, celiac disease, allergy reaction caused by milk, protein, etc.) are generally considered adverse non-toxic events, they were considered in the analysis given the nature of reported adverse events including gastrointestinal upset and allergy (e.g. rash, hives). Based on the results of the hazard identification, ingredients were categorized as low, medium, or high safety consideration to consumers, based on criteria shown in **Table 1**.

Table 1. Ingredient Safety Categorization

Safety Categorization	Regulatory & Safety Considerations
LOW	• Established history of safe use in humans • Generally Recognized as Safe (GRAS) for intended purpose
MEDIUM	• Potential safety concerns for specific sensitive populations • Regulatory labeling requirements • Identification of an established acceptable contaminant levels (i.e., an exposure limit with a factor of safety added)
HIGH	• No available safety information • Identification of toxicological effect following consumption in general population • Regulation-based restricted use in food or dietary supplements

Risk Assessment

The second step of the assessment was to perform a risk analysis for those ingredients identified as medium or high safety concern to consumers. Unlike the health hazard evaluation, a risk assessment provides information regarding the likelihood of a consumer experiencing an adverse effect under certain consumption conditions. For ingredients identified as medium or high safety concern, a risk assessment was conducted for the health outcome(s) reported to F-Factor by consumers. Consumer estimated dietary

intake (EDI) to the ingredient/substance of concern was calculated based on product labeling (e.g. serving size and recommended use) and available laboratory certificates of analysis (CoA) for each F-Factor Fiber/Protein Powder or Bar product. EDIs were compared to health-based guidance values (HBGV; e.g. recommended daily intake, tolerable daily intake) established by relevant scientific and/or regulatory agencies. EDI values less than HBGV indicate the ingredient of concern is unlikely to pose a risk to consumer under conditions of expected use.

Comparison with US FDA Adverse Events Reporting Data

The US FDA maintains a downloadable database of adverse event reports related to products, including foods and dietary supplements, submitted to the Agency by healthcare professionals, consumers, and manufacturers (USFDA, 2020a). As of September 2020, the US FDA Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS) database was publicly available for download for adverse events entered through March 31, 2020. The database was searched from January 1, 2018 to March 31, 2020 for adverse events related to F-Factor products and vitamin C, the latter considered a ubiquitous and safe dietary nutrient.

Results

Review of Product Complaints

A review of product complaint logs provided by F-Factor identified a total of 183 consumer complaints related to adverse health effects which were submitted to F-Factor as of September 10, 2020. Fifty seven percent of complaints involved some form of gastrointestinal distress, followed by 25% of complaints for allergy-related effects (e.g. rash, hives). Adverse events not related to GI or allergy issues were reported in 28% of complaints, which included a variety of medically disparate effects including headache/migraines, hair loss, urinary tract infection, miscarriage, bleeding, and muscle aches. Lastly, 8% of reports did not include specifics of the adverse health effects (e.g. felt strange, sick, side effects). Based on the available information, most adverse health events associated with F-Factor Fiber/Protein Powder and Bar products reported by consumers were related to gastrointestinal distress and hypersensitivity (allergy). These effects, along with general and specific toxicological effects, were the focus of the hazard evaluation described the following section.

Ingredient Hazard Evaluation

Review of product formulation sheets for the six F-Factor Fiber/Protein powder and bar products identified a cumulative set of 28 unique ingredients (**Table 2**).

Table 2. Ingredients in F-Factor Fiber/Protein Powders and Bars with Safety Consideration Level

INGREDIENT	IN PRODUCT(S)*	SAFETY CATEGORIZATION	COMPONENT RESPONSIBLE FOR INGREDIENT'S SAFETY CONCERN
Whey Protein Concentrate	PU, PV, PC	Low	Milk, Lactose
Hydrolyzed Guar Gum	PU, PC, PV	Low	Fiber
Sunflower Lecithin	PU, PV	Low	-
Cocoa Bean Powder	PC	Medium	Heavy Metals
Natural Milk Chocolate Flavor Powder	PC	Low	-
Natural Vanilla Flavors	PV	Low	-
Lo Han Guo (Monk) Fruit Extract	PV, PC	Low	-
Steviol Glycosides	PC	Low	-
Stevia Leaf Extract	PV	Low	-
Soluble Corn Fiber	CB, PB, BB	Low	Fiber
Chicory Root Fiber	PB	Low	Fiber
Brown Rice Protein Concentrate	CB, PB, BB	Medium	Heavy Metals
Pea Protein Crisp	CB, BB	Medium	Cross-reactivity to major allergens
Inulin	PB	Low	Fiber
Glycerin	CB, PB, BB	Low	-
Oats	CB, BB	Low	-
Palm Kernel Oil	CB, PB	Low	-
Dutch Cocoa Powder	CB	Medium	Heavy metals
Natural Milk Chocolate Flavor	CB	Low	-
Sea Salt	CB, PB, BB	Low	-
Sunflower Lecithin	CB, BB	Low	-
Almond Butter	CB, PB, BB	Medium	Almonds
Peanut Butter Paste	PB, BB	Medium	Peanuts
Peanut Flour	PB	Medium	Peanuts
Peanuts	PB	Medium	Peanuts
Peanut Extract	PB	Medium	Peanuts
Blueberry Flavor	BB	Low	-
Steviol Glycosides	CB, PB, BB	Low	-

*F-Factor Fiber/Protein Products: PU – Powder, Unflavored; PC – Powder, Chocolate Flavor; PV – Powder, Vanilla Flavor; PB – Bar, Peanut Butter; CB – Bar, Chocolate Brownie; BB – Bar, Blueberry

- **Ingredients with Low Safety Concern**

Sixteen of the 28 unique ingredients present in F-Factor Fiber/Protein powder and bar products were identified with low safety concerns. Nearly all of these ingredients appeared in Title 21 of the Code of Federal Regulations (21 CFR), GRAS Notice Inventory[1], Substances Added to Food Inventory, Notification for New Dietary Ingredients, or FEMA GRAS publications. For example, whey protein concentrate, lecithin, and soluble corn fiber are listed in 21 CFR, stevia leaf and extracts are included in the GRAS Notice Inventory, and monkfruit extracts were identified in GRAS Notice Inventory, FEMA GRAS publications, and Notifications for New Dietary Ingredients. No toxicological concerns were identified for these 16 ingredients as intended for consumption in foods and/or dietary supplements.

Several flavor ingredients were identified as containing 'natural flavors'. These included:

1) Natural Milk Chocolate Flavor Powder
2) Natural Creamy Chocolate Flavor Powder
3) Natural Vanilla Flavors
4) Natural Milk Chocolate Flavor
5) Blueberry Flavor

According to US FDA, a natural flavor is defined as "the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material … , whose significant function in food is flavoring rather than nutritional" (USFDA, 2019). While specific chemical/substance constituents were proprietary to the ingredient supplier, each was identified as 'US FDA approved' or 'listed as GRAS' in statements provided by the vendor. While such statements should not be interpreted alone to assure safety of the ingredient, there were no major toxicological concerns identified in the scientific literature for these ingredients (e.g. chocolate, vanilla, and blueberry) related to their use in foods and dietary supplements.

Five ingredients identified as low safety concern were associated with the potential for food intolerance in sensitive people. It is important to recognize that intolerance to certain foods in not considered a toxicological response, hence the categorization of these ingredients as low safety concerns. These ingredients, including fiber sources and whey protein concentrate containing lactose, are discussed in further detail below.

[1] US FDA GRAS designation is based upon intended use for a specific food ingredient. Additional investigation of technical rationale may be required to determine compliance with regulatory standards.

- *Dietary Fiber*

Four ingredients were identified with potential intolerance issues in sensitive populations. These included various fiber sources used in the F-Factor Fiber/Protein Powder and Bars:

1) Hydrolyzed Guar Gum
2) Soluble Corn Fiber
3) Inulin
4) Chicory Root Fiber

Each of these fiber sources are soluble fibers commonly found in food and dietary supplement products. Soluble fiber is as essential part of the diet known to provide key health benefits including hunger regulation, slowing digestion, regulation of blood sugar levels, decreasing cholesterol levels and promoting health intestinal function. Adequate dietary intakes of fiber range from 22 to 39 g per day depending on gender, age and physiological state (e.g., pregnant or lactating) (IOM, 2006). The F-Factor diet recommendation for 35 g of fiber per day is consistent with IOM adequate intake levels. It is worthwhile to note that an adequate intake is defined as a level assumed to ensure nutritional adequacy for the general population. It does not represent a level above which adverse health effects would be expected.

Fiber is commonly identified as a deficient nutrient in US diets, with recommendations for increased dietary fiber intake through increased consumption of vegetables, fruits, and whole grains (USDA, 2020). A sudden increase in dietary fiber (not specific to a single type of fiber) has been associated with the onset of unpleasant gastrointestinal symptoms, including bloating, nausea, flatulence, belching, vomiting, stomach cramping, constipation, diarrhea, and dehydration. In rare cases when fiber intake is substantially greater than recommended intake levels weight changes, decreased nutrient absorption and intestinal blockage may occur (NRC, 1989). Maltodextrin, found in soluble corn fiber, may induce acute gastrointestinal effects including bloating, gas, flatulence, and weight gain. These short-term, transient effects are attributable to fermentation of maltodextrin by bacteria in the intestine and absorption of water by maltodextrin itself. Constipation and dehydration may result if water intake is not increased during intake of maltodextrin. Typically sourced from chicory root, inulin may present similar unpleasent gastrointestinal effects at other soluble fibers. Adverse effects from inulin consumption are more likely to occur at intake levels exceeding 5 to 10 g per day.

Based on product CoAs and labels, a single serving of F-Factor Fiber/Protein Powders and Bars is estimated to provide 20 grams of fiber, constituting 51% to 91% of the adequate intake recommended by the Institute of Medicine (IOM). As a result, it would be expected for some consumers, particularly those whose diet does not typically contain adequate dietary fiber intake, to experience unpleasant gastrointestinal effects including, bloating, nausea, gas, flatulence, belching, vomiting, stomach cramps, diarrhea, constipation, feeling too full, and dehydration. It is important to recognize that these symptoms are natural physiological response to increased fiber intake and would be expected to resolve upon

ceasing regular product use or physiological adaption to increased dietary intake. These responses are not considered a toxicological event capable of disruption normal physiological function or frank tissue damage.

- *Lactose*

Whey protein concentrate used in F-Factor Fiber/Protein powders was found to contain lactose as a constituent. Lactose intolerance develops as a result of normal down-regulation of lactase enzymatic activity in the intestine that occurs after weaning in most ethnic groups. In these individuals, undigested lactose is degraded by intestinal bacteria to lactic acid, acetic, acid and carbon dioxide. Adverse effects of lactose intolerance can lead to abdominal pain, bloating, flatulence, and diarrhea. Consuming a diet with reduced lactose content is the only known treatment for lactose intolerance (EFSA, 2010).

Recent analyses have determined that most lactose intolerant individuals can tolerate 12 g of lactose at a single sitting, or a daily intake of 18 g of lactose (Corgneau et al., 2017). EFSA (2010) noted that some individuals may experience gastrointestinal-related discomfort at intake levels as low of 3 to 5 g. Based on the specification sheets provided by the ingredient vendor and product formulation sheets, a single serving of F-Factor Fiber/Protein Powders contains <2 g of lactose per serving (**Table 3**). Therefore, adverse effects resulting from lactose intolerance is not likely to occur during consumer use of F-Factor Fiber/Protein Powder products.

Table 3. Estimated Lactose Content of F-Factor Fiber/Protein Powders

F-Factor Fiber/Protein Powder	Lactose Content in Whey Protein Concentrate (g / 100 g)	Whey Protein Concentrate per serving of Powder (g)	Lactose per Serving (g)
Unflavored	7.7*	24.0570	*1.85*
Vanilla	7.7*	23.5521	*1.81*
Chocolate	4.0-7.0	26.630	*1.06-1.86*

*Reported as 7.7 g of sugar per 100 g of ingredient. Assumed all sugar to be lactose.

- **Ingredients with Medium Safety Concern**

    - *Hypersensitivity (Allergy)*

Seven ingredients were identified as medium-level safety concerns based upon potential allergen issues:

1) Almond Butter
2) Pea Protein Crisp
3) Peanut Butter Paste
4) Peanut Flour
5) Peanuts
6) Peanut Extract/Oil
7) Whey Protein Concentrate

Milk, tree nuts (e.g., almonds, walnuts), and peanuts are among the eight "major food allergens" identified by the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 (US Congress, 2004). For example, whey protein concentrate used in F-Factor Fiber/Protein 20/20 powders contains milk proteins, while almond butter and peanuts or peanut-based ingredients (e.g., peanut flour, peanut butter, peanut extract/oil) are also used in F-Factor Fiber/Protein Bars. Further, F-Factor Fiber/Protein Bars contain pea protein as a protein source. While pea proteins have not been identified as a major allergen recognized by FALCP, there is some evidence of cross-reactivity of pea protein in peanut-allergic children (Lavine and Ben-Shoshan, 2019; Richard et al., 2015)

Approximately two percent of the US population is affected by food allergies, with 90% attributed to the eight major allergies. Commonly experienced symptoms attributed to food allergies include hives, flushed skin or rash, itching of the mouth, swelling of the tongue, lips, face or throat, abdominal cramps, vomiting, and diarrhea. Meanwhile, severe reactions can include dizziness, difficulty breathing, and anaphylactic shock. Since there is no cure and treatment options for food allergies are limited, the best method of prevention is proper labeling as described under FALCPA and consumer avoidance (US Congress, 2004; USFDA, 2018).

While these seven ingredients were identified as medium safety concerns for consumers, a risk analysis was not performed. F-Factor Fiber/Protein Powder and Bar products are clearly labeled in accordance with FALCPA requirements for major allergens to allow for product avoidance for individuals sensitive to these ingredients (Appendix A).

    - *Heavy Metal Content*

Some ingredients were identified as a medium safety concern based on potential presence of naturally-occurring heavy metals. These included rice-based (Brown Rice Protein Concentrate) and cocoa-based ingredients (Cocoa Bean Powder, Dutch Cocoa Powder). Metals, including those essential to good health

and those with no known health benefit, are present in many foods. Because metals are ubiquitous in the air, water, and soil in the environment, they are an inherent component of food. Some specific foods such as fish, rice, and certain fruits and vegetables may contain higher levels of metals than others based on origin, environment (e.g. soil, water) in which food is produced, and agricultural and manufacturing processes. US FDA and other regulatory and scientific agencies monitor and test foods and set standards where appropriate to limit the presence of harmful metals in foods. For example, US FDA has established action levels for arsenic in infant rice cereals (USFDA, 2020b), while EFSA has established maximum allowable cadmium levels in cocoa and chocolate products (EUR-Lex, 2006).

To determine any potential consumer risk associated with heavy metal content of F-Factor Fiber/Protein Powders and Bars, we first identified tolerable intake levels for heavy metals established by federal and international agencies (**Table 4**). Tolerable intake levels are defined as the highest level of intake of a substance that is likely to pose no risk of adverse health effects in the general population (Government of Canada, 2006).

Table 4. Established Tolerable Intake Levels for Heavy Metals

Agency	Intake Value		Equivalent Dose (µg/day)*	Reference
Lead				
US FDA	Interim Reference Level	12.5 µg/day	12.5	(Flannery et al., 2020)
Health Canada	Tolerable Daily Intake	0.0036 mg/kg-day	288	(Health Canada, 2010)
Cadmium				
US EPA	Reference Dose (RfD) - Food	0.005 mg/kg-day	400	(IRIS, 1987)
ATSDR	Intermediate MRL	0.1 µg/kg-day	8	(ATSDR, 2012)
ATSDR	Chronic MRL	0.1 µg/kg-day	8	(ATSDR, 2012)
Health Canada	Tolerable Daily Intake	0.008 mg-kg-day	640	(Health Canada, 2010)
JECFA	Provisional Tolerable Monthly Intake	25 µg/kg-month	67	(WHO, 2013)
Arsenic (inorganic)				
US EPA	Reference Dose (RfD)	0.0003 mg/kg-day	24	(IRIS, 1988)
ATSDR	Chronic MRL	0.0003 mg/kg-day	24	(ATSDR, 2007)
Mercury (inorganic)				
ATSDR	Intermediate MRL	0.007 mg/kg-day	560	(ATSDR, 1999)
ATSDR	Chronic MRL	0.002 mg/kg-day	160	(ATSDR, 1999)

Health Canada	Tolerable Daily Intake	0.0003 mg/kg-day	24	(Health Canada, 2010)
JECFA	Provisional Tolerable Weekly Intake (Total Mercury)	4 µg/kg-week	46	(WHO, 2011)

*Assuming 80-kg adult where necessary (USEPA, 2011).

Next, we estimated dietary intake levels of heavy metals resulting from consumption of F-Factor Fiber/Protein Powders and Bars and compared to these tolerable intake levels. Based on product CoAs (Appendix B) and recommended use, metal intake was determined for F-Factor Fiber/Protein Powders and Bars on a per serving basis (**Table 5**). While there are significant variations in tolerable intake level between agencies, any potential intake of heavy metals from F-Factor Fiber/Protein Powders and Bars is at least 2.4-times less than the most health-conservative established tolerable intake level (**Figure 1**). Further, consuming one serving each of F-Factor Fiber/Protein Powders and Bars would not exceed daily tolerable intake levels.

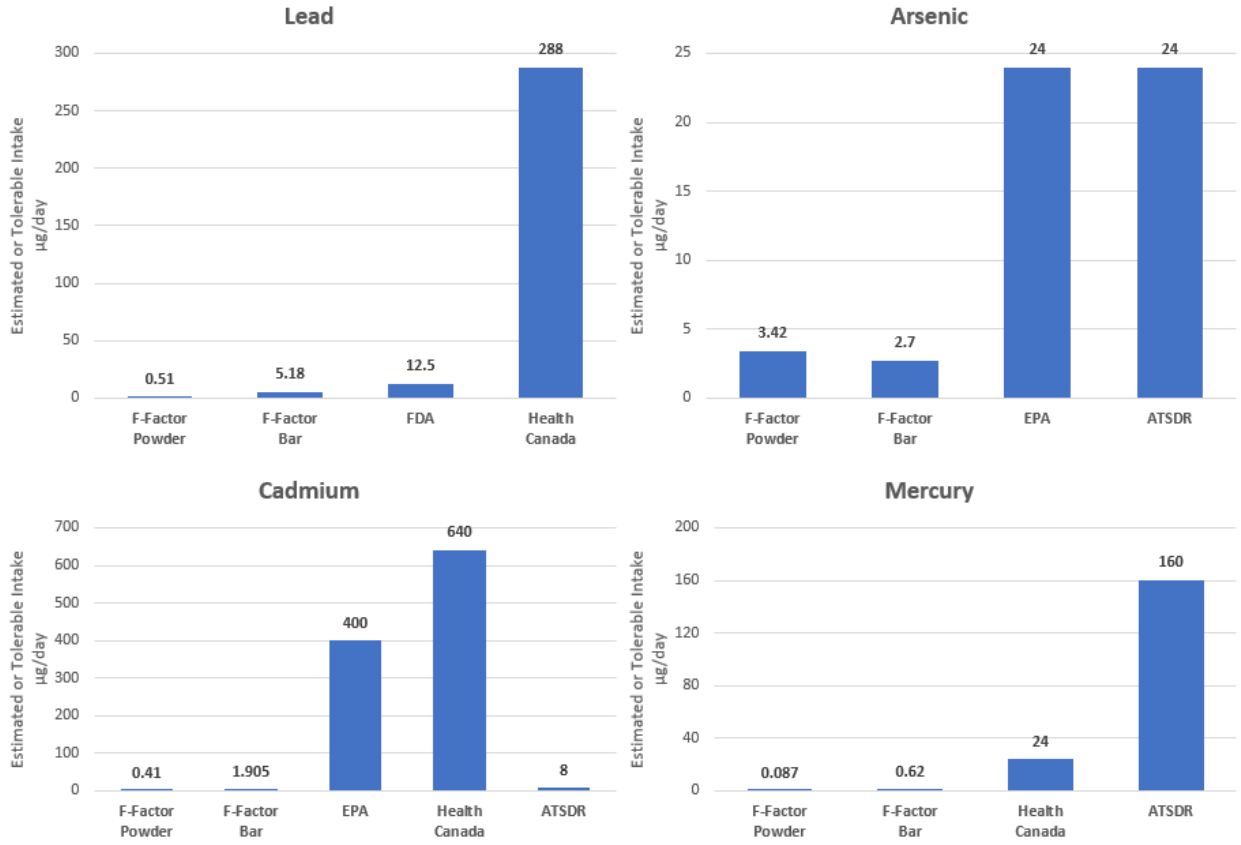
Table 5. Estimated Metal Intakes Per Serving for F-Factor Fiber/Protein Powders and Bars

Product	Serving Size (g)	Lead (µg/serving)	Cadmium (µg/serving)	Arsenic (µg/serving)	Mercury (µg/serving)
Powder – Unflavored	46	0.28	0.05	4	0.078
Powder - Vanilla	48	0.82	0.06	3.41	0.096
Powder – Chocolate	54	0.43	1.13	2.86	NA
Bar – Chocolate Brownie	62	5.76	1.61	3.18	<0.620
Bar – Peanut Butter	62	4.59	2.2	2.22	<0.620
Bar - Blueberry	62	NA	NA	NA	NA
Intake Assuming 1 Powder and 1 Bar[$]	NA	5.69	2.32	6.12	<0.71

*Metal analysis was not available for F-Factor Fiber/Protein Blueberry Bar

[$]Intake based on average metal content for F-Factor product category.

Figure 1. Comparison to Estimated Metal Intakes from F-Factor Fiber/Protein Powders and Bars to Tolerable Intake Levels



*Intake based on average metal content for F-Factor product category

In addition, US FDA previously tested rice and rice-based products for inorganic arsenic content and conducted a risk assessment for health risks. Results indicated that 12 dietary supplement products and 29 grain-based meal replacement/energy bars were tested as part of the study. Average inorganic concentrations were 1.9 µg per serving (range: 0.1 – 5.7 µg) and 2.0 µg per serving (range: 0.2-3.9 µg), respectively. These values are consistent with inorganic arsenic levels reported in F-Factor Fiber/Protein Powders and Bars. As a result of their findings, US FDA established regulatory guidance (e.g. action level guidance) for inorganic arsenic in infant rice cereals but did not for other rice-based products (USFDA, 2016).

- **Ingredients with High Safety Concern**

No ingredients were identified that posed a high risk for safety considerations. While the amount of available safety information from the scientific literature varied for each ingredient, there was no indication that major toxicological concerns were apparent for these ingredients related to their use in foods and dietary supplements.

Comparison with US FDA CAERS Data

As of September 2020, the US FDA CAERS database was available for adverse events submitted through March 31, 2020. A search revealed no entries related to F-Factor products in the US FDA CAERS database.

A search was also performed for adverse event reports associated with consumption of a ubiquitous and safe nutrient, vitamin C. A total of 303 adverse event reports were submitted between January 2018 and March 2020, of which 4 were associated with death and 73 were categorized as life threatening, disabling, or requiring hospitalization (Appendix B). This comparison does not suggest that vitamin C products incur a higher risk of adverse health effects than F-Factor Fiber/Protein products, as there are likely far more vitamin C product users in the US than F-Factor Fiber/Product products user over this same time period. It does, however, suggest that adverse event reporting should be used as a trigger for further, more rigorous investigation, but not for serving as the sole basis for product safety declarations (USFDA, 2020a). Further, it provides evidence that reports of co-incidental adverse events are not uncommon for foods and dietary supplements with well-documented safety profiles.

Summary

The CTEH hazard evaluation demonstrated that most ingredients present in F-Factor Fiber/Protein Powders and Bars presented minimal safety concerns for consumers. Several ingredients were identified as a concern due to intolerance in some populations, the presence of allergens, and potential heavy metal contamination. Based on labeling requirements and the risk assessment described above, these ingredients do not present a safety concern to consumers as present in F-Factor Fiber/Protein products. Reports of adverse events including gastrointestinal distress following consumption of F-Factor Fiber/Protein Powders and Bars are likely attributable to normal physiological reaction to large increases in daily fiber intake. Meanwhile, toxicity is defined by acute or chronic changes caused by an agent that results in permanent disruption of normal physiological function or tissue damage. Based on the described hazard and risk analyses, there is no evidence that F-Factor Fiber/Protein Powders and Bars pose a toxicological risk to consumers.

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