



Chemical Regulation and Food safety

**UPDATED ILSI NA HEAVY
METAL SCREENING TOOL
DOCUMENTATION REPORT
AND USER'S GUIDE**

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Acronyms and Abbreviations

AI	Adequate Intake
ATSDR	Agency for Toxic Substances and Disease Registry
BMDL ₀₁	Benchmark Dose of 1% Extra Risk
CFR	Code of Federal Regulations
CONTAM	Contaminants in the Food Chain
DRIs	Dietary Reference Intakes
EFSA	European Food Safety Authority
EPA	U.S. Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organization
FDA	U.S. Food and Drug Administration
IRIS	Integrated Risk Information System
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOAEL	Lowest Observed Adverse Effect Level
MCL	Maximum Contaminant Level
MRL	Minimum Risk Level
NAS	National Academy of Sciences
NHANES	National Health and Nutrition Examination Surveys
NOAEL	No Observed Adverse Effect Level
NSRL	No Significant Risk Level
PTTI	Provisional Total Tolerable Intake
PTWI	Provisional Tolerable Weekly Intake
RDA	Recommended Dietary Allowance
REL	Reference Exposure Level
RfD	Reference Doses
RIVM	National Institute for Public Health and Environment (RIVM; Netherlands)
TDI	Tolerable Daily Intake
UL/TUL	Tolerable Upper Intake Level
WHO	World Health Organization

1 BACKGROUND

Under contract with ILSI North America Exponent developed a heavy metal screening tool (the HMS tool) for ingredients that are used in the processing of food products using a risk-based approach. The five heavy metals included in the tool are arsenic, cadmium, chromium, lead, and mercury. Exposure situations are assumed to have duration of six months to one year and US based.

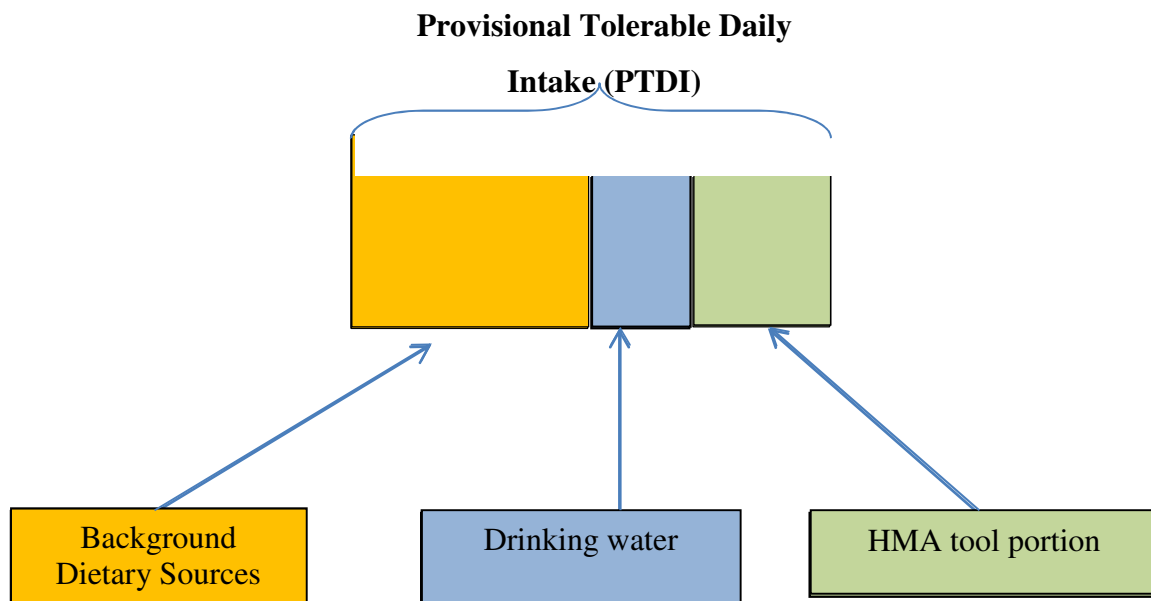
The HMS tool has three key components: 1) hazard characterization, 2) dietary exposure assessment and 3) risk characterization, which are organized into three respective modules. This report describes the data and supporting rationale for each module, intended application and the tool limitation. A user-guide on how to operate the tool is also included.

WARNING: The HMS tool is a screening tool using default assumptions. Users must always check the concentration levels versus existing regulatory limits. The HMS tool cannot be used to override these existing regulatory limits.

2 MODULE 1: HAZARD CHARACTERIZATION

In this module, for each of the metals of interest, a default portion of existing exposure limits such as the Provisional tolerable daily intake (PTDI) is established as available for use in the HMS tool. This HMS tool portion of the PTDI is the remaining portion after accounting for existing dietary exposure (food and water), see Figure 1.

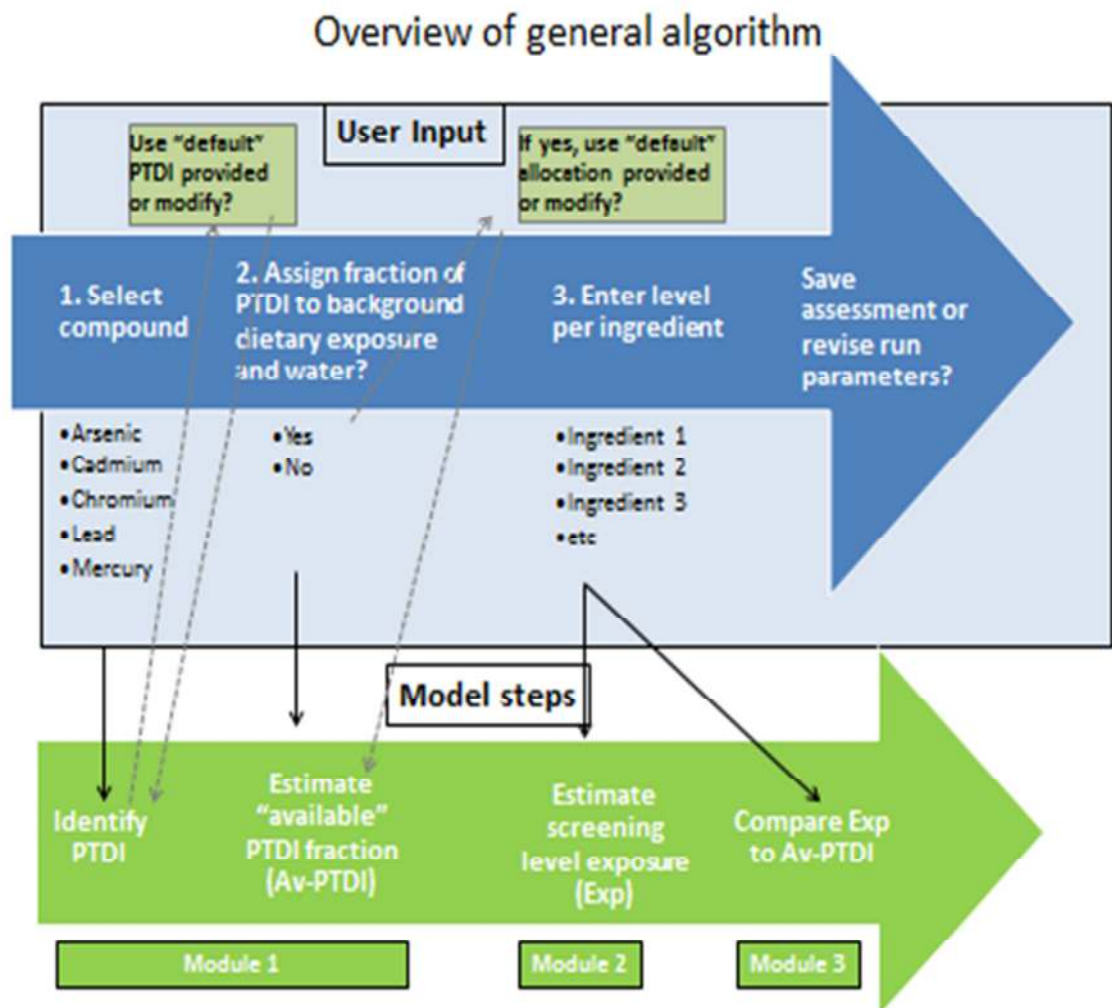
Figure 1. Schematic of PTDI apportionment



Based on a review of the published literature, the currently available exposure limits (such as PTDI, TDI, RfD, etc...) and major dietary sources for each of the five metals are summarized below. The current approach to establish the portion of the existing exposure limits (e.g., PTDIs) that can be apportioned to food sources being evaluated using the HMS tool is also summarized. These initial values are being incorporated into the HMS tool. However, to allow for flexibility to account for emerging science, the user will have the option to input alternative exposure limits based on the latest science, and/or to select the relevant background (food and drinking water) exposure to be accounted for in setting the exposure limits (e.g., whether

only background drinking water exposure or dietary exposure should be included or both). See Figure 2 below on overview of general model algorithm.

Figure 2. Summary of the algorithm to be used in the HMS tool.



2.1 Inorganic Arsenic

2.1.1 Existing Exposure Limits

The FDA (21 CFR 165.110) has established a quality standard limit for inorganic arsenic in bottled water of 10 ppb. Consumption of 2L of water per day containing 10 ppb arsenic results in an intake of 20 µg/day or approximately 0.3 µg/kg bw/day for a 60 kg individual.

The Agency for Toxic Substances and Disease Registry (ATSDR 2007) has derived a non-cancer chronic-duration (365 days or more) oral minimum risk level (MRL) of 0.3 µg /kg bw/day for inorganic arsenic, based on a NOAEL of 0.8 µg/kg bw/day for dermal effects found in a Taiwanese farming population exposed to arsenic in well water (Tseng 1977; Tseng et al. 1968; as cited by ATSDR, 2007). An uncertainty factor of 3 (for human variability) was applied.

The Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS, 1993) derived a chronic oral reference dose (RfD) of 0.3 µg /kg bw/day for inorganic arsenic, based on a no-observed-adverse-effect level (NOAEL) of 8 µg /kg bw/day for dermal effects (hyperpigmentation and keratosis) and possible vascular complications in a Taiwanese farming population exposed to arsenic in well water (Tseng 1977; Tseng et al. 1968; as cited by EPA, 1993). In 1998, EPA established a cancer slope factor for arsenic (based on skin cancer). The 1998 and current inorganic arsenic slope factor is 1.5 (mg/kg bw/day)⁻¹ (EPA, 1998). More recently, in 2010, the EPA issued a draft revised cancer slope factor for inorganic arsenic that would make it 17 times more potent than the current cancer slope. The proposed slope factor is 25.7 (mg/kg bw/day)⁻¹ (EPA, 2010). This slope factor, however, is currently slated for a review by the National Research Council.

In 2009, the European Food Safety Authority (EFSA) Panel on Contaminants in the Food Chain (CONTAM Panel) reported that new data had established that inorganic arsenic causes cancer of the lung and urinary tract in addition to skin, and that a range of adverse effects had been reported at exposures lower than those reviewed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1989 when JECFA established (withdrawn February 2010) the PTWI of 15 µg /kg bw. The CONTAM Panel focused on more recent data on the main adverse effects reported to be associated with longer-term (i.e., not acute) ingestion of inorganic arsenic in humans, including skin lesions, cancer, developmental toxicity, neurotoxicity, cardiovascular diseases, abnormal glucose metabolism, and diabetes. Effects at the lowest doses, i.e. the data for cancers of the urinary bladder, lung and skin, and skin lesions, causally associated with long-term oral exposure to inorganic arsenic, were considered by the CONTAM Panel as providing an appropriate reference point. The CONTAM Panel concluded that an overall range

of BMDL₀₁ values of 0.3 to 8 µg/kg bw/day should be used instead of a single reference point in the risk characterization for inorganic arsenic.

Recently, inorganic arsenic was re-reviewed at the Seventy-second meeting of JECFA (JECFA 2011). The JECFA Expert Committee noted that the approach to quantitative assessment of cancer risk from inorganic arsenic is limited by the lack of information on total (water and food) exposure in the available epidemiological studies. The inorganic arsenic BMDL for a 0.5% increased incidence of lung cancer was determined by using a range of assumptions to estimate exposure from drinking-water and food with differing concentrations of inorganic arsenic. The BMDL_{0.5} was computed to be 3.0 µg/kg bw/ day. The Committee noted that the PTWI (Provisional Tolerable Weekly Intake) of 15 µg/kg bw per week (2.1 µg /kg bw/day) that was established in 1989 is in the region of the BMDL_{0.5} and therefore was no longer appropriate and the Committee withdrew the previous PTWI.

Exposure Limits – Inorganic Arsenic		References
Oral reference dose (RfD) – chronic	0.3 µg/kg bw/day	EPA (IRIS); last revised 1993
TDI (based on bottled water standard – 10 ppb) - chronic	0.3 µg/kg bw/day	FDA, based on 21 CFR 165.110
Minimum Risk Level (MRL) - chronic	0.3 µg/kg bw/day	ATSDR, 2007
BMDL ₀₁	0.3 -0.8 µg/kg bw/day	EFSA, 2009
BMDL _{0.5}	3 µg/kg bw/day	JECFA (2010)
MRL – acute	5 µg/kg bw/day	ATSDR, 2007
Cancer slope factor	1.5 (mg/kg bw/day) ⁻¹	EPA (IRIS, 1998)
	25.7 (mg/kg bw/day) ⁻¹	EPA Proposed, 2010

2.1.2 Background Dietary Sources

Based on the FDA TDS, estimates of 1.34-12.54 µg Inorganic As/day were provided for the US population (FDA TDS 1991-1997; Tao and Bolger, 1998). The Institute of Medicine (IOM) Dietary Reference Intakes (DRI) for vitamins and minerals (IOM, 2001) also reported estimated intake of total arsenic for children 1-3 y and 4-8 y to be 13.8 and 17.25 µg/day, respectively, based on data from the FDA TDS (1991-1997). Assuming a body weight of 10 kg, estimated

arsenic intake is 1.4 µg/kg bw/day for children 1-3 y. The IOM's estimates are also consistent with EFSA's range of intake estimates for children under 3 years of age. EFSA (2009) has estimated inorganic arsenic exposures from food and water across 19 European countries, using lower bound and upper bound concentrations, to range from 0.13 to 0.56 µg/kg bw/day for average consumers and from 0.37 to 1.22 µg/kg bw/day for 95th percentile consumers. For children under three years of age, estimates reported in two different studies showed an inorganic arsenic intake ranging from 0.50 to 2.66 µg/kg bw/day.

2.1.3 HMS Tool Portion

The existing TDI (0.3 µg/kg bw/day) will be used in establishing the limit for food ingredients in the HMS tool. Based on high background levels of arsenic in the diet, it is assumed that 95% of the TDI is assigned to background diet and drinking water exposure and the remaining 5% of the current TDI for arsenic will be available for food sources being evaluated using the HMS tool, i.e. 0.015 µg/kg bw/day. The allowance of 5 % of the PTDI for the HMS Tool is based on the notion that when everything is contaminated to some extent (i.e. unavoidable risk) and the PTDI is exceeded it does not mean that the food/ingredient under consideration is unsafe for the following reasons: 1) the PTDI is based on chronic long term exposure and the relevant exposure durations for the HMS Tool is of shorter durations of 6 months to one year and 2) limited portion of the food supply is assumed to be affected. It should be noted that with the ongoing discussing on the potential cancer effects and proposed EPA 's cancer slope factor that is 17 times more potent than the current cancer slope factor, the approach laid out here could be changed in the near future.

Arsenic, Inorganic	µg/kg bw/day	References
Exposure limit	0.3	TDI (FDA, based on 21 CFR 165.110)
Dietary sources & Drinking water source	0.285	Default: 95% combined food + water
<i>HMS tool portion</i>	<i>0.015</i>	

2.2 Cadmium

2.2.1 Existing Exposure Limits

The Joint Expert Committee on Food Additives (JECFA), the World Health Organization/Food Agriculture Organization (WHO/FAO) committee responsible for international risk assessment of food additives and contaminants, has a long history of evaluating cadmium health hazard and establishing tolerable levels. JECFA considered renal tubular dysfunction to be the critical health outcome/endpoint. JECFA stated that *'cadmium accumulates in the kidney, and because of its long half-life in humans, steady-state concentrations in the renal cortex are reached only after about 40 years'* (Summary and Conclusions of JECFA's 61st meeting, June 2003).

As far back as its first evaluation of cadmium at the 16th meeting, JECFA has set the PTWI for cadmium at 7 µg/kg-bw (although it was not expressed on a kg body weight basis at that time) (Summary and Conclusions of JECFA's 61st meeting, June 2003). This PTWI was maintained in the 2003 JECFA meeting. In 2010, JECFA changed the PTWI to a monthly intake due to cadmium's long half-life in the body and set a provisional tolerable monthly intake (PTMI) at 25 µg/kg bw (Summary and Conclusions of JECFA's 73rd meeting, June 2010). ATSDR (ATSDR 2008a) has established a chronic MRL of 0.1 µg/kg bw/day which is about 8 times lower than the JECFA level and also 10 times lower than EPA's reference dose for food of 1×10^{-3} mg/kg bw/day (last revised in 1985).

A guideline value for cadmium in drinking water of 3 µg/L was established based on a 10% allocation of the original PTWI to drinking water (JECFA 2000). The revision of the PTWI to a PTMI has no effect on the guideline and was maintained. FDA has set a maximum allowable level of 5 µg/L in bottled water (FDA, 2007).

Exposure Limits - Cadmium		References
Oral reference dose (RfD) – chronic	0.5 µg/kg bw/day (water) 1 µg/kg bw/day (food)	EPA (IRIS); last revised 1985
Chronic minimum risk level	0.1 µg/kg bw/day	ATSDR 2008a
Drinking water (bottled) Limit	0.005 mg/L	FDA, 2007
Provisional Tolerable Monthly Intake (PTMI)	25 µg/kg bw/month	JECFA, 2010
PTWI	5.8 µg/kg bw/week	

2.2.2 Background Dietary Sources

Based on the FDA TDS (FDA –TDS 2006-2008), estimated mean daily cadmium for the US 2+ is 0.19 µg/kg bw/day; mean daily intake were the highest among infants 6-11 months and children 2-6 years at 0.42 µg/kg bw/day. The 90th percentile estimated daily intake for the US 2+ is 0.36 µg/kg bw/day and is the highest among infants 6-11 months at 0.68 µg/kg bw/day. At the 55th meeting of the JECFA Committee, dietary intake of cadmium was evaluated using the GEMS/Food regional diets and average concentrations of cadmium with intakes ranging from 2.8-4.2 µg/kg bw per week (or 0.4 - 0.6 µg/kg bw/day) (JECFA, 2000).

2.2.3 HMS Tool Portion

FDA normally accepts JECFA evaluations for use in its consideration of food safety, therefore for the HMS tool the JECFA PTDI will be relied upon. Bottled water limit for Cadmium is 0.005 mg/L (FDA, 2007); assuming a daily intake of 2L/day and a 60 kg bw, a maximum daily intake from drinking water sources is estimated to be 0.17 µg/kg bw/day. The background dietary intake of cadmium is based on the TDS 2006-2008 data for the US 2+ at the mean (0.19 µg/kg bw/day) and 90th percentile (0.36 µg/kg bw/day). The default fraction of the PTDI available for use in the HMS tool is the portion of the PTDI remaining after intake from water and background dietary sources have been accounted for:

Cadmium	µg/kg bw/day		Reference
Exposure limit (PTDI)	0.83		5.8 µg/kg bw/week; JECFA 2010
Drinking water source	0.17		Bottled water limit, FDA 2007
Dietary sources	<u>Mean</u>	<u>90th</u>	TDS 2001-2006 (US 2+)
	0.19	0.36	
<i>HMS tool portion</i>	<i>0.47</i>	<i>0.3</i>	

2.3 Chromium

2.3.1 Existing Exposure Limits

Chromium is generally considered an essential element for humans. An Adequate Intake (AI) of 35 µg/day and 25 µg/day for young men and women, respectively, has been set based on estimated mean intakes (IOM 2001). Few serious adverse effects have been associated with excess intake of chromium from food. Therefore, a Tolerable Upper Intake Level (UL) was not established. Adult women in the United States consume about 23 to 29 µg of chromium per day from food, which meets their AIs unless they are pregnant or lactating. In contrast, adult men average 39 to 54 µg per day, which exceeds their AIs (IOM 2001). In an evaluation by EFSA's Panel on Food Additives and Nutrient Sources added to Food, the addition of chromium III to food was determined to be safe provided the intake did not exceed 250 µg/day based on the WHO established limit for supplemental intake of chromium III (EFSA, 2010; WHO, 1996). ATSDR (2008b) reports the average level of total chromium in drinking water to be 1.8 µg/L. The EPA has set a drinking water limit of 1 mg/L while the FDA has determined that chromium levels in bottled water should not exceed 0.1 mg/L (ATSDR, 2008b; FDA 2007).

Chromium occurs in several valence states. Only the valence states (0), (III), and (VI) are considered stable. Hexavalent (VI) chromium is considered more toxic than trivalent (III) chromium. The chronic oral reference dose for chromium VI is 0.0009 mg/kg bw/day derived from the BMDL₁₀ of 0.09 mg/kg bw/day and an uncertainty factor of 100 (EPA- IRIS, Draft 2010). The WHO has also set a drinking water limit of 0.05 mg/L (WHO, 1996) for chromium VI. Hexavalent chromium is unstable in acid solutions and would be rapidly reduced to the less toxic form of trivalent chromium. In addition, any ingested chromium would come in contact

with the highly acidic environment of the stomach and only enhance the rate of reduction of any present hexavalent chromium. Trivalent chromium is much less absorbed from the gastrointestinal (GI) tract than is hexavalent chromium.

Exposure Limits - Chromium			References
Chromium III	supplements	250 µg/day	EFSA, 2010; WHO, 1996
Chromium VI	Oral Reference Dose	0.0009 mg/kg bw/day	EPA, IRIS Draft 2010
	Drinking water Limit	0.05 mg/L	WHO, 1996
	Drinking water (bottled) Limit (Total chromium)	0.1 mg/L	FDA, 2007

2.3.2 Background Dietary Sources

As noted earlier, adult women in the United States consume about 23 to 29 µg of chromium per day from food, which meets their AIs unless they are pregnant or lactating. In contrast, adult men average 39 to 54 µg per day, which exceeds their AIs (IOM 2001). Other reported intakes include: 18-51 µg/day (women) and 15-43 µg/day (men) (Anderson, 1993).

2.3.3 HMS Tool Portion

As there is no established TUL by the IOM for total chromium, the maximum daily amount from supplements (250 µg/day) based on an EFSA evaluation is used as an upper exposure limit for total chromium. Bottled water limit for total chromium is 0.1 mg/L per day (FDA, 2007) and assuming 2 liters of drinking water a day, the daily intake from drinking water is approximately 0.2 mg/day. However, the ATSDR (2008) estimate of 1.8 µg/L of total chromium in drinking water would result in a daily intake of 3.6 µg/day (assuming 2L/day). Assuming that the ATSDR's estimate is the mean, the 90th percentile can be approximated to be 7.2 µg/day (2 x 3.6 µg/day). For the purpose of this tool, the ATSDR 90th percentile estimate of total chromium intake from water sources is used to assign the proportion of the exposure limit to drinking water. The default fraction of the existing exposure limit for total chromium assigned

to food in the HMS tool is the portion of the exposure limit remaining after taking into account intake from water and background dietary sources and summarized below:

Chromium III	µg/day	Reference
Exposure limit	250	Supplements, EFSA 2010; WHO 1996
Drinking water source	7.2	Total chromium, 90 th percentile, ATSDR 2008
Dietary sources	15 – 54	IOM
<i>HMS tool portion</i>	<i>188.8 – 227.8</i>	<i>The lower limit is applied as default in the HMS Tool</i>

For chromium VI, based on the drinking water limit of 0.05 mg/L (WHO, 1996) and assuming 2L/day and 60 kg body weight, a daily intake from water based on the exposure limit is 0.0017 mg/kg bw/day. This drinking water exposure is well above the EPA's reference dose of 0.0009 mg/kg bw/day for chromium VI (EPA, 2010). Given the high background levels of chromium VI in drinking water sources, 5% of the current RfD for chromium VI will be assumed to be available for food sources being evaluated using the HMS tool. The allowance of 5 % of the PTDI for the HMS Tool is based on the notion that when everything is contaminated to some extent (i.e. unavoidable risk) and the PTDI is exceeded it does not mean that the food/ingredient under consideration is unsafe for the following reasons: 1) the PTDI is based on chronic long term exposure and the relevant exposure durations for the HMS Tool is of shorter durations of 6 months to one year and 2) limited portion of the food supply is assumed to be affected.

Chromium VI	µg/kg bw/day	Reference
Exposure limit	0.9	EPA, 2010
Drinking water source	1.7	WHO, 1996 limit
Dietary sources		
<i>HMS tool portion</i>	<i>0.045 Assumed 5% of RfD</i>	

2.4 Lead

2.4.1 Existing Exposure Limits

The FDA (21 CFR 165.110) has established an allowable level of lead in bottled water of 5 ppb. FDA has developed safe/tolerable exposure levels or provisional total tolerable intake (PTTI) levels of lead for particular age and sex groups (Carrington and Bolger, 1992). The PTTI levels were established for the at-risk population groups of children, pregnant and lactating women and adult women. Blood lead levels of 30 µg/dL have been associated with elevated blood pressure and other adverse effects in adults. The dietary exposure that resulted in these blood levels of concern were estimated to be 60 µg/day for children age 6 years or younger (based on cognitive and related effects at blood levels of 10 µg/dL), 250 µg/day for pregnant women (based on 10 µg/dL in blood), and 750 µg/day for adults (based on 30 µg/dL in the blood). The PTTI levels were derived by applying a factor of 10 to obtain exposure levels that would include a margin of safety. The established PTTI levels were 6, 25, and 75 µg/day, respectively (i.e., 0.6 µg/kg bw/day (for a 10 kg child), <0.4 µg/kg bw/day (for a 60 kg child-bearing age or lactating females), and 1 µg/kg bw/day (for a 75 kg adult), respectively).

Exposure Limits – Lead		References
Provisional Total Tolerable Intake (PTTI)	6 µg/day (children 0-6yrs)	FDA (Carrington and Bolger, 1992)
	15 µg/day (children 7+ yrs)	
	25 µg/day (pregnant/lactating women)	
	75 µg/day (adults)	
Provisional Tolerable Weekly Intake (PTWI)	25 µg/kg bw/wk	JECFA, 1999 ** WITHDRAWN IN 2010
Provisional Tolerable Daily Intake (PTDI)	3.5 µg/kg bw/day	

2.4.2 Background Dietary Sources

Based on the FDA TDS, estimates of daily lead intake ranged from 0.8 µg/day among infants 6-11 months to 19.6 µg/day among adults (FDA TDS 1991-1996; Egan et al, 2002).

2.4.3 HMS Tool Portion

The FDA PTTI is used in the HMS tool. The default fraction of the PTTI remaining for use in the HMS tool is the portion of the PTTI remaining after intake from water and background dietary sources have been accounted for. Background lead intake estimates from the TDS (Eagan et al, 2002) were from 0.8 to 3.5 µg/day for infants, 2 and 6 yrs old (i.e. on average about 50% of the PTDI of 6 µg/day (when ND=0)). For children 10 yrs+ the background intake is ~ 4 µg/day (i.e. on average about 1/3 of the PTDI of 15 µg/day. Based on these background intake, 50% of the PTDI is assigned as background lead exposure for children and pregnant/lactating females. For adults, the background intake from the TDS is roughly 1/3 of the PTDI for adults, therefore, 2/3 of the PTTI will be available for the HMS tool.

	µg/day				References
	Children 0-6 yrs	Children 7+ yrs	Pregnant Lactating Females	Adults	
Lead					
Exposure limit PTTI	6	15	25	75	FDA (Carrington and Bolger, 1992)
Dietary sources & Drinking water source	3	7.5	12.5	25	50% of PTTI for vulnerable population; 2/3 of PTDI for adults
HMS tool portion	3	7.5	12.5	50	

2.5 Mercury

At JECFA's 63rd meeting, the expert committee withdrew the previous PTWI of 5 µg/kg bw per week and established a new PTWI for inorganic mercury of 4 µg/ kg bw per week. This level was based on the lowest BMDL₁₀ of 0.11 mg/kg bw per day as mercury (II) chloride for relative kidney weight increase in male rats corresponding to 0.06 mg/kg bw per day as mercury, adjusted for the dosing schedule and for the percent contribution of inorganic mercury to mercury (II) chloride dose with a 100-fold safety factor. This PTWI for inorganic mercury was "considered applicable to dietary exposure to total mercury from foods other than fish and

shellfish” (JECFA, 2011). In drinking water, the FDA has set a maximum allowable level of 0.002 mg/L for total mercury in bottled water (FDA, 2007).

The original PTWI of 3.3 µg/kg bw per week for methyl mercury was withdrawn and the new PTWI of 1.6 µg/kg bw per week was confirmed at JECFA’s 61st meeting in 2003 (JECFA, 2003). This PRWI for methyl mercury was based on developmental neurotoxicity endpoints in humans.

Exposure Limits – Mercury		References
PTWI (inorganic mercury “...but applicable to dietary exposure to total mercury”)	4 µg/kg bw (0.57 µg/kg bw/day)	JECFA, 2011
PTWI – methyl mercury	1.6 µg/kg bw/wk	JECFA, 2003
Drinking water limit	0.002 mg/L in bottled water	FDA, 2007
Oral reference dose (RfD) – methyl mercury, chronic	0.1 µg/kg bw/day	EPA (IRIS); last revised 2001

2.5.1 Background Dietary Sources

The mean estimated daily intake of total mercury in the US, based on the FDA TDS (2001-2006) is 0.06 µg/kg bw/day (0.14 µg/kg bw/day at the 90th percentile) for the US population 2+. Background average dietary exposure to total mercury using the 2001-2006 TDS survey was estimated to be 0.05 µg/kg bw/day (0.10 µg/kg bw/day at the 90th percentile) among women of childbearing age.

2.5.2 HMS Tool Portion

Based on the FDA’s maximum allowable level of 0.002 mg/L for total mercury in bottled water (FDA, 2007) and assuming 2L of water consumed per day, the estimated intake of total mercury from drinking water is 0.004 mg/day (or 0.067 µg/kg bw/day, assuming 60 kg bw). The default fraction of the PTDI that remain for use in the HMS tool is the portion of the PTDI remaining after intake from water and background dietary sources have been accounted for.

Mercury (Total)	µg/kg bw/day		References
Exposure limit (PTDI)	0.57		4 µg/kg bw/week (JECFA, 2011)
Drinking water source	0.067		Based on bottled water limit, FDA 2007
Dietary sources	<u>Mean</u>	<u>90th</u>	TDS 2001-2006 (US 2+)
	0.06	0.14	
<i>HMS tool portion</i>	<i>0.44</i>	<i>0.36</i>	

2.6 Additional Consideration

For contaminants such as **cadmium** and **mercury** where more than 50% of PTDI remains available for use in the HMS tool, it is highly possible that in situations involving food/ingredients with very small intake and very high levels of contaminants, the EDI would remain below the HMS portion of the PTDI. As such, for cadmium and mercury, further assessment should be made to ensure that not all of the remaining PTDI would be inappropriately assigned to a single or a few foods/ingredients with low intake. Further, when exposure limits exist for certain food/ingredients, such as those established by FCC, Codex, FDA, such limits must be followed and the HMS tool cannot be used to justify ingredient levels exceeding existing limits.

3 MODULE 2: DIETARY EXPOSURE ASSESSMENT

Dietary intake of a food component, such as a micronutrient, a food ingredient, such as a food additive, or a contaminant, such as a pesticide residue, is often indirectly estimated based on two parameters: 1) the concentration of the food component at the time of consumption ($C_f = \text{mg/kg}_{\text{food}}$) and 2) the amount of the food consumed ($L = \text{kg}_{\text{food}}/\text{day}$). To account for dietary intake of a contaminant from the consumption of multiple foods, Formula 1 is applied. Under this general framework, exposure to a contaminant can be estimated as either the product of an average consumption of a food and an average concentration of the contaminant in or on that food, or as the product of the probability distributions of food intakes and contaminant concentrations.

Formula 1:

$$E_t = \sum_i (C_f)_i (L)_i$$

i = number of different food types consumed.

C_f = concentration in foods (mg/Kg)

L = Amount of food consumed (kg/day)

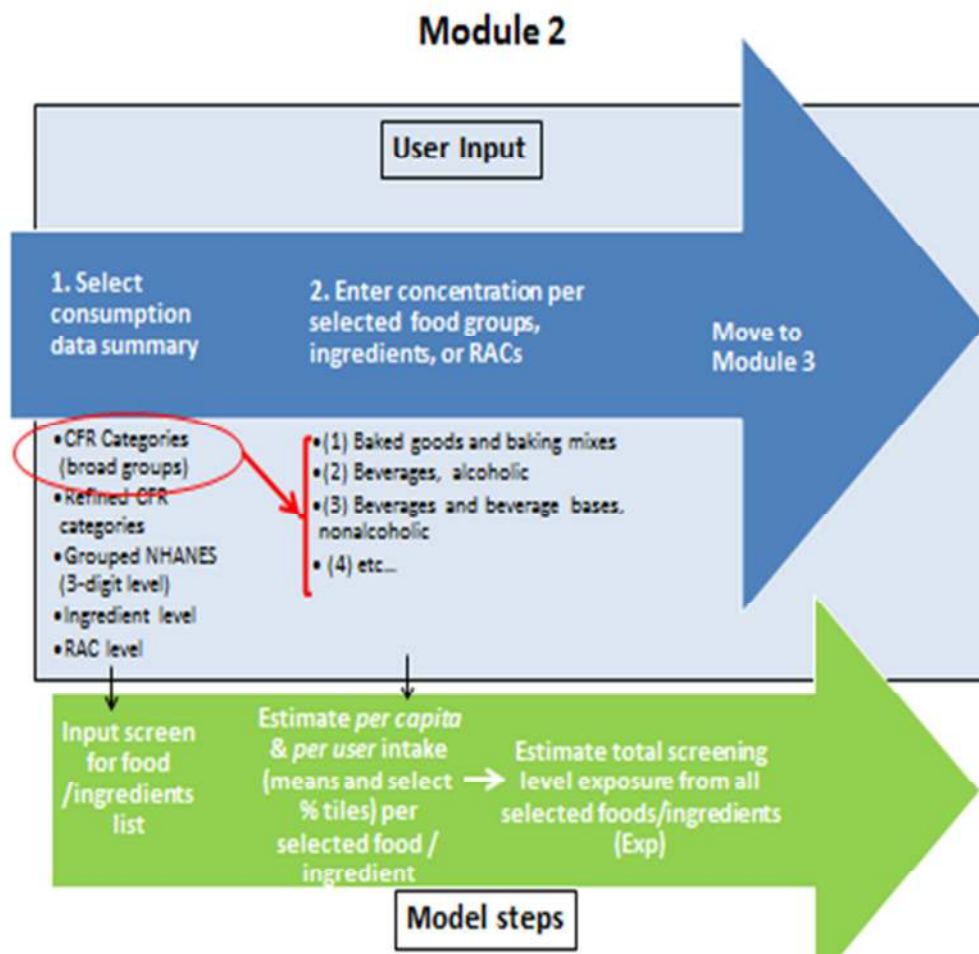
This two-component model (amount of food consumed and metal concentration) is incorporated in the exposure assessment module of the HMS Tool. The following sections describe these two model compartments in more details.

3.1 Concentration Data

The exposure assessment module is a spreadsheet model with data entry fields allowing user to enter metal concentration data for various foods or ingredient of interest using drop down menu screens. It is the responsibility of the user to assure that the concentration data being input into the model is accurate and that the user understands if the value being entered is representative of the food/ingredient being evaluated, or it is a worst case value based on assumption. The user would need to be able to document the reference sources from which

the concentration data were derived and supporting rationale if an assumed worst case value is being used.

Based on the user's selection of the types of foods or food ingredient of interest and user's concentration data entry, a behind the scene algorithm is applied to combine metal concentration to food/ingredient consumption rates to generate screening-level exposure estimates for the metal of concern.



3.2 Food Consumption Data

Presently, there are five options available in the HMS tool:

Option 1: . The National Health and Nutrition Examination (NHANES) 2005-2010 consumption data were pre-processed and aggregated into **45** categories reflecting the 21 CFR food categories.

Option 2: . The NHANES 2005-2010 consumption data were pre-processed and aggregated into **320 food categories** that provides more granularity to the 45 broad food categories used in Option 1

Option 3: The US EPA developed the Food Commodity and Ingredient Database (FCID) recipes that provide the breakdown of the NHANES 2003-2006 foods into raw agricultural commodities (RAC, e.g. wheat flour, raw apples, apple juice, etc...) and associated food forms (FF, e.g. fresh, canned, frozen, dried, etc...). These RAC and FF codes were aggregated into **353 RAC categories** under option 3.

Option 4: Foods from the FDA Total Diet Study (TDS Foods)

Option 5: Published FITS Data as reported in the US EPA Exposure Factor Handbook

More detail descriptions of the consumption data sources and associated food consumption estimates for the five options are summarized below.

3.2.1 NHANES 2005-2010

NHANES is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The NHANES interview includes demographic, socioeconomic, dietary, and health-related questions. The NHANES datasets provide nationally representative nutrition and health data and prevalence estimates for nutrition and health status measures in the U.S. As part of the examination, trained dietary interviewers collect detailed information on all foods and beverages consumed by respondents in the previous 24 hour time period (midnight to midnight). A second dietary recall is administered by telephone 3 to 10 days after the first dietary interview, but not on the same day of the week as the first interview.

In a traditional dietary exposure assessment, food consumption records collected as part of the NHANES would be accessed to obtain each NHANES individual's reported consumption of foods. However, for a screening exposure assessment, foods reported as consumed in the NHANES are aggregated into food categories and consumption estimates for the food categories are used. The foods reported consumed in NHANES are assigned numerical food codes and the 8-digit level food codes were mapped to food categories to reflect the 21 CFR170.3 food categories (option 1) and sub-categories (option 2).

3.2.1.1 Option 1: 21 CFR170.3 Food Categories

Foods reported consumed in NHANES 2005-10 were grouped into 45 broad grouping based on the 21CFR170.3 food categories (See Table 1). Consumption estimates for baby foods (including infant formula) and baby foods (excluding formula) and water were also included under option 1.

Table 1. Broad Grouping of NHANES Foods Based on 21CFR170.3 Food Categories

(-2) Baby water	(21) Fruit and water ices
(-1) Baby food	(22) Gelatins, puddings, fillings
(0) Water	(23) Grain products and pastas
(1) Baked goods and baking mixes	(24) Gravies and sauces
(2) Beverages, alcoholic	(25) Hard candy
(3) Beverages and beverage bases, nonalcoholic	(26) Herbs, seeds, spices, flavorings
(4) Breakfast cereals, RTE, instant, hot	(28) Jams and jellies, commercial
(5) Cheese	(29) Meat products, commercially processed
(6) Chewing gum	(30) Milk & Milk Products
(7) Coffee and tea	(31) Milk Products, drinks, dry, milk origin
(8) Condiments and relishes	(32) Nuts and nut products
(9) Confections and frostings	(33) Plant protein products, meat substitutes
(10) Dairy product analogs	(34) Poultry products, commercially prepared
(11) Egg products, liquid, frozen, dried, egg dishes	(35) Processed fruits and fruit juices
(12) Fats and oils	(36) Processed vegetables and vegetable juices
(13) Fish products	(37) Snack foods, chips, pretzels, salty snacks
(14) Fresh eggs and fresh egg products	(38) Soft candy

(15) Fresh fish	(39) Soups, home prepared
(16) Fresh fruits and fruit juices	(40) Soups and soup mixes, commercially prepared
(17) Meat, fresh and dishes from	(41) Sugar, white
(18) Fresh poultry and dishes from	(42) Sugar substitutes
(19) Fresh vegetables	(43) Sweet sauces, toppings and syrup
(20) Frozen Dairy Desserts	

Category #27 (home-prepared jams, jellies, fruit butters, preserves, and sweet spreads) was excluded

3.2.1.2 Option 2: 21CFR Food Sub-Categories

NHANES foods that were aggregated into the 45 broad food types according to the 21CFR170.3 food categories and the two baby food groups under option 1 were sub-categorized to generate a total of 320 food groups that provides more distinction about types of foods under option 2. For instance, within the broad category of “Soups and soup mixes, commercially prepared”, foods were divided into 6 categories: (i) cheese soups, (ii) grain-based soups, (iii) legume-based soups, (iv) meat-based soups/broth, (v) seafood-based soups/broth, and (vi) vegetable-based soups. Consumption estimates were derived for these 320 food categories and incorporated into the current version of the HMS Tool. Appendix A provides the lists these 320 food categories.

3.2.1.3 Intake Estimates

For each food category under options 1 and 2, two-day average food consumption estimates were derived for the total US population age 2+ y, Infants 6m to 2y, Children 2 to 6 y, Children 6 to 12 y, and Females 14 to 45 y. The two-day average daily intake was derived for each individual in the NHANES survey who reported consuming any food in each category on either of the survey days and individual’s responses for both survey days were used to estimate his/her 2-day average daily intake. For example, if a person reported consuming 100 grams of a food on day 1 and 50 grams on day 2, his/her 2-day average consumption for that food would be 75 grams $([100+50]/2)$. Statistically weighted values from the survey were used in the analyses. The statistical weights compensate for variable probabilities of selection, adjust for non-response, and provide intake estimates that are representative of the U.S. population and the selected age-gender subgroups.

Summary statistics of the two day average food intake rates, i.e. mean, 90th, 95th and 99th percentiles are derived on both a *per capita* and *per user* basis. The *per capita* approach includes all non-consumers and consumers of a food category in deriving the summary statistics and the *per user* approach includes only users in the derivation of the summary statistics. In this analysis, a “user” is anyone who reported consuming a food category on either of the survey days. This approach is consistent with the definition of “user” followed by the United States Department of Agriculture (USDA).

For each of the food types, intake estimates were derived on a g/day basis, and adjusted using average age specific body weight where necessary. Average age-specific body weights were derived from body weights reported in NHANES.

3.2.2 Option 3 – Raw Agricultural Commodities (RAC) Foods and the Commodity Intake Database (FCID)

US EPA and USDA have developed the Food Commodity Intake Database (FCID) that provides data on the edible amount of agricultural food commodities contained in each food reported eaten in the NHANES 2003-2006. FCID was developed for the purpose of estimating human exposure to pesticide residues through the consumption of foods and beverages. Food intakes in FCID are expressed in terms of raw agricultural commodities (RAC). For example, a piece of apple pie is translated quantitatively into the following commodities: wheat flour, peeled apple, sugar (from sugar cane or beet), cinnamon, and the specific vegetable oils comprising shortening. There are approximately 1200 RAC and associated food forms (e.g. fresh, canned, frozen, dried, etc...) in the FCID. For the HMS Tool, these 1200 RAC were grouped into 91 RAC categories as “baby foods” (see Appendix B), and 262 RAC categories in “regular” foods (see Appendix B).

For each RAC category under option 3, 2-day average food consumption estimates were derived for the total US population age 2+ y, Infants 6m to 2y, Children 2 to 6 y, Children 6 to 12 y, and Females 14 to 45 y. Summary statistics of the two day average food intake rates, i.e. mean, 90th, 95th and 99th percentiles are derived on both a *per capita* and *per user* basis. For

each RAC group, intake estimates were derived on a g/day basis, and adjusted using average age specific body weight where necessary. Average age-specific body weights were derived from body weights reported in NHANES.

3.2.3 Option 4 - Total Diet Study (TDS)

The Total Diet Study (TDS) is an ongoing FDA program that determines levels of various contaminants and nutrients in foods. A unique aspect of the TDS is that foods are prepared as they would be consumed (table-ready) prior to analysis, so the analytical results provide the basis for realistic estimates of the dietary intake of these analytes. The foods collected in the TDS represent the major components of the diet of the U.S. population. Currently, there are about 280 foods collected and analyzed in the TDS. FDA has derived estimates of consumption amounts for each of these foods based on data from USDA's 1994-96, 1998 Continuing Survey of Food Intakes by Individuals (CSFII). Each year of the 1994-96 CSFII comprises a nationally representative sample of non-institutionalized persons residing in the 50 States and Washington, DC. The 1998 CSFII was conducted to increase the 1994-96 CSFII sample for children. The 1994-96 and 1998 CSFII were conducted using the same methodology and can be combined for analysis. The CSFII data include a sample weight for each respondent, indicating the number of people the sample represents. In the CSFII, 2 nonconsecutive days of dietary data for individuals of all ages were collected 3 to 10 days apart through in-person interviews using 24-hour recalls. The 1994-96 CSFII data set includes information on the food intakes of 15,303 individuals, while the 1998 CSFII data set includes 5,559 children up to age 9. The respondents in the CSFII provided a list of foods consumed. Over 5,000 different foods were reported in the CSFII, these foods were grouped according to their similarity to TDS foods and a "mapping" file was created and each survey food was assigned to one of the TDS foods. Average per-capita daily consumption amounts were calculated for each TDS food, based on the intake of the corresponding (mapped) survey foods. Appendix C lists the 286 foods in the TDS. It is likely that consumption patterns have changed since 1994-98 when the CSFII data were collected, and although there are more recent consumption surveys, to our knowledge FDA has not yet developed TDS consumption values based on these more recent data.

3.2.4 Option 5 - Feeding Infants and Toddlers Study (FITS) Data

Published food intake for infants and toddlers age 4 – 24 months from the Feeding Infants and Toddlers Study (FITS) 2002 as summarized in the US EPA's Exposure Factor Handbook (EPA 2011) were adopted into the HMS Tool. The FITS data were cited in chapter 9 (intake of fruits and vegetables), chapter 11 (meat, dairy products, and fats), and chapter 12 (grain products) of the EPA's Exposure Factor Handbook. The FITS was sponsored by Gerber Products Company and was conducted to obtain current information on food and nutrient intakes of children, ages 4 to 24 months old, in the 50 states and the District of Columbia. FITS was based on a random sample of 3,022 infants and toddlers for which U.S. The *Exposure Factors Handbook* provides information on various physiological and behavioral factors commonly used in assessing exposure to environmental chemicals. The handbook was first published in 1989 and was updated in 1997 and again in July 2011.

Average portion sizes consumed per eating occasion by children 4 to 24 months of age who participated in the FITS and percent of participants who are consumers of the major food groups, including fruits and vegetables, meat, dairy products and fats, grain products are reported in the handbook. Reported portion sizes (e.g. teaspoon, cup, etc...) were converted to gram per eating occasion based on the USDA NDB SR23. Children were grouped into six age categories: 4 to 5 months, 6 to 8 months, 9 to 11 months, 12 to 14 months, 15 to 18 months, and 19 to 24 months. Foods with reported intake from FITS, summarized in the EPA's Exposure Factor Handbook and incorporated in the HMS Tool are summarized in Table 2.

Table 2. FITS Foods included in HMS tool

Infants 4-11 months	Infants 12 months – 24 months
100% juice	100% juice
Baby food applesauce	Beef
Baby food bananas	Bread
Baby food desserts	Candy
Baby food dinners	Canned fruit
Baby food green beans	Cheese

Baby food peaches	Chicken or turkey, plain
Baby food pears	Chicken nuggets
Baby food squash	Cookies
Baby food sweet potatoes	Corn
Baby foot carrots	Crackers
Bread	Deep yellow vegetables
Canned fruit	Fresh apple
Cheese	Fresh banana
Cooked vegetables, excluding French Fries	Fresh grapes
Mashed Potatoes	Frozen milk desserts and puddings
Cookies	Green beans
Crackers	Hot cereal, prepared
Fresh fruit	Hot dogs, luncheon meats, sausages
Infant cereal, dry	Infant formula
Infant Formula	Mashed potatoes
Non baby food meats	Milk
Ready to eat cereal	Pancakes and waffles
Scrambled eggs	Pasta
Sweetened beverages	Peanut butter
Yogurt	Peas
	Ready to eat cereal
	Rice
	Rolls
	Salty snacks
	Scrambled eggs
	Sweetened beverages
	Syrup, jam, jelly, preserves, honey
	Yogurt

3.3 Estimating Exposures

In the HMS Tool, exposure to a contaminant in a given food type (estimated daily intake, EDI) is estimated as the product of a mean, 90th, 95th or 99th percentile consumption estimate and the contaminant concentration in that food that have been entered by the user. For exposure scenarios when multiple food categories are involved, total exposure from the combined food categories are derived as followed:

Per capita mean: sum of *per capita* means for individual foods

Percent users: The maximum percent users across all food categories included in the assessment is used as a conservative estimate of the combined percent users from any of the food categories included in the assessment.

Per user mean: ratio of per capita mean /combined percent users

Per user percentiles: using FDA guidance for estimating pseudo percentiles:

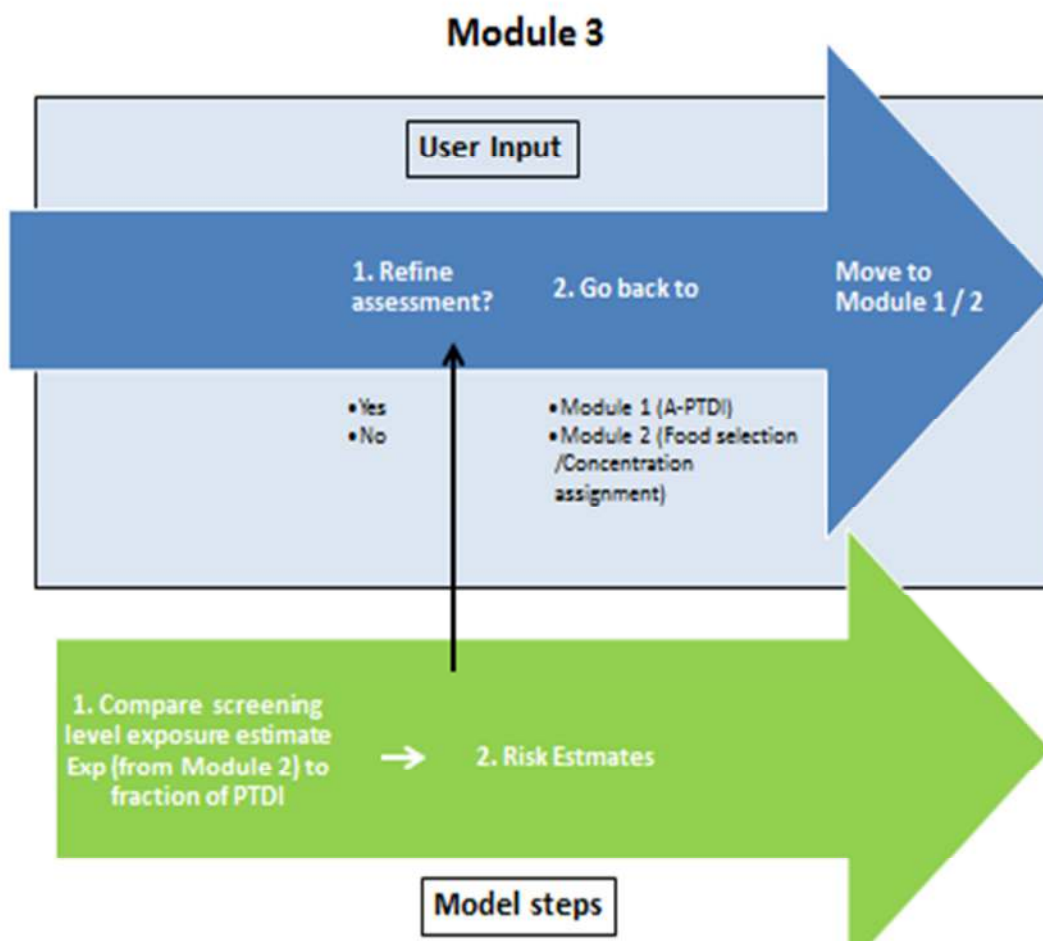
90th percentile = 2 x per user mean; 95th percentile = 4 x mean. No guidance for 99th percentile: the Tool assumes 99th percentile = 6 x mean

Per capita percentiles: No guidance is available from FDA, the Tool uses the same approach as for *per user* percentiles.

MODULE 3: RISK CHARACTERIZATION

In the risk characterization module, two types of risk estimates can be derived:

1) Exposure as a Percent of the PTDI: The screening-level estimated daily intakes (EDIs) from module 2, on both the *per capita* and *per user* basis, are compared to the fraction of the PTDI available to HMS tool after accounting for the fraction assigned to background exposures from food and water. Screening-level risk estimates are expressed as a % of the available PTDI fraction.



2) Maximum Number of Servings per day: Exposure to the metal contaminant on a per serving basis is derived using either the default 21CFR RACC serving sizes or user's input

serving size. If a food category includes multiple foods with varying RACC serving sizes, the model applies the mode (i.e., most common serving size). Based on the per serving exposure estimates and the fraction of the PTDI available to HMS tool after accounting for the fraction assigned to background exposures from food and water, the maximum number of servings per day is generated (i.e. available PTDI fraction/per serving exposure). For Chromium and Lead, the PTDI's were provided on the $\mu\text{g}/\text{kg bw}/\text{day}$ basis, as such they were converted to $\mu\text{g}/\text{day}$ using the following age-specific default body weight derived from the NHANES 2005-2010:

Age group	Average BW (kg)
US 2+	71.1
Infants 6m-2y	10.5
Children 2-6 y	18.5
Children 7-12 y	39.2
Women of Child-Bearing Age (WCBA)	72.3
FITS Data:	
4-5m	7.7
6-8m	8.5
9-11m	9.6
12-14m	10.2
15-18m	11
19-24m	12.2

When multiple food categories are under consideration, two estimates of the maximum number of servings can be generated:

1. The first estimate is based on assigning the entire fraction of the PTDI that is available to the HMS Tool independently to each food category in the assessment, i.e. total exposure from all foods involved is not considered.
2. The second estimate is based on apportioning the fraction of the PTDI available for the HMS tool to all the foods included in the assessment. The fraction apportioned to each food category is proportional the contribution of each category to the total *per capita* daily mean intake estimates when NHANES data are used, and in when FITS data used, based on percent consumers since per capita estimates are not available for these data.

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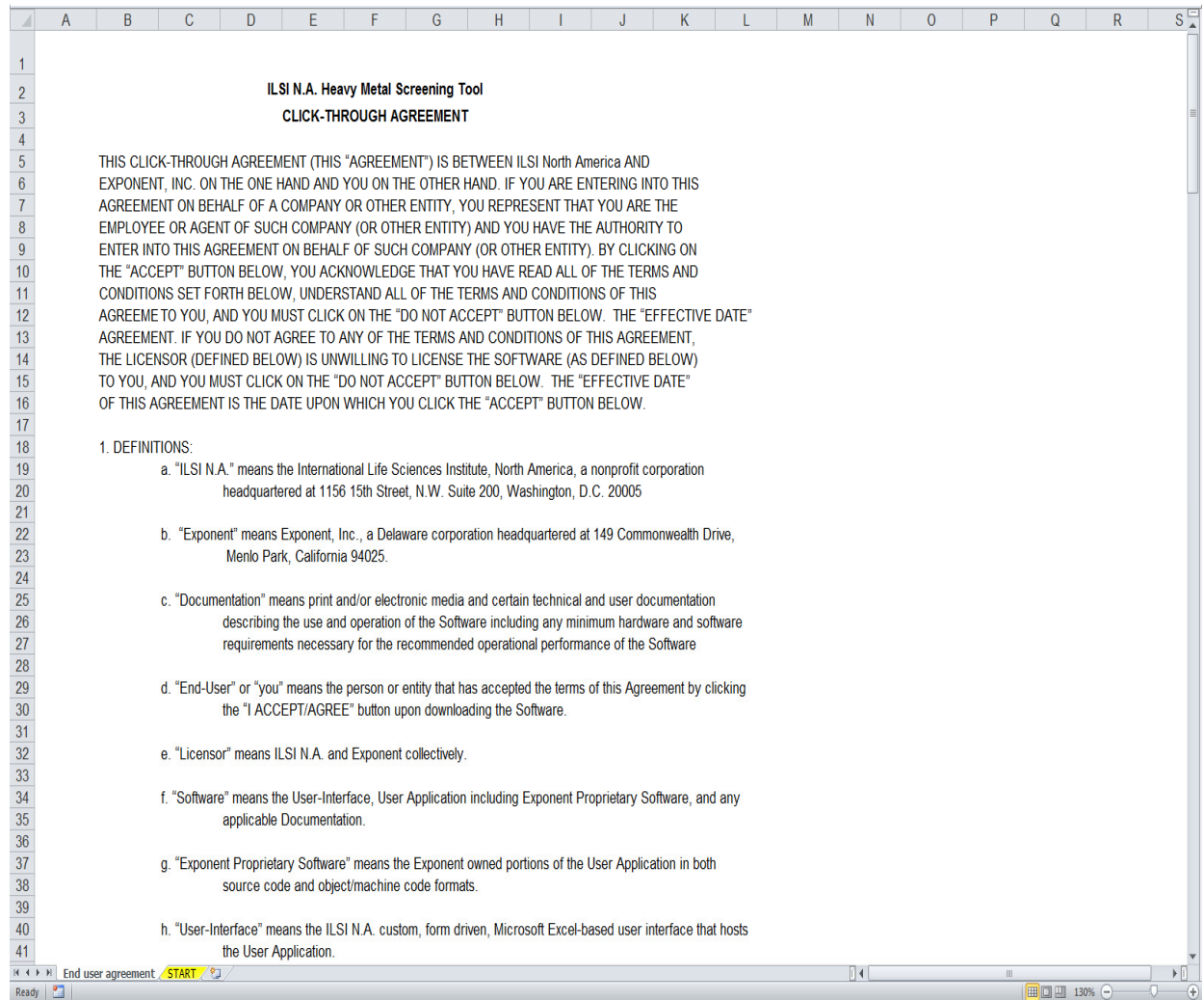
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5 USER'S GUIDE

Administrative Screen: Before beginning using the HMS Tool, the user is required to read and “accept” the End user agreement.

Once acceptance is completed the user is taken to the “START” screen.



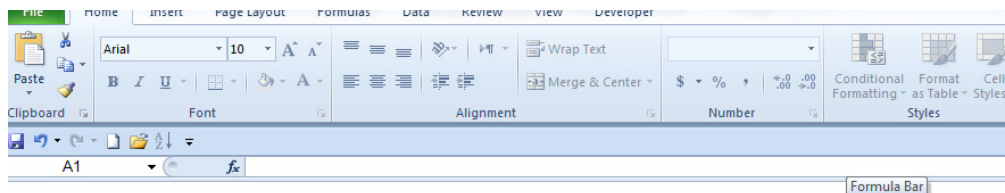
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199	of Deny Orders. By downloading or using the Software, you are agreeing to the foregoing and you represent and																		
200	warrant that you are not located outside of the United States, located in, under the control of, or a national or																		
201	resident of any such country or on any such list.																		
202																			
203	15. TERMINATION. This Agreement may be terminated by Licensor at any time on three (3) days notice (which																		
204	may be posted to the Website) and by End-User on thirty (30) days written notice. Notwithstanding the foregoing,																		
205	Licensor shall have the right, in addition to any other rights and remedies available to Licensor, to terminate this																		
206	Agreement effective immediately upon written notice to End-User if End-User violates Licensor's intellectual																		
207	property rights, the restrictions in Section 3 or the obligations of Sections 4 and 7. End-User agrees that in the																		
208	event this Agreement is terminated, in whole or in part, End-User shall cease using and remove, destroy, or return																		
209	to Licensor the Software and all parts thereof, including all copies, modifications and merged portions, regardless																		
210	of form. In the event that End-User fails to remove, destroy or return the Software as set forth above, Licensor																		
211	shall have the right to enter the End-User's premises to the extent allowed by law to access the End-User's																		
212	computer systems for the purpose of removing or destroying the Software. In addition to all definitions and this																		
213	sentence, the following sections will survive any termination or expiration of this Agreement: 3, 4, 5, 6, 7, 8, 9, 10,																		
214	11, 13, 15, 16 and 17.																		
215																			
216	16. SEVERABILITY. Should any section or any part of a section within this Agreement be rendered void, invalid																		
217	or unenforceable by any court or law for any reason, such invalidity or unenforceability shall not void or render																		
218	invalid or unenforceable any other section or part of a section to this Agreement.																		
219																			
220	17. GOVERNING LAW. This Agreement will be governed by the law of the State of California without regard to its																		
221	principles of conflicts of laws. The parties stipulate and agree that any litigation arising from or relating to this																		
222	Agreement will be filed and prosecuted before a court of competent subject matter jurisdiction in Santa Clara																		
223	County, California. The parties consent to the jurisdiction of such courts over them, stipulate to the convenience,																		
224	efficiency and fairness of proceeding in such courts, and covenant not to assert any objection to proceeding in																		
225	such courts based on the alleged inconvenience, inefficiency or unfairness of such courts.																		
226																			
227	18. ENTIRE AGREEMENT. This Agreement is the complete and exclusive statement of the agreement between																		
228	Licensor and End-User, superseding all prior agreements, representations, proposals, oral or written, and all other																		
229	communications between the parties relating to the subject matter hereof. All terms and provisions of this																		
230	Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective permitted																		
231	transferees, successors and assigns. This Agreement may be modified by Licensor from time to time, and any																		
232	changes will be posted to the Website.																		
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I ACCEPT/AGREE

I DO NOT ACCEPT

End user agreement
START

START Screen: In this screen, user will reset the program and starting a new assessment



"HEAVY METAL SCREENING TOOL"

Under contract with ILSI North America, Exponent developed this Heavy Metal Screening tool (the HMS tool) to derive screening level exposure and risk estimates for food and food ingredients using a risk-based approach. The five heavy metals that are of interest and included in the tool are inorganic arsenic, cadmium, chromium, lead, and mercury. Exposure situations are assumed to be have duration of six months to one year and US based. Specifically the HMS tool was constructed with three key components of a risk assessment process, including three modules: 1) hazard characterization, 2) dietary exposure assessment and 3) risk characterization.

WARNING: The HMS tool is a screening tool using default assumptions. User must always check the concentration levels versus existing regulatory limits. The HMS tool cannot be used to override these existing regulatory limits.

Module 1	In the hazard chacterization module (Module 1) , a default portion of existing exposure limits such as the Provisional tolerable daily intake (PTDI) is established as available for use in the HMS tool for each of the metals of interest. This HMS tool portion of the PTDI is the remaining portion after accounting for existing dietary exposure (food and water). Default PTDI values and associated fractions assigned to background exposures are incorporated into the HMS tool. However, to allow for flexibility to account for emerging science, the user has the option to input alternative exposure limits based on the latest science, and/or to select the relevant background (food and drinking water) exposure to be accounted for in setting the exposure limits (e.g., whether only background drinking water exposure or dietary exposure should be included or both).
Module 2	The dietary exposure assessment module (Module 2) , uses food consumption data from the 2005-10 National Health and Nutrition Examination Surveys (NHANES) in combination with user provided concentration data to derive screening level exposure estimates. The NHANES consumption data have been pre-processed an aggregated into food categories. The user has the option to select the food aggregation level that best suits the contamination data available and exposure scenario under consideration. <u>Aggregated food consumption data:</u> Option 1: NHANES food consumption data were aggregated into 43 categories reflecting the 21 CFR food categories. Option 2: NHANES food consumption data were aggregated into 312 categories that refine the 43 broad 21 CFR food categories used in Option 1. Option 3: Foods reported consumed in NHANES were disaggregated into their various ingredients (e.g., wheat flour, raw apples, apple juice, etc.) using the Food Commodity and Ingredient Database (FCID) recipes developed by US EPA. The FCID recipes breakdown the NHANES food codes into about 1,200 Raw Agricultural Commodities (RAC) and associated food forms (FF) (e.g., fresh, canned, frozen, dried, etc.). The 1,200 RAC and FF codes were grouped into 353 categories and consumption estimates were derived for these categories. Note that the FCID recipes are currently available for NHANES 2003-06 data, hence consumption estimates for the RAC food categories were derived for NHANES 2003-06. Option 4: Foods from Total Diet Study (TDS Foods) - Note that TDS data are only <i>per capita</i> data and that the publicly available consumption data are for CSFII 1996-98 Option 5: Publicly Available Published FITS Data for % users and per serving amounts Two-day average consumption estimates were derived for the total US population age 2+ y, infants 6m to 2y, Children 2 to 6 y, Children 6 to 12 y, and Females 14 to 45 y. Estimates were derived on a g/day basis, and adjusted using average age specific body weight where necessary. Average age-specific body weights were derived from body weights reported in NHANES. Intakes per day: Exposure estimates are derived on a <i>per capita</i> and <i>per user</i> basis. Total estimates for multiple food categories are derived as follow: Per capita mean: sum of <i>per capita</i> means for individual foods Percent users: The maximum percent users across all food categories included in the assessment is used as a conservative estimate of the combined percent users from any of the food categories included in the assessment. Per user mean: per capita mean /combined percent users Per user percentiles: using FDA guidance for estimating pseudo percentiles: 90th percentile = 2 x per user mean; 95th percentile = 4 x mean. No guidance for 99th percentile: the Tool assumes 99th percentile = 6 x mean



Microsoft Excel interface showing a table with two modules and their descriptions.

Module	Description
Module 2	<p>Option 2: NHANES food consumption data were aggregated into 312 categories that refine the 43 broad 21 CFR food categories used in Option 1.</p> <p>Option 3: Foods reported consumed in NHANES were disaggregated into their various ingredients (e.g., wheat flour, raw apples, apple juice, etc.) using the Food Commodity and Ingredient Database (FCID) recipes developed by US EPA. The FCID recipes breakdown the NHANES food codes into about 1,200 Raw Agricultural Commodities (RAC) and associated food forms (FF) (e.g., fresh, canned, frozen, dried, etc.). The 1,200 RAC and FF codes were grouped into 353 categories and consumption estimates were derived for these categories. Note that the FCID recipes are currently available for NHANES 2003-06 data, hence consumption estimates for the RAC food categories were derived for NHANES 2003-06.</p> <p>Option 4: Foods from Total Diet Study (TDS Foods) - Note that TDS data are only <i>per capita</i> data and that the publicly available consumption data are for CSFII 1996-98.</p> <p>Option 5: Publicly Available Published FITS Data for % users and per serving amounts</p> <p>Two-day average consumption estimates were derived for the total US population age 2+ y, Infants 6m to 2y, Children 2 to 6 y, Children 6 to 12 y, and Females 14 to 45 y. Estimates were derived on a g/day basis, and adjusted using average age specific body weight where necessary. Average age-specific body weights were derived from body weights reported in NHANES.</p> <p>Intakes per day:</p> <p>Exposure estimates are derived on a <i>per capita</i> and <i>per user</i> basis. Total estimates for multiple food categories are derived as follow:</p> <p>Per capita mean: sum of <i>per capita</i> means for individual foods</p> <p>Percent users: The maximum percent users across all food categories included in the assessment is used as a conservative estimate of the combined percent users from any of the food categories included in the assessment.</p> <p>Per user mean: per capita mean /combined percent users</p> <p>Per user percentiles: using FDA guidance for estimating pseudo percentiles: 90th percentile = 2 x per user mean; 95th percentile = 4 x mean. No guidance for 99th percentile: the Tool assumes 99th percentile = 6 x mean</p> <p>Per capita percentiles: No guidance is available from FDA, the Tool uses the same approach as for <i>per user</i> percentiles.</p>
Module 3	<p>In the risk characterization module (Module 3), the per day exposure estimates are compared to the fraction of the PTDI available to HMS tool after accounting for the fraction assigned for background exposures from food and water.</p> <p>In addition exposure estimates on a per serving basis are also derived and compared to the fraction of the PTDI available for the HMS Tool and an estimate of the maximum number of servings "allowable" is derived. The Tool uses default CFR serving sizes (if a food category includes multiple foods with varying CFR serving sizes, the model uses the mode (i.e., most common serving size)). The user has the option of providing alternate default serving sizes.</p> <p>Two estimates of the maximum number of servings are provided:</p> <p>The first assumes the entire fraction of the PTDI that is available to the HMS Tool is assigned independently to each food category in the assessment</p> <p>The second apportions the fraction of the PTDI available for the HMS tool to all the foods included in the assessment. The fraction apportioned to the individual food categories is proportional the contribution of each category to the per capita daily mean intake</p>

START (Go to Module 1) Reset

End user agreement START

In the Start screen the user should click on "Reset" to delete all user entered data from the previous round and then click on "START (Go to Module 1)" to get started – this would take the user to Module 1 - Step 1

Module 1 - Step 1: Selection of Compound and PTDI

MODULE 1: Step 1			
Select compound and PTDI			
Select compound	Inorganic Arsenic		
Use Default PTDI?	No		
Please Enter User Assigned PTDI			
Compound	PTDI		Explanation
Inorganic Arsenic	0.02	ug/kg/day	
Go to Module 1: Step 2			

Hint to Users:

Click the cell to view and select options from drop down menu

Requires user data entry

HMS Tool - do not change

[Help](#)

In Module 1 - Step 1 the user will first select the compound from a drop down menu. Once the compound is selected the user then selects whether the default PTDI will be used in the assessment or not. If "Yes" (default) is selected, the model provides the user with the default PTDI and rationale and the user can move to Model 1 Step 2 by clicking on "Go to Module 1 Step 2". If the user select "No" the screen changes into a data entry screen where user will need to enter the alternative PTDI and provide supporting rationale for the alternative PTDI.

The user will not be allowed to move to Model 1 step 2 unless either the default PTDI has been selected or an alternative PTDI has been entered.

Module 1 Step 2: Review/Modify Fraction of PTDI Assigned to Background

MODULE 1: Step 2			
View and/or Modify Default PTDI Fraction Assigned to Background Exposure from Food and Water			
Use Default Fraction of PTDI?	No		
Please Enter User Assigned Fraction to Background			
Compound	Assigned to Background	Rationale	
Inorganic Arsenic	0.0102	ug/kg/day	
Go to Module 1: Step 3			

Hint to Users:

Click the cell to view and select options from drop

Requires user data entry

HMS Tool - do not change

[Help](#)

In Module 1 - Step 2 the user will have the option of either accepting the default fraction assigned to background or entering an alternative background value. If user select “Yes” (default background), the model applies the default fraction and rationale and the user can move on to Model 1 Step 3 by clicking on “Go to Module 1 Step 3”. If the user selects “No” to the default background, the screen changes into a data entry screen where users will need to enter the alternative background fraction and provide a rationale for the alternative value.

Note that user cannot move to Model 1 Step 3 unless the default fraction has been selected or an alternative background fraction has been entered.

Module 1 Step 3: Review Hazard Data Summary

MODULE 1: Step 3		
Review Selected PTDI and Fraction Assigned to HMS Tool		
Compound	PTDI	Rationale
Inorganic Arsenic	0.02 ug/kg/day	User assigned: No rationale
Compound	Assigned to Background	Rationale
Inorganic Arsenic	0.0102 ug/kg/day	User assigned: No rationale
Compound	Assigned to HMS Tool	
Inorganic Arsenic	0.0098 ug/kg/day	

Hint to Users:

HMS Tool - do not change

[Help](#)

Go back to Module 1: Step 1
Go back to Module 1: Step 2
Accept and Go To Module 2 - Step 1
Print/Save

In Module 1 - Step 3 the user will see a summary of their selections in Steps 1 and 2 and the value assigned to the Tool. User will review the selected PTDI and fraction assigned to background (whether default or user specified) and the rationale, and the fraction available to the Tool. User will have the option of going back to Module 1 Step 1 or Accepting and moving to Module 2 Step 1. Note that if user has entered a background value that exceeds the PTDI the model will return an error message and will not allow user to proceed to module 2. The user can also print or save the table into a PDF file. Note that the user would need to set their print option prior to clicking the "Print/Save". Specifically, the user needs to go to "File"/"Print" and select from the list of printers available to them or select the PDF option.

Module 2 - Step 1: Selection of Consumption Data Base and Food Types

MODULE 2: Step 1: Select food

Select food consumption data

Select food consumption data for use in assessment

CFR (sub-categories)

Enter search term below to help in selecting foods

cheese Search Reset

Hint to Users:
Click the cell to view and select options from drop down menu
Requires user data entry
[Help](#)

Go to Module 2 - Step 2

CFR (sub-categories)	To Select Foods Choose "Yes" from Drop Down List
(1) (20) Baked goods and baking mixes, pastry - fruit or cheese filled	
(5) (1) Cheeses, natural, processed, spread, dip, cheese spread	
(5) (2) Cheeses, natural, processed, spread, dip, Cheese, other	
(5) (3) Cheeses, natural, processed, spread, dip, cottage cheese	Yes
(5) (4) Cheeses, natural, processed, spread, dip, Natural cheeses, regular and dry grated	
(5) (5) Cheeses, natural, processed, spread, dip, Processed cheeses	
(5) (6) Cheeses, natural, processed, spread, dip, ricotta cheese	
(33) (6) Plant protein products, meat substitutes, soy cheese, yogurt, dessert	
(40) (1) Soups and soup mixes, commercially prepared, Cheese soups	

In Module 2 - Step 1 the user will first select the consumption data for use in the assessment. The user has the option of selecting "CFR categories", "CFR Refined categories" "Raw agricultural commodities", "FITS data (4-11m)" or "FITS data (12-24m)" from a drop down menu. Once the consumption database is selected the list of "foods" available in this database pops up. The user have two options to select foods; 1) go through the entire list and select "Yes" for the foods of interest or 2) enter a search term and the food list gets filtered on the foods that have names containing the search term and then user can select "Yes" for foods of interest. The user can repeat the process until all foods of interest have been selected. Once food selection is completed, click on "Go to Module 2 Step 2". Note that users would not be allowed to move to Module 2 Step 2 unless at least 1 food has been selected.

Module 2 - Step 2: Enter Concentration Data

[illegible]

In Module 2 - Step 2 the user enter the concentration data for the foods that were selected in step 1. Before entering concentration data, the user will be asked to answer the following questions using a drop down menu in the HMS Tool with answering option as “yes” or “no”:

1. Are the concentration data for the finished product (e.g., baked goods) or for an ingredient (e.g., flour) in a finished product. This feature is not applicable if the database selected in Module 2 Step 1 was “Raw Agricultural Commodities” since the foods in the FCID database are food ingredients.
2. If the available concentration data are for inorganic arsenic or total arsenic. This second question is only applicable if the compound selected in Module 1 Step 1 was “inorganic arsenic”.

After answering the applicable questions, the user will need to enter the concentration data detected in the food. If ingredient was selected in answering the above questions, the user is

also given the option of entering the % ingredient in the finished product. If the user does not enter a % ingredient, the model assumes 100%.

For arsenic, since the default PTDI in module 1 is based on inorganic arsenic, if the user is working with concentration data for total arsenic, the user is given the option to enter the fraction of the total arsenic concentration data that would be inorganic arsenic. Estimated fractions of total arsenic that are inorganic arsenic for various foods found in the published literature can be viewed in the HMS Tool. The model automatically assumes 100% of the concentration data entered as inorganic arsenic when fraction data are not entered.

Once the concentration data are entered the user can go to Module 2 step 3. Note that the user cannot move to Module 2 Step 3 unless concentration data for all foods that were selected in Module 2 Step 1 have been entered.

Module 2 Step 3: Review and Change Default Serving Size

[illegible]

In Module 2 step 3 the user will review the default CFR RACC serving sizes assigned to finished products. This feature is only applicable if “CFR (categories)” or “CFR sub-categories” options were selected in Module 2 Step 1. The user has the option of accepting the default CFR RACC serving sizes, or entering alternative serving sizes.

Module 2 Step 4: Review Selected Inputs for Module 2

MODULE 2: Step 4				
Review Selected Foods, Assigned Concentrations and Default Serving Sizes (if Applicable)				
Consumption data selected: CFR (sub-categories)				
Contaminant data available at: Ingredient level				
Contaminant data available as: Total arsenic				
CFR (sub-categories): Selected foods	Assigned concentration (ppm)	Assigned RACC serving size (g)	% Ingredient in Finished Product	Conversion Factor to Inorganic Arsenic
(1) (10) Baked goods and baking mixes, cake, cupcakes 80 g serving size	0.003	80	5%	5%
(5) (3) Cheeses, natural, processed, spread, dip, cottage cheese	0.002	110	100%	5%
(30) (1) Milk fluid, whole, skim, Lowfat	0.001	240	100%	5%

Go back to Module 2: Step 1

Accept and View Results

Print/Save

In Module 2 Step 4 the user reviews the selections in Steps 1-3 of Module 2, i.e., consumption data, food types, contaminant concentration entered, % ingredient (if applicable), and % inorganic arsenic (if applicable). In this step the user has the option to: “Accept and View results” or go back to “Module 2 step 1” to make corrections. The user can also print/save the data entry in module 2. As mentioned earlier the user needs to set their print option prior to clicking the “Print/Save”.

When the “Accept and View Results” option is selected, the user will be taken to the Module 2 – Estimated Daily Intake Result Summary screen, unless the two FITS data options were selected, in which case the user will be taken to the “FITS estimates” screen.

Module 2 - Estimated Daily Intake Result Summary

Results: Estimated Daily Intake of Inorganic Arsenic (ug/kg/day) Using Consumption Estimates from CFR (sub-categories)								
Subpopulation	PTDI	Assigned to Background	Available for HMS tool	Per Capita (%tiles estimated using multiplier approach)				
				% users	Mean	90th percentile	95th percentile	99th percentile
US 2+	0.02	0.0102	0.0098	36%	0	0	0	0
INFANTS 6m - 2y	0.02	0.0102	0.0098	7%	0	0	0.001	0.001
Children 2-6 y	0.02	0.0102	0.0098	54%	0.001	0.002	0.003	0.004
CHILDREN 7 -12	0.02	0.0102	0.0098	52%	0	0	0.001	0.001
FEMALES 14-45	0.02	0.0102	0.0098	32%	0	0	0	0
Subpopulation	PTDI	Assigned to Background	Available for HMS tool	Per User (mean estimated using minimum % users for all food groups & %tiles estimated using multiplier approach)				
				% users	Mean	90th percentile	95th percentile	99th percentile
US 2+	0.02	0.0102	0.0098	36%	0	0	0.001	0.001
INFANTS 6m - 2y	0.02	0.0102	0.0098	7%	0.002	0.004	0.008	0.013
Children 2-6 y	0.02	0.0102	0.0098	54%	0.001	0.003	0.006	0.008
CHILDREN 7 -12	0.02	0.0102	0.0098	52%	0	0.001	0.001	0.002
FEMALES 14-45	0.02	0.0102	0.0098	32%	0	0	0.001	0.001

Print/Save Results

Compare to PTDI Fraction (Go to Module 3)

In this screen, the user will be able to view the estimated daily intake (EDI) (in $\mu\text{g}/\text{kg}$ bw/day or $\mu\text{g}/\text{day}$ in the case of lead and chromium), on the *per capita* and *per user* basis, based on the data that were selected/entered in modules 1 and 2. The PTDI and fraction assigned to background and the fraction of the PTDI available for the HMS tool are also summarized on this view screen. The user can “print” the results either to a printer (or a pdf file). As mentioned earlier the user needs to set their print option prior to clicking the “Print/Save Results”.

After reviewing the EDI in this screen, the user can select to proceed to “Compare to PTDI Fraction (Go to Module 3).”

Module 3 – Risk Characterization Results

In module 3, the user will be presented with two types of risk characterization results: 1) EDI as a % of the fraction of the PTDI available for the HMS Tool, and 2) the maximum number of servings per day. User should be noted that the second risk characterization output is not available when TDS and RAC foods are selected in module 2.

1. Review EDI as % of PTDI fraction available for the Tool

Results: Estimated Daily Intake of Inorganic Arsenic as % of Available PTDI Fraction Using Consumption Estimates from CFR (sub-categories)								
Subpopulation	PTDI	Assigned to Background	Available for HMS tool	Per Capita (%tiles estimated using multiplier approach)				
				% users	Mean	90th percentile	95th percentile	99th percentile
US 2+	0.02	0.0102	0.0098	36%	0%	0%	0%	0%
INFANTS 6m - 2y	0.02	0.0102	0.0098	7%	0%	0%	10%	10%
Children 2-6 y	0.02	0.0102	0.0098	54%	10%	20%	31%	41%
CHILDREN 7 -12	0.02	0.0102	0.0098	52%	0%	0%	10%	10%
FEMALES 14-45	0.02	0.0102	0.0098	32%	0%	0%	0%	0%
Subpopulation	PTDI	Assigned to Background	Available for HMS tool	Per User (mean estimated using minimum % users for all food groups & %tiles estimated using multiplier approach)				
				% users	Mean	90th percentile	95th percentile	99th percentile
US 2+	0.02	0.0102	0.0098	36%	0%	0%	10%	10%
INFANTS 6m - 2y	0.02	0.0102	0.0098	7%	20%	41%	82%	133%
Children 2-6 y	0.02	0.0102	0.0098	54%	10%	31%	61%	82%
CHILDREN 7 -12	0.02	0.0102	0.0098	52%	0%	10%	10%	20%
FEMALES 14-45	0.02	0.0102	0.0098	32%	0%	0%	10%	10%

Print/Save Results Go to Start Go to Module 2 View Intake Results on Per Serving Basis

In this screen, the user can review the EDI (*per capita* and *per user*) as % of the PTDI fraction available for tool. The user can “print” the results either to a printer (or a pdf file). If changes need to be made to data entry, user can return to module 2. As mentioned earlier, the user needs to set their print options before clicking on the “Print/Save Results” button.

From this screen the user can select to go to the next screen to “view the results at the per serving level”

2. Review Maximum Number of Servings per Day

In this result screen the user can review the estimated exposure on the per serving basis and the number of maximum number of servings per day given the PTDI fraction available for the Tool. This type of risk characterization is not applicable if the user had selected TDS, RAC, or FITS foods in Module 2 Step 1. Five summary tables (one for each population subgroup) can be viewed in this screen (scrolling across columns). Each table includes the selected PTDI, background fraction and fraction remaining for the tool. It also lists the foods selected in module 2 Step 1, the selected serving size and the estimated exposure corresponding to one serving. The maximum number of servings consumed per day that would take up the entire PTDI fraction available to the HMS Tool is also provided in these summary tables. Two types of estimates of are provided:

1. The first is on a single food basis – which provides the maximum number of daily servings that would take up the entire available PTDI fraction when assuming that only one food is contaminated.
2. The second estimate allocates the available PTDI fraction to all foods selected in Module 2 Step 1. The allocation is proportionately based on the per capita mean exposures when using CFR categories/subcategories and percent consumers when using FITS data. The maximum daily servings per each food is based on the proportionally allocated fraction to that food.

Screen shots for the first two subpopulations from the Per Serving estimates when CFR categories/subcategories are used:

A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	Results: Estimated Daily Intake of Mercury per Serving (US 2+y)						Results: Estimated Daily Intake of Mercury per Serving (Infants 6m - 2y)						
4	PTDI	40.5	ug/day				PTDI	3.65	ug/day				
5	Fraction to background	9.24	ug/day				Fraction to background	0.832	ug/day				
6	Fraction to HMS Tool	31.3	ug/day				Fraction to HMS Tool	2.82	ug/day				
7				Approach 1	Approach 2						Approach 1	Approach 2	
8	Foods with assigned concentration	Serving Size (g)	Estimated intake (ug per serving)	# of servings, assuming only 1 food	% of Fraction to HMS Tool Allowed to Specific Food (%)	# of servings assuming all foods	Foods with assigned concentration	Serving Size (g)	Estimated intake (ug per serving)	# of servings, assuming only 1 food	% of Fraction to HMS Tool Allowed to Specific Food (%)	# of servings assuming all foods	
9	(2) Beverages, alcoholic, cocktail mixes	240	1.2	26.1	80%	20.9	(2) Beverages, alcoholic, cocktail mixes	240	1.2	2.35	0%	0	
10	(4) Breakfast cereals, RTE, instant, hot	30	0.09	348	20%	68.5	(4) Breakfast cereals, RTE, instant, hot	30	0.09	31.3	100%	31.3	
11													
12													
13													
14													
15													
16													
17													
18													
Module 2-Step 3 Module 2-Step 4 Intake per day Module 3 Per serving estimates													

Screenshots from the "FITS results" screen:

Results: Estimated Daily Intake of Mercury per Serving (Infants 4-5 m)					
PTDI	4.4	ug/day			
Fraction to background	1.0	ug/day			
Fraction to HMS Tool	3.4	ug/day			
Foods with assigned concentration	Serving Size (g)	Estimated intake (ug per serving)	Approach 1	Approach 2	
			# of servings, assuming only 1 food	% of Fraction to HMS Tool Allowed to Specific Food (%)	# of servings assuming all foods
Baby food applesauce	59.2	0.237	14.3	100%	14.3
Baby food desserts	NC	0	NC	0%	NC

Results: Estimated Daily Intake of Mercury per Serving (Infants 6-8 m)					
PTDI	4.8	ug/day			
Fraction to background	1.1	ug/day			
Fraction to HMS Tool	3.7	ug/day			
Foods with assigned concentration	Serving Size (g)	Estimated intake (ug per serving)	Approach 1	Approach 2	
			# of servings, assuming only 1 food	% of Fraction to HMS Tool Allowed to Specific Food (%)	# of servings assuming all foods
Baby food applesauce	73.6	0.294	12.7	62%	7.9
Baby food desserts	82.6	0.413	9.1	38%	3.4

Results: Estimated Daily Intake of Mercury per Serving (Infants 9-11 m)					
PTDI	5.5	ug/day			
Fraction to background	1.2	ug/day			
Fraction to HMS Tool	4.2	ug/day			
Foods with assigned concentration	Serving Size (g)	Estimated intake (ug per serving)	Approach 1	Approach 2	
			# of servings, assuming only 1 food	% of Fraction to HMS Tool Allowed to Specific Food (%)	# of servings assuming all foods
Baby food applesauce	89.6	0.358	11.8	51%	6.0
Baby food desserts	86.8	0.434	9.7	49%	4.8

The user can “print” the results either to a real printer (or a pdf) and can then “Return to Start”. As mentioned earlier, the user needs to set their print option prior to clicking the “Print/Save Results”.

Appendix A. Option 2 – 21CFR170.3 Food Sub-Categories

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
-2	1	Baby, bottled water	Water, baby, bottled, unsweetened
-1	1	Baby food, Baby juice	Apple, grape, mixed fruit, pear, orange, banana juices
-1	2	Baby food, Semi-solid-grain and pasta-regular	Macaroni and cheese, macaroni with beef and tomato sauce, ravioli with tomato sauce - toddler or junior
-1	3	Baby food, Semi-solid-grain and pasta-strain	Strained macaroni and cheese, macaroni with vegetables
-1	4	Baby food, Semi-solid-meat and poultry-dinner, soup, stew	Beef and chicken stew, potato and cheese with ham - toddler
-1	5	Baby food, Semi-solid-meat and poultry-regular	Meat sticks, beef, chicken, turkey, chicken noodle dinner, turkey with rice and vegetables - NS as to strained or junior, junior
-1	6	Baby food, Semi-solid-meat and poultry-strained	Strained beef, ham, chicken, beef with vegetables, chicken and rice dinner
-1	7	Baby food, Semi-solid-process fruit and fruit juices-apple	Applesauce, applesauce with other fruits, Dutch apple dessert - NS as to strained or junior, junior
-1	8	Baby food, Semi-solid-process fruit and fruit juices-bananas	Bananas, bananas and pineapple - NS as to strained or junior, junior
-1	9	Baby food, Semi-solid-process fruit and fruit juices-other	Fruit dessert, fruit flavored snack - junior or NS
-1	10	Baby food, Semi-solid-process fruit and fruit juices-peach/apricots	Peaches, apricots, peach cobbler - NS as to strained or junior, junior
-1	11	Baby food, Semi-solid-process fruit and fruit juices-pear	Pears, pears and pineapple - NS as to strained or junior, junior
-1	12	Baby food, Semi-solid-process fruit and fruit juices-plums	Plums - NS as to strained or junior, junior
-1	13	Baby food, Semi-solid-process fruit and fruit juices-strained	Strained applesauce with and without other fruit, prunes, pears, bananas, pudding desserts, apples with ham

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
-1	14	Baby food, Semi-solid-process veggies-regular	Broccoli, carrots, squash, sweet potatoes, creamed corn - NS as to strained or junior, junior
-1	15	Baby food, Semi-solid-process veggies-strained	Strained creamed spinach, corn, squash, string beans, vegetables and chicken
-1	16	Baby food, Solid	Cookie, cereal bar, crackers
-1	17	Baby food, Semi-solid-custard and pudding-regular	Custard pudding, flavors other than chocolate - NS as to strained or junior, junior
-1	18	Baby food, Semi-solid-custard and pudding-strained	Strained custard pudding, flavors other than chocolate
-1	19	Baby food, Semi-solid-RTE cereals-instant, snacks	Dry, instant cereals (barley, oatmeal, rice) with and without fruit
-1	20	Baby food, Semi-solid-RTE cereals-jarr	Jarred cereals (rice, oatmeal) with and without fruit
0	1	Water, Water	Water as an ingredient, tap water
1	1	Baked goods and baking mixes, Bagel	Bagel toasted and untoasted, with raisins or other fruit, whole wheat, wheat bran, multigrain
1	2	Baked goods and baking mixes, Biscuits, corn bread, muffins	Biscuits (baking powder or buttermilk type), scone, cornbread, gordita/scope shell, hush puppy, muffin
1	3	Baked goods and baking mixes, Bread stuffing	Bread stuffing
1	4	Baked goods and baking mixes, Breads and rolls - rye, oat, other	Breads and rolls (rye, pumpernickel, black, oatmeal, barley)
1	5	Baked goods and baking mixes, Breads and rolls - white	Breads and rolls (white, Cuban, French or Vienna, Italian), croissant, English muffin
1	6	Baked goods and baking mixes, Breads and rolls - whole/cracked wheat, multigrain	Breads and rolls (whole wheat, whole grain, wheat or cracked wheat), English muffin (wheat bran, whole wheat)
1	7	Baked goods and baking mixes, Breakfast/cereal and granola bars	Breakfast tart, bar (Kellogg's Nutri-Grain bars, Kashi), granola bars
1	8	Baked goods and baking mixes, Cake - rice	Cake or pancake made with rice flour and/or dried beans, cake made with glutinous rice and dried beans

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
1	9	Baked goods and baking mixes, Cake, cupcakes 80 g serving size	Cake and cupcakes with or without icing (black forest, Boston, butter, chocolate, other flavors than chocolate, pound)
1	10	Baked goods and baking mixes, Cookie dietetic	Cookie, dietetic (chocolate chip, sandwich type, sugar or plain)
1	11	Baked goods and baking mixes, Cookies and brownies	Brownies (with or without icing, filled, low fat, fat free), cookies with chocolate (sandwich, oatmeal, chocolate covered, wafer)
1	12	Baked goods and baking mixes, Crackers	Crackers (animal, graham, oatmeal, matzo, saltine, cheese, snack, oat, oyster, rice)
1	13	Baked goods and baking mixes, Doughnut	Doughnuts (regular and cake type), churros, cruller
1	14	Baked goods and baking mixes, Flour	White flour
1	15	Baked goods and baking mixes, Pastries	Cream puff, sopaipilla, baklava, pastry puff, Danish pastry
1	16	Baked goods and baking mixes, Pastry - fruit or cheese filled	Mixed fruit tart filled with custard or cream cheese
1	17	Baked goods and baking mixes, Pie shell	Pie shell
1	18	Baked goods and baking mixes, Pies	Pies (fruit, cream, pumpkin, squash, chocolate-marshmallow, pecan, pudding)
1	19	Baked goods and baking mixes, Tortilla	Tortilla (corn, flour, whole wheat), taco shells
1	20	Baked goods and baking mixes, Bread, misc	Bread sticks, crouton, toast (melba, anisette, zwieback)
1	21	Baked goods and baking mixes, Cookies - non chocolate	Cookies non-chocolate (almond, applesauce, butterscotch, coconut, fruit-filled, fig bar, granola, oatmeal)
1	22	Baked goods and baking mixes, Cakes, coffee, sponge cake 55 g serving size	Angel food cake, butter cake, sponge cake, coffee cakes
1	23	Baked goods and baking mixes, Cakes 125 g serving size	Cake with or without icing (banana, carrot, cheesecake, cream, fruit, nut)

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
1	24	Baked goods and baking mixes, Pancakes, crepes, waffles	Pancakes (plain, high fiber, with fruit or chocolate chips, cornmeal, sour dough), waffle (plain, wheat, chocolate chip), French toast, crepe - plain, funnel cake
2	1	Beverages, alcoholic, cocktail mixes, Beers and ales	Beer and lite beer
2	2	Beverages, alcoholic, cocktail mixes, Cocktails	Bloody Mary, cape cod, daiquiri, gimlet, Manhattan, martini
2	3	Beverages, alcoholic, cocktail mixes, Distilled liquors	Cordial or liqueur, brandy, whiskey
2	4	Beverages, alcoholic, cocktail mixes, Nonalcoholic beers, wines, cocktails	Nonalcoholic mixes (pina colada, whiskey sour, wine, malt)
2	5	Beverages, alcoholic, cocktail mixes, Wines	Red, white, rice, dessert, wine cooler, sangria
3	1	Beverages and beverage bases, nonalcoholic, Beverages, non-carbonated, fruit-flavored	Fruit-flavored drinks (made from powdered mix), fruit-flavored beverage (dry powder/concentrate, not reconstituted)
3	2	Beverages and beverage bases, nonalcoholic, Beverages, other (oatmeal, corn meal beverage)	Horchata, oatmeal, and rice beverages
3	3	Beverages and beverage bases, nonalcoholic, Coffee substitutes	Postum beverage and as dry powder, chicory, cereal beverage
3	4	Beverages and beverage bases, nonalcoholic, Fruit flavored gelatin drink (meal replacement)	Gelatin drink
3	5	Beverages and beverage bases, nonalcoholic, Fruit-ades and drinks	Apple-cherry, lemonade, fruit, orange, apple cider, fruit-flavored, Gatorade, PowerAde drinks (regular, low calorie, vitamin C added)
3	6	Beverages and beverage bases, nonalcoholic, Fruit-ades and drinks-dry mix	Fruit-flavored concentrate, dry powder, low calorie, thirst quencher
3	7	Beverages and beverage bases, nonalcoholic, Soft drinks, carbonated	Carbonated water, cola-type soft drinks, cream soda, fruit-flavored, ginger ale, root beer, carbonated juice drink (regular, caffeine free, reduced sugar)

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
3	8	Beverages and beverage bases, nonalcoholic, Water, plain or flavored (fruit2O, propel, vitamin waters)	Sweetened and unsweetened bottled water, Propel Fitness Water, Vitamin Water
3	9	Beverages and beverage bases, nonalcoholic, Energy drinks	Red Bull, Monster Energy drink, Mountain Dew AMP, Vault
4	1	Breakfast cereals, RTE, instant, hot, Regular and instant hot-cooked	Oatmeal (regular, instant, quick), cream of wheat (regular, instant, quick), cooked whole wheat cereal, cooked bran cereal
4	2	Breakfast cereals, RTE, instant, hot, Regular and instant hot-uncooked	Raw/unprocessed or uncooked wheat bran, oats, rice polishings
4	3	Breakfast cereals, RTE, instant, hot, RTE	Kashi, All-Bran, Cheerios, Kix, Cap'n Crunch, Chex, Corn flakes, Malt-O-Meal, Raisin Bran
5	1	Cheeses, natural, processed, spread, dip, Cheese spread	Cream cheese, cheese spread
5	2	Cheeses, natural, processed, spread, dip, Cheese, other	Cheese dip, imitation cheese, topping from pizza, cheese fondue, sauce
5	3	Cheeses, natural, processed, spread, dip, Cottage cheese	Creamed, with fruit or vegetables, dry curd, low fat with or without fruit, with gelatin dessert
5	4	Cheeses, natural, processed, spread, dip, Natural cheeses, regular and dry grated	Camembert, brie, natural cheddar or American Type, Feta, Monterey, Mozzarella
5	5	Cheeses, natural, processed, spread, dip, Processed cheeses	Processed American, Swiss, cheddar type, with vegetables
5	6	Cheeses, natural, processed, spread, dip, Ricotta cheese	Ricotta cheese
6	1	Chewing gum, Chewing gum	Chewing gum (sugared and sugarless)
7	2	Coffee and tea, regular, instant, Coffee, decaffeinated	Decaffeinated coffees, made from ground, made from instant, espresso, latte, Frappuccino
7	3	Coffee and tea, regular, instant, Coffee, decaffeinated-dry instant	Coffee, dry instant powder, decaffeinated
7	4	Coffee and tea, regular, instant, Coffee, regular	Café con leche, regular made from ground, Turkish, espresso, Cuban, latte, mocha, made from instant

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
7	5	Coffee and tea, regular, instant, Coffee, regular-dry instant	Dry instant powder, regular, coffee and cocoa, with whitener
7	6	Coffee and tea, regular, instant, Coffee, regular-liquid concentrate	Liquid concentrate coffee
7	7	Coffee and tea, regular, instant, Tea, NFS, decaf, or herbal	Tea (not specified, decaffeinated, or herbal), unsweetened, sweetened, low calorie, leaf, made from powdered instant
7	8	Coffee and tea, regular, instant, Tea, regular	Tea (regular), leaf, sweetened, low calorie sweetener, made from powdered instant, presweetened
7	9	Coffee and tea, regular, instant, Tea, regular-dry instant	Powdered instant tea, unsweetened
8	1	Condiments and relishes, Others	Hummus, chutney, horseradish, mustard, sandwich spread
8	2	Condiments and relishes, Sauce	Miso, soy, teriyaki, enchilada, barbecue, tartar sauces
8	3	Condiments and relishes, Pickled/sauerkraut	Pickled vegetables (tomato, beans, cabbage, cucumbers, sauerkraut)
8	4	Condiments and relishes, Relish	Cranberry-orange, tomato, corn relishes
8	5	Condiments and relishes, Salsa	Uncooked and cooked red relish, made with fruit
8	6	Condiments and relishes, Olives	Olives (green and black)
9	1	Confections and frostings, Other (honey, molasses, icing, marshmallows)	Honey, molasses, icing (white and chocolate), dietetic topping, marshmallow
9	2	Confections and frostings, Sugars (confectioner's, brown, cinnamon)	White confectioner's, brown, cinnamon, raw sugars
10	1	Dairy product analogs, Cream substitute	Frozen, liquid, powdered (light, flavored, fat free, sugar free)
10	2	Dairy product analogs, Non-dairy milk	Ready-to-drink soy milk (light, non fat, chocolate), non-soy imitation milk
10	3	Dairy product analogs, Whipped topping	Canned, frozen, made from mix (low fat, fat free, sugar free)
11	1	Egg products, liquid, frozen, dried, egg dishes, Egg products	Benedict and deviled eggs, egg salad, egg foo young, scrambled eggs (frozen meal)

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
11	2	Egg products, liquid, frozen, dried, egg dishes, Egg substitute	Egg substitute, scrambled egg (made from powdered, frozen, liquid mixture)
12	1	Fats and oils, margarine, dressings, butter, Animal fat	Animal fat or drippings, ghee, lecithin
12	2	Fats and oils, margarine, dressings, butter, Butter	Stick, whipped, tub (salted, unsalted, light)
12	3	Fats and oils, margarine, dressings, butter, Margarine	Stick, tub, liquid, margarine-like spread (salted, unsalted, reduced calorie)
12	4	Fats and oils, margarine, dressings, butter, Mayonaise/dressing	Regular, made with tofu, imitation, salad dressing (cholesterol-free, fat free, low-calorie)
12	5	Fats and oils, margarine, dressings, butter, Other (blends, butter-replacement)	Vegetable oil-butter spread, butter-margarine blend, butter replacement powder
12	6	Fats and oils, margarine, dressings, butter, Salad dressing	Caesar, Italian, poppy seed, yogurt, blue, French (regular, low calorie, fat free)
12	7	Fats and oils, margarine, dressings, butter, Vegetable oil	Vegetable, corn, flaxseed, olive, soybean oils
13	1	Fish products, main dishes, salads, processed, Canned/processed fish	Fish and shellfish (dried, canned, smoked, pickled), fish stick or patty or fillet
13	2	Fish products, main dishes, salads, processed, Mixed dishes (incl. frozen meals)	Seafood Newburg, shrimp scampi, salmon cake or patty, bouillabaisse, shrimp with rice
13	3	Fish products, main dishes, salads, processed, Mixed dishes (incl. frozen meals)-fish shellfish in sauces	Fish with cream sauce, deviled carb, curried shrimp, fish curry, mussels with tomato-based sauce,
13	4	Fish products, main dishes, salads, processed, Mixed dishes (incl. frozen meals)-frozen	Fish dinner
13	5	Fish products, main dishes, salads, processed, Mixed dishes (incl. frozen meals)-meals	Shrimp in lobster sauce (mixture), fish and rice with mushroom soup, shellfish mixture and vegetables
13	6	Fish products, main dishes, salads, processed, Mixed dishes (incl. frozen meals)-others	Stuffed clams, crab cake, fish cake, shrimp toast, lomi salmon

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
13	7	Fish products, main dishes, salads, processed, Mixed dishes (incl. frozen meals)-sandwich	Tuna salad sandwich
13	8	Fish products, main dishes, salads, processed, Seafood salad (crab, lobster, tuna, shrimp salads)	Crab, lobster, salmon, tuna, shrimp, seafood salads
14	1	Fresh eggs and fresh egg products, Egg mixtures-with meat	Egg and cheese on biscuit; egg, cheese, and meat on English muffin/biscuit/bagel
14	2	Fresh eggs and fresh egg products, Egg mixtures-without meat	Egg omelet or scrambled egg, plain, with cheese, with vegetables, egg white omelet or scrambled egg, fried egg sandwich, egg and cheese on biscuit
14	3	Fresh eggs and fresh egg products, Eggs (whole, whites, and yolk only)	Egg (whole, white only, yolk only), raw, cooed, boiled, fried, baked, pickled
15	1	Fresh fish, shellfish, aquatic animals, Fish	Fish (carp, catfish, cod, salmon, flounder, haddock), cooked, baked or broiled, breaded or battered, floured or breaded
15	2	Fresh fish, shellfish, aquatic animals, Fish-dry, roe	Dried cod, shad roe, sturgeon roe
15	3	Fresh fish, shellfish, aquatic animals, Fish-raw	Raw herring, mackerel, and tuna
15	4	Fresh fish, shellfish, aquatic animals, Shellfish	Shellfish (clams, crab, crayfish, lobster), cooked, baked, broiled, fried, breaded, steamed
15	5	Fresh fish, shellfish, aquatic animals, Shellfish-dry, roe	Dried shrimp, squid
15	6	Fresh fish, shellfish, aquatic animals, Shellfish-raw	Raw clams, oysters
16	1	Fresh fruits and fruit juices, Fruit juices	Fresh grapefruit, lemon, lime, orange juices
16	2	Fresh fruits and fruit juices, Fruits	Raw, baked, frozen, candied, chocolate covered fruits (grapefruit, lemon, tangerine, apple, watermelon)
17	1	Fresh meats and dishes from, Beef, roast, ground, steak, or	Beef steak, short ribs, roast, brisket, ground (cooked, fried, broiled or

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
		stew meat	baked)
17	2	Fresh meats and dishes from, Beef-Sandwich	Sloppy Joe on bun, Rueben sandwich, roast beef sandwich
17	3	Fresh meats and dishes from, Game meats, goat	Goat (boiled, fried, baked, cooked)
17	4	Fresh meats and dishes from, Game meats, other	Rabbit, moose, bar, bison, wild pig (cooked)
17	5	Fresh meats and dishes from, Game meats, venison/deer	Venison/deer (roasted, cooked, breaded or floured, stewed)
17	6	Fresh meats and dishes from, Lamb	Lamb chop, loin, ribs, hocks, ground (cooked)
17	7	Fresh meats and dishes from, Meat dishes-beef	Beef goulash, chili con carne, stroganoff, beef curry, meatballs with sauce, shepherd's pie
17	8	Fresh meats and dishes from, Meat dishes-chicken or turkey	Chicken or turkey and noodles with sauce, soufflé, chicken or turkey stew with potatoes and vegetables
17	9	Fresh meats and dishes from, Meat dishes-other meat	Lamb curry, veal parmigiana, lamb loaf, stuffed grape leaves with lamb and rice
17	10	Fresh meats and dishes from, Meat dishes-pork or ham	Ham with gravy (mixture), ham stroganoff, ham croquette, pot pie, ham and noodles, ham and potatoes
17	11	Fresh meats and dishes from, Meat dishes-sandwich	Wrap sandwich, pastrami, steak sandwich, club sandwich, Sloppy Joe
17	12	Fresh meats and dishes from, Organ meats	Beef liver, heart, brains, tongue
17	13	Fresh meats and dishes from, Pork-bacon, fat	Bacon, pork bacon, fat back, pork skin
17	14	Fresh meats and dishes from, Pork-ham	Ham (fried, breaded or floured, cooked), prosciutto
17	15	Fresh meats and dishes from, Pork-other	Cracklings, ears, neck bones, feet
17	16	Fresh meats and dishes from, Pork-steaks, ribs, ground, chop	Pork chop, ground, steak or cutlet, roast, tenderloin (cooked, breaded or floured, broiled, baked, fried)
17	17	Fresh meats and dishes from, Veal	Veal chop, cutlet, steak (broiled, fried, cooked)
17	18	Fresh meats and dishes from,	Beef bacon

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
		Beef-bacon	
17	19	Fresh meats and dishes from, Meat dishes-beef burger	Cheeseburger, double/triple cheeseburger, bacon cheeseburger, hamburger, on bun, with or without mayonnaise, tomato, chiliburger, taco burger
18	1	Fresh poultry and dishes from, Chicken	Chicken, NS as to part, breast, leg, thigh, drumstick, wing, back, skin, feet, patty, ground, nuggets (fried, roasted, stewed, baked or fried, coated, broiled)
18	2	Fresh poultry and dishes from, Chicken or turkey in sauces, mixed dishes	Chicken or turkey cacciatore, chicken with gravy, chicken with barbecue sauce, chicken curry, chicken kiev, chicken or turkey and vegetables, kung pao chicken
18	3	Fresh poultry and dishes from, Chicken or turkey salad	Chicken or turkey salad, chicken or turkey garden salad, oriental chicken or turkey garden salad with crispy noodles
18	4	Fresh poultry and dishes from, Chicken or turkey sandwich	Chicken sandwich, chicken fillet sandwich, wrap sandwich, turkey submarine sandwich
18	5	Fresh poultry and dishes from, Game birds	Duck (cooked, roasted, pressed), cornish game hen, quail, pheasant
18	6	Fresh poultry and dishes from, Organ meats	Chicken liver (braised, fried), chicken liver paste, gizzard
18	7	Fresh poultry and dishes from, Turkey	Turkey, light/dark meat, drumstick, thigh, neck, wing, rolled roaste, tail, ground, nuggets
18	8	Fresh poultry and dishes from, Turkey bacon	Turkey bacon
19	1	Fresh vegetables, tomatoes, potatoes, Dark-green vegetables-cooked	Chard, collards, kale, mustard greens, spinach, broccoli
19	2	Fresh vegetables, tomatoes, potatoes, Dark-green vegetables-creamed, sauce	Spinach (creamed, soufflé, casserole), broccoli with cheese or mushroom sauce
19	3	Fresh vegetables, tomatoes, potatoes, Dark-green vegetables-raw	Raw beet greens, collards, mustard greens, broccoli

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
19	4	Fresh vegetables, tomatoes, potatoes, Legumes-cooked	Soybeans, lima beans, cowpeas, pigeon peas (cooked)
19	5	Fresh vegetables, tomatoes, potatoes, Legumes-creamed, sauce	Lima beans with mushroom sauce
19	6	Fresh vegetables, tomatoes, potatoes, Legumes-raw	Pea salad
19	7	Fresh vegetables, tomatoes, potatoes, Orange/Yellow vegetables-cooked	Carrots, peas and carrots, pumpkin, winter type squash, sweet potato (cooked, mashed, fried)
19	8	Fresh vegetables, tomatoes, potatoes, Orange/Yellow vegetables-creamed, sauce	Carrots in tomato sauce, squash soufflé
19	9	Fresh vegetables, tomatoes, potatoes, Orange/Yellow vegetables-raw	Raw carrots, carrot salad
19	10	Fresh vegetables, tomatoes, potatoes, Other vegetables & mixtures-cooked	Artichoke, asparagus, string beans, cabbage, cauliflower corn, celery, vegetable combination
19	11	Fresh vegetables, tomatoes, potatoes, Other vegetables & mixtures-creamed, sauce	Cucumber salad with dressing, ratatouille, creamed or with sauce vegetables (asparagus, cauliflower, corn, mushrooms)
19	12	Fresh vegetables, tomatoes, potatoes, Other vegetables & mixtures-herbs	Raw chives, cilantro, garlic
19	13	Fresh vegetables, tomatoes, potatoes, Other vegetables & mixtures-miscellaneous	Raw vegetables (sprouts, cactus, pepper), cooked vegetables (onions, hot peppers), seaweed
19	14	Fresh vegetables, tomatoes, potatoes, Other vegetables & mixtures-raw	Raw asparagus, string beans, beets, eggplant, mushrooms
19	15	Fresh vegetables, tomatoes, potatoes, Other vegetables & mixtures-salad	Broccoli salad, cabbage salad, artichoke salad
19	16	Fresh vegetables, tomatoes, potatoes, Tomatoes-raw, cooked	Raw and cooked tomatoes
19	17	Fresh vegetables, tomatoes, potatoes, Vegetable Salad-Salad	Tomato and cucumber salad, lettuce salad, spinach salad

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
19	18	Fresh vegetables, tomatoes, potatoes, White potatoes and other starchy vegetables-cooked	Cooked (baked, roasted, stewed, mashed) white potatoes, potato salad, plantain, cassava
19	19	Fresh vegetables, tomatoes, potatoes, White potatoes and other starchy vegetables-fried	White potato French fries, hash browns
19	20	Fresh vegetables, tomatoes, potatoes, White potatoes and other starchy vegetables-raw	Raw white potato, ripe plantain
20	1	Frozen dairy desserts and mixes, Ice cream and novelties-frozen flavoured ice pop	Creamsicle, fudgesicle
20	2	Frozen dairy desserts and mixes, Ice cream and novelties-sundae	Ice cream sundae (regular, light), with or without topping
20	3	Frozen dairy desserts and mixes, Yogurt, frozen	Frozen yogurt (various flavors), frozen yogurt cone
20	4	Frozen dairy desserts and mixes, Ice cream and novelties	Ice cream (regular, light, fat free, rich, soft serve, no sugar added), bar or stick, sandwich, ice cream cone, ice cream pie, sherbet, milk dessert, tiramisu
21	1	Fruit and water ices, Frozen fruit-frozen Juice Bar	Fruit juice bar, frozen (regular, low calorie)
21	2	Fruit and water ices, Frozen fruit-sorbet	Fruit sorbet
21	3	Fruit and water ices, Water ices	Ice fruit, ice pop (regular, low calorie), snow cone
22	1	Gelatins, puddings, fillings, Fillings (pie)	Lemon, cherry, blueberry pie filling
22	2	Gelatins, puddings, fillings, Gelatin	Gelatin dessert (snack, with and without topping), dietetic gelatin dessert
22	3	Gelatins, puddings, fillings, Gelatin-dry	Gelatin powder, dry, sweetened regular or with low-calorie sweetner, dietetic
22	4	Gelatins, puddings, fillings, Pudding (incl. custard)	Pudding (rice, tapioca, canned), custard, mousse, meringues, low fat, prepared from dry mix, made with milk, low calorie,

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
23	1	Grain products and pastas, Cooked breakfast - type cereals (grits, cornmeal, millet, cream of rice)	Grits, cooked, corn or hominy with or without additions (regular, quick or instant), cornmeal mush, millet, cream of rice
23	2	Grain products and pastas, Cooked macaroni, noodles, pastas	Macaroni, noodles, long rice noodles, chow fun noodles, spaghetti (cooked)
23	3	Grain products and pastas, Corn starch powder	Cornstarch, dry, powder
23	4	Grain products and pastas, Egg roll, wonton, puffs, dumplings	Matzo ball, dumpling, egg roll, empanada, cornmeal fritter, knish, filled turnover
23	5	Grain products and pastas, Enchilada, flauta, tamala, chalupa, chimichanga, tacos, burritos	Burritos, enchilada, flauta, taco or tostada, soft taco, tamale, nachos with additions
23	6	Grain products and pastas, Grain mixed dish frozen	Regular and diet frozen meals (lasagna, macaroni and cheese, ravioli, pasta with vegetables, pancakes)
23	7	Grain products and pastas, Grain mixed dishes-pasta, noodles	Tortilla casserole, tamale, crepe, gnocchi, turnover, lasagna, ravioli, spaghetti, other pasta
23	8	Grain products and pastas, Pasta salad	Macaroni or pasta salads
23	9	Grain products and pastas, Pizza	Pizza (with various toppings and all crust types), white pizza, calzone
23	10	Grain products and pastas, Plain cooked grains (barley, rice, bulgar, couscous)	Cooked barley, rice, couscous
23	11	Grain products and pastas, Rice mixed dish-140 g	Sushi, stuffed pepper, rice pilaf, flavored rice
23	12	Grain products and pastas, Rice mixed dish-240g	Fried rice, rice with vegetables, rice with beans
23	13	Grain products and pastas, Sandwich	Croissant sandwiches, wrap sandwich
24	1	Gravies and sauces, Creamy sauces	White sauce, milk gravy, garlic sauce, lemon-butter sauce
24	2	Gravies and sauces, Meat sauces and gravies	Gravy all types (poultry, giblet, mushroom), sausage gravy, spaghetti sauce

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
24	3	Gravies and sauces, Specialty sauces (fish, mole verde, black bean, pesto)	Clam sauce, black bean sauce, pesto sauce, mole verde sauce
24	4	Gravies and sauces, Tomato sauce	Tomato sauce and paste, spaghetti sauces
25	1	Hard candy, Hard candy	Butterscotch, dietetic or low calorie hard candy
26	1	Herbs, seeds, spices, flavorings, Herbs seeds spices	Vinegar and yeast extract spread
28	1	Jams and jellies, commerical, Jams and jellies	Jelly, jam, fruit butter, marmalade (all flavors, dietetic, low sugar)
28	2	Jams and jellies, commerical, Jams and jellies-paste	Guava, bean paste
29	1	Meat products, commercially processed, Frankfurter or hot dog	Frankfurter or hot dogs
29	2	Meat products, commercially processed, Game meats	Venison jerky, deer bologna
29	3	Meat products, commercially processed, Lunch meats, spreads	Bologna, capicola, luncheon meat, sliced ham, meat spreads
29	4	Meat products, commercially processed, Processed meat-bacon	Pork bacon
29	5	Meat products, commercially processed, Processed meat-jerky	Beef and pork jerky
29	6	Meat products, commercially processed, Sausages	Beef sausage, knockwurst, mortadella, pepperoni, Italian sausage
29	7	Meat products, commercially processed, Processed meat-cured, canned, pickled or cooked	Corned beef, pastrami, smoked or cured ham, pork roll, pickled beef
29	8	Meat products, commercially processed, Processed meat mixed dishes	Frankfurter or hot dog on bun, corned beef hash, sausage and vegetable mixture
29	9	Meat products, commercially processed, Meat-frozen meal	Frozen Salisbury steak with gravy dinner, meat loaf dinner, meatballs in sauce with noodles
30	1	Milk fluid, whole, skim, Lowfat	Fluid cow's milk (1%, 2% fat)
30	2	Milk fluid, whole, skim, Milk, NFS	Fluid cow's milk, not specified
30	3	Milk fluid, whole, skim, Nonfat	Fluid cow's milk (skim or nonfat)
30	4	Milk fluid, whole, skim, Whole	Fluid cow's milk (whole), goat's milk

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
31	1	Milk Products, drinks, dry, milk origin, Buttermilk fluid	Fluid buttermilk (nonfat, 1%, 2% fat)
31	2	Milk Products, drinks, dry, milk origin, Cream	Cream (light, fat free, half and half, heavy, whipped, pressurized)
31	3	Milk Products, drinks, dry, milk origin, Dry reconstituted milk	Dry reconstituted milk (whole, low fat, non fat)
31	4	Milk Products, drinks, dry, milk origin, Evaporated, condensed milk	Evaporated milk (whole, 2%, skim, sweetened, diluted)
31	5	Milk Products, drinks, dry, milk origin, Flavored dry mixtures	Reconstituted and not reconstituted cocoa mixture or malted dry mix
31	6	Milk Products, drinks, dry, milk origin, Flavored milk and milk drinks, fluid	Chocolate milk, hot chocolate, cocoa beverage, other flavors, eggnog
31	7	Milk Products, drinks, dry, milk origin, Milk shake, smoothie	Milkshake (homemade, fountain-type, carryout), orange Julius, fruit smoothie drink
31	8	Milk Products, drinks, dry, milk origin, Milk, dry, not reconstituted	Dry milk, not reconstituted
31	9	Milk Products, drinks, dry, milk origin, Milk-based meal replacements, fluid	Fluid Instant breakfast (fluid canned, milk added to powder), meal supplement or replacement
31	10	Milk Products, drinks, dry, milk origin, Sour cream	Sour cream (regular, reduced fat, light, fat free), sour cream based dip
31	11	Milk Products, drinks, dry, milk origin, Whey, dry	Why, sweet, dry
31	12	Milk Products, drinks, dry, milk origin, Yogurts	Yogurts (plain, all flavored, fruit variety, with and without nuts), whole, low fat, non fat
31	13	Milk Products, drinks, dry, milk origin, Milk-based meal replacements, not reconstituted	Powder, dry, not reconstituted fluid Instant breakfast, meal supplement or replacement
32	1	Nuts and nut products, Nut beverage (coconut-based)	Coconut milk, cream, water
32	2	Nuts and nut products, Other nuts and seeds (almonds, cashew, macadamia, walnut, coconut, mixed nuts, sunflower seeds)	Almonds, cashew, coconut meat, mixed nuts, sunflower seeds, sugared pecans

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
32	3	Nuts and nut products, Peanut butter sandwich	Peanut butter sandwich, peanut butter and jelly sandwich
32	4	Nuts and nut products, Peanut butter, other nut spreads	Almond, sesame, peanut butter or paste
32	5	Nuts and nut products, Peanuts	Whole peanuts, boiled, roasted with and without said, chocolate covered
33	1	Plant protein products, meat substitutes, Meal replacement bar	High protein bar, Zone Perfect Classic, Clif Bar, South Beach Living Protein bar
33	2	Plant protein products, meat substitutes, Meal replacement/supplement beverage	Liquid meal replacement or supplement, Ensure with fiber, soy-based
33	3	Plant protein products, meat substitutes, Meal replacement/supplement powder	Protein powder, protein supplement powder
33	4	Plant protein products, meat substitutes, Meatless products (bacon, burger/patty, frankfurter, meatball, spreads)	Meatless bacon strip, bits, link, frankfurter, luncheon slice, meatball, vegetarian fillet
33	5	Plant protein products, meat substitutes, Other	Bee pollen, textured vegetable protein - dry
33	6	Plant protein products, meat substitutes, Soy cheese, yogurt, dessert	Soybean curd cheese, soy yogurt, tofu frozen dessert
33	7	Plant protein products, meat substitutes, Soy-based snacks	Soy nuts and chips
33	8	Plant protein products, meat substitutes, Tofu	Soybean curd, tofu and vegetables
34	1	Poultry products, commercially processed, Frozen meal	Chicken divan, chicken parmigiana, chicken and vegetable mixture, turkey dinner, turkey tetrazzini
34	2	Poultry products, commercially processed, Poultry-canned or smoked (nonfrozen dishes)	Canned chicken, smoked turkey
34	3	Poultry products, commercially processed, RTE luncheon meats and spread	Chicken or turkey loaf, turkey ham, chicken salad spread
34	4	Poultry products, commercially processed, Sausages	Turkey breakfast sausage including sausage containing turkey, pork and beef

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
35	1	Processed fruits and fruit juices, Berries, cooked or canned	Cooked or canned blueberries, cranberries, raspberries
35	2	Processed fruits and fruit juices, Citrus fruit, canned or frozen	Canned or frozen citrus fruit (grapefruit, oranges)
35	3	Processed fruits and fruit juices, Citrus fruits juices	Citrus fruit juices including grapefruit, orange, grape-tangerine-lemon, pineapple-orange juices
35	4	Processed fruits and fruit juices, Citrus fruits juices-canned or frozen	Canned or frozen citrus fruit juices including grapefruit, orange, grape-tangerine-lemon, pineapple-orange juices
35	5	Processed fruits and fruit juices, Citrus fruits juices-lemon/lime	Lemon and lime juices (frozen, canned or bottled)
35	6	Processed fruits and fruit juices, Fruit cocktail or mix	Fruit cocktail (cooked or canned), fruit soup
35	7	Processed fruits and fruit juices, Fruit juices and nectars	Fruit juices (apple, prune, strawberry, pineapple) and nectars (apricot, guava, mango)
35	8	Processed fruits and fruit juices, Fruit salad	Fruit salads with salad dressing, cream, pudding or marshmallow
35	9	Processed fruits and fruit juices, Fruit-ades and drinks	Grape juice drink, guava juice drink, orange drink
35	10	Processed fruits and fruit juices, Guacamole	Guacamole
35	11	Processed fruits and fruit juices, Non-citrus fruit, cooked or canned	Cooked or canned non-citrus fruit including applesauce, apricot, mango, peach, pineapple
35	12	Processed fruits and fruit juices, Non-citrus fruit, dried	Dried non-citrus fruit including apple, apricot, banana chips, cranberries, peach, prune
35	13	Processed fruits and fruit juices, Raisins	Raisins
36	1	Processed vegetables and vegetable juices, Dark-green vegetables-canned	Canned collards, kale, mustard greens, spinach
36	2	Processed vegetables and vegetable juices, Dark-green vegetables-frozen	Frozen collards, kale, mustard greens, spinach

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
36	3	Processed vegetables and vegetable juices, Legumes	Cooked white beans, fava beans, lima beans, refried beans, falafil, bean cake, bean mixtures
36	4	Processed vegetables and vegetable juices, Legumes-canned	Canned pinto beans, red kidney beans, cowpeas
36	5	Processed vegetables and vegetable juices, Legumes-frozen	Frozen cowpeas
36	6	Processed vegetables and vegetable juices, Orange/Yellow vegetables-candied	Candied sweet potato
36	7	Processed vegetables and vegetable juices, Orange/Yellow vegetables-canned	Canned carrots, peas and carrots, sweet potatoes
36	8	Processed vegetables and vegetable juices, Orange/Yellow vegetables-chips	Sweet potato chips
36	9	Processed vegetables and vegetable juices, Orange/Yellow vegetables-frozen	Frozen carrots, peas and carrots, pumpkin
36	10	Processed vegetables and vegetable juices, Orange/Yellow vegetables-juice	Carrot juice
36	11	Processed vegetables and vegetable juices, Other vegetables & meat mixtures	Fried stuffed potatoes, rice plantain meat pie, eggplant and meat casserole
36	12	Processed vegetables and vegetable juices, Other vegetables & mixtures	Corn, stuffed artichokes, hominy, onion rings, vegetable tempera, vegetable curry
36	13	Processed vegetables and vegetable juices, Other vegetables & mixtures-canned	Canned asparagus, string beans, cauliflower, corn, mushroom, peas, squash
36	14	Processed vegetables and vegetable juices, Other vegetables & mixtures-dried	Dried algae, corn, mushroom
36	15	Processed vegetables and vegetable juices, Other vegetables & mixtures-frozen	Frozen asparagus, lima beans, cauliflower, corn, snow pea
36	16	Processed vegetables and vegetable juices, Other vegetables & mixtures-juice	Mixed vegetable juice, celery juice

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
36	17	Processed vegetables and vegetable juices, Other vegetables & tomato mixtures	Tomato and vegetables (lima beans, okra, onion, corn)
36	18	Processed vegetables and vegetable juices, Tomatoes-canned	Canned tomatoes
36	19	Processed vegetables and vegetable juices, Tomatoes-dried	Dried tomatoes
36	20	Processed vegetables and vegetable juices, Tomatoes-juice	Tomato juice (low sodium, cocktail)
36	21	Processed vegetables and vegetable juices, White potato and starchy vegetables-canned	Canned white potatoes
36	22	Processed vegetables and vegetable juices, White potato and starchy vegetables-fried potatoes fast food	French fries, breaded and battered
36	23	Processed vegetables and vegetable juices, White potato and starchy vegetables-fried potatoes frozen	French fries from frozen, potato puffs
36	24	Processed vegetables and vegetable juices, White potato and starchy vegetables-from dry mix	Hash brown and mashed potatoes from dry, made with milk
36	25	Processed vegetables and vegetable juices, White potato and starchy vegetables-frozen	Stuffed white potatoes, baked
36	26	Processed vegetables and vegetable juices, White potato, stuffed	Stuffed white potatoes, baked
36	27	Processed vegetables and vegetable juices, White potato and starchy vegetables-other	Potato puffs, potato skins with adhering flesh with additions, potato pancake, plantain chips, taro chips
37	1	Snack foods, chips, pretzels, salty snacks, Chips and sticks (potato)	Potato chips and sticks (restructured, reduced fat, fat free)
37	2	Snack foods, chips, pretzels, salty snacks, Popcorn	Popcorn (unbuttered, popped in oil, unsalted, salted, caramel-coated)
37	3	Snack foods, chips, pretzels, salty snacks, Pretzels	Hard and soft pretzels, yogurt-covered, cheese-filled

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
37	4	Snack foods, chips, pretzels, salty snacks, Salty snacks	Corn chips, corn puffs, tortilla chips, multigrain chips
38	1	Soft candy, including bars, chocolates, mints, nougat, Dietetic candy	Dietetic or low calorie candy (gumdrops, chocolate covered)
38	2	Soft candy, including bars, chocolates, mints, nougat, Non-dietetic candy, other	Butterscotch morsel, espresso coffee beans, coconut candy, fondant, licorice, nougat, taffy
38	3	Soft candy, including bars, chocolates, mints, nougat, Non-dietetic candy, chocolate or chocolate candies	M&M's, milk chocolate candy, white chocolate, Sixlets Truffles
38	4	Soft candy, including bars, chocolates, mints, nougat, Non-dietetic candy, caramel	Caramel (with nuts, chocolate covered), Rolo
38	5	Soft candy, including bars, chocolates, mints, nougat, Non-dietetic candy, bars	Toblerone, TWIX, Kit Kat, Milky Way
38	6	Soft candy, including bars, chocolates, mints, nougat, Non-dietetic candy, fudge	Fudge (chocolate, peanut butter, caramel)
38	7	Soft candy, including bars, chocolates, mints, nougat, Non-dietetic candy, peanut or peanut flavored candies	Peanut candy including M&M's, peanut brittle, Reese's pieces, morsels
38	8	Soft candy, including bars, chocolates, mints, nougat, Non-dietetic candy, fruit, raisin	Fruit peel, fruit leather, fruit snack, yogurt coated raisins
39	1	Soups, home prepared, Grain-based soups	Beef noodle soup, matzo ball soup, wonton soup, other noodle soups
39	2	Soups, home prepared, Legume-based soups	Pinto bean soup, bean soup, bean and rice soup, lentil soup
39	3	Soups, home prepared, Meat-based soups/broth	Ham and noodle soup, chicken rice soup, fish and vegetable soup, seafood soup
39	4	Soups, home prepared, Seafood-based soups/creamy	Fish chowder, cream of crab soup, oyster stew, cream style salmon soup
39	5	Soups, home prepared, Vegetable-based soups	Spinach soup, cabbage soup, vegetable soup, minestrone soup

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
39	6	Soups, home prepared, Vegetable-based soups/creamy	Potato and cheese soup, cream of corn soup, potato chowder
39	7	Soups, home prepared, Broth/stock	chicken, fish, meat broth or stock
39	8	Soups, home prepared, Seafood-based soups	Fish and vegetable soup, shrimp gumbo, seafood soup with potatoes and vegetables
40	1	Soups and soup mixes, commercially prepared, Cheese soups	Cheddar cheese soup, beer soup
40	2	Soups and soup mixes, commercially prepared, Grain-based soups	Noodle soup, beef/chicken noodle soup, instant noodle soup
40	3	Soups and soup mixes, commercially prepared, Grain-based soups/creamy	Cream of chicken noodle soup
40	4	Soups and soup mixes, commercially prepared, Legume-based soups	Bean soup, black bean soup, bean and ham soup, chunky pea and ham soup, split pea
40	5	Soups and soup mixes, commercially prepared, Meat-based soups	Oxtail soup, chili beef soup, beef vegetable soup, Italian wedding soup, chicken gumbo soup, chicken soup, bird's nest soup
40	6	Soups and soup mixes, commercially prepared, Meat-based soups/broth	Beef and chicken broth, bouillon or consomme
40	7	Soups and soup mixes, commercially prepared, Meat-based soups/creamy	Cream of chicken or turkey soup, chicken and mushroom soup, cream of bacon soup
40	8	Soups and soup mixes, commercially prepared, Meat-based soups-bouillon dry	Chicken broth, bouillon, or consomme, dry, not reconstituted
40	9	Soups and soup mixes, commercially prepared, Seafood-based soups/creamy	Crab soup, clam chowder, cream of shrimp
40	10	Soups and soup mixes, commercially prepared, Vegetable-based soups	Tomato soup, tomato beef soup, tomato rice soup, beet soup, onion soup, pea soup, seaweed soup, vegetable soup

21CFR Category	Sub-Category	Sub-Category Description	Food Examples included in Sub-Category
40	11	Soups and soup mixes, commercially prepared, Vegetable-based soups/creamy	Potato soup, broccoli soup, cream of tomato soup, cream of asparagus, cream of celery, cream of mushroom soup
40	12	Soups and soup mixes, commercially prepared, Seafood-based soups	Tomato-base crab soup
40	13	Soups and soup mixes, commercially prepared, Meat-based soups-undiluted (all types)	Undiluted canned chicken or turkey soup
40	14	Soups and soup mixes, commercially prepared, Grain-based soups-undiluted (all types)	Chicken noodle soup, canned, undiluted
40	15	Soups and soup mixes, commercially prepared, Vegetable-based soups-undiluted (all types)	Undiluted canned, tomato soup, mushroom, cream of onion, vegetable soup
41	1	Sugar, white, Sugar, white	Sugar (white, granulated or lump)
42	1	Sugar substitutes, Liquid	Sugar substitute (liquid)
42	2	Sugar substitutes, Powder	Sugar substitute (powder)
43	1	Sweet sauces, toppings, syrups, fruit, Sweet sauces	Sweet and sour sauce, fruit sauce, plum sauce
43	2	Sweet sauces, toppings, syrups, fruit, Syrup	Pancake syrup, corn syrup, maple syrup, chocolate syrup
43	3	Sweet sauces, toppings, syrups, fruit, Topping	Butterscotch or caramel topping, marshmallow topping, fruit topping

Appendix B. Option 3 – RAC Foods

91 Baby RAC Foods

3B	Apple canned	151B	Palm oil
4B	Apple fresh or n/s	154B	Parsley
5B	Apple juice	155B	Parsnip
6B	Apricot canned	157B	Pea canned
9B	Apricot juice	158B	Pea fresh or n/s
14B	Banana & Plantain	160B	Peach canned
15B	Barley	163B	Peach juice
16B	Basil	167B	Pear canned
18B	Bean succulent canned	169B	Pear juice
21B	Beef organs & meat byproducts	170B	Pepper bell
22B	Beef fat	171B	Pepper black and white
23B	Beef meat	172B	Pepper nonbell
24B	Beet garden roots	176B	Pineapple canned
26B	Beet sugar	179B	Pineapple juice
27B	Blueberry canned	180B	Plum
30B	Broccoli	181B	Plum prune juice
36B	Carrot canned	183B	Pork organs and meat byproducts
37B	Carrot fresh or n/s	184B	Pork fat
40B	Cassava	185B	Pork meat
42B	Celery	186B	Potato
45B	Cherry canned	196B	Rapeseed oil
48B	Cherry juice	197B	Raspberry canned
50B	Chicken organs and meat byproducts	200B	Raspberry juice
51B	Chicken fat	202B	Rice
52B	Chicken meat	205B	Safflower oil
53B	Chickpea	207B	Seaweed
58B	Cinnamon	211B	Sheep fat
60B	Coconut	212B	Sheep meat
61B	Coconut oil	213B	Soybean flour
66B	Corn syrup	214B	Soybean oil
67B	Corn field	217B	Spices other
70B	Corn sweet	218B	Spinach canned
73B	Cottonseed oil	221B	Squash summer canned
77B	Cranberry juice	224B	Squash winter canned
85B	Egg	231B	Strawberry juice
96B	Garlic	232B	Sugarcane molasses

105B	Grape juice	233B	Sugarcane sugar
111B	Herbs other	234B	Sunflower oil
121B	Lemon juice	236B	Sweet potato canned
125B	Lime juice	237B	Sweet potato fresh or n/s
126B	Mango	244B	Tomato canned
138B	Oat	245B	Tomato fresh or n/s
141B	Onion	249B	Turkey organs and meat byproducts
143B	Orange juice	250B	Turkey fat
147B	Other berry juice	251B	Turkey meat
		261B	Wheat

262 Adult RAC Foods

1A	Alfalfa, seed	132A	Millet, grain
2A	Amaranth, leafy	133A	Mushroom
3A	Apple, canned	134A	Mustard greens
4A	Apple, fresh or n/s	135A	Nectarine
5A	Apple, juice	136A	Nut
6A	Apricot, canned	137A	Nut, oil
7A	Apricot, fresh or n/s	138A	Oat
8A	Apricot, frozen	139A	Olive
9A	Apricot, juice	140A	Olive, oil
10A	Arugula	141A	Onion
11A	Asparagus	142A	Orange
12A	Avocado	143A	Orange, juice
13A	Balsam pear	144A	Other berry, canned
14A	Banana & Plantain	145A	Other berry, fresh or n/s
15A	Barley	146A	Other berry, frozen
16A	Basil	147A	Other berry, juice
17A	Bean, seed	148A	Other citrus
18A	Bean, succulent, canned	149A	Other crops
19A	Bean, succulent, fresh or n/s	150A	Other root vegetables
20A	Bean, succulent, frozen	151A	Palm, oil
21A	Beef organs & meat byproducts	152A	Papaya
22A	Beef, fat	153A	Papaya, juice
23A	Beef, meat	154A	Parsley
24A	Beet, garden, roots	155A	Parsnip
25A	Beet, garden, tops	156A	Passionfruit, juice
26A	Beet, sugar	157A	Pea, canned
27A	Blueberry , canned	158A	Pea, fresh or n/s
28A	Blueberry , fresh or n/s	159A	Pea, frozen

29A	Blueberry , frozen	160A	Peach, canned
30A	Broccoli	161A	Peach, fresh or n/s
31A	Brussels sprouts	162A	Peach, frozen
32A	Buckwheat	163A	Peach, juice
33A	Butternut	164A	Peanut
34A	Cabbage	165A	Peanut, butter
35A	Cantaloupe	166A	Peanut, oil
36A	Carrot , canned	167A	Pear , canned
37A	Carrot , fresh or n/s	168A	Pear , fresh or n/s
38A	Carrot , frozen	169A	Pear, juice
39A	Carrot, juice	170A	Pepper, bell
40A	Cassava	171A	Pepper, black and white
41A	Cauliflower	172A	Pepper, nonbell
42A	Celery	173A	Peppermint
43A	Celery, juice	174A	Peppermint, oil
44A	Chayote, fruit	175A	Persimmon
45A	Cherry , canned	176A	Pineapple , canned
46A	Cherry , fresh or n/s	177A	Pineapple , fresh or n/s
47A	Cherry , frozen	178A	Pineapple , frozen
48A	Cherry, juice	179A	Pineapple, juice
49A	Chestnut	180A	Plum
50A	Chicken organs and meat byproducts	181A	Plum, prune, juice
51A	Chicken, fat	182A	Pomegranate
52A	Chicken, meat	183A	Pork organs and meat byproducts
53A	Chickpea	184A	Pork, fat
54A	Chicory, roots	185A	Pork, meat
55A	Chicory, tops	186A	Potato
56A	Chinese waxgourd	187A	Potato, fried
57A	Chive	188A	Poultry, other organs and meat byproducts
58A	Cinnamon	189A	Poultry, other, fat
59A	Cocoa bean	190A	Poultry, other, meat
60A	Coconut	191A	Pumpkin
61A	Coconut, oil	192A	Pumpkin, seed
62A	Coffee	193A	Rabbit, meat
63A	Collards	194A	Radicchio
64A	Coriander, leaves	195A	Radish, roots
65A	Coriander, seed	196A	Rapeseed, oil
66A	Corn syrup	197A	Raspberry , canned
67A	Corn, field	198A	Raspberry , fresh or n/s
68A	Corn, field, oil	199A	Raspberry , frozen

69A	Corn, pop	200A	Raspberry, juice
70A	Corn, sweet , canned	201A	Rhubarb
71A	Corn, sweet , fresh or n/s	202A	Rice
72A	Corn, sweet , frozen	203A	Rutabaga
73A	Cottonseed, oil	204A	Rye
74A	Cranberry, canned	205A	Safflower, oil
75A	Cranberry, fresh or n/s	206A	Savory
76A	Cranberry, frozen	207A	Seaweed
77A	Cranberry, juice	208A	Sesame, oil
78A	Cucumber	209A	Sesame, seed
79A	Dandelion, leaves	210A	Sheep organs and meat byproducts
80A	Dasheen, corm	211A	Sheep, fat
81A	Dasheen, leaves	212A	Sheep, meat
82A	Date	213A	Soybean, flour
83A	Dill, seed	214A	Soybean, oil
84A	Dillweed	215A	Soybean, seed
85A	Egg	216A	Soybean, soy milk
86A	Eggplant	217A	Spices, other
87A	Endive	218A	Spinach , canned
88A	Fig	219A	Spinach , fresh or n/s
89A	Fish-freshwater finfish	220A	Spinach , frozen
90A	Fish-freshwater finfish, farm raised	221A	Squash, summer , canned
91A	Fish-saltwater finfish, other	222A	Squash, summer , fresh or n/s
92A	Fish-saltwater finfish, tuna	223A	Squash, summer , frozen
93A	Fish-shellfish, crustacean	224A	Squash, winter , canned
94A	Fish-shellfish, mollusc	225A	Squash, winter , fresh or n/s
95A	Flax seed, oil	226A	Squash, winter , frozen
96A	Garlic	227A	Starfruit
97A	Ginger	228A	Strawberry, canned
98A	Goat organs & meat byproducts	229A	Strawberry, fresh or n/s
99A	Goat, fat	230A	Strawberry, frozen
100A	Goat, meat	231A	Strawberry, juice
101A	Gooseberry	232A	Sugarcane, molasses
102A	Grape , fresh or n/s	233A	Sugarcane, sugar
103A	Grape , frozen	234A	Sunflower, oil
104A	Grape, canned	235A	Sunflower, seed
105A	Grape, juice	236A	Sweet potato, canned
106A	Grape, wine and sherry	237A	Sweet potato, fresh or n/s
107A	Grapefruit	238A	Swiss chard
108A	Grapefruit, juice	239A	Tamarind
109A	Guar, seed	240A	Tangerine

110A	Guava	241A	Tangerine, juice
111A	Herbs, other	242A	Tanier, corm
112A	Honey	243A	Tea
113A	Honeydew melon	244A	Tomato, canned
114A	Hop	245A	Tomato, fresh or n/s
115A	Horseradish	246A	Tomato, frozen
116A	Infant formula	247A	Tomato, juice
117A	Kale	248A	Triticale, flour
118A	Kiwifruit	249A	Turkey organs and meat byproducts
119A	Leek	250A	Turkey, fat
120A	Lemon	251A	Turkey, meat
121A	Lemon, juice	252A	Turmeric
122A	Lentil, seed	253A	Turnip, greens
123A	Lettuce	254A	Turnip, roots
124A	Lime	255A	Vinegar
125A	Lime, juice	256A	Water
126A	Mango	257A	Water chestnut
127A	Mango, juice	258A	Watercress
128A	Maple syrup	259A	Watermelon
129A	Maple, sugar	260A	Watermelon, juice
130A	Meat, game	261A	Wheat
131A	Milk	262A	Yam

Appendix C. Option 4 -TDS Foods

Milk, whole, fluid	Macaroni and cheese, prepared from box mix	Pretzels, hard, salted
Milk, lowfat (2%), fluid	Quarter-pound hamburger on bun, fast-food	Syrup, chocolate
Milk, chocolate, lowfat, fluid	Meatloaf, beef, homemade	Jelly, any flavor
Milk, skim, fluid	Chicken potpie, frozen, heated	Yellow mustard
Milk shake, chocolate, fast-food	Soup, chicken noodle, canned, cond, prep w/ water	Black olives
Cheese, American, processed	Soup, tomato, canned, cond, prep w/ water	Sour cream
Cheese, cheddar, natural (sharp/mild)	Soup, vegetable beef, canned, cond, prep w/ water	Coffee, from ground
Beef, ground, regular, pan-cooked	Dill cucumber pickles	Carbonated beverage, fruit-flavored, regular
Beef roast, chuck, oven-roasted	Margarine, regular (salted)	Fruit drink (10% juice), canned or bottled
Ham, cured (not canned), baked	Butter, regular (salted)	Infant formula, soy-based, RTF
Pork chop, pan-cooked w/ oil	Mayonnaise, regular, bottled	BF, bananas
Pork sausage (link/patty), oven-cooked	Half & half cream	BF, teething biscuits
Pork bacon, oven-cooked	Cream substitute, non-diary, liquid/frozen	Salmon, steaks/fillets, baked
Pork roast, loin, oven-roasted	Sugar, white, granulated	BF, squash
Lamb chop, pan-cooked w/ oil	Syrup, pancake	BF, cereal, oatmeal, dry, prep w/ water
Turkey breast, oven-roasted	Honey	BF, cereal, rice, dry, prep w/ water
Liver (beef/calf), pan-cooked w/ oil	Tomato catsup	BF, cereal, rice w/apples, dry, prep w/ water
Frankfurter (beef/pork), boiled	Ice cream, light, vanilla	BF, veal and broth/gravy
Bologna (beef/pork)	Cake, chocolate w/ icing	BF, lamb and broth/gravy
Salami, luncheon-meat type (not hard)	Sweet roll/Danish pastry	BF, turkey and broth/gravy
Fish sticks or patty, frozen, oven-cooked	Chocolate chip cookies	Meal replacement, liquid RTD, any flavor
Eggs, scrambled w/ oil	Sandwich cookies w/ crème filling	Cottage cheese, creamed, lowfat (2% milk fat)
Eggs, boiled	Apple pie, fresh/frozen	Sour cream dip, any flavor
Pinto beans, dry, boiled	Pumpkin pie, fresh/frozen	Beef steak, loin/sirloin, broiled
Pork and beans, canned	Candy bar, milk chocolate, plain	Luncheon meat (chicken/turkey)
Lima beans, immature, frozen, boiled	Gelatin dessert, any flavor	Chicken breast, fried, fast-food (w/ skin)
Peas, green, frozen, boiled	Carbonated beverage, cola, regular	Chicken thigh, oven-roasted (skin removed)

Peanut butter, creamy	Fruit drink, from powder	Chicken leg, fried, fast-food (w/ skin)
Peanuts, dry roasted, salted	Carbonated beverage, cola, low-calorie	Catfish, pan-cooked w/ oil
Rice, white, enriched, cooked	Tea, from tea bag	Tuna, canned in water, drained
Oatmeal, plain, cooked	Beer	Refried beans, canned
Cream of wheat (farina), enriched, cooked	Wine, dry table, red/ white	White beans, dry, boiled
Corn/hominy grits, enriched, cooked	Infant formula, milk-based, high iron, RTF	Sunflower seeds (shelled), roasted, salted
Corn, fresh/frozen, boiled	Infant formula, milk-based, low iron, RTF	Pancakes, frozen, heated
Corn, canned	BF, beef and broth/gravy	Breakfast tart/toaster pastry
Bread, white, enriched	BF, chicken and broth/gravy	Macaroni salad, from grocery/deli
Cornbread, homemade	BF, vegetables and beef	Spaghetti, enriched, boiled
Biscuits, refrigerated-type, baked	BF, vegetables and chicken	Apricots, canned in heavy/light syrup
Bread, whole wheat	BF, vegetables and ham	Fruit juice blend (100% juice), canned/bottled
Tortilla, flour	BF, chicken noodle dinner	Cranberry juice cocktail, canned/bottled
Bread, rye	BF, macaroni, tomato and beef	Orange juice, bottled/carton
Muffin, fruit or plain	BF, turkey and rice	Potato salad, mayonnaise-type, from grocery/deli
Crackers, saltine	BF, carrots	Potato, mashed, prepared from fresh
Corn/tortilla chips	BF, green beans	Coleslaw, mayonnaise-type, from grocery/deli
Noodles, egg, enriched, boiled	BF, mixed vegetables	Carrot, baby, raw
Corn flakes cereal	BF, sweet potatoes	Lettuce, leaf, raw
Fruit-flavored cereal, presweetened	BF, peas	Sweet potatoes, canned
Shredded wheat cereal	BF, applesauce	Tomato salsa, bottled
Raisin bran cereal	BF, peaches	Beef and vegetable stew, canned
Crisped rice cereal	BF, pears	Lasagna w/ meat, frozen, heated
Granola w/ raisins	BF, juice, apple	Beef w/ vegetables in sauce, from Chinese carry-out
Oat ring cereal	BF, juice, orange	Chicken w/ vegetables in sauce, from Chinese carry-out
Apple (red), raw (w/ peel)	BF, vanilla custard/pudding	Fried rice, meatless, from Chinese carry-out
Orange (navel/Valencia), raw	BF, fruit dessert/pudding	Burrito w/ beef, beans and cheese, from Mexican carry-out
Banana, raw	Yogurt, lowfat, fruit-flavored	Chicken filet (broiled) sandwich on bun, fast-food
Watermelon, raw/frozen	Cheese, Swiss, natural	Soup, Oriental noodles (ramen noodles), prep w/ water
Peach, raw/frozen	Cream cheese	Pudding, ready-to-eat, flavor other than chocolate
Applesauce, bottled	Luncheon meat (ham)	Cake, yellow w/ icing
Pear, raw (w/ peel)	Chicken breast, oven-roasted	Granola bar, w/ raisins

	(skin removed)	
Strawberries, raw/frozen	Chicken nuggets, fast-food	Candy bar, chocolate, nougat, & nuts
Fruit cocktail, canned in light syrup	Shrimp, boiled	Popcorn, microwave, butter-flavored
Grapes (red/green), raw	Bread, cracked wheat	Sweet & sour sauce
Cantaloupe, raw/frozen	Bagel, plain, toasted	Brown gravy, canned or bottled
Grapefruit, raw	English muffin, plain, toasted	Salad dressing, creamy/buttermilk type, regular
Pineapple, canned in juice	Crackers, graham	Salad dressing, creamy/buttermilk type, low-calorie
Raisins	Crackers, butter-type	Salad dressing, Italian, regular
Avocado, raw	Peach, canned in light/medium syrup	Olive oil
Orange juice, frozen conc, reconstituted	Pear, canned in light syrup	Vegetable oil
Apple juice, bottled	Pineapple juice, frozen conc, reconstituted	Bottled drinking water (mineral/spring), not carbonated or flavored
Grapefruit juice, frozen conc, reconstituted	Grape juice, frozen conc, reconstituted	Decaffeinated coffee, from ground
Prune juice, bottled	Potato, french-fried, fast-food	Decaffeinated tea, from tea bag
Lemonade, frozen conc, reconstituted	Carrot, fresh, peeled, boiled	BF, cereal, barley, dry, prep w/ water
Spinach, fresh/frozen, boiled	Tomato juice, bottled	BF, cereal, mixed, dry, prep w/ water
Collards, fresh/frozen, boiled	Brussels sprouts, fresh/frozen, boiled	BF, juice, apple-banana
Lettuce, iceberg, raw	Mushrooms, raw	BF, juice, apple-cherry
Cabbage, fresh, boiled	Eggplant, fresh, peeled, boiled	BF, juice, apple-grape
Broccoli, fresh/frozen, boiled	Turnip, fresh/frozen, boiled	BF, juice, mixed fruit
Celery, raw	Okra, fresh/frozen, boiled	BF, juice, pear
Asparagus, fresh/frozen, boiled	Mixed vegetables, frozen, boiled	BF, juice, grape
Cauliflower, fresh/frozen, boiled	Beef stroganoff w/ noodles, homemade	BF, pears and pineapple
Tomato, raw	Tuna noodle casserole, homemade	BF, plums w/ apples and/or pears
Tomato sauce, plain, bottled	Quarter-pound cheeseburger on bun, fast-food	BF, bananas and pineapple
Green beans, fresh/frozen, boiled	Fish sandwich on bun, fast-food	BF, apricots w/ mixed fruit
Green beans, canned	Egg, cheese, and ham on English muffin, fast-food	BF, banana dessert
Cucumber, peeled, raw	Taco/tostada w/ beef and cheese, from Mexican carry-out	BF, peach cobbler/dessert
Summer squash, fresh/frozen, boiled	Pizza, cheese and pepperoni, regular crust, from pizza carry-out	BF, fruit yogurt dessert
Pepper, sweet, green, raw	Soup, bean w/ bacon/pork, canned, cond, prep w/ water	BF, dutch apple/apple cobbler
Squash, winter (Hubbard/acorn),	Clam chowder, New England,	BF, arrowroot cookies

fresh/frozen, boiled	canned, cond, prep w/ whl milk	
Onion, mature, raw	Ice cream, regular, vanilla	BF, zweiback toast
Beets, canned	Sherbet, fruit-flavored	BF, cereal, oatmeal w/ fruit, prep w/ water
Potato, boiled (w/out peel)	Popsicle, fruit-flavored	BF, chicken w/ rice
Potato, baked (w/ peel)	Doughnut, cake-type, any flavor	BF, beef and noodles/beef stroganoff
Potato chips	Brownie	BF, vegetables and turkey
Spaghetti w/ meat sauce, homemade	Sugar cookies	BF, macaroni and cheese
Chili con carne w/ beans, canned	Candy, hard, any flavor	BF. apples with berries
		BF, apples w/ fruit other than berries