

HEAVY METAL SCREENING TOOL USER MANUAL

IAFNS and JIFSAN

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What is Heavy Metal Screening Tool?

"The frequency of detection of trace or higher levels of metal in foods and food ingredients has been on the rise over the past decade. This is due in part to improvement in analytical methodology to detect and quantify at low levels, in the parts per billion (ppb), or lower range." This tool is "designed to be used by risk assessors/managers to rapidly evaluate potential public health risk when confronted with the detection of select heavy metals in foods and food ingredients."

The HMST is composed of three key elements of a dietary risk assessment: 1) hazard characterization, 2) dietary exposure assessment and 3) risk characterization. The tool (HMST), available below, "has been parameterized with objective and publicly available data (NHANES, TDS, FCID and published exposure limits and background exposure information) and the algorithm used in HMST are based on well -defined dietary exposure and risk assessment constructs." The tool "should be viewed as the beginning of a broader and iterative assessment process, such that for issues not set aside using HMST, more refine risk assessment based on improved data and with less reliance on conservative default assumptions would need to be carried out."

Terminologies

Reference Value: calculated daily maximum safe exposure levels via food and water based on lifetime intake without significant adverse health effects

Background Value: the amount of the metal consumed daily from food and water

Available for Tool: the difference between reference value and background value

Default Values for the Tool

Heavy Metal/Metalloid	Default Reference Value	Background Value
Arsenic	0.3 ug/kg/day (EPA 1991) Inorganic As	0.18 ug/kg/day [0.02 ug/kg/day + 0.16 ug/kg/day] (Xue 2010, Adults) + (EPA 2001 MCL) Inorganic As
Cadmium	1 ug/kg/day EPA 1989	0.26 ug/kg/day [0.18 ug/kg/day + 0.08 ug/kg/day] (JECFA 2013, Adults) + (EPA 2016 MCL)
Lead	0.26 ug/kg/day Young Children (0-6 years old)	0.24 ug/kg/day [0.11 ug/kg/day + 0.13 ug/kg/day] (hybrid mean) + (Median Levels from Water Quality Reports)
Lead	0.16 ug/kg/day Older Children and Adult	0.11 ug/kg/day [0.03 ug/kg/day + 0.075 ug/kg/day] (JECFA 2011, Adults) + (Median Levels from Water Quality Reports)
Mercury	0.1 ug/kg/day (EPA 2001), MeHg	0.05 ug/kg/day [0.02 ug/kg/day + 0.03 ug/kg/day] (Xue 2012, Adult MeHg) + (EPA 2016, inorganic Hg)

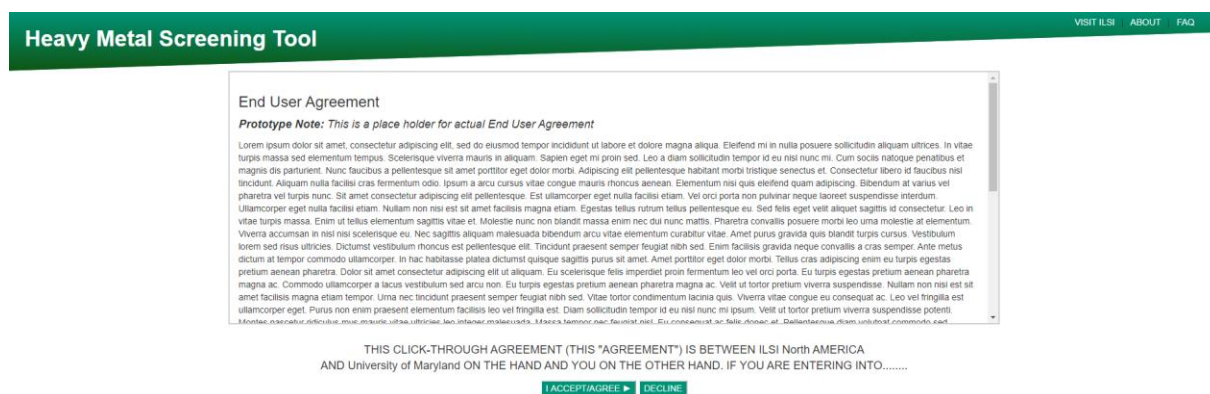
Databases That the Tool Uses

- a. **FCID (Food Commodity Intake Database)**
U.S. EPA's What We Eat in America – Food Commodity Intake Database, 2005-2010 (WWEIA-FCID 2005-2010)
- b. **TDS (Total Dietary Study Foods)**
Total Dietary Study Foods 2003-2014
- c. **NHANES (National Health and Nutrition Examination Survey)**
National Health and Nutrition Examination Survey 1999-2016

How to Use the Tool

1. User-Agreement

- a. Read the End-User agreement and click accept if you agree.



The screenshot shows the 'Heavy Metal Screening Tool' interface. At the top, there is a green navigation bar with links for 'VISIT ILSI', 'ABOUT', and 'FAQ'. Below this is a white box titled 'End User Agreement' with a 'Prototype Note' stating it is a placeholder. The main content area contains several paragraphs of placeholder text (Lorem Ipsum). At the bottom of the agreement box, there is a statement: 'THIS CLICK-THROUGH AGREEMENT (THIS "AGREEMENT") IS BETWEEN ILSI North AMERICA AND University of Maryland ON THE HAND AND YOU ON THE OTHER HAND. IF YOU ARE ENTERING INTO.....'. Below this statement are two buttons: 'I ACCEPT/AGREE' and 'DECLINE'.

2. Select Compound (Arsenic, Cadmium, Lead, Mercury, or Custom).

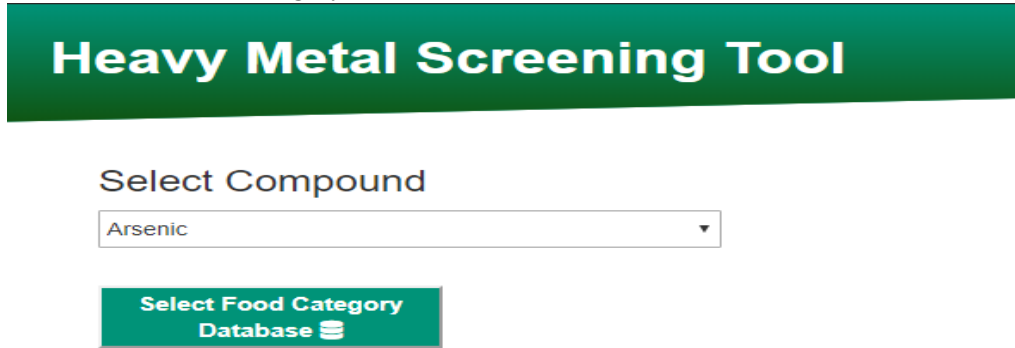


The screenshot shows a green banner with the text 'Heavy Metal Screening Tool' in white. Below the banner is a white box with the text 'Select Compound' in a dark blue font. Underneath this text is a dropdown menu with a blue border and a small downward-pointing arrow on the right side. The word 'Arsenic' is currently selected and displayed in the dropdown menu.

- a. Choosing Custom will prompt the user to provide custom reference and background values where results can be generated and downloaded after completing steps 3-10.

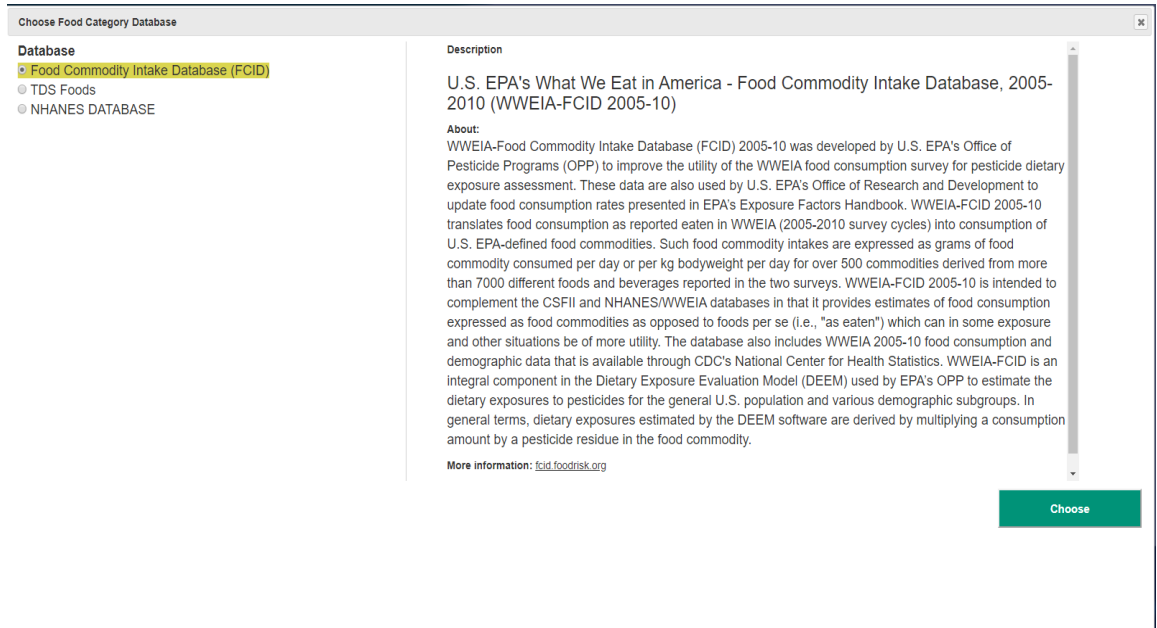
3. Choose Database

a. Click “Select Food Category Database”



b. A pop up box will show that allows you to select food category database (default to Food Commodity Intake Database (FCID))

- FCID is Food Commodity Intake Database 2005-2010
- TDS is Total Dietary Study Foods 2003-2014
- NHANES is National Health and Nutrition Examination Survey 1999-2016



c. Selecting TDS Foods database will present food items listed as part of the Total Dietary Study. Due to large number of food items that must be matched, it may take longer to generate results.

d. Selecting NHANES Database will prompt you to select from dropdown the from and to year cycle.

Choose Food Category Database

Database

- Food Commodity Intake Database (FCID)
- TDS Foods
- NHANES DATABASE**
Select from and to year cycle:
From 1999-2000 ▼ To 2003-2004 ▼

Description

National Health and Nutrition Examination Survey
NHANES DATA from 1999-2016

About:

National Health and Nutrition Examination Survey (NHANES) is conducted by Department of Health and Human Services (DHHS) to assess the health and nutritional status of a nationally representative sample of children and adults in the United States. The data are representative of the civilian, non-institutionalized U.S. population. What We Eat in America (WWEIA) and its predecessor the Continuing Survey of Food Intake by Individuals (CSFII) is the dietary intake interview component of the National Health and Nutrition Examination Survey (NHANES). It is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). WWEIA consists of two non-consecutive days of 24-hour dietary recall data.

Note: Two-Day Average Consumption is NOT available for 1999-2002

More info: <https://www.fda.gov/food/total-diet-study/total-diet-study-design>

Choose

e. Click “Choose” after selecting your database.

4. Choose Consumption Selection (Single-Day or Two-Day Average Consumption)

Select Compound

Arsenic ▼

Change Food Category Database

Consumption Selection

- Single Day Consumption
- Two-Day Average Consumption

Commodity Grouping

- Individual
- Combined

5. Choose Commodity Grouping (Individual or Combined)

Select Compound

Change Food Category Database

Consumption Selection

- Single Day Consumption
- Two-Day Average Consumption

Commodity Grouping

- Individual
- Combined

6. Search by Text or Food Code

- a. Type in the search box labeled “Search by Text or Food Code” the food(s) you want to add (example: okra) and, on the container, labeled “Searched Commodities” food(s) will show up if they are on the selected database.

Select Compound

Change Food Category Database

Consumption Selection

- Single Day Consumption
- Two-Day Average Consumption

Commodity Grouping

- Individual
- Combined

Food Commodity Intake Database (FCID)

Search by Text or Food Code

Searched Commodities

802234000 Okra

Add Selected

Add All

7. Adding Food(s) to Container

- a. Click on the food(s) you want to add in the container. After clicking, it should be highlighted with a checkmark at the end to show you have selected it/them.

Select Compound
Arsenic

Change Food Category Database

Consumption Selection
 Single Day Consumption
 Two-Day Average Consumption

Commodity Grouping
 Individual
 Combined

Food Commodity Intake Database (FCID)
Search by Text or Food Code okra

Searched Commodities

802234000 Okra	✓
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Add Selected Add All

- b. Click “Add Selected” to add what you have clicked/selected (highlighted with check mark) if you wish to add them. Clicking “Add All” will add all from the container whether they are selected or not. After clicking “Add Selected” or “Add All”, the foods will appear in the “Selected Commodities” container.

Select Compound
Arsenic

Change Food Category Database

Consumption Selection
 Single Day Consumption
 Two-Day Average Consumption

Commodity Grouping
 Individual
 Combined

Food Commodity Intake Database (FCID)
Search by Text or Food Code okra

Searched Commodities

Selected Commodities

802234000 Okra

Add Selected Add All Remove Selected Remove All

8. Removing Food(s) from Container

- a. Similar concept from Step 8, clicking “Remove Selected” will remove selected food(s) from the “Selected Commodities” container and clicking “Remove All” will remove all selected food(s) from the “Selected Commodities” container.

9. Submitting the data

- Click Submit to generate results.
- The tool generates a table for the compound and tables for the consumption data with Max Available for Tool Allowable PPM for you to analyze.

Results:

Arsenic

Database: Food Commodity Intake Database (FCID)
 Compound: Arsenic
 Consumption Type: Single Day Consumption
 Commodity Grouping: Individual

[DOWNLOAD RESULTS ▶](#) [Enter Detected Concentration](#)

Subpopulation	Reference Value	Reference Source	Background Value	Background Source	Available for Tool
Total Population	0.3 ug/kg/day	(EPA 1991) Inorganic As	0.18 ug/kg/day	[0.02 ug/kg/day + 0.16 ug/kg/day] (Xue 2010, Adults) + (EPA 2001 MCL) Inorganic As	0.12 ug/kg/day

[Okra](#) [Customize PTDI](#)

Per Capita Body Mass

Type	Number of Users	Mean	90th percentile	95th percentile	99th percentile
Total Population	49346	<0.005 g/kg/day	0 g/kg/day	0 g/kg/day	0 g/kg/day
Max Available for Tool Allowable PPM		24 PPM	---	---	---

Per User Body Mass

Type	Number of Users	Mean	90th percentile	95th percentile	99th percentile
Total Population	249	0.73 g/kg/day	1.6 g/kg/day	2.7 g/kg/day	4.5 g/kg/day
Max Available for Tool Allowable PPM		0.16 PPM	7.50e-2 PPM	4.44e-2 PPM	2.67e-2 PPM

10. Download Results

- Clicking on “Download Results” will download a pdf file containing the information from the screen.

Other Features of the Tool

Detected Concentration

- Clicking “Enter Detected Concentration” will show a pop-up box to ask the user to input food percent (default to 100) and the PPM for that food percentage.

FoodPercent % (10%, 20%....) **Detected Concentration**

Okra PPM X

[Submit](#)

- b. Click “Submit” to enter detected concentration.
- c. After submitting, a third row on the consumption tables after “Max Available for Tool Allowable PPM” will be added labeled “Detected Concentration PPM”.

Database: Food Commodity Intake Database (FCID)
 Compound: Arsenic
 Consumption Type: Single Day Consumption
 Commodity Grouping: Individual

[DOWNLOAD RESULTS](#) [Enter Detected Concentration](#)

Subpopulation	Reference Value	Reference Source	Background Value	Background Source	Available for Tool
Total Population	0.3 ug/kg/day	(EPA 1991) Inorganic As	0.18 ug/kg/day	[0.02 ug/kg/day + 0.16 ug/kg/day] (Xue 2010, Adults) + (EPA 2001 MCL) Inorganic As	0.12 ug/kg/day

[Okra](#) [Customize PTDI](#)

Per Capita Body Mass

Type	Number of Users	Mean	90th percentile	95th percentile	99th percentile
Total Population	49346	<0.005 g/kg/day	0 g/kg/day	0 g/kg/day	0 g/kg/day
Max Available for Tool Allowable PPM		24 PPM	---	---	---
Detected Concentration PPM		2436.00 PPM	---	---	---

Per User Body Mass

Type	Number of Users	Mean	90th percentile	95th percentile	99th percentile
Total Population	249	0.73 g/kg/day	1.6 g/kg/day	2.7 g/kg/day	4.5 g/kg/day
Max Available for Tool Allowable PPM		0.16 PPM	7.50e-2 PPM	4.44e-2 PPM	2.67e-2 PPM
Detected Concentration PPM		16.68 PPM	7.61 PPM	4.51 PPM	2.71 PPM

Customize Default Tool Values

Clicking on “Customize Default Tool Values” will allow user to change subpopulation, reference and background values. Reference and background source cannot be edited. It will show the page like this:

Results:

Custom

Database: Food Commodity Intake Database (FCID)
 Compound: Custom Compound
 Consumption Type: Single Day Consumption
 Commodity Grouping: Individual

[Okra](#)

Subpopulation	Reference Value	Reference Source	Background Value	Background Source	Available for Tool
Total Population	0 ug/kg/day	Custom PTDI Source	0 ug/kg/day	Custom Background Source	

[Submit and Finish](#) [Add Row +](#)

- a. Clicking “Add Row +” will add a row and clicking the trash can icon at the very right of a row will delete that row.

b. Select Subpopulation on the dropdown. Selecting “Custom Demographic” from the dropdown will show a pop up that will ask user for custom demographic information.

Min 1 ≤ Age(YEARS) < Max 10

All Males

Females

All

Pregnant

Breast Feeding

All

Save Cancel

c. Clicking Save will add the “Custom Demographic” subpopulation.

Subpopulation	Reference Value	Reference Source	Background Value	Background Source	Available for Tool
Custom Demographic	0 ug/kg/day	Custom PTDI Source	0 ug/kg/day	Custom Background Source	

Age: 1 to < 10 years old
Gender: M,F
Female Status: all
Race: all

Submit and Finish Add Row +

d. Clicking on the edit icon (below the “Race” label) will show the similar pop-up with the current information to edit. Click Save to save edits.

Min 1 ≤ Age(YEARS) < Max 10

All Males

Females

All

Pregnant

Breast Feeding

All

Save Cancel

e. Click “Submit and Finish” to generate new results with customized default too values and new PPMs.

Database: **Food Commodity Intake Database (FCID)**
 Compound: **Custom Compound**
 Consumption Type: **Single Day Consumption**
 Commodity Grouping: **Individual**

DOWNLOAD RESULTS ▶ **Enter Detected Concentration** ⁰

Subpopulation	Reference Value	Reference Source	Background Value	Background Source	Available for Tool
1 to < 10 years old Gender: M,F Female_status: all Race: all	0 ug/kg/day	Custom PTDI Source	0 ug/kg/day	Custom Background Source	0 ug/kg/day

Okra **Customize Default Tool Values**

Per Capita Body Mass

Type	Number of Users	Mean	90th percentile	95th percentile	99th percentile
1 to < 10 years old Gender: M,F Female_status: all Race: all	9442	<0.005 g/kg/day	0 g/kg/day	0 g/kg/day	0 g/kg/day
Max Available for Tool Allowable PPM		0.00e+0 PPM	---	---	---

Per User Body Mass

Type	Number of Users	Mean	90th percentile	95th percentile	99th percentile
1 to < 10 years old Gender: M,F Female_status: all Race: all	34	1.27 g/kg/day	3.5 g/kg/day	5.7 g/kg/day	5.7 g/kg/day
Max Available for Tool Allowable PPM		0.00e+0 PPM	0.00e+0 PPM	0.00e+0 PPM	0.00e+0 PPM