**Inorganic Arsenic in Rice Case Study**

**Exposure Scenario**
Routine testing of ingredients used by frozen meal producer detected inorganic arsenic in raw rice ingredient at 0.09 ppm.

**Initial assessment**
In the initial assessment the default values for inorganic arsenic in module 1- hazard characterization - of the MDEST is used, i.e. TDI of 0.3 µg/kg bw/day to all subpopulations, and since background arsenic levels in foods are relatively high, an arbitrary 5% of the TDI is assumed to be the portion available for MDEST screening level assessment. It is not possible to identify frozen meals using the broad CFR categories, hence, the assessment used nine refined CFR categories, including fish products, main dishes, salads, processed mixed dishes (frozen meals), grain products and pastas (grain mixed dish frozen), meat products (commercially processed frozen meal), and poultry products (commercially processed frozen meal). Since the inorganic arsenic was detected in the raw rice used the frozen meal, the 0.09 ppm concentration was assigned to the fraction of raw rice in the frozen meal. It was assumed that 20% of the meal would be raw rice. A very small fraction of the US population consume the foods of interest, thus, the per capita exposure estimates are low, however the per user estimates are well over the fraction of the TDI assigned to the MDEST as well as the total TDI based on this initial screen level assessment with MDEST (see Table 5).

**Revised assessment**
The results of the initial screening assessment do not imply actual risks, rather, they prompt for a revised assessment to better reflect the situation under consideration and available data. A potential refinement of the initial screening assessment is to apply an alternate estimate of the background exposures instead of the arbitrary assumption of 95% of the TDI as background exposure in the MDEST. Also, considering that the large background exposure to arsenic includes arsenic in rice, an adjustment to only assess exposure relating to the incremental increase above arsenic levels that are routinely found in rice is needed to avoid double counting. In the revised assessment the estimated background exposure was replaced with an estimate from the published literature (~0.6 µg/day) and water's contribution (~3 µg/day) was excluded from the fraction assigned to background (Tsuji et al, 2007). This increased the fraction of the TDI available for the MDEST from 0.015 µg/kg/day to 0.25 µg/kg/day (assuming 60 kg bw) in Module 1. Further refinement was made by adjusting the residue level detected in rice (0.09 ppm) for background levels of arsenic in raw rice (0.072 ppm, Yost et al. 2004).
This is justifiable since the background exposure to arsenic in rice is already accounted for in the estimate assigned to background in Module 1. Hence, the revised assessment assumed arsenic level in rice ingredient of 0.02 ppm instead of 0.09 ppm. These adjustments result in screening level exposure and risk estimates that are well below those derived in the initial assessment. However, on per user basis, infants and children age 2-6 y exceed the fraction of the TDI assigned to the tool, and infants exceed the total TDI (Table 5).
Case study summary: The fraction of the population potentially exposed is small. The intake estimates in the revised assessment are below those derived in the initial assessment due to the use of an adjusted concentration that represents the "excess" arsenic over background levels. The associated risk estimates are also well below those estimated in the initial assessment, due not only to the smaller intake estimates, but also due to allowing a larger fraction of the TDI to be used. Based on the results of the screening-level assessments, it could be concluded that the

detected “excess” arsenic over background levels in rice is not of concern for the overall US population; however, more refined assessment would be needed for infants and children 2-6 y. Further assessment to understand what frozen meals children and infants are consuming and to confirm that the assumed percent rice in these meals is correct may be needed, particularly given that the default assignment of a fraction of the TDI to background exposure implies that all consumers of frozen foods have the same background intakes of inorganic arsenic.
While the MDEST approach is appropriate for a screening levels assessment such as the one considered here, a more refined assessment, accounting for the entire diet, at the person level, may result in total inorganic intakes that are below the TDI. This case study illustrated that the MDEST is a useful tool in setting priorities for: (1) further exposure assessment refinement, (2) need for further analytical and other data, and (3) determining urgency of risk management actions and decisions.

**Table 5. Inorganic arsenic in rice case study - comparison of initial and revised screening level estimated intakes**

| Sub population | TDI (µg/kg bw/day) | | | % users | *Initial Assessment* | | | | *Revised Assessment* | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | *Per Capita (µg/kg bw/day) (% of MDEST TDI Portion)* | | | | | | | |
| | **TDI** | **Background** | **MDEST TDI Portion** | | **Mean** | **90th percentile** | **95th percentile** | **99th percentile** | **Mean** | **90th percentile** | **95th percentile** | **99th percentile** |
| US 2+ | 0.3 | 0.285 (Initial) 0.05 (Revised) | 0.015 (Initial) 0.25 (Revised) | 2% | 0.00213 (14%) | 0.00428 (29%) | 0.00855 (57%) | 0.0128 (85%) | 0.000517 (0%) | 0.00103 (0%) | 0.00206 (1%) | 0.00311 (1%) |
| INFANTS 6m - 2y | | | | 1% | 0.00328 (22%) | 0.00656 (44%) | 0.0131 (87%) | 0.0197 (131%) | 0.000872 (0%) | 0.00174 (1%) | 0.00349 (1%) | 0.00523 (2%) |
| CHILDREN 2 - 6 y | | | | 1% | 0.00292 (19%) | 0.00584 (39%) | 0.0117 (78%) | 0.0175 (117%) | 0.000676 (0%) | 0.00135 (1%) | 0.0027 (1%) | 0.00404 (2%) |
| CHILDREN 7 - 12 | | | | 1% | 0.0016 (11%) | 0.00321 (21%) | 0.00643 (43%) | 0.00964 (64%) | 0.000372 (0%) | 0.000747 (0%) | 0.00149 (1%) | 0.00224 (1%) |
| FEMALES 14 - 45 y | | | | 3% | 0.00165 (11%) | 0.00331 (22%) | 0.00661 (44%) | 0.00992 (66%) | 0.000445 (0%) | 0.000892 (0%) | 0.00178 (1%) | 0.00267 (1%) |
| **Sub population** | **TDI (µg/kg bw/day)** | | | **% users** | ***Per User (µg/kg bw/day) (% of MDEST TDI Portion)*** | | | | | | | |
| | **TDI** | **Background** | **MDEST TDI Portion** | | **Mean** | **90th percentile** | **95th percentile** | **99th percentile** | **Mean** | **90th percentile** | **95th percentile** | **99th percentile** |
| US 2+ | 0.3 | 0.285 (Initial) 0.05 (Revised) | 0.015 (Initial) 0.25 (Revised) | 2% | 0.0869 (579%) | 0.174 (1160%) | 0.347 (2313%) | 0.522 (3480%) | 0.0211 (8%) | 0.0421 (17%) | 0.0842 (34%) | 0.126 (50%) |
| INFANTS 6m – 2y | | | | 1% | 0.333 (2220%) | 0.667 (4447%) | 1.33 (8867%) | 2 (13333%) | 0.0887 (35%) | 0.177 (71%) | 0.354 (142%) | 0.532 (213%) |
| CHILDREN 2 - 6 y | | | | 1% | 0.205 (1367%) | 0.411 (2740%) | 0.822 (5480%) | 1.23 (8200%) | 0.0475 (19%) | 0.0951 (38%) | 0.19 (76%) | 0.285 (114%) |
| CHILDREN 7 - 12 | | | | 1% | 0.131 (873%) | 0.263 (1753%) | 0.526 (3507%) | 0.786 (5240%) | 0.0304 (12%) | 0.061 (24%) | 0.122 (49%) | 0.183 (73%) |
| FEMALES 14 - 45 y | | | | 3% | 0.0658 (439%) | 0.132 (880%) | 0.263 (1753%) | 0.396 (2640%) | 0.0177 (7%) | 0.0355 (14%) | 0.0711 (28%) | 0.107 (43%) |