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### **TASK DESCRIPTION 2**

#### F963 Section 4.3 Toxicology

#### 1. Background

Using the European Union's EN 71-3 Safety of Toys standard as a guideline, the American Society for Testing and Materials (ASTM) International implemented soluble metal content restrictions in the F963 voluntary standard for toy safety. The standard assumes repeated exposure by ingestion of a product of 8mg/day. Under the Consumer Product Safety Improvement Act (CPSIA), F963 was adopted as a rule under the Consumer Product Safety Commission and became a mandatory safety standard in February 2009. The CPSIA requires the Commission to evaluate the adequacy of the requirements that address hazards associated with small magnets; toxic substances; toys with spherical ends; hemispheric-shaped objects; cords, straps, and elastics; and batteryoperated toys. Section 4.3.5.2 of F963, toxic substances, prohibits the use of seven (7) metals (in addition to lead) in paint and similar surface-coating materials when the soluble metal content exceeds levels ranging from 25 ppm to 1000 ppm (specific level for each metal). Under the CPSIA, lead is restricted by a total content limitation. In consideration of this, and to begin evaluating section 4.3.5.2 for possible update and incorporation of more recent scientific data, the Commission staff requires information on metal toxicity.

### 2. Objective

The objectives of this task are to review the toxicological data on metals identified in ASTM F963: arsenic, chromium, mercury, and selenium, and determine any possible updates or other changes needed to the mandatory standard for consideration by the Commission.

### 3. Description of Task

The Contractor will: (1) review selected key studies and develop acceptable daily intakes (ADI) based on new/current non-cancer dose response data and No Observed (Adverse) Effect Levels (NO(A)EL) found; (2) provide a report comparing developed ADIs with current ADIs found in the ASTM F963 standard, providing appropriate level of detail needed to justify findings; (3) create toxicological profiles discussing the general findings in the literature and highlighting specific concerns and considerations discovered; and (4) provide feedback about the appropriateness of the current migration restrictions on the identified metals. Information on environmental effects is of secondary interest. Deliverables may be developed as a single document.

# 4. Deliverables or Performance

The Contractor shall provide the requested information in the form of a written report to the CPSC Project Officer within ninety (90) days. The report shall be in the format of a scientific report with full citations, tables, and figures as appropriate. The reviewer shall e-mail the report to the Project Officer in a Microsoft Word (preferred) or WordPerfect file.

## 5. Delivery Schedule

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| Item(s)   | Quantity  | Delivery or Performance  |
|---|---|--|
| The CPSC Project Officer and<br>Contractor will meet by<br>teleconference or in person to   | 1   | No later than<br>June 15, 2010   |
| discuss and initiate the project  |   |  |
| The CPSC Project Officer will<br>be available to consult with the<br>Contractor by teleconference<br>or in person.                                  | As appropriate  | As specific questions or comments comes up.  |
| The Contractor will provide a draft report comparing current and suggested ADIs for each metal.   | 1   | Within (90) days after<br>initiation of the project by<br>CPSC Project Officer and<br>Contractor (see first item in<br>delivery schedule). |
| The Contractor will provide<br>draft toxicological profiles, to<br>include requested feedback as<br>described above, to the CPSC<br>Project Officer | 1   | Within (90) days after<br>initiation of the project by<br>CPSC Project Officer and<br>Contractor (see first item in<br>delivery schedule). |
| The CPSC Project Officer will<br>provide written comments on<br>the draft report(s) to the<br>Contractor.   | 1   | Within (45) days after receipt<br>of the draft report.   |
| The Contractor shall submit a final report to the CPSC Project Officer.   | The Contractor will revise the draft report as appropriate.   | Within (30) days after receipt of comments.  |
| Inspection and Acceptance   | The Final report will be reviewed by the CPSC Project Officer | Within (30) days after receipt<br>of the Peer Review report  |

### 6. Place of Delivery

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U.S. Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814

CPSC Project Officer and contact information: Dominique J. Williams <u>dwilliams@cpsc.gov</u> 301-504-7597

## 7. Inspection and Acceptance

The Draft Toxicity Review report submitted to the U.S. Consumer Product Safety Commission will be reviewed within (45) days of receipt of the draft final report for any additional questions and/or comments. If returned to the Contractor as a result of the review, the Contractor shall address and/or revise their report accordingly and return the final version to the Project Officer within (30) days of receipt. The CPSC Project Officer will then have an additional (30) days to review the Final Toxicity Review report.

# 8. Requirement for CPSC Clearance

The final report is the property of the U.S. Consumer Product Safety Commission. The Contractor will not publish the final report, present the information at scientific meetings, or in any other way make the findings public in any form without the written permission of the Project Officer. Any publication must be cleared following CPSC procedures, as outlined in the Consumer Product Safety Act.