

## CPSC Reaction To Consumer Misuse May Cost Companies

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Product liability suits and regulatory product defect enforcement actions associated with foreseeable — and unforeseeable — consumer misuse have become the norm. Consumer product companies can mitigate these risks by focusing on use-related hazards and user-centered designs in an effort to reduce injuries and improve the usability of products. But the real question is how far to go with these efforts — at what cost, and for what incremental benefit.

On March 15, 2018, the U.S. Consumer Product Safety Commission published draft guidance on the application of human factors to consumer products, for industry comment by May 14, 2018. The draft guidance was developed in conjunction with Health Canada's Consumer Product Safety Directorate. The CPSC and Health Canada aim to increase product safety by explaining to product designers and manufacturers how to incorporate human factors[1] into the design process.

The draft guidance describes the product design process and provides guidance on human factors considerations at each stage (summarized in the table at the end of this article). Because the guidance is not an enforceable rule, no cost-benefit analysis accompanies the myriad of product design recommendations proposed.

While manufacturers and designers already include some human factors elements in their design processes, attempting to incorporate all or even enough of the CPSC's draft guidance recommendations to meet these regulatory expectations will be costly. It could require, among other things, hiring a human factors specialist; implementing foreseeable-use analysis; enhancing traceability of design decisions as well as products; establishing simulated-use testing regimens; and altering advertising campaigns.

Failure to incorporate any final guidance recommendations could be used against a manufacturer in product misuse liability suits, even those involving blatant consumer misuse and obvious risks, or those that simply could not have been prevented by user-centered design.

While the guidance indicates it is not a rule and does not establish legally enforceable responsibilities, the tone of the draft guidance itself indicates that consumer misuse events will regularly be considered evidence of product defects. The reality is that companies regulated by the CPSC look at agency



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guidance as an obligation, despite the disclaimers on enforceability.

The draft guidance provides an excellent roadmap of human factors design considerations based on science from human system integration developed for NASA space flights, military systems and industrial product design in addition to consumer products. But the draft guidance, untethered to specific products and applications, may present extraordinary costs and undue burdens given its applicability over such a wide range of consumer products.

The U.S. Congress required the CPSC to think critically about costs and benefits whether making rules (15 U.S.C. § 2058(c)) or deciding on whether a product presents an “unreasonable risk,” by balancing the utility of a product against misuse by consumers (15 U.S.C. § 2064; 16 C.F.R. §1115.6) for this very reason. Indeed, the draft guidance may go beyond the rulemaking authority of the CPSC, because it does not tie its design recommendations to a specific product and the nature of the risk of injury associated with the product. As such, it might better be styled as a research project and investigation into the prevention of product-related injuries (15 U.S.C. §2052) than a guidance document.

Without following the enabling act’s requirements for cost-benefit analysis, neither the CPSC nor the U.S. Department of Justice should use the guidance to justify enforcement actions or recall decisions. And yet the CPSC’s recent enforcement action against Britax, alleging a design defect that manifests only with consumer misuse, evidences a zero-tolerance policy for products that can be misused. The prosecution of the case will necessarily require the CPSC to advance these human factors design principles that have never been subject to the rigors of the APA or the cost-benefit analysis required by the Consumer Product Safety Act.

Not all consumer misuse can be designed away. Despite the best of intentions and the devotion of considerable resources, product designers cannot address the myriad ways we humans can make accidents happen. Some personal responsibility must still play a role in determining liability, whether those decisions are being made by regulators or in the courts.

Businesses should begin preparing to revisit internal regulatory reporting triggers — tuning them to take into account an aggressive consumer misuse perspective. To help direct and clarify the commission’s positions on human factors design elements and on consumer misuse, consumer product designers and manufacturers should consider options for commenting on the draft guidance, both individually and as part of industry associations.

<b>Design Stage</b>	<b>Draft Guidance Recommendations</b>
<b>Product planning</b>	Identify the activities to be accomplished by the human factors specialist, including any studies or analyses.
	Determine the schedule for completion of the human factors tasks and activities.
	Determine the resources required for completion of the human factors tasks and activities.
<b>Idea and</b>	Identify potential users of the product.

<b>concept generation</b>	Determine user needs. Analyze competing products and search for a gap between what consumers want and what is available in the marketplace.
<b>Design and development</b>	Identify all possible users; determine user characteristics.
	Conduct task analysis.
	Identify foreseeable use and misuse scenarios and hazards associated with those scenarios.
	Estimate and evaluate the risk level for each identified hazard.
	Determine ways to eliminate or reduce the hazard.
	Convert the results of task analysis data into a detailed design to create a human-system interface that will operate within human performance capabilities, meet the desired functional requirements and accomplish the product's objectives.
	Review layouts and drawings for all designs with potential impact on the human-system interface, and identify for corrective action those designs that may induce use-related error or be unsafe.
	Apply human factors principles to the engineering drawings and computer-aided design representations to ensure the final product can be used effectively, efficiently, reliably and safely.
	Ensure that the human functions and tasks identified through human factors analyses are organized and sequenced for efficiency, safety and reliability, and provide inputs to the technical documentation.
Participate in developing the look, feel and content of controls and displays, including multifunction displays, to ensure that the user interface supports efficient data input and retrieval, access to required information and execution of decisions and commands.	
<b>Testing and validation</b>	Plan the human factors test to identify the data to be collected, the test procedures, the test criteria and the reporting process.
	Prepare the test documentation (e.g., checklists, data sheets, test participant descriptors, questionnaires and operating procedures), and make it available at the test location.
	Determine the tasks to be performed (to include critical tasks at a minimum), or a simulation thereof, if actual performance is not feasible.
	Determine criteria for acceptable performance or rejection of the test results.

	<p>Recruit participants who are representative of the range of the intended or foreseeable user population(s) in terms of aptitudes, skills, capabilities, experience, size and strength; and who are wearing suitable clothing and equipment appropriate to the task.</p>
	<p>Conduct human factors tests to demonstrate that the consumer product will be efficient, effective and safe in the hands of the user. Collect task performance data in actual operational environments or in simulated environments, if collection in the actual operating environment is not feasible.</p>
	<p>Review the failures that were recorded during testing to differentiate among failures of hardware/software alone, failures resulting from human-system incompatibilities and use-related failures.</p>
	<p>Analyze use-related errors to determine the reason for their occurrence. Identify the design characteristics or procedures that may contribute use-related errors.</p>
	<p>Determine appropriate corrective action.</p>
<b>Production</b>	<p>Participate in the design and development of work stations to ensure that physical working conditions are satisfactory including environment (e.g., good lighting, controlled temperature and humidity) for the manufacture of safe products.</p>
	<p>Maintain the instructions for assembly, packaging and shipping operations affecting safety, i.e., work instructions.</p>
	<p>Incorporate human factors principles into the design and development of packaging and advertising materials.</p>
<b>Post-production evaluation</b>	<p>Analyze the returns to determine if the reason for the return is related to the product-use interface.</p>
	<p>Examine the repair data to determine the reasons for repairs of the product and the fix applied.</p>
	<p>Evaluate customer satisfaction surveys, incident reports and calls to the help desk to determine if any trends emerge relating to the use of the product.</p>
	<p>Verify that recall communication is clear and motivates compliance.</p>
	<p>Improve traceability of products.</p>

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[1] The draft guidance defines Human Factors Engineering as:

The application of knowledge about human capabilities and limitations to product design and development to achieve efficient, effective and safe performance considering cost, skill levels and training demands. Human factors engineering ensures that the product design, required human tasks and use environment are compatible with the sensory, perceptual, mental and physical attributes of the user who will operate and maintain the product.