



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

This document has been electronically
approved and signed.

DATE: February 12, 2020

BALLOT VOTE SHEET

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: John G. Mullan, General Counsel
Mary T. Boyle, Executive Director

FROM: Hyun S. Kim, Acting Assistant General Counsel, Regulatory Affairs
Meridith L. Kelsch, Attorney, Regulatory Affairs

SUBJECT: Revised CPSC Information Quality Guidelines

BALLOT VOTE DUE: Wednesday, February 19, 2020

Staff is forwarding to the Commission draft revised CPSC Information Quality Guidelines (IQGs). The Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2002 (Pub. Law No. 106-554)) required the Office of Management and Budget (OMB) to issue government-wide guidelines that “provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.” Pursuant to OMB’s guidelines, the Commission issued IQGs in October 2002, and posted them on CPSC’s website. On April 24, 2019, OMB updated its guidance regarding these guidelines, and clarified the guidance on June 3, 2019, directing agencies to make certain updates to their information quality guidelines and procedures. Attached is a draft revision to CPSC’s IQGs, which includes the revisions directed by OMB.

Please indicate your vote on the following options:

- I. Approve the revised CPSC IQGs, and post them to CPSC’s website, as drafted.

(Signature)

(Date)

II. Approve the revised CPSC IQGs, and post them to CPSC's website, with the specified changes.

(Signature)

(Date)

III. Do not approve the revised CPSC IQGs, and post them to CPSC's website.

(Signature)

(Date)

IV. Take other action specified below.

(Signature)

(Date)

Attachment: Draft Revised CPSC Information Quality Guidelines

Information Quality Guidelines

Background

This document provides the U.S. Consumer Product Safety Commission's (CPSC's) Information Quality Guidelines. These guidelines incorporate comments CPSC received from the public and the U.S. Office of Management and Budget (OMB).

OMB issued government-wide Information Quality Guidelines under Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554). OMB prepared the guidelines to ensure and maximize the quality, utility, objectivity, and integrity of the information federal agencies disseminate.

These guidelines directed all Federal agencies to issue their own implementing guidelines by October 1, 2002. OMB's guidelines were published in the *Federal Register* on September 28, 2001 (66 FR 49718) and updated on January 3, 2002 (67 FR 369). OMB published a corrected version of the guidelines in the *Federal Register* on February 22, 2002 (67 FR 8452). In response to the OMB directive, CPSC issued its draft Information Quality Guidelines for public comment on April 30, 2002 (67 FR 21222). These draft guidelines addressed the scope of the guidelines, a description of CPSC's information quality standards, and an administrative mechanism by which the public can seek correction of information CPSC disseminates. After considering comments on them, CPSC posted its Information Quality Guidelines on its website (67 FR 63382 (Oct. 11, 2002)).

On April 24, 2019, OMB issued updated guidance to federal agencies regarding the Information Quality Act (IQA). OMB Memorandum M-19-15, *Improving Implementation of the Information Quality Act* (Apr. 24, 2019) (<https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf>). CPSC is committed to complying with the IQA and to implementing the updates listed in M-19-15. CPSC revised certain provisions of the agency's guidance in response to M-19-15.

CPSC works to save lives and keep families safe by reducing the risk of injuries and deaths associated with consumer products. CPSC does this by:

- Developing voluntary standards with industry;
- Obtaining the recall of products or arranging for their repair;
- Issuing and enforcing mandatory standards or banning consumer products if no feasible standard would adequately protect the public;
- Conducting research on potential product hazards; and
- Informing and educating consumers through the media, state and local governments, private organizations, and by responding to consumer inquiries.

In meeting its mission, CPSC disseminates information in a number of ways, including:

- Press releases and video news releases;
- Publications;

- Product safety alerts;
- Special technical reports;
- Advisory opinions; and
- Regulatory guidance letters.

This information is used by the media, the public, and other government agencies, to reduce the risk of product-related deaths and injuries. Businesses use the information to ensure that products they manufacture or import comply with the requirements of applicable regulations and to discharge the various obligations that the laws the Commission administers impose on firms.

CPSC's Information Quality Guidelines substantially follow the provisions of OMB's guidelines referenced above. Under OMB's Information Quality Guidelines, three aspects of quality must be considered: (1) utility, (2) objectivity, and (3) integrity. In addition, for influential data, higher standards of transparency and reproducibility must be met. CPSC's guidelines use the definitions of the key statutory terms, such as "information," "disseminate," "utility," "objectivity," "integrity," "influential," "transparency," and "reproducibility," as defined in the OMB guidelines. For the purpose of these guidelines, most of the information CPSC disseminates does not meet the standard of "influential," as defined by the OMB guidelines. Each of these aspects of quality is described below.

Utility

Utility involves the usefulness and availability of the information for its intended use. Utility is achieved by continuously monitoring information and developing new information sources or by revising existing information-collection methods, models, and information products, where appropriate.

CPSC's efforts to ensure the usefulness of information include:

- Internal analyses and review of information requirements and products;
- Discussions with policy-makers and analysts at all levels of government;
- Consultations with data providers and data users; and
- Preparation of "plain English" guides and summaries of information.

CPSC's efforts to ensure the availability of information include:

- Participating in industry-sponsored and government-sponsored meetings, conferences, and workshops;
- Exploring and implementing multiple vehicles with which to disseminate information; and
- Providing expanded website access to publicly available information.

Objectivity

Objectivity involves a focus on ensuring that information is accurate, reliable, and unbiased, and that information products are presented in an accurate, clear, complete, and unbiased manner. Objectivity is achieved by using reliable data sources and sound analytical techniques, by having

information products prepared by qualified people using proven methods, and by carefully reviewing the content of all information products.

Use of Reliable Data Sources

CPSC is a data-driven agency that bases its decisions on the data it collects to assess the causes and scope of product-related injuries and deaths. Many of the information products CPSC disseminates are created using information in death, injury, and compliance action databases. These databases contain information used to perform standards-effectiveness studies, special investigation studies, emerging hazard evaluations, and other technical analyses. CPSC conducts ongoing internal quality assurance reviews of information in its database systems. These reviews include checks for accuracy, completeness, and consistency to ensure high quality. Often these databases contain information from external sources. Data and procedures are reviewed to ensure that data from external sources are properly transferred into the database.

When analysis requires using samples from databases, CPSC employs statistically acceptable methods to design and select the samples. Data samples are designed and compiled by staff, who are knowledgeable about the content, structure, and limitations of the administrative data files employed. In addition, those staff members maintain working relationships with agency personnel, who create, update, and maintain those files to ensure that their understanding of files is current and complete. When information products require administrative files linked to external data sources, CPSC employs sound procedures for extracting and linking data from external sources, based on a thorough understanding of the relevant components of the data sources.

Occasionally, CPSC conducts surveys of product use, customer satisfaction, and service quality. CPSC employs and documents accepted professional standards and practices for all survey activities, including sample frame development, sample design, questionnaire design and testing, data collection, analysis of sampling and coverage errors, imputation of missing data, weighting, and variance estimation. CPSC surveys follow guidelines and policies set forth in the Paperwork Reduction Act (PRA) and other regulations related to the conduct of government surveys. CPSC is already required to demonstrate in its PRA submissions to OMB the “practical utility” of a proposed collection of information that CPSC plans to disseminate to the public. Additionally, for all proposed collections of information that will be disseminated to the public, CPSC demonstrates in its PRA clearance submissions to OMB that the proposed collection of information will result in information that will be collected, maintained, and used consistent with OMB’s and CPSC’s Information Quality Guidelines.

CPSC information products also may include data produced or maintained by other U.S. government agencies or other private organizations. CPSC assesses all such information before using it. Information that CPSC disseminates may include third party information. Although third party sources may not be directly subject to OMB’s Information Quality Guidelines, when CPSC uses the data to develop information products, the material must follow CPSC’s Information Quality Guidelines.

Use of Sound Analytic Techniques

CPSC's analytical reports are prepared using a variety of techniques, including simple tabulations with descriptive summary statistics and multivariate statistical methods. For example, these reports can include integrating injury and incident information with laboratory testing and analysis, assessing human exposure to various risks, and correlating human behavior and risk. Qualified staff reviews the appropriateness of the analytical techniques to the data and the analysis being conducted, and clearly identifies this information in reports.

CPSC also conducts economic studies, developing injury cost projections to estimate potential benefits associated with CPSC actions. These projections are based on standard techniques and use the most relevant and up-to-date information available.

Occasionally, CPSC uses models to conduct engineering analyses and to forecast product injury information. CPSC staff or CPSC contractors develop most of these models. When CPSC uses a proprietary model from another organization, CPSC analyzes the model to ensure its appropriateness before including the model results as part of an agency information product. CPSC models have detailed documentation describing the goals and objectives of the model, the data sources used, and the methodologies and assumptions employed. CPSC models are based on best judgments of current and future behavioral relationships and methods of projection. Periodically, CPSC updates these models to reflect input from internal and external reviews and research findings on behavioral relationships. In addition, CPSC documents any updates.

Preparation of Information Products

CPSC information products are based on internal data and analyses, surveys, models, and external information sources. Appropriate procedures are used in all steps of the information product preparation process. Documentation available with CPSC information products is designed to improve understanding of the information so that users may assess the suitability of the information for their needs. Staff prepares reports using a variety of sound analytical techniques ranging from simple tabulations and descriptive summary statistics to multivariate statistical methods and econometric models. Staff members preparing analytic reports and policy studies are knowledgeable in their use of relevant administrative data files, external data sources, and projections from simulation models.

Review Prior to Dissemination

Technically qualified staff review information products before disseminating them to ensure their quality. Products that are considered more technically complex may also be reviewed by independent experts to provide additional perspective. The level of review before dissemination depends on the characteristics of the product and established CPSC review procedures. (See 15 U.S.C. § 2055(b)(6) and CPSC Directives.) CPSC describes analytical techniques and clearly identifies data sources in reports. When CPSC bases its analyses on projections from models, CPSC identifies the assumptions used to produce the projections, as well as the rationale for the assumptions and the impact of using alternative assumptions. By statute, if the information disseminated by CPSC publicly identifies the manufacturer or private labeler of a product, CPSC

provides the manufacturer or private labeler with advance notice and the opportunity to comment on the information.

Policy for Correcting Errors and Revising Previously Disseminated Information

CPSC may revise its information products after disseminating them to reflect more complete information, corrections, or other changes. CPSC information products identify information that is preliminary and expected to be revised, as well as revisions made to information previously disseminated.

Integrity

Integrity, as used in the OMB Information Quality Guidelines, refers to the security of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. CPSC policies and practices protect the confidentiality of information the agency holds.

To ensure the integrity of its administrative information, CPSC employs rigorous controls recognized to represent sound security practices. CPSC has in place programs and policies to secure its resources, as required by the Government Information Security Reform Act (Public Law 106-398, title X, subtitle G). Those policies and procedures address all major components of information security and apply to all CPSC operating components. In addition, CPSC is subject to statutory requirements to protect the sensitive information it gathers and maintains on individuals. The statutes and other materials below set forth those requirements:

- Privacy Act of 1974;
- Freedom of Information Act;
- E-Government Act of 2002;
- Computer Security Act of 1987;
- Federal Information Security Modernization Act;
- Government Information Security Reform Act;
- Federal Managers' Financial Integrity Act of 1982;
- OMB Circulars A-123, A-127, and A-130; and
- OMB Memoranda M-03-22 and M-17-12.

Transparency and Reproducibility

CPSC's Information Quality Guidelines substantially follow the definitions for "influential," "transparency," and "reproducibility" in the OMB guidelines referenced above. OMB's guidelines state that information disseminated by federal agencies is considered "influential" if it does or will have a clear and substantial impact on important public policies or important private sector decisions. OMB's guidelines require that agencies disseminating influential information must have quality guidelines that include a high degree of transparency about data and methods to facilitate reproducibility of such information. "Reproducibility," as set forth in the OMB guidelines, means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision.

Most of the information CPSC disseminates does not fall under OMB's definition of "influential." However, some CPSC information could be "influential." For example, the types of information below could be "influential":

- Risk assessments for economically significant rulemakings;
- Regulatory analyses for economically significant rulemakings; and
- Certain staff and contractor technical reports related to engineering, health science, or hazard analysis issues that potentially have impacts on important public policies and private sector decisions, such as changes in voluntary standards.

CPSC recognizes the importance of peer review before disseminating influential information. CPSC conducts such peer reviews in accordance with OMB's Final Information Quality Bulletin for Peer Review (70 FR 2664 (Jan. 14, 2005)).

CPSC's influential information should be highly transparent and capable of being reproduced by qualified persons. CPSC strives to achieve a high degree of transparency about information and methods in order to improve understanding and to facilitate reproducibility by qualified third parties. To achieve transparency and reproducibility, CPSC's guidelines require documentation of systems and models and appropriate explanatory material to accompany disseminated information (specific data sources and quantitative methods and assumptions used). Some estimates and projections in CPSC's information products are not directly reproducible by the public because the underlying data sets used to produce them are confidential. Additionally, some estimates and projections may not be easily reproducible by third parties due to the complexity and detail of the methods and data. CPSC places great emphasis on its review process to ensure the quality of information it disseminates.

CPSC also achieves transparency through widespread dissemination of its information. Reports and other data products are available in print form and electronically. CPSC announces these materials on its website, and most electronic versions can be accessed and downloaded directly from the website.

To ensure reproducibility, CPSC creates archival files of data and model results that are used as input to CPSC information products.

Risk Assessment

Some of the influential information that CPSC disseminates is based on an analysis of the risks to the public of certain actions or exposures to hazardous substances. For purposes of this guidance, CPSC defines "risk" as the likelihood that injury or damage is or can be caused by a substance, technology, or activity. CPSC uses risk analysis (the integration of risk assessment with risk management and risk communication) as a tool to enhance the scientific basis for its regulatory decisions.

The OMB guidelines provide special considerations that must be taken into account in certain risk assessments, those that provide the basis for the dissemination of influential information.

The guidelines state: “With regard to analysis of risks to human health, safety, and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (SDWA) (42 U.S.C. § 300g-1(b)(3)(A) and (B)).”

The SDWA risk assessment principles are:

1. To the degree that the agency action is based on science, the agency shall use:

- the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and
- data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data).

2. In the dissemination of public information about risks, the agency shall ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.

3. In a document made available to the public in support of a regulation, the agency shall specify, to the extent practicable:

- Each population addressed by any estimate of applicable risk effects;
- The expected risk or central estimate of risk for the specific populations affected;
- Each appropriate upper-bound or lower-bound estimate of risk;
- Each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and
- Peer-reviewed studies known to the agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile the inconsistencies in the scientific data.

Many of CPSC’s actions are based on scientific experts’ judgments using available data, are essentially qualitative, and are generally carried out for non-cancer-causing hazards. Such assessments provide useful answers in most instances that are sufficient for regulatory purposes, and much more elaborate, quantitative estimates extrapolating beyond the data are unnecessary. Although CPSC might analyze the economic costs of the regulations and consider alternatives, regulations like these do not lend themselves to the types of full quantitative risk assessments contemplated by the SDWA principles. As a result, CPSC has adapted the general principles for risk assessments from the SDWA to fit these situations. The principles CPSC intends to apply to risk assessments involving the dissemination of influential information affecting product approval actions or regulations that do not lend themselves to quantitative risk assessment are as follows:

1. The agency will use —

- the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed studies and supporting studies where available; and
- data collected by best-available method or accepted methods (if reliability of the method and the nature of the decision justify use of the data).

2. In the dissemination of public information about risks, the agency will ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.

CPSC rarely performs quantitative risk assessments. However, in situations requiring a quantitative risk assessment, CPSC generally follows basic risk assessment principles in the NAS paradigm of 1983. Thus, CPSC also subscribes to the statement from NAS when it revisited the risk assessment process in 1994 (*Science and Judgment in Risk Assessment*, NAS 1994): “Risk assessment is not a single process, but a systematic approach to organizing and analyzing scientific knowledge and information.” In each of the areas CPSC regulates, it applies risk assessment practices to the specific task that are widely accepted among relevant domestic and international public health agencies.

For quantitative risk assessments to support disseminating influential information, CPSC intends to apply the following principles, following the SDWA risk assessment principles:

1. The agency will use —

- the best available science and supporting studies conducted in accordance with sound and objective scientific practices; and
- data collected by accepted methods (if reliability of the method and the nature of the decision justifies use of the data).

2. In disseminating public information about health risks, the agency shall ensure that the presentation of information is comprehensive, informative, and understandable, within the context of its intended purpose.

3. In a risk assessment document made available to the public, the agency shall specify, to the extent practicable —

- Each population addressed by any estimate of applicable effects;
- The expected or central estimate of risk for the specific populations affected;
- Each appropriate upper-bound and/or lower-bound risk estimate;
- Data gaps and other significant uncertainties identified in the process of the risk assessment and the studies that would assist in reducing the data gaps and other uncertainties; and
- Additional studies not used to produce the risk estimate that support or fail to support the findings of the assessment, the rationale of why they were not used, and the methodology used to reconcile the inconsistencies in the scientific data.

Information Not Subject to CPSC's Information Quality Guidelines

CPSC's guidelines do not apply to:

- Procedural, operational, policy, and internal manuals prepared for the management and operations of the agency that are not primarily intended for public dissemination;
- Information disseminated by CPSC employees that is not put forth as a CPSC product (*e.g.*, materials presented by an individual at a professional meeting); and
- Other materials specifically exempted in the OMB guidelines.

Historically, CPSC has used standards, policies, and other operational guidance to ensure the quality of all its activities. CPSC has confidence in the quality of information it disseminated before October 1, 2002. However, CPSC regards information originally disseminated before October 1, 2002, as being subject to these Information Quality Guidelines, only if the information remains readily available to the public (*e.g.*, it is posted on the CPSC website) and it continues to play a significant, active role in CPSC programs or decisions.

Administrative Correction Mechanisms

CPSC has established procedures for any person to request corrections to information disseminated by CPSC when the information does not comply with CPSC's or OMB's Information Quality Guidelines. A person who believes that information CPSC has disseminated does not adhere to CPSC's or OMB's Information Quality Guidelines, and who would like to request correction of specific information, should write to the U.S. Consumer Product Safety Commission, Office of the General Counsel, Division of the Secretariat, 4330 East West Hwy, Bethesda, MD 20814, or send an e-mail to IQA@cpsc.gov. The request should be captioned "Information Quality Guidelines" and should provide the following information:

- Information identifying the requestor;
- A specific description of the information to be corrected;
- Potential adverse impacts from the information identified for correction; and
- A specific reason why and how the information should be corrected.

Based on a review of the information provided, CPSC will take the following actions:

- Perform an acceptance review to confirm that the requestor provided the necessary information regarding the correction.
- Submit the request for review to a management official who is knowledgeable about the subject matter related to the request. The designated management official may consult with other federal agencies or CPSC staff in responding to the request for correction, as appropriate.
- Determine whether a correction is warranted and, if so, what action will be taken.
- Respond to a request for correction of information within 90 calendar days of receipt of the request. If the request requires more than 90 calendar days to resolve, then CPSC will

inform the requestor that more time is required, state the reason why, and include an estimated decision date.

In the response to the requestor, CPSC will:

- Endeavor to provide a point-by-point response and will refer to a peer review if the issue the requestor raises was considered in a peer review; and
- Not opine on the requestor's or agency's policy position.

If the requestor is not satisfied with CPSC's final response to the request, the requestor may submit an appeal to the U.S. Consumer Product Safety Commission, Office of the Executive Director, 4330 East West Hwy, Bethesda, MD 20814. The requestor must use the following process to appeal a decision:

- Submit an appeal within 30 calendar days of receipt of CPSC's notification of denial or notification of the corrective action. (Only the original requestor may appeal the decision.)
- Identify the original request for correction, and specify the CPSC response being appealed.
- Describe the basis for the appeal and how the response failed to resolve the request for correction.

The appeal will be evaluated by an agency official, typically at the Executive Director level. The evaluation will be made by individuals who were not involved in the initial response to the request for correction. The appeal review will be limited to the basis of the appeal. The requestor will be notified of the agency's decision regarding the appeal within 60 calendar days. If the request requires more than 60 calendar days, then CPSC will tell the requestor that more time is required, state a reason why, and include an estimated decision date.

The correction and appeal process that will address data quality challenges does not apply to information disseminated by CPSC through a comprehensive public comment process (e.g., *Federal Register* notices of proposed rulemakings, regulatory analyses, requests for comments on information collections subject to the PRA, environmental impact statements, and other documents for which CPSC solicits public comments). Persons questioning the quality of information disseminated in those documents, or documents referenced or relied upon in those documents, must submit comments as directed in the *Federal Register* or other notices requesting public comment on the given document. CPSC will use its existing processes for responding to public comments in addressing the request for correction, and will describe the actions it has taken with regard to the request in the *Federal Register* notice of the final agency rule, regulatory analysis, or other final action. In cases where the agency disseminates a study, analysis, or other information prior to the final agency action or information product, requests for correction will be considered prior to the final agency action or information product in those cases where the agency has determined that an earlier response would not unduly delay issuance of the agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the agency's dissemination if the agency does not resolve the complaint prior to the final agency action or information product.

The correction process is designed to address the genuine and valid needs of affected persons without disrupting agency operations. Requestors should be aware that they bear the burden of proof with respect to both the need for correction and the type of correction requested. In determining whether to correct information, CPSC may reject claims made in bad faith or without justification. CPSC is required to undertake only the degree of correction that it concludes is appropriate for the nature and timeliness of the information involved.

References

- 67 FR 8452 (Feb. 22, 2002), Office of Management Budget Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. Final Guidelines. Effective January 3, 2002.
- 2003 Budget and Performance Plan (Operating Plan), <https://cpsc.gov/cpscpub/pubs/reports/2003opplan.pdf>.
- Public Disclosure of Information, 15 U.S.C. § 2055, <https://www.govinfo.gov/content/pkg/USCODE-2017-title15/html/USCODE-2017-title15-chap47-sec2055.htm>.
- Science and Judgement in Risk, National Research Council, National Academy Press, 1994, <http://www.nap.edu/books/030904894X/html/index.html>.