Environmentally preferable products – Hard surface cleaners

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NSF/ANSI 143 – 2006

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NSF International Standard/
American National Standard

Environmentally preferable products —
Hard surface cleaners

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Foreword² (This foreword is not part of ANSI/NSF 143– 2006.)

Over the last decade, federal Executive Orders and new procurement regulations have been enacted to require the increased use of recycled and environmentally preferable products by the federal government. At the same time, private sector manufacturing operations have continued to make their operations more environmentally benign and their products more sustainable and environmentally preferable. This trend is expected to remain as society continues to seek less polluting methods of production and customers continue to demand products with a more favorable environmental profile.

The purpose of NSF/ANSI 143 – 2006 is to establish requirements for a Product Development Process: Environmental Management System (PDP-EMS) for any hard surface cleaners having quantifiable positive environmental attributes. Certification to this Standard serves as a communication tool between manufacturers, regulatory agencies, and consumers. This Standard provides evaluation criteria to allow for the determination that a product is deemed environmentally preferable if it produces a smaller environmental footprint when compared to other competing products in the market. An implemented PDP-EMS is used to enhance the manufacturer’s capabilities at every stage of product design decision-making to minimize upfront environmental and human health risks. This standard provides an alternative approach to product specific standards by guiding manufacturers in the development of an environmental management system showing continual improvement. By creatively blending flexibility and specific, measurable EPP criteria, this standard may serve as a complement to existing EPP standards.

This standard was funded in part by the U.S. Environmental Protection Agency, under the “Small Grant-Environmentally Preferable Purchasing Pilot” program. This Standard was developed by the NSF Joint Committee on Environmentally Preferable Products including participation and technical guidance provided by representatives of the U. S. Environmental Protection Agency and the U.S. Department of Agriculture using the consensus process described by the American National Standards Institute.

This Standard uses inch-pound units as the primary units with SI (metric) units provided in parentheses for informational purposes. The Joint Committee carried a motion that this convention be adopted in future revisions to this Standard. The SI units provided in parentheses generally represent a hard conversion of the inch-pound units, meaning that the SI value may have been rounded to provide a reasonable and measurable dimension.

Suggestions for improvement of this Standard are welcome. Comments should be sent to Chair, Environmentally Preferable Products, c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan, 48113-0140, USA.

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NSF/ANSI Standard
for Environmentally Preferred Products —

Environmentally preferable products —
Hard surface cleaners

1 General

1.1 Purpose

This Standard was written to provide a management strategy guide for manufacturers in establishing a product stewardship practice in designing, developing, and marketing environmentally preferable products (EPP). Product stewardship dictates that the manufacturer makes continual effort to minimize the product’s environmental impacts throughout all stages of its product life cycle.

Specifically, this Standard establishes requirements for a Product Development Process: Environmental Management System (PDP-EMS) for hard surface cleaners. The PDP-EMS can be used to achieve any quantifiable environmental performance goals specified by the manufacturer and/or customer (e.g., market, government, contractual or self-imposed criteria). Conformance to this Standard will positively identify the manufacturer’s product as a product that is “designed, developed, and marketed through a PDP-EMS.” By positively identifying the use of PDP-EMS, this Standard also addresses the importance of evaluating a product stewardship practice as a significant part of EPP purchasing criteria. In addition to establishing a PDP-EMS, the manufacturer can qualify an EPP to its environmental performance goals by means of internal or third party testing and auditing.

1.2 Scope

This Standard specifies requirements for a PDP-EMS for hard surface cleaner products. A hard surface cleaner developed and produced under a PDP-EMS that meets the requirements of this Standard and specified environmental attribute targets shall be considered an EPP to the extent that the attribute targets express EPP. An EPP is a product that produces a smaller environmental footprint when compared to other competing products in the market.

This Standard (1) addresses the ethics of pollution prevention and responsible energy use in the entire product life cycle through which environmental issues are systematically integrated into product design and (2) addresses biodegradability and enables identification of chemicals that may potentially persist, bio-accumulate, and be toxic in the environment, i.e., PBT chemicals. This Standard does not itself set but does suggest specific environmental performance criteria for hard surface cleaners or for their product development processes. It does suggest example product performance criteria that could be useful in building a PDP-EMS for hard surface cleaners. This example can be used to establish goals for internal EPP criteria to be used by the manufacturer or used in conjunction with any standard appropriate to individual customer or marketplace.

This Standard shall enable a manufacturer of hard surface cleaners to formulate a PDP-EMS covering those environmental aspects that the manufacturer can control. The implemented PDP-EMS shall enhance the manufacturer's capabilities at every stage of product design decision-making to minimize
upfront environmental and human health risks. Annex A contains suggested parameters for certification programs.

Conformance to this Standard ensures that the manufacturer has demonstrated the use of a continually improvable PDP-EMS to develop an EPP. Marketing EPPs promotes environmentally preferable purchasing practices among consumers, industry, and government purchasers.

2 Normative references

The following documents contain provisions that, through reference, constitute provisions of this NSF/ANSI Standard. At the time this Standard was balloted, the editions listed below were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the recent editions of the documents indicated below.

There are currently no normative references (see annex A).

3 Definitions

For the purposes of this Standard, the following definitions apply.

3.1 cleaner: A formulated product designed to assist in removing undesirable matter from a surface.

3.2 continual improvement: Process of enhancing the PDP-EMS to achieve improvements in overall environmental performance in line with the manufacturer's environmental policy.

NOTE – The process need not take place in all areas of activity simultaneously.

3.3 environment: Surroundings in which a manufacturer or its products operate, including air, water, land, natural resources, flora, fauna, humans, and their interrelations.

3.4 environmental aspect: Element of a manufacturer’s product development process that can interact with the environment.

NOTE – A significant environmental aspect is one that has or can have a significant environmental impact.

3.5 environmental impact: Any change to the environment, whether adverse or beneficial, wholly or partially resulting from a manufacturer's activities, products, or services.

3.6 environmental management system: The part of the overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, processes, and resources for developing, implementing, achieving, reviewing, and maintaining the environmental policy.

3.7 environmental objective: Overall environmental goal, arising from the environmental policy, that a manufacturer sets itself to achieve, and which is quantified where practicable.

3.8 environmental performance: Measurable results of the PDP-EMS, related to a manufacturer's control of its environmental aspects, based on its environmental policy, objectives, and targets.

3.9 environmental policy: Statement by the manufacturer of its intentions and principles in relation to its overall environmental performance, which provides a framework for action and for the setting of its environmental objectives and targets (also see 3.2.)

3.10 environmentally preferable products (EPP): Products that have a lesser or reduced effect on human health and the environment while providing the appropriate benefits to public health and the
environment obtained from effective cleaning and maintenance when compared with competing products that serve the same purpose. The product comparison may consider research and development, raw materials acquisition, production, manufacturing, packaging, distribution, reuse, operation, maintenance, or disposal. (EO 13101, Section 201.)

The five environmentally preferable purchasing guiding principles are:

**Guiding Principle 1:** Environment + price + performance = environmentally preferable purchasing

Environmental considerations should become part of normal purchasing practice, consistent with such traditional factors as product safety, price, performance, and availability.

**Guiding Principle 2:** Pollution prevention

Consideration of environmental preferability should begin early in the acquisition process and be rooted in the ethic of pollution prevention, which strives to eliminate or reduce, up-front, potential risks to human health and the environment.

**Guiding Principle 3:** Life cycle perspective/multiple attributes

A product or service’s environmental preferability is a function or multiple attributes from a life cycle perspective.

**Guiding Principle 4:** Comparison of environmental impacts

Determining environmental preferability might involve comparing environmental impacts. In comparing environmental impacts, users should consider: the reversibility and geographic scale of the environmental impacts, the degree of the difference among competing products or services, and the overriding importance of protecting human health.

**Guiding Principle 5:** Environmental performance information

Comprehensive, accurate, and meaningful information about the environmental performance of products or services is necessary in order to determine environmental preferability.

3.11 environmental target: Detailed performance requirement, quantified where practicable, applicable to the manufacturer or parts thereof, that arises from the environmental objectives and that needs to be set and met in order to achieve those objectives.

3.12 hard surface: Any non-textured surface that is essentially impervious to the penetration of water or soils.

3.13 hard surface cleaner: A cleaner intended for use on hard surfaces such as glass, porcelain, ceramic, metal, vinyl, sealed, or painted.

3.14 interested party: Individual or group concerned with or affected by the environmental performance of a manufacturer.

3.15 manufacturer: The enterprise responsible for the decisions that affect the product performance and environmental impact.
3.16 **pollution prevention**: Use of practices that avoid or reduce pollution at the source, prior to recycling, treatment, or disposal. The term may include equipment or technology modifications, process changes, control mechanisms, efficient use of resources, and material substitution.

NOTE – The potential benefits pollution prevention includes the reduction of adverse environmental impacts, improved effectiveness, and reduced costs.

3.17 **product development process: environmental management system (PDP-EMS)**: A system to determine whether environmental considerations play a role in the decisions and processes involved in product design and development.

3.18 **product development process – environmental management system audit**: A systematic and documented verification process of objectively obtaining and evaluating evidence to determine whether a manufacturer’s PDP-EMS conforms to the PDP-EMS audit criteria set by the manufacturer and for communication of the results of this process to management. (See annex A, section A.2)

3.19 **risk assessment**: the process of gathering data and making assessments to estimate short- and long-term harmful effects on human health or the environment from exposure to hazards associated with a particular product or activity as well as the beneficial effects of the product or activity in eliminating hazards.

3.20 **sustainability**: meeting the needs of today without compromising the ability of future communities to meet their needs. This involves taking account of the costs to the environment and depletion of natural resources.

4 **PDP-EMS requirements**

4.1 **General requirements**

The manufacturer of hard surface cleaners for which EPP goals are to be set shall establish and maintain a PDP-EMS. It is intended that the implementation of such a system, as described by the specification, will result in improved product environmental performance. The specification is based on the concept that the organization shall periodically review and evaluate its PDP-EMS in order to identify opportunities for improvement and implementation. Improvements in its PDP-EMS are intended to result in additional improvements in environmental performance of the product.

The PDP-EMS shall provide a structured process for the achievement of continual improvement, the rate and extent of which shall be determined by the organization in the light of economic and other circumstances. Although some improvement in environmental performance can be expected due to the adoption of a systematic approach, it shall be understood that the PDP-EMS is a tool, which enables the organization to achieve and systematically control the level of a product's environmental performance set by itself. These EPP goals shall be well-recognized marketplace criteria, standards, purchasing specifications, and uniquely tailored EPP criteria agreed upon by manufacturers and customers. These EPP goals may also be self-imposed criteria established to produce a product with a specific environmental footprint or to create a continuous improvement process. The establishment and operation of a PDP-EMS may not, in itself, necessarily result in an immediate reduction of adverse environmental impacts, which can be achieved if the finished product meets the EPP specified criteria.

The level of detail and complexity of the PDP-EMS, the extent of documentation, and the resources devoted to it, shall depend on the size of the manufacturer and the nature of its products, especially for small and medium-sized enterprises.

This Standard contains management system requirements, based on the dynamic cyclical process of “plan, implement, check, and review.”
4.2 The environment and product development: policy overview

Environmental policy is the driver for implementing and improving the manufacturer's PDP-EMS so that the manufacturer can maintain and potentially improve environmental performance of its products. The policy shall therefore reflect the commitment of executive management to compliance with applicable laws and continual improvement. The policy shall form the basis upon which the organization sets its objectives and targets. The policy shall be sufficiently clear to be capable of being understood by internal and external interested parties and shall be periodically reviewed and revised to reflect changing conditions and information. Its area of application shall be clearly identified.

Executive management shall define and document the organization’s environmental policy and ensure that:

- environmental considerations are taken into account in the choices made in product development in a manner appropriate to the nature, scale, and environmental impacts of the product as well as the company’s associated activities in developing and marketing the product;
- a commitment is made to continual improvement in the product development process and review of the products developed with the goal of pollution prevention;
- a commitment is made to comply with relevant environmental legislation, regulations, and requirements in all target markets and manufacturing facilities. This is a minimum standard for product development;
- a framework for identifying and setting priorities and reviewing environmental objectives and targets in the product development process has been established;
- the policy has been documented, implemented, and maintained;
- the policy has been communicated to all relevant employees involved in product development; and
- the policy is available to the public.

4.3 Environmental aspects of product development

A procedure shall exist to identify the environmental aspects of the organization’s activities, products, or services and determine which ones have significant impacts on the environment for the products under development. Significant aspects shall be considered in setting environmental objectives with regards to the product lifecycle:

- the information shall be reviewed, as appropriate, during the development process;
- provisions shall exist for continuous review and improvement of the process and the products developed using the process;
- this process shall take into account the cost and time of undertaking the analysis and the availability of reliable data; and
- information already developed for regulatory or other purposes may be used in this process.

Manufacturers shall take into account the degree of practical control they may have over the environmental aspects being considered. The control and influence over the environmental aspects of products vary significantly, depending on the market situation of the manufacturer. For example, a
contractor or supplier to the manufacturer may have comparatively little control, while the manufacturer responsible for product design can alter the aspects significantly by changing a single input material.

While recognizing that manufacturers may have limited control over the use and disposal of their products, they shall consider, where practical, proper handling and end-of-life management instructions. This provision is not intended to change or increase an organization's legal obligations.

A manufacturer with no existing PDP-EMS shall, initially, establish its current position with regard to the environment by means of a review. The aim shall be to consider all environmental aspects of the manufacturer's product development process as a basis for establishing the PDP-EMS. Those manufacturers with operating PDP-EMSs do not have to undertake such a review.

The review shall cover four key areas:

- legislative and regulatory requirements;
- identification of significant environmental aspects throughout the entire product life cycle;
- examination of all existing environmental management practices and procedures; and
- evaluation of feedback from the investigation of previous incidents.

Consideration shall be given to routine operating, shutdown, and start-up conditions, as well as realistic potential significant impacts associated with reasonably foreseeable or emergency situations.

A suitable approach to the review may include checklists; interviews; direct inspection and measurement; and results of previous audits or other reviews, depending on the nature of the activities. The process is intended to identify significant environmental aspects associated with each product life cycle stage and shall, where relevant, consider:

| raw material acquisition (material selection) | types, quantities, water emissions, water use, water releases, air emissions, embedded energy, waste quantities |
| manufacturing process | occupational health risks, ecological risks, energy use, water use, water emissions, air emissions, waste quantities |
| package selection/design process | types, quantities, reuse, recycled content, recyclability |
| distribution | transportation energy, use of alternate fuels |
| use/performance of product | occupational health risks, consumer health risks, ecological risks, air releases, water releases |
| disposal of product and/or package | recommendations to retailers/consumers/institutional end users for disposal of unused product and packaging and for recycling and/or reuse of packaging |

4.4 Environmental objectives and targets for the development process

The organization shall establish and maintain documented environmental objectives and targets for the product development process. The objectives shall be specific, and targets shall be measurable where practical and where appropriate take preventative measures into account.

- objectives and targets shall be established at each relevant development phase and shall be reviewed with all relevant personnel;
- significant environmental impacts associated with the product life cycle shall be considered in establishing objectives and targets;
- technological options shall be considered (i.e., a manufacturer may consider using the best available technology where economically viable, cost-effective, and appropriate);
- financial, operational, and business requirements shall be considered;
the views of stakeholders shall be considered; and
the objectives and targets shall be consistent with the corporate environmental policy.

4.5 Environmental management program(s) in product development

An environmental management program tailored to the product development process shall be established for achieving objectives and targets to include:

– specific designation of responsibility for achieving environmental objectives and targets in each relevant product development function and at every level of product development and marketing;
– the means and schedule for accomplishing environmental objectives and targets; and
– the application to changes or improvements in the product development process, in new or modified products, and in manufacturing and in-market services.

4.6 Structure and responsibility

Roles, responsibilities, and authorities shall be defined, documented, and communicated to facilitate effective management. The successful implementation of a PDP-EMS requires the commitment of all employees of the manufacturer to be involved in its product development process. Environmental responsibilities therefore shall not be seen as confined to the environmental function, but shall also include other areas of an organization, such as operational management or staff functions other than environmental.

This commitment shall begin at the highest levels of management. Accordingly, executive management shall establish the manufacturer’s environmental policy and ensure that the PDP-EMS is implemented. As part of this commitment, the executive management shall designate a specific management representative(s) with defined responsibility and authority for implementing the PDP-EMS. In large or complex organizations, there may be more than one designated representative. In small or medium sized enterprises, one individual shall undertake these responsibilities. Executive management shall also ensure that appropriate resources are provided to ensure that the PDP-EMS is implemented and maintained. It is important that the key PDP-EMS responsibilities are well defined and communicated to relevant personnel.

4.7 Training, awareness, and competence

It is recommended that individual decision makers involved in all formulation activities are professionally qualified and trained for understanding of related environmental impact issues, human safety, and other compliance matters. Procedures shall be established and maintained to make appropriate employees aware of:

– the importance of conformance with environmental policy, procedures, and goals of the PDP-EMS;
– the significant environmental impacts of their development decisions and environmental benefits of consistent PDP-EMS implementation;
– their roles and responsibilities in meeting the environmental goals and objectives of the PDP-EMS; and
– the potential consequences of departure from the PDP-EMS process.
Professional qualification shall be achieved and maintained by continual training based on the internal procedures established under the PDP-EMS as well as by training/certification programs provided by external institutions, such as universities, chemical trade associations, and governments. Training subjects efficacy assessment may be related to, but are not limited to, general chemical curricula; environmental health and safety (EH&S); user safety, toxicology; hazardous materials management; chemical inventory management procedures; computing, blending, and compounding procedures; environmental hazard reporting; and the legal statutes governing such procedures as chemical acquisition, formulation, storage, transportation, use and disposal.

The manufacturer shall require that contractors working on its behalf are able to demonstrate that their employees have the requisite training.

4.8 Communication

The company shall establish and maintain procedures for:

– claims development/substantiation to be consistent with FTC Guides for the Use of Environmental Marketing Claims;

– internal communications regarding the PDP-EMS among various levels and functions;

– receiving, documenting, and responding to relevant information and requests from external interested parties;

– customer feedback, external communication, training manuals, MSDS, emergency planning, etc.

4.9 PDP-EMS documentation

Documentation describing the core elements of the PDP-EMS and their interactions shall be established and maintained. Additionally, documentation that provides direction on where to obtain more detailed information on the operation of specific parts of the PDP-EMS shall be included. Related documentation may include: process information, organizational charts, internal standards and operational procedures, and site emergency plans.

4.9.1 Document control

Procedures shall be established for maintaining PDP-EMS documentation to ensure that:

– documents can be located;

– documents are periodically reviewed, revised, and approved by authorized personnel;

– current versions are available at all appropriate locations;

– obsolete documents are promptly removed;

– obsolete documents retained for preservation purposes are identified as such;

– documents are legible, dated, readily identifiable, well maintained, and retained for a specified period of time;

– procedures exist and are maintained for the creation and modification of these documents; and

– holders of these documents are appropriately designated.
The intent is to ensure that organizations create and maintain documents in a manner sufficient to implement the PDP-EMS. The primary focus of manufacturers shall be on the effective implementation of the PDP-EMS and environmental performance, not on creation of a complex documentation control system.

4.9.2 Records

Procedures for identification, maintenance, and disposition of records shall focus on those records needed for the implementation and operation of the PDP-EMS and for recording the extent to which planned objectives and targets have been met. Environmental records may include:

- information on applicable environmental laws or other requirements;
- complaint records;
- training records;
- process information;
- product information;
- inspection, maintenance, and calibration records;
- pertinent contractor and supplier information;
- incident reports;
- information on emergency preparedness and response;
- information on significant environmental aspects;
- audit results; and
- management reviews.

Proper account shall be taken of confidential business information.

4.10 Monitoring and measurement

Procedures shall exist and be documented to regularly monitor and measure the key characteristics of PDP-EMS and its impact on the environment.

Information shall be recorded to track the performance of the PDP-EMS in meeting its objectives and targets. Benchmarking is necessary to establish a baseline for continual improvement.

Monitoring shall be reviewed and evaluated to assure effectiveness of the PDP-EMS as objectively as possible. Records of the process shall be retained.

4.11 Nonconformance and corrective and preventive action

Corporate management shall assign and support authority to identify and investigate nonconformance. It shall establish and maintain procedures to investigate and correct nonconformance. These basic elements shall:

- identify the cause of the nonconformance;
- identify and implement necessary corrective action;
- implement or modify controls necessary to avoid repetition of the nonconformance; and
- record any changes in written procedures resulting from the corrective action.
4.12 PDP-EMS audit

A program and procedures for periodic PDP-EMS audits shall be established and maintained. The audits shall determine whether the PDP-EMS conforms to the established corporate standard and whether the PDP-EMS has been properly implemented and maintained. The program shall provide information on the results of the audits to management; and the procedures shall cover the scope, frequency, methods, responsibilities, and requirements for conducting audits and reporting the results.

The audit program and procedures shall cover:

- activities and areas to be considered in audits;
- frequency of audits;
- responsibilities associated with managing and conducting audits;
- communication of audit results;
- auditor competence; and
- how audits shall be conducted.

Audits shall be performed by personnel from within the organization and/or by qualified third parties selected by the manufacturer.

4.13 Management review

Executive management shall review the PDP-EMS at regular intervals to ensure its suitability, adequacy, and effectiveness, and shall consider the need for changes to policy, objectives, and other elements of the PDP-EMS based upon audit results, changing circumstances, extent to which objectives and targets have been met, concerns amongst relevant interested parties, and a commitment to continued improvement. Observations, conclusions, and recommendations shall be documented for necessary action.
Annex A
(informative)

Key elements of a certification program
for environmentally preferable hard surface cleaners

A.1 General

Conformance to this Standard identifies that a manufacturer designs, develops, produces, and markets products through a product stewardship practice or a PDP-EMS. Conformance to this Standard alone does not imply certification. The manufacturer can further demonstrate the achievement of its environmental performance goals for the product by complementing conformity assessment of the PDP-EMS to this Standard with conformity assessment of the resulting product to recognized criteria for environmentally preferable hard surface cleaners.

Recognized performance criteria for environmentally preferable hard surface cleaners may include, but are not limited to the following:

- GS-37 Green Seal Environmental Standard for General-Purpose, Bathroom, Glass, and Carpet Cleaners Used for Industrial and Institutional Purposes,\(^4\);
- GS-08 Green Seal Household Cleaners\(^4\);
- Ecolabelling of industrial cleaning and degreasing agents, Nordic Ecolabelling v. 1.4\(^5\);
- Ecolabelling of cleaning products, Nordic Ecolabelling v. 3.2\(^5\);
- Ecolabelling of sanitary cleaning products, Nordic Ecolabelling v. 2.4\(^5\);
- European Union Ecolabel, All-purpose cleaners and cleaners for sanitary facilities\(^6\);
- Canada Environmental Choice\(^M\) Program CCD-110 Cleaning and De-greasing Compounds: Biologically-based\(^7\);
- Canada Environmental Choice\(^M\) Program CCD-107 Cleaners – General Purpose\(^7\); or
- Canada Environmental Choice\(^M\) Program CCD-146 Hard surface Cleaners\(^7\).

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\(^4\) Green Seal, 1001 Connecticut Avenue, NW, Suite 827, Washington, DC 20036-5525, USA

\(^5\) SIS Ecolabelling, SE-118 80 Stockholm, Sweden , Sankt Paulsgatan 6

\(^6\) European Ecolabelling, DG Environment, E4, European Commission, Rue de la Loi 200, B-1049 Brussels, Belgium

\(^7\) Environmental Choice Program c/o TerraChoice Environmental Marketing, 1280 Old Innes Suite 801, Ottawa, Ontario K1B 5M7, Canada
In addition, several state governments in the United States have promulgated environmentally preferable procurement criteria. Environmentally preferable hard surface cleaners may also be evaluated against criteria defined by the manufacturer or against criteria defined in a contractual agreement between the manufacturer and one or more product end-users.

Product manufacturers may pursue certification to environmentally preferable criteria independently of certification to NSF/ANSI 143.

A.2  Product certification process

A.2.1  Conformity assessment to NSF/ANSI 143

The manufacturer identifies a certification organization to perform the conformity assessment of the product development process for compliance with NSF/ANSI 143, if applicable.

A.2.2  Identification of environmentally preferable product criteria

The manufacturer identifies to the certifying organization of its choice of which environmentally preferable product criteria to use for the conformity assessment of the manufacturer’s product. The manufacturer may elect to have a product evaluated against more than one set of criteria. The certifying organization should obtain the most recent version of the specified criteria to use as the basis of the product conformity assessment activity.

A.2.3  Conformity assessment to environmentally preferable product criteria

The certifying organization performs the necessary functions to determine whether the manufacturer’s product complies with the specified EPP criteria. This may involve activities such as an audit of the manufacturing facility, review of the product formulation, testing or review of testing documentation for the product’s compliance with the specified product attributes, and review of product labeling and literature.

A.2.4  Issuance of product certification

If the product has been demonstrated to adequately meet the specifications of the EPP criteria, and any issues of noncompliance have been addressed, the certifying organization provides a product certification to the manufacturer. This may include the provision of documentation of certification of the product to the manufacturer, as well as inclusion of the product on any publicly available lists of certified products maintained by the certifying organization. The certifying organization instructs the manufacturer regarding appropriate use of the registered certification mark of the certifying organization.

A.2.5  Monitoring of product compliance

At intervals determined by the certifying organization, the continued conformance of the certified product to the specified environmentally preferable criteria is monitored using periodic facility audits, periodic retesting, or both.

A.3  Suggested requirements for certifying organizations

A certifying organization offering a certification program for environmentally preferable hard surface cleaners should comply with the requirements of ISO/IEC Guide 65 General requirements for bodies operating product certification systems.

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8 International Organization for Standardization (ISO), 1 Rue de Varembe, Case postale 56, CH-1211 Geneva 20, Switzerland
A.3.1 Marking of certified product

The certifying organization should specify requirements for marking of certified products. At a minimum, the requirements for product marking should include the following:

– certified products should bear a registered certification mark of the certifying organization;
– each product should have a unique formulation designation; and
– each product should bear a statement of environmentally preferable claims verified through the certifying organization and substantiated by test data.

A.3.2 Listing certified companies

The certifying organization should maintain a published listing of all certified products. The listing format should include the following minimum information:

– company name and address;
– product description;
– trademark/formulation designation; and
– each efficacy environmentally preferable claim that has been successfully evaluated and is supported by test data.

A.3.4 Audits

The certifying organization should conduct actual physical audits of all facilities and production locations of the certified company at least annually.

A.3.5 Testing

– testing in accordance with all applicable environmentally preferable efficacy claim specifications prior to certification; and
– a retest program that includes re-evaluation and retesting at least once every two years.

A.3.6 Formulation evaluation

Formulation information for each ingredient used in the certified product should be provided to and maintained on file by the certifying organization. The formulation information should include, at a minimum:

– the complete chemical identity or proportion by weight;
– ingredient sources of supply; and
– documentation regarding the human health effects and environmental concern of each ingredient in the material.
A.3.7 Corrective action

Corrective action for all items of noncompliance found during audits and re-evaluation including:

– provisions for review and authorization for modifications to formulations;
– modifications to certified product formulations; and
– documentation and authorization of the modification maintained on file.

A.3.8 Enforcement

To preserve the integrity of the registered certification mark of the certifying organization, enforcement action should be taken by the certifier for the following:

– use of the registered trademark of the certifying organization on a non-certified product;
– general noncompliance;
– unauthorized change to a certified product; and
– unauthorized shipment or disposal of product placed on hold.

A.3.9 Appeals

The certifying organization should have provisions for an appeals process as requested by any party directly affected by a decision, action, or inaction of the certifying organization.

A.3.10 Complaints

The certifying organization should provide for the following:

– investigation of complaints related to certified products;
– misuse of the registered trademark of the certifying organization by a certified company;
– use/misuse of the registered trademark of the certifying organization by a non-certified company; and
– certified company retention and disclosure of complaint records and remedial actions for certified products.

A.3.11 Advertising

A certifying organization should provide guidance to certified manufacturers regarding proper use of the registered trademark of the certifying organization on sales literature, technical publications, promotional materials, packaging, catalogs, and advertising.

A.3.12 Records

A certifying organization should have provisions for verification of complete certified company records, including:

– purchased materials and ingredients; and
– production, shipment, and inventory.

A.3.13 Public notice

Provisions for issuing a public notice for noncompliance with any requirement of certification should be maintained by the certifying organization.
A.3.14 Confidentiality

The certifying organization should have a documented policy of non-disclosure of any confidential information supplied to the certifying organization by the company regarding the product, including formulations, components, processes, ingredients, or the identity of the company’s suppliers and distributors.
Annex B⁹

(informative)

Product design, development, and distribution process

B.1 Guidelines on product design, development, and distribution process

This annex is intended to provide a set of guidelines for development of an EPP and only addresses the product development process - environmental management system requirements contained in section 4. This guideline is organized in a matrix format in which requirements for Performance Criteria, Risk Assessment Including Environmental Impact, Selection of Materials/Energy Use, Emissions and Waste, and Legal/Regulatory compliance for each product life cycle stage are outlined. Elements of the matrix are further supplemented in the following matrix.

B.2 Product design, development, and distribution matrix

The following life cycle stages and impacts should be evaluated. If certain stages/impacts are omitted from the assessment, appropriate explanation and documentation should be provided. The assessment should be conducted in a manner consistent with the ISO 14040 series standards on life cycle assessment (LCA) and applicable health and ecological risk assessment guidelines, such as those published by the USEPA and the OECD. All LCA and risk assessment guidelines/methods/models used in the assessment must be referenced. Examples of risk assessment methods are listed in annex C. All quantities should be reported per unit of ready-to-use product. In addition to evaluating the impacts associated with the current or proposed production process, the assessment should also discuss alternatives considered, comparison to past performance, and plans for improvement.

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Table B1 – Product life cycle stages and impacts

<table>
<thead>
<tr>
<th>Product life cycle stages</th>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
<th>Stage 4</th>
<th>Stage 5</th>
<th>Stage 6</th>
<th>Stage 7</th>
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<tbody>
<tr>
<td></td>
<td>Formulation development</td>
<td>Raw materials acquisition/selection</td>
<td>Manufacturing process</td>
<td>Package selection/design &amp; packaging process</td>
<td>Distribution</td>
<td>Use and performance of product</td>
<td>Disposal of product and/or package</td>
</tr>
<tr>
<td>Performance criteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>see annex c</td>
</tr>
<tr>
<td>Risk assessment including environmental impacts (See annex D)</td>
<td>see note 1</td>
<td>see note 2</td>
<td></td>
<td></td>
<td></td>
<td>see note 3</td>
<td>see note 4</td>
</tr>
<tr>
<td>Materials selection and energy use (separate material selection and energy use)</td>
<td>see note 5</td>
<td>see note 6</td>
<td>see note 7</td>
<td>see note 8</td>
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<tr>
<td>Emission and waste</td>
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<td>see note 9</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Legal and regulatory requirements</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>see note 10</td>
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Table B1 – Product life cycle stages and impacts

<table>
<thead>
<tr>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
<th>Stage 4</th>
<th>Stage 5</th>
<th>Stage 6</th>
<th>Stage 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation development</td>
<td>Raw materials acquisition/selection</td>
<td>Manufacturing process</td>
<td>Package selection/design &amp; packaging process</td>
<td>Distribution</td>
<td>Use and performance of product</td>
<td>Disposal of product and/or package</td>
</tr>
</tbody>
</table>

Note 1 – Consider 1. Type; 2. Quantity; 3. Water use.

Note 2 – Consider 1. Occupational health risks; 2. Ecological risks.


Note 4 – Consider 1. Type of primary and secondary packaging including information on reuse, recycled content and recyclability; 2. Quantity of primary and secondary packaging including information on reuse, recycled content, and recyclability; 3. Recommendations to retailers for disposal of unused products & packaging and for recycling of packaging; 4. Recommendations to consumers for disposal of unused products & packaging and for recycling of packaging.

Note 5 – Consider 1. Type; 2. Quantity; 3. Water use; 4. Embedded Energy (see annex E).

Note 6 – Consider 1. Water use; 2. Energy use (See annex E).

Note 7 – Consider 1. Type; 2. Quantity; 3. Reuse; 4. Recycle content; 5. Recyclability.

Note 8 – Consider transportation energy (See annex E).


Note 10 – Consider 1. Air releases: VOC, other (see annex E); 2. Water releases: toxics, other (see annex E).
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Annex C¹⁰

(informative)

Product evaluation and performance criteria

Environmental attributes of products and packaging should be taken into consideration during the product development process as well as other important criteria such as safety, performance, quality, cost, aesthetics and user convenience. Products are formulated to maximize performance for multiple factors and to meet the needs of the consumer/customer, whether it be less streaking, fast-acting, non-evaporative, non-foaming or other. Performance requirements define the function of the product system. Performance (or efficacy) testing is done to determine how well a product performs to specified claims. Part of the PDP-EMS should include performance testing to assure the cleaner shall clean the predicted soils from appropriate substrates. Selection of the specific performance test or standard would depend on the target soils and surfaces to be cleaned and possibly the target market and performance standards acceptable to these customers.

Voluntary consensus standards for standard tests or product specifications are developed through standard development organizations (e.g., ASTM), industry associations (e.g., CSPA), and federal and state government agencies (e.g., DOD, DLA, GSA) that include performance criteria as part of their specifications. Product manufacturers may also have well established and verified internal performance standards for various product categories such as glass cleaner, hard surface cleaner, textile stain remover, and others.

There are two basic types of performance testing: laboratory and consumer. Laboratory testing may involve mechanical tests, which use machines to measure effectiveness. An example would be testing of a tile cleaner in which soiled tiles would be scrubbed by a machine or other reproducible procedure. The efficacy of soil removal might then be judged using an optical device or involve expert judges. Testing is performed under controlled representative conditions.

In addition to laboratory methods, consumer testing serves several vital roles in assessing performance. Generally, most products go through some degree of consumer testing prior to test market or national introduction. Such testing might include consumer panel testing or consumer research studies. From these test studies, the manufacturer learns how the product will perform under actual use conditions and how consumers/customers will actually perceive and use the products.

The test method should be appropriate for the product. This should be evaluated through the following means:

- quantitative differentiation of products;
- reproducibility and results correlating with real consumer/customer use;
- conditions relevant to target market/customers;
- the product dosage should be typical; and
- water temperature/hardness; soil type; test surface type; machine type; cleaning habits.

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Performance testing should indicate the following:

– that the product functions
– the rate at which the product functions;
– the quantity of product required to perform a task; and
– if use of the product could result in property damage.

Stability testing shall be conducted to ensure the product works beyond the laboratory setting and that environmental or user variables will not adversely affect its performance.

There are several development considerations in the formulation process: the individual performance of ingredients, the combined performance of ingredients, formulating and optimizing the full product, and the completed commercial product. Consider environmental attributes in context of a product and its relative performance for a given task (i.e., environmental performance per functional unit of product). Establish performance targets (efficacy, stability, gross negatives) and product attribute targets (aesthetics and environmental, health and safety), and take these into consideration at each stage of the Product Development Process.

**Examples of typical performance considerations and specifications for hard surface cleaner criteria**

**Efficacy studies** – will demonstrate whether the product works on:

<table>
<thead>
<tr>
<th>different types of soils</th>
<th>greasy soil, lime scale, soap scum, household stains, dried-on food, pet stains</th>
</tr>
</thead>
<tbody>
<tr>
<td>different types of cleaning surfaces/substrates</td>
<td>steel, glass, wood, ceramic, plastic, fabrics, carpets</td>
</tr>
</tbody>
</table>

**Storage stability** – demonstrates whether the product will remain stable under different conditions:

<table>
<thead>
<tr>
<th>physical stability</th>
<th>short term/long term, temperature stable, freeze/thaw characteristics, oxygen exposure, light, humidity, and in package</th>
</tr>
</thead>
<tbody>
<tr>
<td>chemical stability</td>
<td>material/ingredient compatibility, active ingredients, nature of composition (anionic, cationic, nonionic, acid, alkaline, neutral)</td>
</tr>
<tr>
<td>microbiological stability</td>
<td>self-preserving or requires anti-microbial agent</td>
</tr>
</tbody>
</table>

**Gross negatives** – will demonstrate whether the product will cause problems:

<table>
<thead>
<tr>
<th>reactivity to materials</th>
<th>damage to wood, metal, furniture, clothing, appliances, etc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>residues</td>
<td></td>
</tr>
<tr>
<td>encrustation</td>
<td></td>
</tr>
<tr>
<td>filming/streaking</td>
<td></td>
</tr>
</tbody>
</table>
### Product attributes

<table>
<thead>
<tr>
<th>Category</th>
<th>Attributes</th>
</tr>
</thead>
<tbody>
<tr>
<td>aesthetics</td>
<td>color, viscosity, pH range, fragrance, consistency, foaming</td>
</tr>
<tr>
<td>physio-chemical properties</td>
<td>product form (liquid, solid, powder, gel, aerosol), freezing/boiling/melting point, flashpoint, dielectric strength, relative density, specific gravity, vapor density, vapor pressure</td>
</tr>
</tbody>
</table>

### Product EH&S attributes

<table>
<thead>
<tr>
<th>Category</th>
<th>Attributes</th>
</tr>
</thead>
<tbody>
<tr>
<td>environmental assessment factors</td>
<td>biodegradability, bioconcentration factor, disposability, VOC content, packaging – recyclability, recycled content, source reduction</td>
</tr>
<tr>
<td>health assessment factors</td>
<td>toxicity – acute, chronic; skin irritation; exposure characterization</td>
</tr>
<tr>
<td>safety assessment factors</td>
<td>flammability; corrosivity</td>
</tr>
</tbody>
</table>
## Table C1 – Sources for published test methods

<table>
<thead>
<tr>
<th>Source</th>
<th>Address</th>
<th>Phone</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>AATCC (American Association of Textile Chemists and Colorists)</td>
<td>P.O. Box 12215, Research Triangle Park, NC 27709</td>
<td>(919) 549-8141</td>
<td><a href="http://www.aatcc.org">www.aatcc.org</a></td>
</tr>
<tr>
<td>CSPA (Consumer Specialty Products Association)</td>
<td>900 17th Street, NW, Suite 300, Washington, DC 20006</td>
<td>(202) 872-8110</td>
<td><a href="http://www.cspa.org">www.cspa.org</a></td>
</tr>
<tr>
<td>PEI (Porcelain Enamel Institute)</td>
<td>P.O. Box 920220, Norcross, GA 30010</td>
<td>(770) 281-8980</td>
<td><a href="http://www.porcelainenamel.com">www.porcelainenamel.com</a></td>
</tr>
<tr>
<td>ANSI (American National Standards Institute)</td>
<td>25 West 43rd Street, 4th Floor, New York, NY 10036</td>
<td>(212) 642-4900</td>
<td><a href="http://www.ansi.org">www.ansi.org</a></td>
</tr>
<tr>
<td>SDA (The Soap and Detergent Association)</td>
<td>1500 K Street NW, Suite 300, Washington, DC 20005</td>
<td>(202) 347-2900</td>
<td><a href="http://www.sdahq.org">www.sdahq.org</a></td>
</tr>
<tr>
<td>ASTM International</td>
<td>100 Barr Harbor Drive, West Conshohocken, PA 19428-2959</td>
<td>(610) 832-9585</td>
<td><a href="http://www.astm.org">www.astm.org</a></td>
</tr>
<tr>
<td>OECD (Organization for Economic Cooperation and Development)</td>
<td>2, rue André Pascal, F-75775 Paris Cedex 16 France</td>
<td>+33 1.45.24.82.00</td>
<td><a href="http://www.oecd.org">www.oecd.org</a></td>
</tr>
</tbody>
</table>
Annex D
(informative)

Risk assessment

D.1 General

Assessment of the human health risks presented by chemical substances includes the following components of analysis (National Research Council 1983):

a) Hazard Identification is the process of determining whether exposure to a chemical can cause an adverse health effect and whether the adverse health effect is likely to occur in humans.

b) Dose-response Assessment is the process of defining the relationship between the dose of a chemical received and the incidence of adverse health effects in the exposed population. From the quantitative dose-response relationship, toxicity values are derived that are used in the risk characterization step to estimate the likelihood of adverse effects occurring in humans at different exposure levels.

c) Exposure Assessment identifies populations exposed to a chemical, describes their composition and size, and presents the types, magnitudes, frequencies, and durations of exposure to the chemical.

d) Risk Characterization integrates hazard and exposure information into quantitative and qualitative expressions of risk. A risk characterization includes a description of the assumptions, scientific judgments, and uncertainties embodied in the assessment.

D.2 Procedures for hazard identification and dose-response assessment

Persons conducting a risk assessment under this Standard will need to do literature searches to identify relevant hazard information. Users of this Standard may want to consult the guidance for "hazard determination" required under the Occupational Safety and Health Administration's hazard communication standard found at 29 CFR §1910.1200 for guidance. In general, searching an array of toxicological databases from any of the major vendors would provide adequate coverage of the available toxicological literature. For example, searching the Hazardous Substances Data Bank, TOXLINE, and TOXLIT databases from the National Library of Medicine would provide broad coverage of the published toxicological literature. In addition, use of predicted model and expert systems may support hazard assessment. Because relevant health hazard data may come from many types of studies with varying study protocols, this guidance does not prescribe specific standards for judging the adequacy of studies. Users of this Standard should rely on the general guidance in the OSHA hazard communication standard that states, "The results of any studies which are designed and conducted according to established scientific principles, and which report statistically significant conclusions regarding the health effects of a chemical, shall be a sufficient basis for a hazard determination." If more than one relevant study can provide quantitative data for a particular hazard endpoint, data from the study that demonstrates adverse effects at the lowest dose or exposure level should be used. For example, if two reliable chronic studies report different "No-observed-adverse-effect levels" (NOAEL), the lower NOAEL should be used in "Margin-of-exposure" (MOE) calculations for evaluating chronic risk. Cancer potency values to be used in risk assessment, e.g., slope factor or unit risk, should be taken from reliable sources such as USEPA's Integrated Risk Information System, the state of California Office of Environmental Health Hazard

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Assessment’s listings of cancer potency factors, or other sources that use similar procedures for dose-response determination.

D.3 Procedures for exposure assessment

An exposure assessment identifies populations exposed to a chemical; describes their composition and size; and presents the types, magnitudes, frequencies, and durations of exposure to the chemical or chemicals of interest.

The first and most important step in an exposure assessment is to define the purpose for which it is to be used. If an assessment is to be used to screen out chemicals that are not of concern, it is common to use very conservative estimates of exposure such as a bounding estimate. A bounding estimate of exposure is an estimate higher than any real exposure to the population of interest. If a chemical is not a concern using bounding estimates, it will not be a concern at the levels at which people are actually exposed.

Clearly defining the population to be assessed is another critical step in an exposure assessment. If the purpose of the assessment is to look at potential health concerns associated with a particular source, it may be appropriate to look at its potential impact on the most highly exposed subpopulation. If there is a potentially sensitive subpopulation exposed (e.g., children), assessing their exposure and risk may be desirable. In any case, the population being assessed should be defined in the planning stage of the assessment.

In an exposure assessment, it is common to estimate either a media concentration (e.g., indoor air) or a potential dose rate. In the case of indoor air, an appropriate media concentration could be a peak concentration, an 8-h time weighted average, or a long-term average concentration, depending on the characteristics of the hazard endpoint and the exposed population. Alternatively, it may be appropriate to estimate a potential dose rate, which could be for a single exposure event or a long-term average. A potential dose rate accounts for intake (i.e., breathing) but does not account for uptake (i.e., absorption through the lungs). Potential dose rates as defined by the USEPA Exposure Assessment Guidelines (USEPA 1992) include the Average Daily Dose (ADD) and the Lifetime Average Daily Dose (LADD). The ADD is used in non-cancer chronic risk assessments, and the LADD is used in cancer risk assessments. Dose rates for single exposure events can also be estimated. If information is available on the uptake, it should be factored into the risk assessment. Whether an air concentration or a potential dose rate is used in the risk assessment will be determined by the kind of hazard information available for the chemical. The units for the exposure estimate need to match the units of the toxicologic potency value (e.g., the NOAEL, the RfC, etc.) of the chemical under assessment.

In an exposure assessment, the types of inputs that are needed are the media concentrations, physiologic parameters (e.g., breathing rates for different levels of activity, body weights, dermal surface area exposed, etc.) and duration and frequency of exposure. The 1992 USEPA Exposure Assessment Guidelines explain how these inputs are used in an exposure assessment. Some of these factors are available from the 1997 USEPA Exposure Factors Handbook (USEPA 1997). Other inputs must be developed by the assessor. If an assessment is being conducted for chemicals from a source that is only used intermittently (e.g., a floor cleaning product) the factors of frequency and duration of exposure will take on different values than they would for chemicals being emitted from a source that is used routinely (e.g., a general purpose cleaner used daily). Air concentrations to be used in the exposure assessment may be measured under actual use conditions; they may be measured under simulated use conditions in a large environmental chamber; or they may be estimated from models.
D.3.1 Steps in designing an exposure assessment

a) Define the environment and its key parameters:
   – type of building or space, such as residence, office building, school, hospital, retail outlet, vehicle, etc.; and
   – building volume, indoor/outdoor air exchange rate, interzonal airflow rate, portion(s) of building where emission source is located, and other factors as appropriate.

b) Define the event that leads to exposure:
   – the magnitude and duration of the event;
   – the frequency of the event or how often the event occurs, e.g., daily, twice a week, or monthly; and
   – the day(s) of the week on which the event occurs. This can be important because the activity patterns of exposed persons are often different on different days, especially weekdays vs. weekends.

c) Define the exposed population(s):
   – who are they – workers who use the product/equipment being assessed, consumers who use the product/equipment being assessed, other adult occupants of the building, child occupants of the building, etc.;
   – activity pattern of exposed persons – time spent in each of the various exposure zones, total years of exposure;
   – key physiologic parameters – breathing rate, body weight, or dermal area exposed, others as appropriate; and
   – susceptible populations – note groups who may be especially sensitive to the exposures being assessed, e.g., asthmatics for respiratory irritants or children and the elderly for neurotoxic agents.

d) Select appropriate exposure measurements or models and calculate appropriate exposure values:
   – In general, measured concentrations obtained under realistic conditions are preferable to concentrations estimated by modeling. If using a model to estimate concentrations, select a model that is suitable for the scenario being assessed, i.e., that can handle the type of emission data available and can incorporate all relevant parameters related to the environment and the exposed population.
   – Calculate exposure values appropriate for the hazards posed by the emissions, e.g., lifetime average daily dose for carcinogens, average daily dose for chronic toxicants, peak concentration, or highest daily dose for acute toxicants and developmental toxicants.

e) Characterize the results of the exposure assessment:
   – State the purpose, scope, and approach used in the assessment.
Describe the methods and models used to quantify exposure/dose. If models are used, describe the basis for their selection and validation status. If measured data are used, discuss the data quality, including the strengths and weaknesses of the methods used and alternate methods, if appropriate.

Present the exposure estimates by pathway and route for the individuals or populations to be addressed in the risk characterization.

Interpret the results and discuss the overall quality of the assessment and the degree of confidence in the conclusions.

### D.4 Procedures for risk characterization

The risk characterization integrates the information from the hazard identification, dose-response, and exposure assessments, using a combination of qualitative information, quantitative information, and information about uncertainties. The risk characterization includes a discussion of sources of uncertainty and variability. Well-balanced risk characterizations present risk conclusions and information regarding the strengths and limitations of the assessment. The risk characterization should embody the following principles (USEPA 1995):

- Risk assessments should be transparent, in that the conclusions drawn from the science are identified separately from policy judgments, and the use of default values or methods and the use of assumptions in the risk assessment are clearly articulated.
- Risk characterizations should include a summary of the key issues and conclusions of each of the components of the risk assessment, as well as describe the likelihood of harm. The summary should include a description of the overall strengths and limitations, including uncertainties, of the assessment and conclusions.
- Risk characterizations should be consistent in general format but recognize the unique characteristics of each specific situation.

The quantitative aspect of risk characterization can be done either by comparison of estimated exposure levels to established standards such as USEPA Reference Doses/Concentrations and ATSDR Minimal Risk Levels or by calculation of risk values such as MOE and lifetime cancer risk.

### D.5 Risk calculations

The MOE is the ratio of a NOAEL or "lowest-observed-adverse-effect level (LOAEL)" from an appropriate toxicologic or epidemiologic study to an estimated dose or exposure level. High MOE values imply a low level of concern. As the MOE decreases, the level of concern increases (Barnes and Dourson 1988).

Cancer risk for non-threshold carcinogens with a linear dose-response is calculated by multiplying the estimated dose or exposure level by the appropriate measure of carcinogenic potency. For example, an individual with a lifetime average daily dose of 0.3 mg/kg of a carcinogen with a potency of 0.02/mg/kg/d would experience a lifetime cancer risk of 0.006 from exposure to that chemical. Alternatively, a MOE calculation is sometimes more appropriate for carcinogens in which there is evidence of a dose threshold or a nonlinear dose response (USEPA 1986, USEPA 1996).
D.6 Ecological risk

The basic elements of ecological risk assessment are similar to those employed in human health risk assessment and can be described as:

a) a problem formulation phase in which the purpose of the assessment is stated, the problem is defined, and a plan for analyzing and characterizing risk is developed;

b) an analysis phase in which exposures and ecological effects are characterized; and

c) a risk characterization phase that integrates the exposure and effects analyses.

Because of the extremely broad range of ecological endpoints that can be studied (e.g., effects on individuals, populations, communities, ecosystems), a critical element in ecological risk assessment is the identification of relevant ecological effects information. For example, the availability of toxicity data on appropriate aquatic species would be important to the assessment of a cleaning product routinely released to water. Aquatic toxicity data for single species are often expressed as median effect concentrations, LC50 for lethality and EC50 for effects other than lethality. The median effect level is always associated with a time parameter, e.g., a 24-h LC50. Because these tests seldom exceed 96 h in duration, their main value lies in evaluating short-term effects of chemicals. Another common toxicity metric is the maximum acceptable toxicant concentration (MATC). The MATC is the range between the highest test concentration for which effects are not statistically different from controls (the NOAEL) and the lowest concentration at which statistically significant effects are observed (the LOAEL). The MATC can also be reported as the geometric mean of the NOAEL and LOAEL (the GMATC). For chemicals lacking measured aquatic toxicity data, appropriate values can often be estimated with models such as ECOSAR.

The exposure assessment for an ecological risk assessment needs to take into account the frequency and duration of exposure events, the persistence and transport of the subject chemicals in environmental media, and the spatial scale of exposure. If measured data are to be used, e.g., ambient water monitoring data, the assessment must address sampling and quality assurance issues.

When sufficient quantitative exposure and effects data are available, the simplest risk estimation approach is to calculate a ratio of the exposure and effect concentrations, e.g., an estimated ambient water concentration divided by an EC50 or LC50 value for an aquatic species. When applying a quotient method, the effect concentration is frequently adjusted by various uncertainty factors. Exposures below the adjusted effect concentration or concern concentration are expected to present low risk. When characterizing risk estimates from a quotient method, it is important to consider and address, as appropriate, key points such as:

- How does the effect concentration relate to the assessment endpoint?
- What extrapolations are involved?
- How does the point estimate of exposure relate to potential spatial and temporal variability in exposure?
- Are data sufficient to provide confidence intervals on the endpoints? (USEPA 1998, USEPA 1996b).

D.7 Iterative approach to risk assessment

Users of the Standard will find it efficient to approach the risk assessment in an iterative fashion, beginning with simple methods and conservative assumptions (i.e., assumptions that lead to an
overestimate of the risk) and then refining the assessment as necessary. In particular, simplifying assumptions for the exposure assessment can save substantial time and effort. If no concerns are identified in the initial, conservative assessment, no further assessment is necessary. If, on the other hand, the initial assessment does not rule out all concerns, more realistic exposure estimates can be developed by refining the key input parameters (e.g., duration and frequency of exposure event, activity pattern of exposed population, etc.) and employing more sophisticated modeling techniques.

D.8 Report

The report should include a description of the key data, methods, assumptions, and uncertainties from each stage of the risk assessment process:

- hazard identification – toxicologic endpoints associated with each chemical;
- dose-response assessment – NOAELs, LOAELs, cancer unit risk factors, etc.;
- exposure assessment – emission profiles, exposure scenarios, exposure models; and
- risk characterization – calculations, major conclusions.

D.9 References


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12 International Society of Regulatory Toxicology and Pharmacology (ISRTTP) 6546 Belleview Drive, Columbia, MD 21046-1054, USA

13 National Academy of Sciences, 500 Fifth St. N.W., Washington, D.C. 20001

14 United States Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, N.W. MC 2843, Washington DC 20460
Annex E\textsuperscript{15}  
(informative)

Pollutants

Listed below are data elements relevant to the assessment of the life cycle environmental impacts associated with product development activities. These data should be available either directly from company records (e.g., materials, energy, and emissions from manufacturing) or from published sources (e.g., emissions and energy for raw materials acquisition and transportation). Evaluation of these and/or comparable data elements should allow manufacturers to identify key impacts and areas for improvement.

\textbf{E.1 Air releases}

Criteria pollutants

\begin{itemize}
  \item particulate matter;\textsuperscript{*}
  \item carbon monoxide (CO);\textsuperscript{*}
  \item sulfur oxides (SO\textsubscript{x});\textsuperscript{*}
  \item nitrogen oxides (NO\textsubscript{x});\textsuperscript{*}
  \item volatile organic compounds (VOC) (report as total VOC, individual species, or in terms of O\textsubscript{3} formation potency, e.g., ethylene or equivalents or NO\textsubscript{x} equivalents).
\end{itemize}

\textsuperscript{*} These releases will likely depend primarily on the quantity and types of energy used during product manufacture and distribution. An option would be to simply use the energy data as a surrogate for these impacts.

Air toxics

\begin{itemize}
  \item total release (mass) of CAA §112 and EPCRA §313 chemicals
\end{itemize}

\textbf{E.2 Water releases}

Conventional pollutants:

\begin{itemize}
  \item 5-d biochemical oxygen demand (BOD\textsubscript{5}) (mg/l);
  \item total suspended solids (mg/l); or
  \item pH.
\end{itemize}

Nutrients (eutrophication potential):

\begin{itemize}
  \item total nitrogen and phosphorus releases.
\end{itemize}

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Toxic pollutants:

- total release (mass) of CWA\textsuperscript{16} § 307 and EPCRA\textsuperscript{17} § 313 chemicals.

\textbf{E.3 Energy use}

Total quantity and source of energy consumed, including embedded energy of raw materials, energy used during product manufacturer, and transportation energy used during product distribution.

Additional federal and state hazard based regulatory list may be taken into account in the assessment.


\textsuperscript{17} USEPA (1986) Emergency Planning and Community Right to Know Title 42 Chapter 116 http://www.epa.gov/region5/defs/html/epcra.htm
Annex F\textsuperscript{18}  
(informative)

Audit checklist example

Manufacturer must perform a self assessment of environmental performance. It is recommended that an environmental audit team (PDP-EMS team) should be developed to review a checklist tailored for each product subject to the PDP-EMS process. These checklists take the PDP-EMS principles and break them into simpler concepts that the PDP-EMS team will evaluate to assure that every aspect of product development and manufacturer are governed by sound environmental principles.

A good self assessment is the foundation of a good environmental stewardship program. It is an ongoing activity that will be repeated many times in the future. A regular review by the PDP-EMS team will assure that the PDP-EMS applied to each product reflects any recent changes in the product, process, or environmental standards, demonstrating current commitments to environmental quality. This review can identify opportunities for improvement which will help PDP-EMS team choose priorities for action.

Examples of suggested review:

– Have there been any modifications to the PDP-EMS standards since last review? Have all changes been reflected in the PDP-EMS documentation of existing products in the system? Are there changes being reflected in every new product development?

– Is the PDP-EMS documentation available for each product? Have the documents been reviewed to assure they are complete?

– Send a self-assessment checklist to all the team members in advance and ask each to bring appropriate documentation and program descriptions to self-assessment meeting. Set aside several hours in a quiet place to discuss each element.

– Do not be a slave to the form. Given the range of products and services to which a PDP-EMS can apply, there will be ample opportunity to personalize the audit checklist. Just document changes with appropriate justification.

– Once you complete the checklist, you will be ready to move to the next step and decide on your priorities to develop your revised program for the next period.

Example of self-assessment checklist:

– Audit checklists such as the one shown below could be used to assure that all procedures necessary to a PDP-EMS have been followed and documented. The document is a guideline and can be modified with appropriate explanation to meet individual company needs, such as:

  – environmental targets for PDP-EMS Environmental Management Program;
  – structure and responsibility;
  – training, awareness and competence;
  – communication;

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– documentation, document control, and records; and
– monitoring and correction.
### Table F1 – General requirements self-assessment checklist

**NOTE** – The checklist can be completed by a) documentation of the PDP-EMS process and its maintenance and b) procedural connections between PDP-EMS and qualified products.

<table>
<thead>
<tr>
<th>Principle statement</th>
<th>Brief description of current system or approach for this element of PDP-EMS</th>
<th>Assessment of system</th>
<th>Not applicable to our operation</th>
<th>Company document reference and/or company contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have we a PDP-EMS process clearly established for the development, maintenance and improvement of each qualified product?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is our executive management commitment to make environmental considerations integral to the product development process as appropriate to the nature, scale and environmental impacts of the product?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is our executive management commitment to make environmental considerations an important part of the associated activities in development and marketing of the qualified products?</td>
<td></td>
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</tr>
<tr>
<td>What is our executive management commitment to continual improvement in the product development process and review of the products developed with goal of prevention of pollution?</td>
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</tr>
<tr>
<td>How does the company assure compliance with relevant environmental legislation, regulations, and requirements in all target markets and manufacturing facilities?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Has the framework for setting and reviewing environmental objectives and targets in the product development process been established?</td>
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</tr>
<tr>
<td>What assurance is there that the policy has been documented, implemented, and maintained?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>What system is in place to assure the policy has been communicated to all relevant employees involved in product development?</td>
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</tr>
<tr>
<td>How does the company make the policy available to the public?</td>
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<td></td>
</tr>
</tbody>
</table>
Table F2 – Environmental targets for PDP-EMS: Self-assessment checklist

**NOTE** – The checklist can be completed by a) demonstration of environmental goal setting in the PDP-EMS process and b) specific goals for the product(s) under consideration.

<table>
<thead>
<tr>
<th>Principle statement</th>
<th>Brief description of current system or approach for this element of PDP-EMS</th>
<th>Assessment of system</th>
<th>Not applicable to our operation</th>
<th>Company document reference and/or company contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>What system is in place to establish and maintain documented environmental objectives and targets for the product development process?</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>How are objectives and targets reviewed and modified at each relevant development phase and communicated to all relevant personnel?</td>
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<tr>
<td>What technological options have been considered and how were environmental goals incorporated?</td>
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</tr>
<tr>
<td>How have environmental goals been included in consideration of financial, operational, and business requirements?</td>
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<tr>
<td>How are the views of any stakeholders considered?</td>
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</tr>
<tr>
<td>How are the objectives and targets evaluated for consistency with the corporate environmental policy?</td>
<td></td>
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</tr>
</tbody>
</table>
Table F3 – Environmental management program: Self-assessment checklist

NOTE – The checklist can be completed by a) documentation of the PDP-EMS process and its maintenance and b) procedural connections between PDP-EMS and qualified products.

<table>
<thead>
<tr>
<th>Principle statement</th>
<th>Brief description of current system or approach for this element of PDP-EMS</th>
<th>Assessment of system</th>
<th>Not applicable to our operation</th>
<th>Company document reference and/or company contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has an EMS tailored to the product development process been established for achieving objectives and targets?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Does the EMS include specific designation of responsibility for achieving environmental objectives and targets in each relevant product development function and at every level of product development and marketing?</td>
<td></td>
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</tr>
<tr>
<td>Are specific means and scheduling for accomplishing environmental objectives and targets included in the EMS?</td>
<td></td>
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</tr>
<tr>
<td>Does the EMS apply to changes or improvements in the product development process, new or modified products, and changes in manufacturing and in-market services?</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
### Table F4 – Structure and responsibility: Self-assessment checklist

NOTE – The checklist can be completed by a) documentation of the environmental review process and b) procedural connections between that review and development of qualified products.

<table>
<thead>
<tr>
<th>Principle statement</th>
<th>Brief description of current system or approach for this element of PDP-EMS</th>
<th>Assessment of system</th>
<th>Not applicable to our operation</th>
<th>Company document reference and/or company contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there a procedure to define and document roles, responsibilities, and authorities for product development and communicate them to all relevant personnel to facilitate effective management?</td>
<td></td>
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</tr>
<tr>
<td>Are all resources necessary for the implementation and operation of the PDP-EMS provided?</td>
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</tr>
<tr>
<td>Do the management representatives have sufficient authority to: a) establish, implement, and maintain the PDP-EMS; and b) report on the performance of the PDP-EMS to top management?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is a representative assigned responsibility for oversight to implement the PDP-EMS within each product development team and to document the environmental impact decisions in the process?</td>
<td></td>
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</tr>
</tbody>
</table>
### Table F5 – Training, awareness, and competence - Self-assessment checklist

NOTE – The checklist can be completed by a) documentation of training in the PDP-EMS process and b) qualifications of key product development personnel.

<table>
<thead>
<tr>
<th>Principle statement</th>
<th>Brief description of current system or approach for this element of PDP-EMS</th>
<th>Assessment of system</th>
<th>Not applicable to our operation</th>
<th>Company document reference and/or company contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the individual decision makers professionally qualified and trained for understanding of related environmental impact issues, human safety, and other compliance matters?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Have procedures been established and maintained to make appropriate employees aware of the importance of conformance with environmental policy, procedures, and goals of the PDP-EMS?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have procedures been established and maintained to make appropriate employees aware of the significant environmental impacts of their development decisions and environmental benefits of consistent PDP-EMS implementation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have procedures been established and maintained to make appropriate employees aware of their roles and responsibilities in meeting the environmental goals and objectives of the PDPEMS?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have procedures been established and maintained to make appropriate employees aware of the potential consequences of departure from the PDP-EMS process?</td>
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</tr>
</tbody>
</table>
Table F6 – Communication: Self-assessment checklist

NOTE – The checklist can be completed by a) documentation of the product claims and substantiation and b) adequate explanation of the claims.

<table>
<thead>
<tr>
<th>Principle statement</th>
<th>Brief description of current system or approach for this element of PDP-EMS</th>
<th>Assessment of system</th>
<th>Not applicable to our operation</th>
<th>Company document reference and/or company contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the company established and maintained procedures for education, claims development, and claims substantiation?</td>
<td></td>
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</tr>
<tr>
<td>Are there procedures for internal communications regarding the PDP-EMS among various levels and functions?</td>
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</tr>
<tr>
<td>Are there procedures for receiving, documenting, and responding to relevant communication from external interested parties?</td>
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</tr>
<tr>
<td>Have processes for external communication with regards to significant environmental aspects, such as customer feedback, external communication, training manuals, MSDS, and emergency planning regarding the product development process been considered?</td>
<td></td>
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</tr>
</tbody>
</table>
Table F7 – Documentation, document control, and records: Self-assessment checklist

NOTE – The checklist can be completed by a) demonstration of environmental goal setting in the PDP-EMS process and b) specific goals for the product(s) under consideration.

<table>
<thead>
<tr>
<th>Principle statement</th>
<th>Brief description of current system or approach for this element of PDP-EMS</th>
<th>Assessment of system</th>
<th>Not applicable to our operation</th>
<th>Company document reference and/or company contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there written procedures for maintaining PDP-EMS documentation to ensure that: a) documents can be located, b) documents are periodically reviewed, revised, and approved by authorized personnel and c) current versions are available at all appropriate locations?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are obsolete documents managed by the written procedures for PDP-EMS documentation to ensure that: a) obsolete documents are promptly removed from active files and b) there is a policy for maintaining document history?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are all records legible, identifiable, and traceable to the activity, product, or service involved?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Are records easily retrievable and protected from physical damage, deterioration, or loss?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table F8 – Monitoring and correction: Self-assessment checklist

NOTE – The checklist can be completed by a) demonstration of environmental goal setting in the PDP-EMS process and b) specific goals for the product(s) under consideration.

<table>
<thead>
<tr>
<th>Principle statement</th>
<th>Brief description of current system or approach for this element of PDP-EMS</th>
<th>Assessment of system</th>
<th>Not applicable to our operation</th>
<th>Company document reference and/or company contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there procedures for regular monitoring and measurement of PDP-EMS performance?</td>
<td></td>
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</tr>
<tr>
<td>Is monitoring reviewed and evaluated to assure effectiveness of the PDP-EMS?</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>What system is in place to assure the policy has been communicated to all relevant employees involved in product development?</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Is there assigned authority investigating nonconformance and taking the appropriate action?</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Is there a course of corrective and preventive actions appropriate to achieve the goals of the PDP-EMS?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex G\textsuperscript{19}
(informative)

Informational references

The following references are not requirements of this standard, but they are included for the purpose of providing clarification and general information.

16 CFR Part 260 *Guides for the Use of Environmental Marketing Claims*\textsuperscript{20}

ISO 14000 *Environmental Management Standards*\textsuperscript{8}

5 Environmentally Preferable Purchasing Guiding Principles *EPA Guidance on Environmentally Preferable Purchasing*\textsuperscript{14}

Executive Order 13101, *Greening the Government through waste prevention, recycling, and federal acquisition*\textsuperscript{21}

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\textsuperscript{20} Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington DC, 20580

The following standards and criteria established and adopted by NSF as minimum voluntary consensus standards are used internationally:

2 Food equipment
3 Commercial warewashing equipment
4 Commercial cooking, rethermalization, and powered hot food holding and transport equipment
5 Water heaters, hot water supply boilers, and heat recovery equipment
6 Dispensing freezers
7 Commercial refrigerators and freezers
8 Commercial powered food preparation equipment
12 Automatic ice making equipment
13 Refuse processors and processing systems
14 Plastics piping system components and related materials
18 Manual food and beverage dispensing equipment
20 Commercial bulk milk dispensing equipment
21 Thermoplastic refuse containers
24 Plumbing system components for manufactured homes and recreational vehicles
25 Vending machines for food and beverages
29 Detergent and chemical feeders for commercial spray-type dishwashing machines
35 High pressure decorative laminates (HPDL) for surfacing food service equipment
36 Dinnerware
37 Air curtains for entranceways in food and food service establishments
40 Residential wastewater treatment systems
41 Non-liquid saturated treatment systems
42 Drinking water treatment units – Aesthetic effects
44 Residential cation exchange water softeners
46 Evaluation of components and devices used in wastewater treatment systems
49 Class II (laminar flow) biosafety cabinetry
50 Circulation system components and related materials for swimming pools, spas/hot tubs
51 Food equipment materials
52 Supplemental flooring
53 Drinking water treatment units – Health effects
55 Ultraviolet microbiological water treatment systems
58 Reverse osmosis drinking water treatment systems
59 Mobile food carts
60 Drinking water treatment chemicals – Health effects
61 Drinking water system components – Health effects
62 Drinking water distillation systems
75 Non-potentially hazardous foods
140 Sustainable carpet assessment, Draft standard for trial use.
143 Environmentally preferable products: Hard surface cleaners
169 Special purpose food equipment and devices
170 Glossary of food equipment terminology
173 Dietary supplements
177 Shower filtration systems – Aesthetic effects
184 Residential dishwashers
14159-1 Hygiene requirements for the design of meat and poultry processing equipment
14159-2 Hygiene requirements for the design of hand held tools used in meat and poultry processing
14159-3 Hygiene requirements for the design of mechanical belt conveyors used in meat and poultry processing

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THE HOPE OF MANKIND rests in the ability of man to define and seek out the environment which will permit him to live with fellow creatures of the earth, in health, in peace, and in mutual respect.