



Global Supplier Standard

FOR SCA HYGIENE BUSINESS JANUARY 2011



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January 2011

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Preface

SCA strongly believes that our performance and recognition as a sustainable business partner to customers and consumers require high standards in the areas of quality, product safety, environment and social responsibility.

We realise that our ability to actively and constantly raise our standards depends on the supplier base we select for our products. SCA is recognised for its sustainable business, and in our position as a leading hygiene company we shall manage and drive not only our own performance, but also develop the performance of our suppliers. SCA believes that working together with our suppliers for a more sustainable business will create a positive result for both parties.

The Supplier Standard for SCA hygiene business is based on internationally recognised standards and management systems, but it also includes specific requirements for SCA hygiene business.

We are committed to continually improving our total performance in the areas covered by the Supplier Standard. Consequently, in our supplier selection process, supplier performance, improvement and commitment in these areas will play an important role.

You are invited to join us on this journey towards continually higher standards for SCA hygiene business and for your own business. Together with our suppliers we shall provide products that we can all be proud of while fulfilling the high standards of SCA.



Anders Aronsson
Vice President Sourcing
SCA Global Hygiene Sourcing



1 Introduction

This supplier standard applies to suppliers of materials to SCA's tissue and personal care businesses, hereinafter referred to as SCA hygiene business. This standard comprises the requirements for quality and sustainable development imposed by SCA hygiene business on its suppliers. It refers to international standards and defines specific SCA hygiene business requirements.

In this document, the term “material” includes materials, packaging materials, chemical substances and preparations, as well as merchandise. Merchandise can be ready-made hygiene products, cosmetic products, detergents, biocidal products, dispensers as well as promotion articles and others.

If supplier's production takes place on separate sites or if part of the production process is subcontracted, the requirements in this standard continue to apply in full and include all subcontractors.

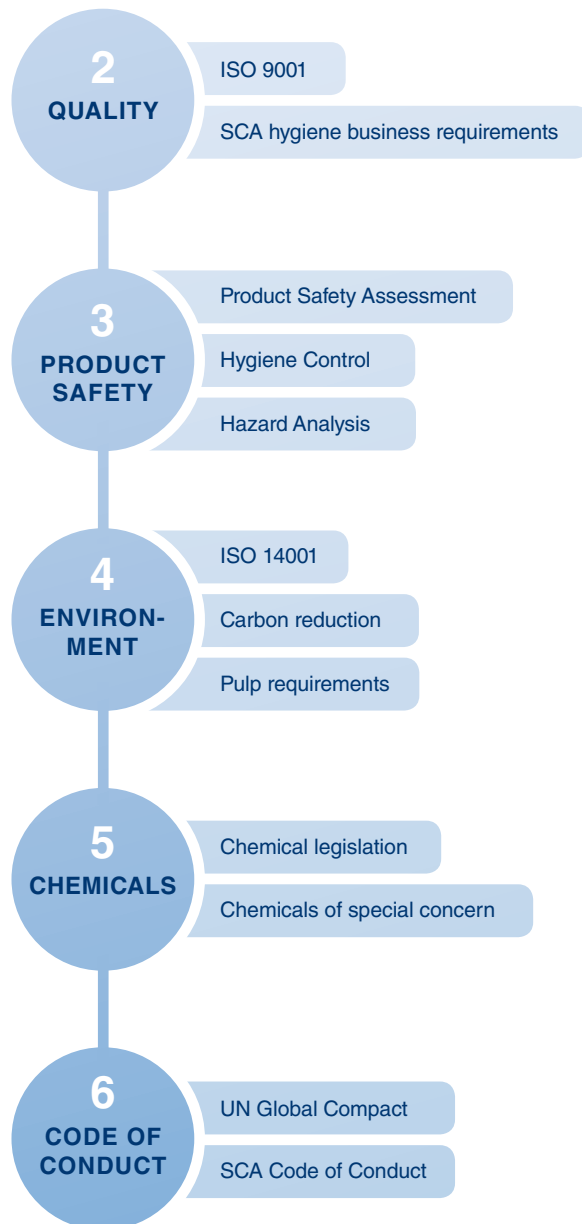
Quality

The SCA hygiene business supplier standard is based on the principles set out in the ISO 9001 standard, notably strong customer focus, continual improvement and process-orientation in quality management systems.

The zero-defect principle has been selected as a means of achieving excellence. Its application is based on the following statements:

- Production processes must be highly reliable
- Process capabilities must meet specification requirements, and it must be possible to continually improve them

Structure and content of the supplier standard



- Preventive action to avoid defects is preferable to quality inspection and correction
- Any defect detected should lead to a corrective and preventive action

Product safety

Product safety is defined as safety for users and others who come in contact with SCA hygiene business's final products. SCA hygiene business works systematically with product safety to ensure its final products are safe for customers, consumers and others to use and handle. A significant part of this is to guarantee that the materials delivered are safe. Critical aspects are e.g. chemical composition, including chemical impurities, and control of general and microbiological contamination during the production of materials.

Environment

For SCA hygiene business, environmental issues are part of the broader concept of sustainability.

Sustainability refers to economic growth and social and environmental care, which enables society to meet the needs of the present without compromising the needs of future generations.

With regard to environmental management systems, this supplier standard is based on the principles set out in the ISO 14001 standard. Other environmental requirements are based on SCA hygiene business's environmental strategies and objectives.

Code of Conduct

SCA has defined and adopted a corporate Code of Conduct. This Code of Conduct defines the principles that SCA regards as fundamental for sustainable development and socially responsible behaviour. It addresses such issues as health and safety, employee relations, human rights, business ethics and community involvement. SCA expects that its suppliers conduct their business to the same high standards.

Supplier evaluation and compliance

Material selection and supplier selection are two distinct processes at SCA hygiene business. Both material and supplier must be evaluated before supply to SCA hygiene business can be authorised.

If the relationship between SCA hygiene business and the supplier is new, an initial evaluation is conducted to assess the potential supplier's ability to meet SCA hygiene business's requirements. Such an assessment can take the form of a questionnaire, visit or a formal audit.

When areas of non-compliance are identified at a supplier, corrective action has to be implemented and the time frame for reaching compliance agreed upon. SCA hygiene business believes in working together with the supplier to improve performance.

The expectations of compliance can also be reinforced in contracts.

Follow-up audits and visits may be carried out to continually evaluate and improve supplier performance.

2 Quality



Management system based on ISO 9001

SCA hygiene business requires that suppliers implement a Quality Management System that conforms to all requirements in the current ISO 9001 standard. The preferred level is an ISO 9001 certification.

In addition to the requirements of the ISO 9001 standard, the supplier should comply with the following requirements.

QUALITY MANAGEMENT SYSTEM

➔ RELATES TO SECTION 4 OF THE ISO STANDARD – ADDITIONAL REQUIREMENTS

Documentation requirements

Control of quality records

Quality records shall be kept available for evaluation by SCA hygiene business for a period of five years after delivery of the material. As a minimum, these records should include

- Specification of the material delivered
- Quality control data/certificates of analysis to prove conformity of the material delivered
- Traceability of raw materials/components used for production of the material delivered

RESOURCE MANAGEMENT

➔ RELATES TO SECTION 6 OF THE ISO STANDARD – ADDITIONAL REQUIREMENTS

Human resources

Competence

Relevant parts of the supplier's organisation shall have a good understanding, with a global perspective if necessary, of the following:

- Products, process and quality assurance in the supplier's field of technology
- Supplier's competitors and their products
- Patents and other intellectual property in the supplier's own field of technology
- Hygiene products and markets

PRODUCT REALISATION

➔ RELATES TO SECTION 7 OF THE ISO STANDARD – ADDITIONAL REQUIREMENTS

Customer-related processes

Interaction with SCA hygiene business's development activities

Suppliers shall ensure that relevant persons in their organisations receive information about and understand the interactions between their own development activities and those of SCA hygiene business.

Customer communication

Suppliers shall document their interaction processes with SCA hygiene business.

Each supplier shall appoint a suitably qualified individual to act as SCA hygiene business coordinator for agreements, orders, customer satisfaction and feedback, claims, queries and corrective actions.

A technical contact person shall be appointed. The contact person shall be responsible for ongoing technical activities and shall be authorised to communicate and take decisions directly with SCA hygiene business.

The roles of technical contact person and SCA hygiene business coordinator can be filled by the same individual if desired. He or she should be able to communicate well in English and be able to travel to SCA hygiene business facilities. Local communication between supplier and SCA hygiene business could be in the local language.

The supplier shall identify a contact person or persons for product safety and environmental-related information.

The content of agreements with and feedback from SCA hygiene business shall be communicated to relevant internal functions.

Upon request, the supplier shall communicate the plans for and status of activities performed in cooperation with or on behalf of SCA hygiene business.

Suppliers are expected to proactively present new developments.

SCA hygiene business expects its suppliers to respond to any queries within a reasonable period of time.

Specifications

All materials must be defined by an agreed specification or technical data sheet, and with a unique identification code, during regular supply and when in development phases.

During the development phase, the identification can be temporary.

Suppliers may not make any changes in raw materials/components used, and/or in their processes, including changes of production unit or line, unless such changes have been communicated to and accepted by SCA hygiene business before implementation. This also applies during the development phase. SCA hygiene business must be notified a minimum of three months but preferably six months in advance if any such changes relating to commercially delivered material take place.

A new material identity shall be used if raw materials or process conditions are significantly changed, particularly if the changes may influence the material's chemical composition.

Design and development

Planning

The development and launch of new materials shall follow a documented cross-functional process. The process description shall include:

- How the customer's expectations are determined
- How material in the developmental phase is transferred to regular production
- How parameters necessary for repetitive production of a material in the developmental phase are documented, e.g. material composition, process parameters

When requested by SCA hygiene business, a formal agreement on the scope and goals of a development project shall be made between the supplier and SCA hygiene business.

A separate confidentiality agreement may also be required.



Development outputs

The initial stage of projects to develop new materials shall include the following considerations:

- Process capability analysis, also valid for pilot machines when applicable
- Patents and other intellectual property
- Cost analysis
- Regulatory and product safety aspects
- Environmental aspects
- Occupational health and safety aspects

Production and service provision

Production

The supplier shall ensure that production and servicing processes are implemented under controlled conditions including the following:

- Process results shall be continuously controlled toward the target value for each property. Where applicable, automatic feedback and control systems and/or statistical process control (SPC) shall be implemented. Process variations shall be evaluated continually and the causes of uncontrolled variations eliminated.
- Suitable preventive maintenance of equipment shall be carried out to ensure continuous process capability.
- Process capability (Cpk/Ppk) calculations shall be completed and documented when applicable.



Hygiene control and product safety

Documented procedures shall be established for hygiene control and product safety (See Chapter 3 and Annex A1).

Hazard analysis for material contamination risks shall be performed and documented when required by SCA hygiene business (see Chapter 3 and Annex A2).

Identification and traceability

Material identification shall be recorded in a manner that permits relevant recall procedures. The supplier shall establish and maintain procedures that allow the traceability of raw materials/components used in material batches.

The supplier shall perform and document an internal audit of the traceability system (once a year at a minimum), covering both traceability of raw materials used and traceability of material produced and delivered.

Traceability records needed to identify delivered material, which have a risk of non-conformity, shall be delivered to SCA hygiene business on demand and in critical situations on short notice.

Transport

Vehicles must be suitable for hygiene product transportation and should be regularly cleaned and inspected to ensure that they are free of odours and contamination. All vehicles, regardless of source, shall be inspected before loading and records of inspection kept.

MEASUREMENT, ANALYSIS AND IMPROVEMENT

↳ RELATES TO SECTION 8 OF THE ISO STANDARD- ADDITIONAL REQUIREMENTS

General

Statistical techniques

Procedures established for selection and application of statistical techniques shall include the use of Cpk/Ppk for capability studies.

Monitoring and measurement

Internal audit

Internal audits shall cover the requirements of the Global Supplier Standard for SCA hygiene business.

Monitoring and measurement

Personnel performing tests on material properties must be proficient in using test methods. Test methods used should be well defined and documented, and preferably recognised standard methods for the specific industry. All measuring instruments must be calibrated and checked in a metrology system.

3 Product safety

Product safety assessment

SCA hygiene business has defined procedures for assessing the safety of a material for the end consumer. Merchandise supplied to SCA hygiene business must also clear a safety assessment, in which information about the merchandise and/or all its included components/materials is normally required and assessed in the same way as for other materials supplied.

All the assessment procedures follow the principles of general risk assessment. These include elements such as hazard identification, exposure assessment and risk characterisation.

Safety assessments are based on legislation and standards relevant to the type of material and the intended market, including but not limited to legislation on (see also Annex A4):

- General product safety, e.g. EU: 2001/95/EC;
USA: Consumer Product Safety Act
AU: Australian Consumer Law
- Cosmetics, e.g. EU: 1223/2009/EC and 76/768/EEC;
USA: Federal Food, Drug and Cosmetic Act
- Food contact, e.g. EU: 1935/2004/EC and BfR Recommendations on
Food Contact Materials
USA: FDA 21 CFR
- Medical devices, e.g. ISO 10993;
EU: 93/42/EC;
USA: Medical Device Safety Act;
- Chemicals, e.g. EU: 1907/2006/EC;
USA: Toxic Substances Control Act and
California Proposition 65
- Electrical equipment, e.g. EU: 2002/96/EC, 2002/95/EC and 2006/66/EC
- Others, e.g. EU: 2009/48/EC and 88/387/EEC;
AU/NZ: TGO AS/NZS 2869-2008 and
AS/NZS ISO 8124

Suppliers will be asked to provide required information that can include:

- Technical product specification.
- Complete composition list, including Chemical Abstracts Service (CAS) numbers for all raw materials, additives and impurities, e.g. residual monomers
- Safety Data Sheet (SDS) according to relevant legislation (e.g. REACH Regulation EC 1907/2006) or other relevant safety information when SDS is not applicable
- Information on toxicological tests already performed (e.g. cell toxicity, skin irritation or sensitisation tests)
- Information on safety performance (including fire rating)/compliance tests performed (e.g. for toys and dispensers)



- Information on restricted substances
- Product information file, according to EU cosmetics legislation

If the supplier prefers, a confidentiality agreement can be signed restricting the use of the information to the persons responsible for performing the product safety assessment, and only for the purpose of assessing health and safety aspects of the material.

Restrictions

Substances subject to special restrictions are listed in Annex A3.

There may be specific documentation requirements for certain materials containing substances listed in Annex A3. These requirements are specified in separate Requirement documents.

Contamination prevention and hygiene control

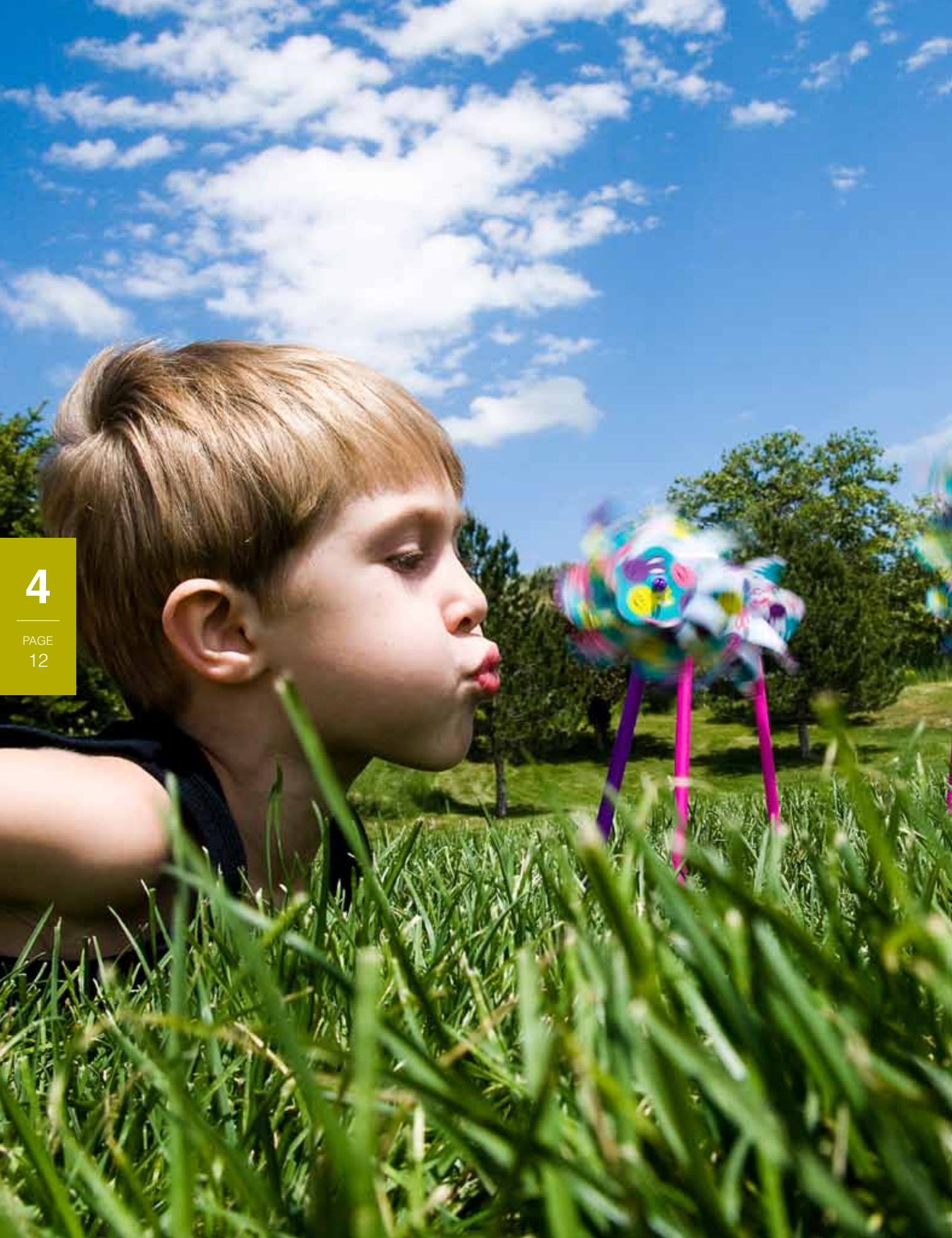
The production of materials for SCA hygiene business shall take place under controlled conditions. These shall include contamination prevention and controlled hygiene conditions in material production and in the handling of raw materials as well as intermediate and finished goods.

Production of materials shall follow the current GMP (Good Manufacturing Practice) applicable for the type of material (e.g. for cosmetics or food contact).

The supplier is expected to meet standards for hygiene control – see Annex A1.

When required by SCA hygiene business, the supplier must perform hazard analysis and contamination prevention – see Annex A2. This will be required for suppliers of, for example:

- Materials to be included in personal care products and selected tissue products
- Ready-made products for personal hygiene
- Cosmetic products



4 Environment

SCA hygiene business considers it important to assess the environmental impact of its products during their life cycle. This in turn requires commitment and transparency from suppliers.

Suppliers must comply with relevant legislation and must be able to demonstrate such compliance upon request.

Environmental management system

SCA focuses on its current environmental status and on future improvements to reduce its environmental impact. Suppliers should be able to demonstrate their commitment and ability to support this initiative. A documented Environmental Management System (EMS) must be implemented.

At a minimum, the EMS should include:

- An Environmental and/or Sustainability Policy
- A documented investigation of the supplier's current environmental impact, including analyses and prioritisations. This to be used as a base for planning of actions to reduce the impact
- Compliance with all legal requirements
- Defined and documented responsibilities, and available resources
- Setting of goals and actions for continual improvement
- Regular management review of the EMS and its effectiveness

The preferred level is a current ISO14001 certification.

Energy and carbon

SCA hygiene business is working to reduce its greenhouse gas emissions from a holistic perspective, i.e. from the extraction of resources, through production, transportation, use, and end of product life. SCA hygiene business expects all suppliers to actively work to reduce emissions, both in terms of energy for manufacturing, transportation, and the source of material.

Suppliers must have an energy efficiency program that includes activities and goals for improving energy efficiency.

SCA hygiene business prefers that its suppliers increase the proportion of renewable¹⁾ energy they use and work with alternative materials that are more environmentally sound.

SCA hygiene business promotes transport modes with low emissions per ton-kilometre and optimizing of the freight and transport between supplier and SCA hygiene business.

¹⁾ According to EU-directive 2001/77/EC: wind, solar, geothermal, wave, tidal, hydropower, biomass, landfill gas, sewage treatment plant gas and biogases.

Environmental questionnaires

SCA hygiene business continually assesses the environmental performance of its suppliers. As part of that, and as input for Life Cycle Assessments and/or environmental labelling, updates and surveys might be necessary.

Suppliers are expected to answer questions on such topics as:

- use of energy (electricity and fuels)
- raw material and finished material
- emissions to air, effluents to water and solid waste
- fibre raw materials and pulp production

SCA hygiene business prefers that suppliers also include environmental information from their sub-suppliers.

If the supplier prefers, a confidentiality agreement can be signed to restrict the use of the information to a level where only the supplier's environmental status is assessed.

Pulp

Responsible use of wood raw material

SCA hygiene business requires its pulp suppliers to use timber that originates only from known sources. Timber from the following types of sources is not accepted:

- Illegally logged timber
- Timber from areas where human rights or the traditional rights of indigenous peoples are being violated
- Timber from high conservation value forests
- Timber from protected areas, parks or similar, where harvesting operations are not complementary to responsible forest management
- Timber originating from Genetically Modified Organisms (GMOs) containing living genes or materials capable of reproduction
- Timber from areas being transformed from natural forests into plantations

Pulp suppliers must have reliable systems and documented procedures in place which enable adequate control of the supply chain and traceability of the origin of wood raw materials. This should ultimately be verified by independent certification (Chain of Custody).

SCA hygiene business expects its suppliers to ensure that the forests from which they are supplying the wood fibre are well managed and, ultimately, are independently certified. The proportion of timber originating from certified forests should be continually reviewed and suppliers are requested to show plans for their forest certification efforts. FSC, PEFC, SFI, and CSA²⁾ are certification schemes recognised by SCA hygiene business.

Other certification schemes may be considered on a case-by-case basis.

Pulp production

The environmental impact of pulp production, i.e. emissions to air (greenhouse gases (GHG), sulphur and nitrogen oxides) and effluents to water (chemical oxygen demand (COD)/total organic carbon (TOC) and/or biological oxygen demand (BOD), adsorbable organic halides (AOX) and phosphorus), contributes to the measurement of suppliers' environmental performance. Levels at the European IPPC (2008/1/EC)/BAT³⁾ standard are preferred.

Fibre based materials

Suppliers of any fibre based material (e.g. packaging, airlaid, tissue, certain merchandise) to SCA hygiene business might be asked to fulfil the same requirements as those for pulp suppliers as regards virgin based fibres. For recycled fibres, the percentage content and information about post-consumer and pre-consumer content may be requested.

Occupational health and safety

All suppliers are required to provide information requested to enable fulfilment of SCA hygiene business's obligations regarding occupational health and safety. Relevant safety information in the local language of the receiver as well as in English must always be available.

²⁾ Forest Stewardship Council, Programme for the Endorsement of Forest Certification Schemes, Sustainable Forestry Initiative, Canadian Standards Association.

³⁾ Integrated Pollution Prevention and Control/Best Available Technique



5 Chemicals

Chemical legislation

All materials delivered must follow applicable chemical legislation.

Suppliers may be required to follow chemical legislation for other parts of the world than where the material is delivered as the final SCA hygiene business product may be distributed globally.

Examples of chemical legislation

- Regulation 1907/2006/EC called REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals).
SCA hygiene business requires suppliers supplying within the EU to take full responsibility for pre-registering, registering, notifying and/or applying for authorisation as and when required. This also applies when customs documents identify SCA hygiene business as the importer
- Toxic Substances Control Act (USA)
- NICNAS, National Industrial Chemicals Notification and Assessment Scheme (AU)
- SEPA Order No 7 (“China REACH”)(China)
- Chemical Substances Control Law (Japan)
- Food contact legislation
- Occupational health & safety (hazardous substances) legislation

Chemicals of special concern

SCA hygiene business has defined chemical substances which are of special concern and are subject to specific restrictions. These chemicals are of special concern if intentionally added to materials supplied to SCA hygiene business, but also if delivered for use as process chemicals in our processes.

In the production processes there may exist such circumstances that make exceptions from this list necessary.

See Annex A3 for chemicals of special concern.



6 Code of Conduct

SCA's Code of Conduct was established in 2004 and is a set of standards that continually builds on our core values Respect, Excellence and Responsibility. As part of this commitment, SCA is also a member of the United Nations Global Compact that consists of 10 principles in the areas of human rights, labour standards, the environment and anti-corruption. SCA also expects suppliers to adhere and act according to the same values as SCA. This section of the supplier standard sets forth the minimum Code of Conduct requirements that suppliers to SCA hygiene business must meet.

National laws and regulations

Suppliers must, as a minimum, comply with applicable international and national laws and regulations. However, it is important to know that SCA hygiene business requirements may sometimes exceed the requirements set out in international and national laws.

Health and safety

A safe and healthy work environment shall be provided for all employees and the supplier shall take effective steps to prevent potential accidents and injuries to workers. A process for continual monitoring and improvement of the work environment shall be in place and a management representative responsible for the health and safety of all personnel shall be appointed. In general, SCA hygiene business expects that its suppliers will provide safe and humane working conditions for all their employees.

Employee relations

- **Non-discrimination**
No discrimination is tolerated based on gender, marital or parental status, ethnic or national origin, sexual orientation, religious belief, political affiliation, age or disability.
- **Wages and benefits**
Suppliers should pay fair wages and benefits that at least meet the minimum legal and/or industry standard (based on local customs and regulations).
- **Freedom of association and the right to collective bargaining**
Suppliers should recognise the fundamental right of employees to decide on whether to be represented by recognised unions of their choice, and should provide the right for employees and their trade unions to engage in collective bargaining. The practices should be based upon internationally recognised labour standards and take into account the customs and regulations of the country in which the supplier operates.

Furthermore, this Supplier Code of Conduct would expect:

- **Employment contracts**
All employees are expected to have an employment contract, whether they are short term, long term or temporary.
- **Working hours**
Suppliers should comply with applicable international and national laws and industry standards on working hours.

Business practice

- **Ethical behaviour**
Suppliers are expected to conduct business in a transparent and ethical manner and shall not participate in any illegal, corrupt or improper business practices.
- **Supplier engagement**
SCA hygiene business expects its suppliers to conduct their operations with consideration for the standards and values expressed in this Code of Conduct down its supply chain.

Respect for human rights

Fundamental human rights should be respected, both in terms of suppliers' own employees and in each supplier's sphere of influence.

- **Child labour**
The supplier shall not engage in or support the use of child labour as defined by international and national laws.
- **Forced or compulsory labour**
The supplier shall not engage in or support the use of forced or compulsory labour as defined by international and national laws. Suppliers shall not inflict or threaten to inflict corporal punishment or any other forms of abuse.

Community relations

SCA hygiene business encourages its suppliers to be corporate citizens and have a positive influence in the communities they operate in.

Communications and privacy of data

SCA hygiene business expects its suppliers to adhere to the confidentiality of information exchange and to respect the privacy of data relating to individual persons.

Grievance/Complaint Procedure

SCA hygiene business expects its suppliers to have a grievance procedure in place where employees can report violations without risk of discrimination.

Environment

Suppliers must comply with relevant legislation and are expected to act in an environmentally responsible manner. See chapter 4, Environment of the Supplier Standard for detailed requirements.



Annex A1

Hygiene control

This annex describes the requirements regarding contamination prevention in the supplier's production processes and premises. Wherever relevant, written instructions should be available.

Personal hygiene

- A.** Personal hygiene is primarily the responsibility of the individual concerned but should be enforced by management where necessary, e.g. in cases in which an employee continually ignores the established procedures.
- B.** Appropriately clean clothing (including clean shoes) must be worn by all employees in all areas where materials are exposed. This includes maintenance operations.
- C.** Where appropriate, employees' hair must be tied back and covered.
- D.** Hand washing facilities should be available within a reasonable distance of production and packing areas.
- E.** Eating and drinking must be prohibited except in designated areas (with the possible exception of drinking water in plastic bottles). Suitable separate premises should be provided where employees may eat.
- F.** The use of tobacco must be prohibited except in designated areas. Such areas must be well away from the production environment.

- G.** Visible and/or detectable plasters or dressings must cover cuts or sores on exposed skin.
- H.** Where appropriate, hygiene regulations should be clearly displayed.

Premises and equipment

- I.** Premises and equipment must be cleaned in accordance with written cleaning instructions. Records should be kept.
- J.** Lighting that is sufficiently intense to allow the detection of defects is required in production, inspection and storage areas.
- K.** Unless the supplier has equivalent expertise and resources, a reputable pest control contractor should be consulted. Written reports are to be provided after each inspection of the pest control system. Appropriate measures should be taken to prevent insects, birds and rodents from entering the premises, e.g. by implementing fly-screening and door-closing routines.
- L.** All sources of glass and brittle plastic in or above the production process must be identified. Appropriate steps must be taken to prevent fragments from contaminating materials or products after a breakage, e.g. by enclosing lights or replacing glass windows. Appropriate procedures must be followed in the event of a breakage.

- M.** Solvents and cleaning agents must be stored in appropriate designated areas. Leaks of oils and lubricants should be prevented by means of an adequate maintenance system. Process additives such as oils, greases, lubricants and cleaning agents should not be allowed to come into contact with materials or products. Contamination from dripping water, condensation, etc., should be prevented.
- N.** Needles, razor blades and similar items are to be kept in designated areas and away from production processes. Used blades, etc., are to be collected in designated boxes.
- O.** During production, all tools and unused spare parts must be kept away from machinery.
- P.** All materials and semi-finished products at all stages of the production process must be stored in such a way as to prevent their contamination. Pallets should be in good condition and should be kept clean and dry. If wooden pallets are used, measures should be taken to prevent contamination of the material (e.g. wood splinters). Where appropriate, clean layer sheets should be used.
- Q.** All repairs and maintenance carried out during production must be suitably monitored to prevent contamination.



Annex A2

Hazard analysis and contamination prevention

A risk analysis shall be conducted each time an important change is introduced in the production process. In all cases, SCA hygiene business recommends that a risk analysis should be performed at least once every two years.

Before a contamination risk analysis begins, a dedicated team should be assigned to the task. Departments in daily contact with the production process should be involved. The size of the team should be in proportion to the size and complexity of the production process. A minimum of three members is recommended.

Identifying potential risk factors

The first step is to create a list of agents that may pose a risk of contamination of the material. This should be completed before the production process itself can be assessed. The following minimum risks should be included:

- Glass and brittle plastic
- Liquids used in the process
- Metals
- Wood splinters
- Tools and spare parts
- Dust and dirt
- Contamination by premises, e.g. walls, floors, etc.
- Contamination by animals, e.g. insects, rodents, etc.
- Contamination by humans, e.g. jewellery, food, etc.

Assessment of production steps

A process flow diagram should be prepared. It should be sufficiently detailed and should cover all steps from receipt of raw materials to loading of finished goods.

Each process step should be assessed on the basis of the above factors and documented as described below.

Risk elimination or minimisation

For each contamination risk identified by the team, the first priority should be to eliminate the risk definitively. This is mainly a question of identifying technical solutions.

Where no realistic definitive solution is identified, a daily prevention or detection system should be defined.

Daily prevention should be described in written procedures and work instructions. The procedures and instructions must be integrated in the supplier's quality management system and, where appropriate, records of daily preventive measures must be kept.

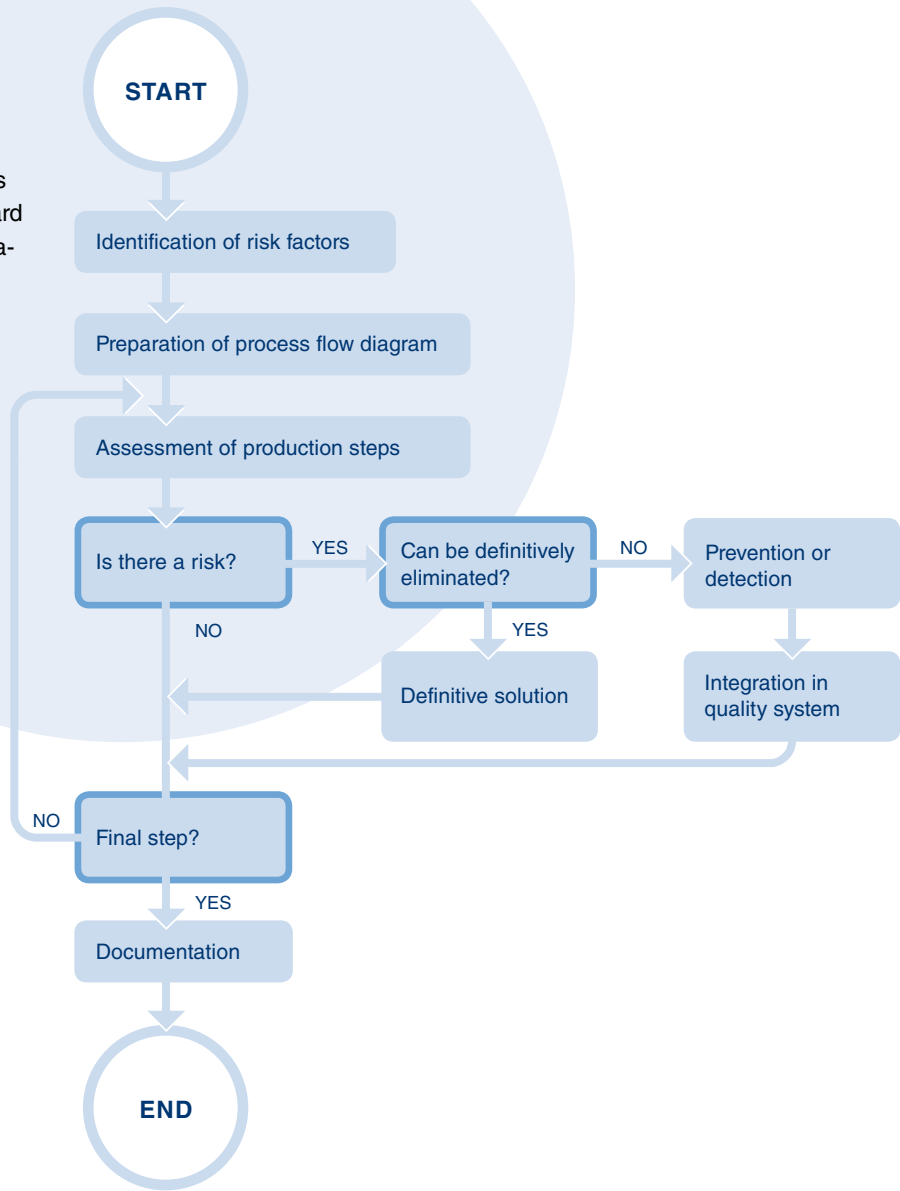
Documentation

The contamination risk analysis should be documented and the documentation should include the following as a minimum:

- Team members
- List of potential risks
- Process flow diagram
- Lists of identified contamination risks at each step in the process
- Solutions identified
 - a) Definitive elimination of the risk
 - b) Daily prevention routine
 - c) Detection system

Flowchart

The following flowchart illustrates the principles and main steps in hazard analysis and contamination prevention:



Annex A3

Chemicals of special concern

Chemicals in Table 1 may not be intentionally added to materials supplied to SCA hygiene business. Exceptions from the list may exist for materials delivered to SCA hygiene business only to be used as process chemicals.

Chemicals in Table 2 are of special concern and their presence as a result of intentional or non-intentional addition will always be assessed in each individual case. Note that this list is not exhaustive.

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Table 1.
Chemical substance

Any substance classified as Carcinogenic, Mutagenic or toxic to Reproduction (CMR substances classified with R45, R46, R49, R60, R61), category I or II under current EU legislation and listed in Annex I of Directive 67/548 or CMR substances in Category 1A and 1B with Hazard statements: H340, H350 and H360 according to The United Nations Globally Harmonised System of Classification and Labelling of Chemicals (UN-GHS), and Classification, Labelling and Packaging of substances and mixtures, Regulation (EC) No 1272/2008 (CLP).
All substances in Annex XIV of EU REACH regulation 1907/2006
Allergens classified with R43 (for fragrance components, and preservatives see Table 2)
Certain metals and their compounds (cadmium, lead, mercury, arsenic, chromium and nickel), exemptions may be made for chromium (3+) in certain applications
Phthalates (for DEP in cosmetic formulations see Table 2)
Polyaromatic hydrocarbons (PAH)
Organotin compounds
Alkylphenols and their ethoxylates
Bisphenol A (BPA)
Perfluorooctanoic acid (PFOA)
Perfluorooctanyl sulphonic acid and its salts (PFOS)
Substances identified as PBT/vPvB substances, according to EU REACH Regulation No. 1907/2006

Table 2. (Non-exhaustive)
Chemical substance

Carcinogenic, Mutagenic or toxic to Reproduction (CMR substances, classified with R40, R68, R62, R63), category III under current EU legislation and listed in Annex I of Directive 67/548 or CMR substances in Category 2 with Hazard statements: H341, H351 and H361 according to The United Nations Globally Harmonised System of Classification and Labelling of Chemicals (UN-GHS), and Classification, Labelling and Packaging of substances and mixtures, Regulation (EC) No 1272/2008 (CLP), or under review by official regulatory bodies, e.g. IARC.
Recognised or documented allergens (e.g fragrances, preservatives etc)
Recognised or documented hormone disturbing substances (endocrine disruptors)
All other substances in the REACH candidate list of EU REACH regulation 1907/2006
Chemical substances on the California Proposition 65 list
Organometallic compounds
Metals and inorganic compounds (e.g silver, copper, cobalt, antimony compounds)
Diethylphthalate in cosmetic formulations
Halogenated compounds (organic and inorganic)
Primary aromatic amines
Organophosphates
Optical brighteners in cellulose
Colourants
Natural rubber



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Annex A4

Legislation and Abbreviations

Legislation and standards

ISO:

- ISO 9001 Quality management systems – Requirements
- ISO 10993 Biological evaluation of medical devices
- ISO 14001 Environmental management systems – Requirements
http://www.iso.org/iso/iso_catalogue.htm

Europe:

- 76/768/EEC: Directive on cosmetic products
- 88/378/EEC: Directive on the safety of toys
- 93/42/EEC: Directive concerning medical devices
- 1223/2009/EC: Regulation on cosmetic products (replacing 76/768/EEC from July 2013)
- 1907/2006/EC: Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) <http://echa.europa.eu/>
- 1935/2004/EC: Regulation on materials and articles intended to come into contact with food
- 2001/95/EC: Directive on general product safety
- 2002/95/EC: Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
- 2002/96/EC: Directive on waste electrical and electronic equipment (WEEE)
- 2006/66/EC: Directive on batteries and accumulators and waste batteries and accumulators

- 2008/1/EC: Directive on integrated pollution prevention and control
- 2009/48/EC: Directive on the safety of toys (replacing 88/378/EEC from July 2011)

For information regarding European legislation:

<http://eur-lex.europa.eu/RECHmenu.do?ihmlang=en>

- BfR Recommendations on Food Contact Materials http://bfr.zadi.de/kse/faces/DBEmpfehlung_en.jsp
- BfR Guidelines for the evaluation of Personal Sanitary Products <http://bfr.zadi.de/kse/faces/resources/INTENGLISCH.pdf>

USA:

- Consumer Product Safety Act <http://www.cpsc.gov/businfo/cpsa.html>
- FDA 21 CFR: Food and drug administration, code of federal regulations title 21 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm>
- Federal Food, Drug and Cosmetic Act <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdact/default.htm>
- Medical Device Safety Act
- Toxic Substances Control Act <http://www.epa.gov/agriculture/lasca.html>
- California Proposition 65 – Safe Drinking Water and Toxic Enforcement Act <http://oehha.ca.gov/prop65/background/p65plain.html>

Australia/New Zealand:

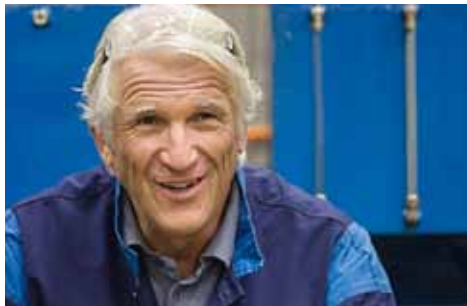
- TGO AS/NZS 2869-2008 Therapeutic Goods Order – Standard for Tampons [http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/52FDF7F3191FAE71CA25756D000E3DF3/\\$file/ExplanStateTGO82Final12209.pdf](http://www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/0/52FDF7F3191FAE71CA25756D000E3DF3/$file/ExplanStateTGO82Final12209.pdf) and <http://www.standards.org.au/Default.aspx>
- AS/NZS ISO 8124 Standard on safety of toys <http://www.standards.org.au/Default.aspx>
- NICNAS http://www.nicnas.gov.au/Chemicals_In_Australia.asp
- Australian Consumer Law (ACL) <http://www.consumerlaw.gov.au/content/Content.aspx?doc=home.htm>

China:

- SEPA order no 7 of the Measures on Environmental Administration of New Chemical Substances, “China REACH”

Abbreviations

AOX	Adsorbable Organic Halides	IPPC/BAT	Integrated Pollution Prevention and Control/Best Available Technology
AS	Australian Standard	NICNAS	National Industrial Chemicals Notification and Assessment Scheme
BAT	Best Available Technology	NZS	New Zealand Standard
BfR	Bundesinstitut for Risikobewertung (Federal Institute for Risk Assessment, Germany)	PEFC	Programme for the Endorsement of Forest Certification Schemes
BOD	Biological Oxygen Demand	REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
CAS	Chemical Abstracts Service	SDS	Safety Data Sheet
COD	Chemical Oxygen Demand	SEPA	State Environmental Protection Administration (China)
Cpk/Ppk	Process capability calculations	SPC	Statistical Process Control
CSA	Canadian Standards Association	TGO	Therapeutic Goods Order
EMS	Environmental Management System	TOC	Total Organic Carbon
EU	the European Union	TSCA	Toxic Substances Control Act (USA)
FSC	Forest Stewardship Council	USA	United States of America
GHG	Green House Gases		
GMO	Genetically Modified Organisms		
GMP	Good Manufacturing Practice		
ISO	International Organisation for Standardisation		



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