OrganiTrust ® Non-food Products and Associated Articles Processing Standard

The contents of this Standard were written based on the Organics Council ® Regulations, and we are officially recognised and approved by the Organics Council ® to licence goods and services in conformity to Organics Council ® Regulations [License number: 20181]

1. Principles and philosophy

1.1. Circular economy principles of OrganiTrust® certification

1.1.1. The OrganiTrust® certification system is designed to assure the highest level of quality, safety and sustainability in product processing and end-user usage, and to guarantee that such products are of circular economy type in its best meaning.
1.1.2. OrganiTrust® certifies the use of chemicals, substances, materials and processes that are considered to have no irreversible and detrimental effects on human and environmental health. The substances considered the greatest risk to circular economy production include (but are not limited to) carcinogens, mutagens, teratogens, reproduction-disrupting substances, endocrine-disrupting substances, persistent pollutants and substances that bioaccumulate.
1.1.3. OrganiTrust® requires that materials, processes and products should be sustainable and not cause the release of polluting substances or end products into the world around us, in addition to being safe to human beings, in the light of the circular economy notion that human health and the planet's health are interdependent.
1.1.4. Full life-cycle assessment of products ensures that circular economy principles are upheld throughout all aspects of product processing.
1.1.5. End-of-life sustainability is a critical element for all OrganiTrust® certified products, and it shall assure no certified products contribute to environmental pollution during disposal or recycling.
1.1.6. The OrganiTrust® certification audit ensures a thorough and complete toxicity risk assessment is carried out, based on the latest scientific knowledge and relating to the safety of both human beings and the environment. No product will be certified if its safety is not confirmed or if there are serious conflicts in the evidence of effects of exposure on human beings or the environment.
1.1.7. OrganiTrust® certification standards confer the highest level of scientific excellence to the audit and risk assessment process, ensure manufacturers maintain the highest quality and guarantee compliance with the highest level of safety and sustainability, assuring that OrganiTrust® certified products are of circular economy type in its best form.

1.2. The scope of this Standard

1.2.1. OrganiTrust® certification framework

1.2.1.1. This Standard covers aspects regulating processing, usage safety and sustainability of non-food consumer products.
1.2.1.2. For OrganiTrust® certification approval, all below statements must be satisfied. This Standard must be applied:

a. only to products already meeting minimum statutory regulation requirements in the intended region of manufacturing and sale;

b. in combination with applicable OrganiTrust® product standards from this list: Food Contact Material (FCM) Product and Associated Article Standard.

1.2.1.3. Compliance with this Standard alone does not result in a product automatically achieving certification, which is subject to the OrganiTrust® Certification Committee decision.

1.2.2. Processing compliance

1.2.2.1. This Standard applies to processing sites for:

a. end product manufacturing;
b. raw material, inputs or final-product-associated article processing, including non-OrganiTrust® final-product-input article distribution to the end-user retailer.

1.2.2.2. Final product provenance verification is required by OrganiTrust®, thus multiple manufacturing sites require an audit, or raw-material or input-article processors may be required to be audited to ensure appropriate supply to the OrganiTrust® certified final product manufacturers.

1.2.2.3. In raw material and final-product-associated article processing, where OrganiTrust® certification is sought for final or intermediate products, multiple distribution facilities for the goods' provenance purposes shall count as manufacturing or processing facilities at the stage of OrganiTrust® logo application on the final or intermediate goods respectively.

1.2.2.4. All manufacturing or processing activities shall be in compliance with all other statutory regulations relevant to the production region and intended market.

1.2.3. Final product compliance

1.2.3.1. The scope of the Standard includes non-food products distributed in the end-user market, whether sold or given to consumers, and raw materials and articles distributed to processors producing consumer products.

1.2.3.2. Products that are retailer-branded, branded or unbranded are covered by this Standard.

1.2.3.3. Specific product standards apply to the product categories listed below:

a. food contact material [OrganiTrust® Standards];
b. personal care and cosmetics ;
c. furniture;
d. children toys;
e. textiles and fabrics;
f. electronics and appliances;
g. building materials;
h. medical and safety equipment;
i. household chemicals and detergents.

1.2.3.4. This Standard is applied to all processing activities directly by processors at the stage of OrganiTrust ® logo application onto final or intermediary product or enforced on manufacturers by the final product retailer, with audits performed at least annually to ensure that these standards are being complied with.

1.3. Exemptions to this Standard

1.3.1. Individual requirements may be excluded on the basis of risk assessment outcomes and providing that compliance with this Standard is not compromised, with documented risk assessments provided with the certification application for evaluation and upon approval of the OrganiTrust® Certification Committee.
1.3.2. The final audit report will include comments on any audit terms deemed to be not applicable or excluded on the basis of risk assessment outcomes and subject to approval by the OrganiTrust® Certification Committee.

1.4. Right of use

1.4.1. These Standards are based on and conform to the Organics Council ® Regulations, which are protected by copyright, and must not be used or copied in any form and for any purpose without the express permission of OrganiTrust ®. Any use of or adaptation to these Standards must reference them as the source and specify they are based on and conform to the Organics Council ® Regulations.

1.4.2. Where these Standards are used as guidance only or for other educational and non-commercial purposes, this phrase must be added in a clear and legible font to the first page of each relevant document: 'The contents of this document have been written based on OrganiTrust ® Standards, which conform to the Organics Council ® Regulations'.

1.4.3. The terms used within this standard conform to the Organics Council ® Regulations Terms and Definitions.

2. OrganiTrust® certified products and processing

2.1. Statutory regulatory compliance

2.1.1. The licensee must show awareness and full and current knowledge of relevant statutory regulations and guidelines for selling products in the intended market, and have a person responsible for those matters.

2.1.2. The licensee must be compliant with the following intended market statutory requirements, where applicable, before applying for certification with OrganiTrust®:

a. general product legislation;
b. product liability laws ensuring product is 'fit for purpose' and does not cause injury or harm, including assurance against any substances potentially (or likely to be) present as non-intentionally added substance (NIAS) contaminants of final products. This includes any obligations concerning declarations of conformity;
c. packaging labelling and/or warning requirements;
d. good manufacturing practice (GMP);
e. laws relating to the need for production data and quality control, where ISO accreditation applies, storage, mandatory reporting and recall of unsafe goods;
f. laws or guidance relating to environmental sustainability aspects or end-of-life and disposal aspects;
g. licensing or approval to manufacture, import or sell products.

2.1.3. Compliance information must be duly managed, and the licensee must ensure that the responsible person is fully trained and authorised to act on the licensee's behalf on the statutory conformity obligations.

2.2. Circular economy requirements

2.2.1. Product

2.2.1.1. OrganiTrust® certification audits take into account all aspects of a product's life cycle and its impact on human and environmental health, requiring a balance of cost, quality, functionality, sustainability and safety, as well as the use of exclusively Organics Council® approved and safe substances as the constituents of the final products.
2.2.1.2. OrganiTrust® certified products must be designed to be safe and sustainable throughout all aspects of the product's life cycle:

a. sourcing of ingredients and raw materials;
b. manufacturing;
c. distribution;
d. use;
e. disposal.

2.2.1.3. Prior to assessment, a full product description report (PDR) must be developed, including all relevant information on product safety, sustainability, quality and functionality. The PDR outline template is provided in annex II and contains the information that must be provided for the audit.
2.2.1.4. It is critical for OrganiTrust® that finished products do not endanger human health in any way; therefore, only the safest Organics Council® approved ingredients and materials may be used in production.
2.2.1.5. The sustainability of OrganiTrust® certified circular economy product aspects shall be evaluated based on the following:

a. reduced use of natural resources;
b. reduction of non-sustainable waste or emission of environmentally harmful substances and materials into the environment;
c. improved product design to minimise non-sustainable end-of-life disposal.

2.2.1.6. Products should be reusable, recyclable or biodegradable, ensuring that the burden of global pollution and landfill saturation is not increased by OrganiTrust® certified products.

2.2.1.6.1. Licensees must demonstrate systems are in place for both post-consumer and post-industrial reuse, recycling or composting as part of the product design.

2.2.1.6.2. The licensee shall action the product's full-cycle design, including via clear and straightforward labelling on the product itself or its packaging, for product reuse, recycling, or otherwise, for life extension of the product or its constituents.

2.2.1.7. Where necessary and feasible, OrganiTrust® supports offsetting schemes to counteract the negative impact of unavoidable processes or practices that may have a negative impact on the environment. These will be considered on a case-by-case basis.

2.2.2. Processing

2.2.2.1. OrganiTrust® certified products must be manufactured using economically sound processes that conserve both energy and natural resources and do not impact negatively the health of both human beings and the planet (or according measures are set in place to mitigate any non-irreversible detrimental effects).

2.2.2.2. The sustainability of OrganiTrust® certified circular economy process aspects shall be evaluated on the basis of the following:

a. incorporating energy efficiency considerations into all new factories or production lines;
b. improving the energy efficiency of existing factories and production lines;
c. improving the efficiency of local regional procurement processes, trying to reduce non-sustainable global procurement processes.

2.2.2.3. OrganiTrust® requires manufacturers producing OrganiTrust® certified goods to embrace new technologies whenever possible during manufacturing, production, storage and dispatch to save energy resources, with evidence of:

a. advancement towards the use of renewable energy where feasible throughout all aspects of the product's life cycle;
b. transition towards using lower-carbon fuels and renewable energy generation on site where feasible.

2.2.2.4. OrganiTrust® requires all forms of natural resource usage to be fully assessed as part of the hazard and risk assessment (HRA), ensuring that sourcing, usage and distribution of energy and all natural resources are managed sustainably and safely.

2.2.2.5. OrganiTrust® requires that HRAs are performed ensuring that during processing human health safety is assured for both staff and the local residents.

2.2.2.5.1. Personnel must be competent to perform the required tasks through training, experience or qualification.

2.2.2.5.2. The processor must identify the need for training and keep documented procedures and records showing training is up to date. Records of training provided to employees shall be available and traceable to the individual employee, ensuring data protection and privacy laws are complied with.

2.2.2.5.3. The processor's standards must be clearly documented and understood by all personnel, including contractors and temporary staff or collaborators.

2.2.2.5.4. Where any risk to human safety is identified as a result of production, risk management shall be implemented to ensure that all risks are effectively controlled and mitigated.

2.2.2.6. Effective health monitoring is compulsory for all staff potentially exposed to any conditions or environments that may have a negative effect on health. Monitoring must be adequately carried out, and outcomes must be documented accordingly.

2.2.3. Energy use

2.2.3.1. Certified goods processors must embrace energy-saving technologies whenever possible.

2.2.3.2. The responsible person must provide evidence of advancement towards the use of renewable energy, where feasible, throughout all aspects of the product's life cycle, as well as transition towards using lower-carbon fuels and renewable energy generation on site, where feasible.

2.2.3.3. Manufacturers must ensure that sustainable energy use is implemented whenever feasible by:

a. incorporating energy efficiency considerations into all new factories and production lines;
b. improving energy efficiency of existing factories and production lines by applying best available techniques (BATs);
c. performing energy efficiency audits aimed at reducing reliance on non-sustainable energy.

2.2.3.4. Greenhouse gas (GHG) emissions must be calculated according to international voluntary measuring and reporting schemes, such as ISO 14064-18 or the Carbon Trust Standard. Carbon audits must also include PAS 20509 or ISO 1404010 for the assessment of the carbon footprint of products, although, until 2025, this does not apply to products with a sales volume lower than one million units per year.

2.2.3.5. For businesses with a sales value below £1mln per year, GHG emissions and carbon footprints may be calculated in-house using UK guidance [UK gov GHG calculations guidance].

2.2.3.6. The processor must meet the zero GHG emissions target by 2025.

2.2.3.7. For GHG emissions offsetting purposes, 100 sq.m. of newly planted trees, at a frequency as per FSC guidelines, of minimum longevity of the species in excess of 100 years,

subject to audit of the number of surviving trees in the second year of growth, equates to an offset of 1300kg/year.
2.2.3.8. For energy-intensive but durable material production (e.g., cement, concrete, steel, etc.), GHG emissions are allowed to be reduced tenfold for offset calculation purposes, so to account for those products' and materials' longevity and durable nature, as well as the lifelong savings in GHG emissions over alternatives that may emit less GHGs in the short term.

2.2.4. Wasteless product end-of-life design

2.2.4.1. OrganiTrust® requires that all products have a clear end-of-life design as outlined in the PDR, ensuring they are either recyclable, reusable or biodegradable.
2.2.4.2. OrganiTrust® certified product recyclates are of the highest quality and therefore hold high recycling value. For some products such as FCMs, licensees may be required to actively implement plans of reverse vending and indicate in their annual audits the progress achieved in plan development, as outlined in specific product standards.
2.2.4.3. It must be possible for the end user to separate and dismantle each different material before the product enters the recycling stream.
2.2.4.4. OrganiTrust® products will only be certified in intended markets where at least one of the following conditions applies:

a. reverse vending schemes approved by OrganiTrust® are used for OrganiTrust® certified products recycling;
b. verifiable recyclate processing regulated by the local municipality is in place for disposed of products to be collected for recycling;
c. a product manufacturer provides an alternative zero-emission collection method for the recycling of the disposed of product;
d. the item is fully compostable or biodegradable;
e. the item has any other clearly defined reuse or sustainable end-of-life design scheme defined in the PDR.

2.2.4.5. Recycling at end of life must be regulated by a reasonable deposit scheme, unless the material being recycled is widely recycled.
2.2.4.6. Product labelling shall display any value recovery possible with recycling, via deposit return schemes or otherwise, pursuant to clause 2.2.3.7.
2.2.4.7. Recycling deposit schemes must conform to the minimum deposit values listed below and be based on recommended retail price (RRP) and inclusive in sale values, unless the remnant value of the product being recycled is greater than the deposit value (e.g., metal recycling), calculated at the point of production of the end product while being certified so during the licensing audit. Note: where no RRP is defined, then RRP is defined as double the value of the trade selling price by the last manufacturer of the supply chain:

a. FCMs containing products at point of sale worth up to £5 (or the equivalent in other currencies) shall include in the final price the container return deposit of 35p, or 70p for all products above £5 value;

b. all non-FCM products, except for items that are normally sold in batches (e.g., building material) should contain in the end product's final value at point of sale a minimum deposit of 5%;
c. where the automated reverse vending is not operated, the manual reverse vending infrastructure shall be assured by leaving at least 30%, rounded up to the decimal value, to the container collection points, (e.g., shops).

2.3. Permitted inputs

2.3.1. Product

2.3.1.1. OrganiTrust ® approved products shall only contain substances that have been fully assessed and approved for both their safety and sustainability and are therefore of circular economy type, according to a gold-standard safety assessment process. All approved substances meet international scientific standards of excellence and are found in the Organics Council ® Approved Substance List (ASL).
2.3.1.2. All substances constituting the final product shall be listed on the ASL. If this is not the case, it is the duty of the licensee to ensure OrganiTrust ® is immediately made aware of this, and it must be notified in the HRA of a new certification application.
2.3.1.3. Any substance not listed in the ASL cannot be used until the Organics Council ® has assessed it. The licensee shall directly request the Organics Council ® to assess the safety of such substance and ensure it passes the Organics Council ® protocolled audits before being used.
2.3.1.4. All inputs shall have documented quality specification records to ensure they conform to OrganiTrust ® standard quality, purity and provenance requirements, with a system in place to manage specifications and technical data for raw materials, components and packaging materials.
2.3.1.5. OrganiTrust ® confirms the traceability of input suppliers during the certification audit by auditing the traceability of randomly selected inputs.
2.3.1.6. All input suppliers must be either ISO 9001 certified or have fully documented raw material rotation and paper record system in place equivalent to ISO 9001.

2.3.2. Processing

2.3.2.1. During processing, monitoring systems must ensure that:

a. any potential risks from raw materials, components or packaging to the safety, sustainability or quality of the product are known and effectively managed;
b. the OrganiTrust ® applicable standards are met.

2.3.2.2. All materials included into methods and processes (including processing aids) must be fully disclosed, and all individual components must meet the full requirements as per specific product requirements detailed within this Standard.

2.4. Marketing and the use of the OrganiTrust ® logo

2.4.1. Labelling

2.4.1.1. The licensee must ensure that all information shown on end-user packaging labels is true and correct and meets the regulatory requirements of the intended market.
2.4.1.2. Product labelling must be indelible.
2.4.1.3. The licensee must ensure that any claims made about a product shall be fully validated.
2.4.1.4. The licensee shall have a product-in-use evaluation (internal or external), reliability trials and shelf-life tests performed by a validated testing body.
2.4.1.5. The use of the OrganiTrust ® logo is protected by copyright and trademark rights, and all rights are reserved.
2.4.1.6. The OrganiTrust ® logo use authorisation stipulations apply to product, packaging and marketing material.
2.4.1.7. The licensee may only use the logo directly on the OrganiTrust ® certified products and may not use it in relation to any non-certified products or any processing or marketing activity without an explicit certification body permission.
2.4.1.8. In order to use the OrganiTrust ® logo, the licensee shall adhere to all logo usage requirements, as detailed within this and other OrganiTrust ® specific product certification Standards (see 1.2.3.3.).
2.4.1.9. The licensee must not use the logo in connection with any activity that is unlawful, libellous, defamatory, obscene or disparaging about OrganiTrust ® or any of its certified products or services, or in any way that infringes the intellectual property or rights of any product, person or entity.
2.4.1.10. By agreeing to the OrganiTrust ® license agreement, the licensee acknowledges that OrganiTrust ® owns all rights to the logo and agrees not to contest the validity of these rights, either during or after the certified period. The licensee will indemnify and hold harmless against any and all claims, actions or demands relating to its business activities or the use of the logo in connection with such activities or otherwise.
2.4.1.11. OrganiTrust ® may immediately terminate the right to use the logo for violation of any of this Standard's terms and conditions, or in the case that certification is duly revoked or expired, or for any other reason deemed reasonable. Upon such termination, the processor must immediately cease the use of the logo or any similar mark, name or other logo, including, without limitation, any name or mark containing the term 'OrganiTrust'.

2.4.1.12. Certified products must display clearly on the labels, as a minimum, but not limited to:

a. name or registered name and address of the responsible person and the country of origin;
b. the nominal content at the time of packaging, either by weight or volume;

c. the date until which the product, when stored as per guidance, is safe for retail or use (e.g., ‘best used before the end of’ or ‘sell by’). The date must be clearly displayed in a durable and permanent manner, in the form of month/year or day/month/year, with a clear indication of any conditions required to guarantee this stability. Indication of the date of ‘sell/use by’ shall not be mandatory for products with a minimum durability of more than thirty months, where an indication of the period of time after opening or of use must be provided instead, for which the product is guaranteed to be safe for public and environmental health.
d. all precautions for safe use;
e. batch number;
f. ingredients and materials;
g. recycling info requirements and any deposit value one may recover upon return, including where to return to;
h. where it is impossible for practical reasons to label the information mentioned above, such information shall be mentioned on an enclosed or attached leaflet, label, tape, tag or card;
i. to meet end-of-life requirements, the product label must state clearly: 'For recycling - dismantle product into individual parts by material type'.

2.4.1.13. To confirm which aspects of the product are conforming to this regulation, fully or partially:

a. if the whole product (content and packaging) conforms to this regulation, then the usage on the label of the approval trademark belonging to the body certificating regulation conformity does not need to differentiate what is licenced (e.g., only the content or only the packaging) or use the third-party approval trademarks in general;
b. if only individual parts (packaging or content) conform to this regulation, then the usage on the label of the approval trademark belonging to the body certificating regulation conformity must differentiate between the product content and its packaging parts and use the third-party approval trademarks together with a note specifying whether the product content or its packaging conforms to this regulation.

2.4.1.14. Labelling, marketing and advertising of products may specify that no tests have been carried out on animals.

2.4.2. Product claims

2.4.2.1. The responsible person must ensure fair product marketing, using factual and unbiased information that meets the regulatory requirements of the intended market.

2.4.2.2. In all marketing, labelling and advertising of certified products, no text, images or any other signs shall imply that the product has characteristics or functions it does not possess.

2.4.2.3. The PDR must determine all reasoning and data justifying the use of a claim, with a product-in-use evaluation (internal or external), reliability trials and shelf-life tests performed by a validated testing body.

2.5. Social fairness

2.5.1. Employment

2.5.1.1. Licensees must promote and annually assess employees' professional development and training in the workplace to ensure that the staff are fully and effectively trained in the skills required.
2.5.1.2. All employees and apprentices must be paid at least a living wage, and wages must be reviewed annually to ensure that they continue to meet the living wage requirements in the region.
2.5.1.3. Licensees are responsible for the health and safety of the employees and must therefore perform health checks and monitor where any potential work-related health risks may be present. A system of regular (at least annual) audits should be in place to ensure that the relevant health checks are carried out, with a defined protocol for action if any adverse health effects are identified and including root cause analysis and preventative and protective measures.
2.5.1.4. Appropriate and sufficient insurance must be in place to protect workers in case of injuries at work and cover other health-associated aspects.
2.5.1.5. OrganiTrust ® accredited employers must ensure a fair and diverse workplace by not discriminating against job applicants or employees due to:

a. age;
b. sex;
c. race;
d. disability;
e. pregnancy;
f. marital status;
g. sexual orientation;
h. gender reassignment;
i. religious background;
j. class.

2.5.1.6. OrganiTrust ® requires that all certified manufacturers meet the requirements of social responsibility guidance ISO 26000.

2.5.2.Operations

2.5.2.1. Organisations must be transparent and honest in all their activities, ensuring that fair operating practices are maintained.
2.5.2.2. Anti-corruption operation methods must be applied within the workplace and to any aspect of purchasing, trading and all services associated with the licensed product or manufacturer.
2.5.2.3. Failure to provide all the information required for an audit will result in automatic failure of any certification assessment.
2.5.2.4. Substantiated cases of deliberate non-compliance will result in the renewal application fee including a penalty fee equal to five times the standard fee for new entities. Where the new OrganiTrust ® licence application director is or was also the director of an entity, whether the same or a different one, that was previously licenced and found to have deliberately breached OrganiTrust ® Standards, the new applicant entity is considered a contract-breaching entity.

2.5.3. Customer support

2.5.3.1. A protocolled system must be in place to effectively manage consumer complaints, including:

a. initial response within seven days of receipt of the complaint;
b. internal investigation of the complaint with outcome response to the customer within twenty-eight days.

2.5.3.2. Where allegations or complaints are substantiated and data has been requested regarding the complaint, the non-proprietary data shall be released to the public within twenty-eight days via the dedicated proprietary means.
2.5.3.3. Where consumer data is collected and stored, data protection and privacy must be maintained.
2.5.3.4. Any proven cases of corrupt activities will result in termination of certification approval, on the grounds of deliberate non-compliance, following an investigation by OrganiTrust ®.

2.5.4. Market safeguarding

2.5.4.1. Annually reviewed systems must be in place for:

a. customer care services;
b. post-purchase support;
c. complaint and dispute resolution.

2.5.4.2. All complaint must be logged, and all management processes recorded as per protocolled systems.
2.5.4.3. For corroborated complaints, no more than a single critical safety breach shall be reported per year per product before the licensing is suspended, pending the reapplication

upon the penal basis, and the licensing is subject to annual review audit upon each critical breach report.
2.5.4.4. All complaints must be reviewed by a predesignated complaints review panel, with defined policies and procedures in place to ensure unbiased investigation into the complaint.

2.5.5. Non-conformity mitigation

2.5.5.1. Protocols must be in place so that in any instance of product non-conformity that may result in a risk to the health of the user, customer, consumer, general public or the environment, the responsible person will immediately implement procedures to:

a. establish the level of hazard where there is non-compliance, based on non-conformity to defined product specifications and critical control points (CCPs);
b. ensure corrective actions are performed to bring the product into conformity;
c. in case of major or critical non-conformity, withdraw the product from the market or recall required stock.

2.5.5.2. Non-conforming stock detection must be done using automated or in-line monitoring where feasible, with evidence of effective use, protocols, data file logs and quality assurance and quality control (QA/QC) confirmed during the audit.

2.5.5.3. In the event of major or critical hazard to human or environmental health, procedures must be present for the responsible person to:

a. take all feasible safety safeguarding measures to ensure that the product is withdrawn or recalled or its availability is suitably restricted to mitigate the hazard;
b. inform the competent authorities, without delay, of the hazard and any measures taken;
c. perform actions within seven days.

2.5.5.4. In case of major or critical hazard to human health, where non-compliance is not limited to an area where immediate product recall is feasible, procedures must be present for the responsible person to immediately notify the competent authorities, informing them of the required measures.

2.5.5.5. Annually tested procedures must be in place for product recall processes.

2.6. Product quality management systems

2.6.1. Contamination control measures

2.6.1.1. The licensee must take all necessary steps to identify and prevent the risk of contamination as identified by the HRA available in annex III.

2.6.1.2. Adequate steps must be taken to identify, eliminate or avoid the risk of product contamination from sources such as, but not limited to:

a. raw ingredient or material contamination;
b. microbiological contamination;
c. foreign objects;
d. chemical;
e. use of recycled materials;
f. deliberate sabotage;
g. packaging materials.

2.6.1.3. Documented facilities and procedures must be in place to control any identified risk.

2.6.1.4. Contamination control measures are considered critical in all OrganiTrust ® approved products and must be conformed with fully, as outlined in this Standard.

2.6.1.5. There should be no unnecessary materials similar to those used within production on production sites (e.g., glass, ceramics and brittle plastic), which may pose a contamination risk.

2.6.1.6. All similar or potentially contaminating materials (other than the product) that are required for production and processing must be controlled and recorded on a register, which must fully detail their storage location, quantity, type and condition.

2.6.1.7. Documented audits of similar or potentially contaminating items and the condition of items must be performed with appropriate frequency, including considering replacing these items to avoid potential product contamination.

2.6.1.8. Breakage of any similar or potentially contaminating material should be isolated and cleaned immediately to avoid any product contamination, and it should be logged in an incident report.

2.6.1.9. Any possibly contaminated products must be removed immediately, transferred to an appropriate staff member for investigation and logged in a contamination report.

2.6.1.10. Processes must ensure effective use, storage and handling of non-production chemicals and biological materials to prevent contamination, including but not limited to:

a. a list of approved chemicals for purchase;
b. Organics Council® Approved Substance Data sheet;
c. material safety data sheets;
d. effective labelling and/or identification of containers of chemicals and biological materials at all times;
e. a designated storage area with access restricted to authorised personnel.

2.6.1.11. Tools and other sharp metal implements used in production must be strictly controlled is any scenario assessed to pose a risk of product contamination. Methods such as, but not limited to, the following may be used:

a. tools permanently attached to equipment to prevent loss;
b. items controlled by an issue listing and registration procedure;
c. recovery of all parts of broken or damaged or otherwise not fit inputs before the issue of a replacement input.

2.6.1.12. Snap-off blades are prohibited.

2.6.1.13. Objects such as staples, paper clips and drawing pins are prohibited in open product areas, but where staples or other items are present as packaging materials or closures, these

should be removed upon receipt of goods and outside the production area, to minimise the risk of product contamination.

2.6.1.14. Glass or other brittle materials shall be excluded or protected against breakage in areas where there is a risk of product contamination.

2.6.1.15. Where there is a potential risk to the product, all glass, ceramic, wood and brittle plastic items present in the production areas (except where the item is part of the product) shall be included in the risk assessment and listed in a register. Documented procedures for handling these materials shall include:

a. regular checks of the condition of these materials, carried out at specified intervals and recorded;
b. recording of all breakages in an incident report;
c. segregation of contaminated product;
d. recording details of cleaning or replacement to minimise potential for product contamination.

2.6.1.16. The HRA must identify any potential use of the equipment to detect or remove foreign body contamination.

2.6.1.17. Filters, scanners and sieves used for foreign body control shall be of a specified mesh size or gauge and documented to effectively provide the maximum protection, as relevant for the product.

a. Any contaminating material retained or removed by the system shall be examined and recorded to identify risks.
b. Filters and sieves shall be regularly inspected and tested for damage at a documented frequency determined by the risk assessment.
c. Defective sieves, scanners and filters shall be segregated, appropriate action shall be taken to replace them, and records shall be maintained, with annual audits of conformity confirming those are fit for purpose.

2.6.1.18. Any sources of contamination must be investigated, and appropriate corrective action must be taken to minimise the risk of further contamination. Reporting processes must be initiated, incident reports logged and records effectively maintained.

2.6.2. Quality control and critical control point monitoring

2.6.2.1. A defined programme of process control and quality control is required to ensure the production of consistently safe, sustainable and legal products, based on the HRA outcomes.

2.6.2.2. Non-conforming goods must be documented and handled accordingly, including:

a. incoming goods, substances, ingredients and materials;
b. components during processing;
c. final product.

2.6.2.3. The licensee must ensure procedures are in place for all non-conforming or non-specification goods, including:

a. rapid identification;
b. removal;
c. quarantine and assessment of full batch to ensure the problem is not batch-wide;
d. recall and customer return systems.

2.6.2.4. Immediate root cause analysis and preventive actions must be implemented and documented to avoid repeat nonconformity episodes. An investigation into the cause of nonconformity must be performed to ensure that it is not likely to reoccur, or that adequate systems are in place to ensure effective management of risk.
2.6.2.5. An annual HRA review must assess any and all nonconformity issues that have arisen in the previous year, with a detailed outline of preventative and protective measures taken to mitigate risk.
2.6.2.6. Nonconformities are established in the HRA, based on the conformity specifications defined in the PDR for each product type.

2.6.2.7. It is the responsibility of the licensee to ensure basic environmental and operational conditions are suitable for the production of safe, sustainable and fully compliant products.
2.6.2.8. The licensee must have a documented and established quality management system (QMS) in place, as outlined in the HRA (annex III), which is fully implemented by a designated individual or team.

2.6.2.9. The licensee must have a plan in place to manage QMS incidents and enable withdrawal and recall of products if required.

2.6.2.10. Documented product withdrawal and recall procedures shall include as a minimum:

a. named key staff or incident management team and their key responsibilities and a list of named persons who can initiate a recall;
b. an up-to-date list of key contacts, as well as external agencies providing advice and support;
c. technical and quality agreements with agents, distributors and other parties in the supply chain to ensure effective withdrawal/ recall;
d. an up-to-date recall protocol, which is readily available to relevant staff.

2.6.2.11. In the event of a product recall, OrganiTrust® must be informed within seven days.

2.6.2.12. Products that are to be disposed of due to a recall, withdrawal or as substandard trademarked materials shall be disposed of securely, with records of such maintained.

2.6.2.13. The product recall and withdrawal procedures shall be regularly audited, at least annually, to ensure their effective operation, with outcomes used to implement improvements as necessary.
2.6.2.14. Where any non-critical control issues are controlled by process monitoring, the process parameters must be clearly defined and evidence that the monitoring is an effective control.
2.6.2.15. In circumstances where process parameters are controlled by in-line monitoring devices, these shall be linked to a suitable failure alert system and routinely tested.
2.6.2.16. A record shall be maintained of in-process checks and of any actions taken where checks identified a failure to meet the control limits.

2.6.3. Processing inputs

2.6.3.1. Nonconformity in any processing inputs is classed as a critical nonconformity, and an immediate alert system must identify nonconforming ingredients or raw materials.

2.6.3.2. Nonconformity classification is identified based on the raw material and component specifications established in the PDR.

2.6.3.3. These must be immediately:

a. quarantined and removed from the production line area;
b. returned to supplier or destroyed, to avoid accidental use.

2.6.3.4. All instances of contamination of raw materials or processing inputs are considered critical nonconformities.

2.6.3.5. The source of contamination must be immediately identified and removed/managed effectively to avoid any further contamination.

2.6.3.6. All potentially contaminated material must be immediately:

a. quarantined and removed from the production line area;
b. destroyed to avoid accidental use.

2.6.4. Composition change

2.6.4.1. Any change in product processing systems or composition must be fully assessed according to the HRA template provided by OrganiTrust®.

2.6.4.2. Any change in the composition without full HRA is considered a critical nonconformity.

2.6.4.3. Process or composition aspects include:

a. all raw materials, ingredients, inputs and components;
b. suppliers of raw materials, ingredients and components;
c. processing methods and systems.

2.6.5. Documentation

2.6.5.1. Any failure in the effectiveness of the traceability system is considered a major nonconformity.

2.6.5.2. OrganiTrust® requires certified products to be subject to customer notice within one day, with follow-up product withdrawal within five days.

2.6.5.3. Any such failure requires a full HRA to assess:

a. the cause of the failure;
b. the number of affected batches;
c. preventative action plan.

2.6.6. Conformity testing requirements

2.6.6.1. The outcomes of the HRA will determine the need for in-line, off-line and random product testing equipment.

2.6.6.2. Detailed specifications must be documented for all CCPs and safety testing parameters to ensure compliance checks are validated, standardised and automatic (see annex III.VI).
2.6.6.3. All in-line testing equipment must provide a system to immediately identify non-conforming products or components.
2.6.6.4. Procedures must be in place to ensure in-line testing is monitored for accuracy and reliability, with specified accuracy and permitted tolerances audited for conformity in accordance with the guidelines provided by the equipment manufacturer.
2.6.6.5. Routine off-line product quality checks must regularly be performed at all appropriate stages of production to ensure that the product conforms with the tolerance levels established by product specifications and HRA.
2.6.6.6. A randomised quality check system must be implemented to identify and remove non-conforming products.
2.6.6.7. The processor must document and implement procedures for routine and random monitoring and testing of all equipment used in product inspection, testing and measurement.
2.6.6.8. Where the processor undertakes or subcontracts analyses of CCPs to product safety, the subcontracted processor must be approved by OrganiTrust ® and provide proof of indemnity insurance or be ISO 17025 accredited for the test undertaken.
2.6.6.9. Manufacturers must provide evidence that production process safety and sustainability conform to the Organics Council ® regulations.
2.6.6.10. The processor must have a system to ensure that stock and finished products are not released unless all agreed control procedures have been completed.
2.6.6.11. Quality checks must both guarantee and fully demonstrate that the finished product conforms to OrganiTrust ® standards for safety and sustainability as well as all statutory requirements.
2.6.6.12. Proof must be available that the final product conforms to all identified CCPs and requirements with a programme for regular product inspection and testing to ensure safety and quality control.
2.6.6.13. The methods and specified limits of testing shall be clearly defined, based on the requirements for each product or product group and using information such as:

a. product description report;
b. outcome of the HRA in conformity with OrganiTrust ® standards;
c. any legal testing requirements for the intended product marketplace;
d. safety and sustainability requirements outlined in specific product standards.

2.6.6.14. For non-critical controls, procedures shall be in place to ensure the accuracy and reliability of test results; these shall include:

a. use of recognised test methods and reference standards approved by OrganiTrust ®;
b. documented testing procedures;
c. ensuring staff are suitably qualified and/or trained and competent to carry out the analysis required;
d. use of a system to verify the accuracy of test results;
e. use of appropriately calibrated and maintained equipment.

2.6.6.15. The licensee shall have a product-in-use evaluation (internal or external), reliability trials and shelf-life tests performed by a validated body.
2.6.6.16. All test and inspection results shall regularly be reviewed to identify trends or changes in production, and appropriate actions shall be implemented promptly to address any unsatisfactory trends.
2.6.6.17. Results falling outside of the defined specification shall be reviewed promptly by an authorised competent person, with the need for corrective action assessed, documented and carried out as necessary.
2.6.6.18. Documented justification must be provided where methods are not explicitly defined.
2.6.6.19. The testing programme shall be fully implemented and performed by a trained individual, and records of all test results must be kept on file.
2.6.6.20. Where testing is submitted to third parties, the analysis requirements must be clearly defined, with documentation showing the agreed number, date and version of test standard or method to be used, as well as a clear written briefing on the purpose and requirements of the test, along with evidence that the testing programme is formally agreed on.
2.6.6.21. Controls must ensure effective stock rotation and that products are completed in the correct order and within the allocated shelf or usage life as applicable.
2.6.6.22. A documented procedure shall be in place to ensure that only products conforming to designed specification are produced upon quality approval by authorised staff according to a defined protocol.

2.6.7. Product storage and dispatch to intermediate customers

2.6.7.1. Storage and dispatch standards apply only to on-site storage facilities and initial systems for dispatch to the intermediate customer. This Standard does not apply to secondary transport, distribution of goods or retail activities.
2.6.7.2. Before starting any packaging processes, documented checks must ensure that the packaging line and relevant areas are suitably isolated and cleared to avoid mixing with materials from previous operations.
2.6.7.3. The licensee must have documented procedures in place for the packaging of products according to traceability and customer requirements, ensuring that the correct products are suitably packaged and placed in the allocated outer packaging. All steps must be fully traceable and verifiable in case of product recall.
2.6.7.4. The quantity of the product should accurately match the product quantity markings, which should be verified and in accordance with the legal requirements in the region(s) of sale.
2.6.7.5. Facilities intended for storage and primary transportation of products must be fit for purpose, avoiding any product contamination, damage or deliberate malicious intervention.
2.6.7.6. It is essential that all products are properly identified and protected from contamination during storage by means of appropriate packaging.
2.6.7.7. All handling during storage shall be managed to prevent product damage.
2.6.7.8. Vehicles or containers used for primary transportation and dispatch must be inspected

prior to loading to ensure that they are fit for purpose, and records of inspection must be maintained.
2.6.7.9. Documented procedures must ensure product safety during loading and transportation.
2.6.7.10. If a product is vulnerable to weather damage, storage and transportation must be designed so as to protect the product.
2.6.7.11. If a third party is used for storage or transport, all requirements shall be harmonised within a contract and effectively managed by a designated individual.
2.6.7.12. Sustainability considerations must be made at every step of the storage and dispatch process, with documented evidence of efforts made to improve sustainability and reduce environmental impact.
2.6.7.13. Effective hygiene standards must be maintained at all times during product storage and transport, with all product transportation equipment (including but not limited to conveyors, lifting trucks, and stacking equipment) regularly cleaned and serviced by trained individuals.
2.6.7.14. Hygiene standards must be ensured for all outgoing products through quality control, test methods and documentation checking.

2.6.8. Traceability

2.6.8.1. Processing

2.6.8.1.1. Licensees must be able to trace all raw materials, components and packaging provided by suppliers through all stages of processing and dispatch to intermediate customers, and a system must be in place to enable tracking by batch or order number.
2.6.8.1.2. Identification of lots/batches of raw materials, packaging, processing aids, intermediate/semi-processed products, part-used materials and finished products must allow for traceability.
2.6.8.1.3. All subcontracted manufacturing of products or components shall be traceable to the same level.

2.6.8.1.4. The traceability of all ingredients, materials and components must be tested at least annually, and results must be kept on file.

2.6.8.2. Final product

2.6.8.2.1. The final product shall be identified with a unique code (such as a batch code) applied to the product or packaging, with documented procedures in place to trace all materials and packaging used to the batch level.
2.6.8.2.2. Any final product displaying the OrganiTrust ® certified logo must be fully traceable to the primary point of consumer dispatch, with information on:

a. the intended purpose and manner of use of the final product;
b. the intended scale of production and sales forecasts;
c. all required aspects associated with full final product safety and sustainability;

d. the final region of sale;
e. any corporate, industrial or other third-party, non-consumer purchasers must be identified along with purchase quantities and intended region of sale.

2.6.8.2.3. The final product traceability system must be tested at least annually, and results must be kept on file.

3. Product risk and hazard assessment

3.1. Principles of risk and hazard assessment

3.1.1. The processor seeking certification must have a full understanding of the potential risks of the products and an effective systems to maintain consistent quality and conformity, as well as to identify and control hazards to product safety and sustainability that are reasonably expected to occur at each step of the production process.

3.1.2. Compliance requires a thorough evaluation of any risks that a product may potentially pose to the consumer, the general public or the environment when the product is used in the intended or a reasonably expected way.

3.1.3. The HRA template is provided in annex III and must:

a. assess the risk of product and any associated articles;
b. identify all potential hazards pertaining to product safety, quality or sustainability during the full product life cycle;
c. ensure the intended market is considered and that interactions with other relevant products, substances or materials are considered.

3.1.4. Assessment relies on the use of risk assessment principles, and the designated risk assessor must be able to demonstrate during site inspection that they have identified, managed and mitigated all potential risks during manufacturing, storage, use and disposal.

3.1.5. Any hazards or risks identified during the OrganiTrust ® certification audit must have an appropriate hazard and risk management system in place for the certification process to proceed, although, if required, a timeline will be established for remedial actions.

3.1.6. HRAs must be objective and ensure:

a. transparent methodology analysis, subject to confidentiality, privacy and legal constraints;
b. completeness in the assessment, identifying all relevant considerations such as injury scenarios, affected subpopulations, potential injury severity, likelihood of exposure, hazard recognition, reasonably foreseeable misuses of the product and any sustainability aspects or potential negative impact on the environment;
c. clear communication of uncertainties, assumptions and description of the parameters considered in the analysis. Sources of uncertainty can include (but not limited to) the quantity and quality of information, non-validated assumptions, the state of current scientific knowledge and limitations of the risk assessment methodology itself;

d. evidence-based risk assessment using scientific evidence and sound judgment. The assessment shall be undertaken by trained and competent internal or external resources;
e. variability within populations should also be considered, particularly in order to identify vulnerable subpopulations, which may be more susceptible and/or less resilient to exposure to a particular product safety hazard.

3.1.7. Processors must ensure that production and processing facilities and machines have established, documented and annually tested safety and protection procedures as per OrganiTrust® HRA requirements.
3.1.8. Specific guidelines and safety measures for production must be implemented as per requirements of OrganiTrust ® Product Standards, good manufacturing guidelines and any relevant regulations in the region of manufacturing.
3.1.9. Any potential environmental risk identified during HRA must have documented control measures in place that are reviewed at least annually to ensure they are sufficient to avoid environmental impact.
3.1.10. High-level work hazards must be effectively identified during HRA and adequately controlled or mitigated.

3.2. Critical control point identification and assessment

3.2.1. Manufacturers must identify any CCPs, defined as those points at which controls are compulsory to prevent or avoid a serious product safety, sustainability, quality or integrity hazard, with a documented control plan to be implemented to ensure critical risks are controlled effectively.
3.2.2. Where a control point is not classified as critical, controls may be performed via a defined system or programme, ensuring sufficient control of identified hazards.
3.2.3. Each hazard identified is referred to as a ‘control point’, and its level of risk must be assessed according to the HRA (annex II), with a full documented control system established, ensuring product safety, sustainability and conformity.
3.2.4. Appropriate specifications or critical limits must be defined to identify whether correct controls are being maintained in the production process, based on reasonable industrial and scientific rationale, and where present, on relevant legislation and codes of practice (clearly documented).
3.2.5. Conformity testing requirements must be identified and specified clearly to confirm conformity to each critical use parameter.
3.2.6. If the HRA determines that no control is required, the processor must provide a full justification for this, which is audited annually.

3.3. Critical control point monitoring and validation

3.3.1. The licensee shall directly undertake or may subcontract CCP audit, though in the latter case, the third party must be duly accredited for this sort of audit work. The audit shall be carried out in conformity to this standard, and the audit work shall be

indemnity-insurance-quality assured or ISO 17025 accredited for the pursuant CCP audit work.
3.3.2. A monitoring system must be in place to ensure compliance with critical limits, with records maintained and documented procedures for the monitoring of each CCP included in internal audits for standard compliance.
3.3.3. Corrective and remedial actions must be taken and documented when monitored results indicate a failure to meet specified control limits, including product, ingredient or material quarantine; evaluating potentially non-specification ingredients, materials or products; and product recall systems.
3.3.4. Procedures for validation, verification and annual review must be in place to confirm that the system is working effectively, including auditing of the system.
3.3.5. Annual reviews are required to ensure that the risks identified for all CCPs are adequately controlled, all information is up to date and, where necessary, to make improvements.
3.3.6. Records shall be kept for a minimum of five years for reviews and include:

a. any significant incidents;
b. any instance of product modification;
c. any production process or product composition changes, or any changes in ingredients or materials, suppliers or other sourcing systems;
d. any product failures or product recalls;
e. any complaints received;
f. outcomes of internal, external and third-party audits;
g. new developments in industry associated with materials, processes or products.

4. Personnel and staff management

4.1. Staff management and commitment to this Standard

4.1.1. The safety, sustainability, conformity and quality of products must be managed, monitored and controlled by designated responsible teams or individuals.
4.1.2. The senior management must maintain a commitment to the continual development of policies on safety and sustainability.
4.1.3. The senior management must demonstrate complete commitment to the requirements of all relevant standards, including through the implementation of processes that facilitate continual improvement of product safety and quality management.
4.1.4. Effective management and control require integrated systems between technical departments and management and demand complete commitment from a broad range of departments, such as production design and operations, maintenance, distribution,

management, procurement of raw materials, customer feedback and human resource activities such as training.

4.1.5. The processor must have a documented policy stating its intention and actions to meet obligations for the production of safe and legal products to a specified quality. The policy must be authorised and signed by the individual designated to have overall responsibility for conformity and compliance, and it must be effectively communicated to staff.

4.1.6. Management review meetings attended by senior management must be undertaken at appropriate planned intervals, at least annually, to review production safety performance, including an assessment of:

a. progress on action plans and time frames established during previous meetings;
b. any results of internal, second- or third-party audits;
c. customer complaints or any customer feedback;
d. all product safety and quality incidents;
e. all process alterations or corrective actions;
f. all non-specification results;
g. any non-conforming ingredients, substances or materials;
h. any reviews of HRA;
i. any changes to legal requirements;
j. any resource requirements.

4.1.7. Detailed meeting records must be filed and used in internal audits to establish objectives and action plans, which must be implemented within specified timescales.

4.1.8. The senior management must provide sufficient resources to ensure safe and compliant production.

4.1.9. The management is responsible for ensuring that OrganiTrust ® recertification audits are organised before the audit due date indicated on the certificate. Otherwise, certification will be revoked.

4.1.10. The management must establish a clear organisational structure, with established processes and lines of communication to enable effective management of product safety, conformity and quality.

4.1.11. The processor must have an accurate organisational chart displaying the management structure, with key staff responsibilities and activities clearly designated.

4.1.12. Senior management with the authority and responsibility to stop production should be specifically identified and adequately trained.

4.1.13. In case of staff absence, there must be clear deputy allocations for all activities that are critical to product safety, sustainability, conformity and quality.

4.1.14. The senior management must ensure that all employees are aware of their duties and responsibilities, have access to documented work protocols, are appropriately trained and maintain an effective record confirming work is completed according to approved protocols.

4.1.15. The senior management must ensure that the causes of all nonconformities identified during the previous audit have been effectively addressed, with steps taken to mitigate recurrence.

4.2. Record-keeping and maintenance

4.2.1. The processor must maintain original, accurate, up-to-date and legible records that show effective control of product safety, sustainability, conformity and quality.

4.2.2. The site shall have a document-control procedure to ensure that all key documents forming part of the product safety and quality system are effectively managed and updated, including:

a. a list of all controlled documents indicating the latest version number and with a documented edit history;
b. the method for the identification and authorisation of controlled documents;
c. a record of the reason for any changes or amendments to documents, as well as the individual who performed the edits;
d. systems for replacement of existing documents when these are updated.

4.2.3. Documents in electronic form must be effectively protected to prevent loss or malicious intervention, with an edit or alteration log maintained.

4.2.4. Records must be easily retrievable, and any alterations must be authorised, with justification for alteration recorded.

4.2.5. Records shall be retained for a minimum period of seven years, unless OrganiTrust ® approved otherwise.

4.3. Internal audit

4.3.1. Via an internal audit process, the processor must show it has systems to verifiy the effectiveness of:

a. product safety and quality systems;
b. sustainability measures as per OrganiTrust ® Circular Economy Standard;
c. HRA and CCP reports;
d. GMP conformity measures;
e. specific product standard requirements.

4.3.2. The scope and frequency of the audits shall be based on HRA and previous audit outcomes.

4.3.3. Internal audits shall be carried out by appropriately trained, independent and competent auditors.

4.3.4. The internal audit programme shall be fully logged and recorded, with a final report identifying conformity and nonconformity issues, and results should report relevant members.

4.3.5. Corrective actions and timescales for their implementation must be established and maintained, with acceptable completion verified.

4.4. Complaint handling

4.4.1. A dedicated complaints officer should be designated and effectively trained.
4.4.2. The processor must have an effective system for the receipt, recording, reporting and investigation of product complaints for all levels of complaint severity.
4.4.3. All complaints must be recorded, with responses or results of the investigation recorded.
4.4.4. The processor shall have a process in place to respond in a timely manner to consumers and customers regarding complaints.
4.4.5. Actions should be appropriate to the seriousness and frequency of the issue identified and summarised in a complaint outcome report, with a focus on avoiding recurrence.
4.4.6. Complaint data shall be analysed for significant trends, with the outcomes reported to relevant staff.

5. Processing site requirements

5.1. General site requirements

5.1.1. The site to be included in the audit shall be clearly defined, with a site plan readily available.
5.1.2. Sites should be clearly designated as for manufacturing, storage or distribution and shall be fit for purpose, of suitable size, construction, layout and location to allow effective maintenance, GMP, prevent contamination and enable the production of safe, sustainable and compliant products.
5.1.3. The external areas surrounding the site must be maintained in good order.
5.1.4. The local environment should be assessed, and any local activities that could result in product contamination should be identified.
5.1.5. Where measures are applied to protect the site from potential contaminants or damage due to the surroundings or local environment, these must be regularly reviewed within the internal audit, at least once a year, in response to any changes.

5.2. Equipment safety, suitability and maintenance

5.2.1. Prior to any operations, documented checks must be performed to ensure that the production line and all associated areas have been cleaned to avoid contamination with materials, ingredients or substances from previous operations.
5.2.2. It must be easy to identify and find the production line through its name or identifying code displayed.
5.2.3. All equipment must be established and validated as suitable for its intended purpose,

with competent and trained staff using it effectively.
5.2.4. The equipment must be checked at regular, defined intervals, ensuring it is fit for purpose, constructed appropriately and calibrated.
5.2.5. The design and positioning of the equipment must ensure effective cleaning and maintenance.
5.2.6. In case of equipment failure, documented procedures must be in place to ensure the safety and compliance of the product are not affected.
5.2.7. A documented preventive maintenance programme must be performed at regular intervals, based on HRA outcomes. This must be ensured for all equipment critical to product safety, conformity and quality.
5.2.8. Substances and materials used for maintenance, such as chemical lubricating oils and paints, shall be assessed to ensure their use poses no risk due to direct or indirect contact with raw materials, components, packaging, intermediate components or finished products.
5.2.9. Equipment repairs or servicing must be completed by competent and trained maintenance personnel.
5.2.10. A list of all pieces of equipment, critical to the monitoring and measurement of product safety, conformity and quality, must be readily available and include maintenance specifications.

5.2.11. Any equipment used to monitor product safety, quality and conformity must be calibrated at defined intervals based on HRA outcomes, or, if present and relevant, in line with the equipment manufacturer guidelines, with a suitable level of accuracy, precision and reliability achieved for its intended purpose.
5.2.12. Any equipment used to accept or reject a product must be checked for calibration validity to a specified accuracy and precision at a defined frequency, or prior to use, ensuring inter- and intra-batch calibrations are valid and regularly reviewed by a competent and trained individual to prepare for routine calibration.
5.2.13. Calibration of listed equipment must be logged, with records traceable to a recognised national standard. If no such standard exists, the rationale and basis of calibration must be verified.
5.2.14. Records of calibration and verification results must be kept for a minimum of five times the product's shelf life or five years, whichever is shorter.

5.2.15. Adjustments or alterations made to any listed equipment by unauthorised staff must be effectively prevented, with equipment clearly displaying its calibration file, including the period of validity.
5.2.16. Procedures must be documented to ensure correct action is taken if any fault is found or if the equipment is not operating within specified tolerances and/or limits, according to the HRA.

5.3. Layout, product flow and segregation

5.3.1. The factory layout, flow of processes and movement of personnel must prevent the risk of product contamination and comply with relevant legislation.

5.3.2. The layout flow of machinery and equipment shall be arranged in a logical manner, avoiding the risk of product contamination and damage.
5.3.3. The site must provide sufficient work and storage space to allow operations to be performed safely and effectively in hygienic conditions.
5.3.4. Facilities and services, such as toilets, cleaning and catering facilities, must be located so as to not pose a risk to the safety, compliance or quality of the product.
5.3.5. Effective segregation systems must be in place to avoid the risk of product cross-contamination, taking into account the flow of production, the nature of substances, ingredients and materials, the equipment used, personnel intervention, waste production, airflow, air quality and utilities.
5.3.6. Documented procedures and evidence of designed layout, product flow and segregation must be in place.
5.3.7. Products requiring segregation must have effective control procedures in place to guarantee product integrity.

5.4 Production site security

5.4.1. Access of unauthorised persons to production and storage areas should be prevented.
5.4.2. Access to any part of the site by employees, contractors and visitors shall be monitored, and a visitor-reporting system shall be in place.
5.4.3. Maintenance and repair contractors must be registered on an approved list, qualified and supervised at all times by a designated individual responsible for maintenance activities, ensuring no interferences affect the safety, conformity or quality of products.

5.5 Production site interior

5.5.1. The site interior must be suitable for the intended purpose.
5.5.2. Maintenance must minimise the potential for product contamination. The quality and finish of the site's infrastructure and facilities should pose no risk to product safety, conformity and quality, and shall be maintained to an appropriate standard. This includes, as defined by the risk assessment, aspects such as but not limited to:

a. a clean, tidy and organised factory;
b. adequate lighting;
c. adequate ventilation;
d. walls, floors, windows, doors and ceilings maintained in a good condition to prevent risks posed by foreign body;
e. suitable and sufficient removal of any by-products and contaminants.

5.5.3. Suitable and sufficient lighting must be provided.
5.5.4. The site must be fully HRA-assessed for any specific product condition requirements, such as controlled temperature, humidity and electrostatic discharge. All requirements must be applied, with documented calibration and regular monitoring and review.

5.5.5. Water and air quality must not pose a risk to the final product and must comply with the specifications to prevent contamination. Records must be maintained and regularly monitored.

5.6. Staff facilities

5.6.1. Staff facilities must adequately accommodate personnel and be designed and operated ensuring risk of product contamination is avoided, such as being maintained in a good and clean condition.
5.6.2. Staff facilities such as washrooms must be provided and maintained in a clean condition, while being well-separated from production areas to prevent product contamination.
5.6.3. Where a site provides food service, the food-related areas must be clean, fit for purpose and fully separated from production areas.
5.6.4. Storage facilities must be of adequate size to accommodate all reasonable personal items and provided for all personnel who work in areas where they are unable to keep possessions with them.
5.6.5. The site must use HRA outcomes to determine where a change to workwear is required, with appropriate changing facilities provided for all personnel.
5.6.6. Changing areas must be situated providing direct access to appropriate production, packing or storage areas, avoiding exposure to any contaminating areas. If this is not possible, the site must use HRA outcomes to establish systems to mitigate any risk, and the procedure must be documented.
5.6.7. Suitable and effective hand-cleaning facilities must be provided at access points to production areas, as well as any other appropriate points within the production areas.

5.7. Hygiene and general maintenance

5.7.1. Hygiene, maintenance and cleaning systems must be in place to ensure adequate standards are maintained at all times, avoiding any risk of product contamination.
5.7.2. Equipment, production and storage areas must be kept in a hygienic state, with cleaning procedures in place to minimise the risk of contamination, and cleaning records must be kept.
5.7.3. An approved list of cleaning chemicals must be available, with substances clearly labelled and controlled to avoid product contamination. Chemicals should only be decanted into properly labelled containers and stored in suitable facilities, avoiding potential risks to the safety, conformity and quality of the product.
5.7.4. If cleaning services are outsourced, the service providers must have a signed contract, detailing the scope and frequency of the work, as well as designated areas, with records maintained and a responsible individual designated to ensure the work is carried out satisfactorily.
5.7.5. Documented cleaning procedures must be established and made available to relevant

individuals. If more than basic cleaning is required, cleaning procedures must include as a minimum:

a. staff member responsible for cleaning;
b. item/area to be cleaned;
c. frequency required;
d. method of cleaning;
e. cleaning materials to be used;
f. cleaning records and responsibility for verification.

5.7.6. Cleaning procedures must be revalidated following any major alterations, building work, maintenance or changes to equipment.

5.8. Pest control

5.8.1. The processor must implement an effective preventive pest control programme to minimise the risk of pests, with sufficient resources in place to respond rapidly and effectively to any issues that might occur, ensuring at all times that no risk is posed to the product, and as approved by OrganiTrust®.

5.8.2. Any pest control methods employed must be safe, approved and not have any negative effect on the environment.

5.8.3. If no pest control processes are in place, the processor must provide a full and detailed justification, with the policy reviewed at least annually.

5.8.4. If the processor does not use an approved external contractor, there must be designated and trained staff responsible within the organisation.

5.8.5. If it is necessary at any point for materials, goods or products to be directly pest-treated or fumigated, an incident report should be made and kept on record, and no treated goods may be supplied to customers without full professional safety clearance and correct clearance documentation.

5.8.6. All fumigation operations must be carefully controlled by competent staff with appropriate professional qualifications and/or training.

5.8.7. Full Organics Council ® data sheet, if available, and material safety data sheets for all chemical pest control agents must be submitted to OrganiTrust® and, if approved, be available to relevant staff at all times and kept in a designated place.

6. Certified product processing waste handling and disposal

6.1. Waste reuse and recyclability

6.1.1. OrganiTrust® requires the maximum feasible reuse and recycling of waste generated as part of the manufacturing and production of OrganiTrust® certified products, while ensuring that waste safety meets all the requirements of Organics Council® approved substances.

6.1.2. Waste materials must be adequately controlled, clearly labelled and quarantined where necessary, to mitigate contamination of non-waste production flows, with regular internal audits in place to show that waste production is adequately controlled and managed, with continual efforts to reduce waste.

6.1.3. OrganiTrust® supports the export and sale of waste products and materials to external and third-party organisations, ensuring that no risk to human or environmental health exists and that a full HRA has been performed on this aspect.

6.1.4. OrganiTrust® supports the use of recycled materials, substances and ingredients during manufacturing and production, ensuring that they meet the standards defined by the Organics Council® ASL.

6.1.5. OrganiTrust® requires that manufacturers actively reduce waste production via:

a. the prevention of waste production;
b. recycling and recovery of waste;
c. maximising the use of renewable inputs and energy.

6.1.6. Licensees must have evidenced systems for the post-industrial recycling of materials, ensuring maximum process sustainability.

6.1.7. As part of the HRA, manufacturers must identify any additional pollutants defined by the Environmental Protection Agency (EPA) as conventional, toxic or priority pollutants, which may reasonably be expected to occur in industrial waste or emissions.

6.1.8. Documented and annually audited emergency systems must be in place and regularly tested to ensure that failure of waste or emissions treatment systems results in:

a. immediate identification of treatment failure;

b. immediate shut off of release lines to ensure no uncontrolled release of non-treated waste or emissions to the environment.

6.1.9. Manufacturers must have evidence of continual work towards the implementation of best management practices and best available technology economically achievable.

6.1.10. The same levels of treatment of waste, emissions and effluents are required, regardless of the allocated sensitivity of the release zone, ensuring that no polluting substances are released into the natural environment, municipal systems or any other disposal or release route.

6.2. Waste water treatment

6.2.1. The HRA must assess the total volume of waste water generated and evaluate the capacity of the manufacturer to cope with water treatment.
6.2.3. Documented and annually reviewed emergency systems must be in place and regularly tested to ensure that failure of waste water treatment systems results in:

a. immediate identification of treatment failure;
b. immediate shut off of effluent lines to ensure no uncontrolled release of non-treated waste water to the natural environment or municipal sewage systems.

6.2.4. Waste water run-offs must be effectively treated or controlled to ensure that discharged effluents meet the Organics Council ® limits, in line with both EPA (2002) and the Clean Water Act (1972) (CWA) regulations, as well as any other relevant effluent discharge regulation.

6.2.5. Waste water must meet the following set limits, in compliance with EPA (2002) regulations:

Parameter	**Unit**	**Maximum permissible limit**	
		Land/ Underground	**Surface water courses**
Total coliforms	MPN per 100 ml	-	<400
Escherichia coli	MPN per 100 ml	<1000	<200
Free chlorine	mg/l	-	0.5
Total suspended solids	mg/l	45	35
Reactive phosphorus	mg/l	10	1
Temperature	^{0}C	40	
pH	-	5-9	
Chemical oxygen demand	mg/l	120	

Biochemical oxygen demand Note: the thresholds for the substances listed below are still subject to Organics Council ® safety assessments, including aquatic toxicity effects, and until such assessments are completed, temporal thresholds are permitted at 50% of the figures shown.	mg/l	40
Chloride	mg/l	750
Sulphate	mg/l	750
Sulphide	mg/l	0.002
Ammoniacal nitrogen	mg/l	1
Nitrate as N	mg/l	10
Total Kjeldahl nitrogen	mg/l	25
Nitrite as N	mg/l	1
Aluminium	mg/l	5
Arsenic	mg/l	0.1
Beryllium	mg/l	0.1

Boron	mg/l	0.75
Cadmium	mg/l	0.01
Cobalt	mg/l	0.05
Copper	mg/l	0.5
Iron	mg/l	2.0
Lithium	mg/l	2.5
Manganese	mg/l	0.2
Molybdenum	mg/l	0.01
Nickel	mg/l	0.1
Selenium	mg/l	0.02
Sodium	mg/l	200
Total chromium	mg/l	0.05
Vanadium	mg/l	0.1
Zinc	mg/l	2
Banned waste water substances		
Lead	mg/l	0
Mercury	mg/l	0

Oil and grease	mg/l	0
Total pesticides	mg/l	0
Total organic halides	mg/l	0
Cyanide (as CN^-) or free cyanide	mg/l	0
Phenols	mg/l	0
Detergents (as linear alkylate sulphonate)	mg/l	0

6.2.6. OrganiTrust® requires that manufacturers comply with all EU defined limits according to the Second Schedule of the Environmental Protection Act regulations, with tighter restrictions in place when the processor is within a distance of 200 metres from a high water mark.
6.2.7. No effluent should be discharged onto land, into a watercourse or into a waterbody unless the processor ensures that the parameters of the effluent do not exceed the permissible limits set out by the CWA (1972) and EPA (2002).
6.2.8. Under no circumstances must any industrial effluent discharge enter a waterbody or watercourse used or earmarked to be used for potable water supply.
6.2.9. OrganiTrust® requires that manufacturers apply emission reduction treatment processes at minimum using the best practicable control technology currently available, defined in CWA section 304(b)(1), or the best conventional pollutant control technology, defined in CWA section 304(b)(4).
6.2.10. Manufacturers should continually work towards the implementation of the best available technology economically achievable, defined in CWA section 304(b)(2) and ultimately the new source performance standards, defined in CWA section 306. Definition of ‘new source’ for direct dischargers: 40 Code of Federal Regulations (CFR) 122.2, 122.29
6.2.11. Best management practices (BMPs) are defined in the USA as a permit condition used along with effluent limits. OrganiTrust® requires that waste water discharge should conform to BMP regulations for direct dischargers: 40 CFR 122.2, 40 CFR 122.44(k) or indirect dischargers: 40 CFR 403.3(e).

6.3. Atmospheric emissions

6.3.1. OrganiTrust ® requires that all certified site emissions meet Organics Council ® emission requirements, which in turn meet the USA National Ambient Air Quality Standards (established national air quality limit values for only six main pollutants), as well as the standards set by the EU Directive 2008/50/EC on ambient air quality and cleaner air for Europe and EU Directive on national emissions ceilings adopted in 2001 for:[1]

a. *carbon monoxide;
b. nitrogen dioxide;
c. NOx;
d. *sulphur oxides;
e. *ozone;
f. *particulate matter (PM2.5 and PM10);
g. *lead;
h. benzene;
i. polyaromatic hydrocarbons;
j. cadmium;
k. arsenic;
l. nickel;
m. mercury.

6.3.2. Fluorinated greenhouse gases (FGHGs) are strictly banned in any newly procured equipment or any designed processes for certified product production, ensuring that a climate-friendly alternative is available. A continual process of replacement should focus on removing any FGHGs from the production process.

6.3.3. Both the external atmospheric emissions and internal air quality in the production site must meet the following Organics Council ® standard requirements:

Pollutant	Concentration	Averaging period
Fine particles (PM2.5)	10 µg/m3	24 hours
	3 µg/m3	1 year
Sulphur dioxide	350 µg/m3	1 hour
	125 µg/m3	24 hours

[1] The full includes EU-regulated pollutants, whereas those marked with an asterisk show USA-regulated pollutants.

Nitrogen dioxide	200 µg/m3	1 hour
	40 µg/m3	1 year
PM10	15 µg/m3	24 hours
	5 µg/m3	1 year
Lead	0	~
Carbon monoxide	10 mg/m3/	24 hours
Benzene	0	~
Ozone	120 µg/m3	Maximum daily 8 hour mean
Arsenic	3 ng/m3	1 year
Cadmium	3 ng/m3	1 year
Nickel	3 ng/m3	1 year
Mercury	0	~
Polycyclic aromatic hydrocarbons	0	~
Total aerosol limit	1 mg/m^3	24 hours
Combustible dust	5 g/m3	24 hours

6.4. Disposal of solid waste

6.4.1. All OrganiTrust ® certified manufacturers are required to ensure that all waste that can be recycled or recovered is isolated and removed from the solid waste disposal route.
6.4.2. The prospective licensee is by default responsible for ensuring that waste management is performed correctly and that the solid waste characterisation information is correct.
6.4.3. Production must not contribute to landfill, except for temporary arrangements (up to six months) and with fully reasoned explanations as to why it is unavoidable. Landfilling disposal of solid waste should be limited to a minimum.
6.4.4. OrganiTrust ® requires that all sites designated for the temporary storage of waste should comply with the relevant requirements of Directive 75/442/EEC.
6.4.5. Waste must not accumulate and must be sufficiently segregated to avoid any risk of contamination or unhygienic conditions.
6.4.6. Unavoidable landfill waste must not have any associated environmental pollution, with long-term persistence and leaching characteristics assessed in an HRA. All potentially leaching landfill components must be ASL approved and may only be present at safe concentrations according to ASL database and HRA outcomes.
6.4.7. All reasonable measures should be taken to reduce the production of methane gas from landfill through a reduction in landfill disposal of biodegradable waste.

6.4.8. As a minimum requirement of the HRA, OrganiTrust® requires manufacturers to have a documented and annually reviewed standard procedure for preparation of processing waste going to landfill.

6.4.8.1. Waste must be fully characterised.

6.4.8.2. If required, waste must be treated before being landfilled.

6.4.8.3. Hazardous waste must be assigned to a hazardous waste landfill.

6.4.8.4. Landfills for non-hazardous waste must be used for municipal waste and for other non-hazardous waste only.

6.4.8.5. Landfill sites for inert waste must be used only for inert waste.

6.4.9. Basic characterisation of solid waste is required to gather all necessary information for safe disposal, including:

6.4.9.1. Basic information such as:

a. Source and origin of the waste
b. Information on the process that produced the waste
c. Description and characteristics of raw materials and products
d. Description of any waste treatment applied
e. Appearance of the waste (smell, colour, physical form)

f. Code according to the European waste list (Commission Decision 2001/118/EC)

6.4.9.2. Basic information for understanding the behaviour of waste in landfills and options for treatment as laid out in Article 6(a) of the Landfill Directive, including data on the leaching behaviour of waste.

6.4.9.3. Assessment of waste against relevant limit values.

6.4.9.4. Detection of key parameters for compliance testing and outline of a plan for frequency for compliance testing.

6.4.9.5. For hazardous waste, in case of mirror entries, the relevant hazard properties according to Annex III to Council Directive 91/689/EEC of 12 December 1991 on hazardous waste(2).

6.4.9.6. The landfill class at which the waste may be accepted:

a. with information to prove that the waste does not fall under the exclusions of Article 5(3) of the Landfill Directive;
b. if required, all precautions to be taken at the landfill.

6.5. Hazardous waste management

6.5.1. Where required, waste may need to be removed by approved, licensed contractors, with records of disposal maintained at the site.

6.5.2. Effective and documented hazardous waste management systems must be in place, with a clear HRA defining why hazardous waste production is unavoidable, and with the exceptional circumstances detailed and an annually reviewed management plan.

6.5.3. Contaminating or hazardous waste substances must be allocated a Hazard Group Code from Annex III of Council Directive 91/689/EEC, based on the criteria laid down by Annex VI, to Council Directive 67/548/EEC:

H 1 ‘Explosive’: substances and preparations which may explode under the effect of flame or which are more sensitive to shocks or friction than dinitrobenzene.

H 2 ‘Oxidizing’: substances and preparations which exhibit highly exothermic reactions when in contact with other substances, particularly flammable substances.

H 3-A ‘Highly flammable’:

— liquid substances and preparations having a flash point below 21 °C (including extremely flammable liquids), or

— substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or

— solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or

— gaseous substances and preparations which are flammable in air at normal pressure, or

— substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities.

H 3-B ‘Flammable’: liquid substances and preparations having a flash point equal to or greater than 21 °C and less than or equal to 55 °C.

H 4 ‘Irritant’: non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, can cause inflammation.

H 5 ‘Harmful’: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve limited health risks.

H 6 ‘Toxic’: substances and preparations (including very toxic substances and preparations) which, if they are inhaled or ingested or if they penetrate the skin, may involve serious, acute or chronic health risks and even death.

H 7 ‘Carcinogenic’: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence.

H 8 ‘Corrosive’: substances and preparations which may destroy living tissue on contact.

H 9 ‘Infectious’: substances and preparations containing viable micro-organisms or their toxins which are known or reliably believed to cause disease in man or other living organisms.

H 10 ‘Toxic for reproduction’: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce non-hereditary congenital malformations or increase their incidence.

H 11 ‘Mutagenic’: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce hereditary genetic defects or increase their incidence.

H 12 Waste which releases toxic or very toxic gases in contact with water, air or an acid.

H 13 (1) ‘Sensitizing’: substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitization such that on further exposure to the substance or preparation, characteristic adverse effects are produced.

H 14 ‘Ecotoxic’: waste which presents or may present immediate or delayed risks for one or more sectors of the environment.

H 15 Waste capable by any means, after disposal, of yielding another substance, e.g. a leachate, which possesses any of the characteristics listed above.

7. Specific technical processing guidance

7.1. Ventilation requirements

7.1.1. Effective systems must be in place to avoid harmful processing emissions and vapours during manufacturing and production.

7.1.2. Licensees manufacturing products associated with potentially harmful atmospheric emissions, gases or vapours must ensure adequate ventilation or appropriate breathing apparatus or personal protective equipment (PPE), as processing vapours may cause irritation to the eyes, skin and respiratory tract.

7.1.3. Sensitive individuals and individuals with respiratory impairments may be significantly affected by exposure to components in processing vapours. The licensee must therefore have systems in place to ensure a rapid and acceptable response to any such scenario.

7.1.4. Lubricating oils may react with polymer materials for both high-density polyethylene (HDPE) and polypropylene (PP). Lubricating oils should thus not come into direct contact with plastic materials, and full-conformity testing must confirm that no traces of lubricating oils are present on final plastic products.

7.1.5. The licensee must ensure adequate ventilation exists in production facilities, ensuring that particles that are combustible and may be explosive are identified during the HRA.

7.1.6. The licensee must ensure production facilities are properly cleaned, as grease-like processing vapour condensing on ventilation ductwork, moulds and other surfaces can cause irritation and injury to the skin.

7.1.7. Production sites must have adequate cooling fans and good ventilation in place to sufficiently reduce the temperature of the working environment and aid the evaporation of sweat.

7.1.8. In high-temperature work environments, heat refuges must be provided in convenient places close to areas of high ambient heat to ensure employees can take breaks, remove protective clothing and regulate their body temperatures.

7.1.9. Licensees must have relevant and adequate systems in place to minimise environmental impact due to atmospheric emissions.

7.1.10. Adequate cleaning and ventilation systems must ensure no build-up of oils, lubricants and other reagents may vapourise, causing a wide range of risks such as the inhalation of toxic particle components and accumulation on surfaces and machinery.

7.1.11. Effective monitoring processes must be implemented to ensure that the processor is alerted to any reduction in air quality and ventilation or any build-up of harmful vapours or vapour deposits.

7.1.12. Adequate ventilation and filtration systems must be in place to ensure safe working conditions with air quality in the premises meeting the OrganiTrust ® approved maximum exposure limit value for the emission of aerosols in industrial premises of 1 mg/m^3.

7.1.13. Adequate ventilation and filtration systems must be in place to ensure safe working conditions with air quality in the premises meeting the OrganiTrust ® approved maximum exposure limit value for total dust concentrations of 3 mg/m^3.

7.1.14. Adequate ventilation and filtration systems must be in place to ensure safe working conditions with air quality in the premises meeting the OrganiTrust® approved maximum exposure limit value for inhalable dust concentrations of 1 mg/m^3.
7.1.15. The upper limit concentration of any contaminating or potentially harmful substance is 0.1 mg/m^3 unless specific exposure limits have been specified by the Organics Council®.
7.1.16. Where required, personal protective equipment must be supplied by the processor, such as class P1 dust respirators (disposable or silicone half-face respirators).
7.1.17. Adequate housekeeping and maintenance must ensure that hazardous dust build-ups and the risk of dust exposure are effectively avoided. Cleaning should be completed with the use of wet wiping or vacuuming (vacuum fitted with high-efficiency particulate air filter) to reduce the risk of dust inhalation by operators.

7.2. Incidental waste spillage monitoring

7.2.1. Measures must be in place to ensure that no spillage or release occurs for any substance, ingredient and material into the environment.
7.2.2. Monitoring must be performed at regular predefined intervals to confirm that no leakage, loss or accidental release of waste or any other harmful substances utilised during production occurred.
7.2.3. Licensees must have relevant and adequate systems in place to minimise environmental impact due to incidental waste spillage.

7.3. Heat exposure

7.3.1. Operators subjected to ongoing high levels of heat stress have a higher potential to suffer from heat-related illness. Precautionary measures must be taken, such as (but not limited to):

a. all staff must be effectively trained to ensure competence and capability for the work;
b. manufacturers must ensure that all members of staff have received a relevant medical assessment.

7.3.2. The licensee must ensure that all staff are aware of the symptoms of heat stress and injury. Effective monitoring must identify the early stages and onset of heat-related illnesses, such as:

a. loss of alertness or inability to concentrate;
b. fatigue, discomfort and irritability;
c. dizziness or loss of coordination and dexterity.

7.3.3. Symptoms of potential heat stroke, heat syncope (fainting), heat exhaustion, oedema, heat rash and heat cramps as a minimum must be monitored by a trained individual, with an incident report completed upon the identification of any symptoms.
7.3.4. Licensees must identify all activities where exposure to high temperatures or thermally stressful conditions is likely, with a risk assessment performed and appropriate control measures implemented to control the duration and extent of heat exposure.

7.3.5. Heat shielding or insulation around heat sources must be reviewed as part of the HRA to ensure the maximum possible reduction of radiant heat reaching machinery operators.
7.3.6. Suggested good practice to assess heat risk is to apply:

a. BS ISO 7933: 'Ergonomics of the thermal environment – Analytical determination and interpretation of heat stress using calculation of the predicted heat strain',
b. Heat Stress Index: to examine the contributory factors and investigate control measures;
c. BS ISO 12894: 'Ergonomics of the thermal environment – Medical supervision of individuals exposed to extreme hot or cold environments';
d. BS ISO 9886: 'Ergonomics – Evaluation of thermal strain by physiological measurements'.

7.3.7. Supervisors must ensure that shift arrangements take account of the need for an acclimatisation and recovery period.
7.3.8. Licensees must ensure that drinking fluids and appropriate rest facilities are available.
7.3.9. Licensees must ensure that all necessary suitable PPE is available and that the use of any PPE is safety-assessed and supervised.
7.3.10. Lone working is strictly prohibited in thermally stressful conditions, and workers must either work in pairs or groups or be under direct supervision.
7.3.11. Effective arrangements for first aid and emergency procedures must be in place, with staff effectively informed of the procedures. First-aiders must be specifically trained to recognise and manage heat illnesses, and there must be a clear emergency procedure in place to deal with any serious injury or illness from heat or fire exposure.
7.3.12. Emergency fire action procedures must be in place and regularly reviewed for effectiveness. Plans must include the responsibilities for isolating machinery and associated utilities, a plan for the loss of utilities and effective use of the applicable firefighting equipment available.

7.4. Machine safety

7.4.1. Cutting and sawing machine safety

7.4.1.1. 'Kickback' is a common problem associated with machinery, in which case, guarding is essential for the protection of machine operators. OrganiTrust® considers machine-guarding violations to be critical nonconformity issues.
7.4.1.2. Push pads and push sticks should be used as mechanical aides to assist operators where possible, ensuring that push sticks are not used to remove cuts from a running machine or to heat up a blade by applying a friction force using the stick.
7.4.1.3. The licensee must ensure that any guard will, as far as possible, prevent access to any danger point or area. Guarding tools must be installed and maintained by a suitably qualified and competent person.

7.4.1.4. The preferred guarding options include:

a. a permanent physical barrier (this is the preferred choice when there is no requirement for access during operation, maintenance or cleaning);
b. if this is not feasible, an interlocking physical barrier that is movable or has a movable part should be applied, where movement of the guard prevents motion of the dangerous parts, acting as a lock while the guard is open;
c. if this is not feasible, a physical barrier (fixed guard) should be applied, preventing access to the dangerous part of the machinery and providing protection to the operator. The physical barrier should only be altered or removed by using a specific tool;
d. if this is not feasible, a presence-sensing system is applicable, through the use of devices capable of electronically detecting intrusion into the hazardous area of a machine and shutting off the power.

7.4.1.5. Effective lockout-tagout (LOTO) systems must be in place to avoid the unexpected start-up or release of energy stored in the equipment, which can result in critical nonconformity, serious injury or death to workers.

7.4.1.6. It is the employer's responsibility to protect workers using effective LOTO systems and to ensure staff are trained and able to follow procedures, especially prohibition against attempting to restart or re-energise machines or other pieces of equipment that are locked or tagged out.

7.4.1.7. Any employees authorized to lockout machines or equipment or to perform servicing and maintenance operations on locked out equipment must be effectively trained to recognise applicable hazardous energy sources in the workplace, establish the type and magnitude of energy in the workplace and be up-to-date in the most effective methods of controlling the energy.

7.4.2. Mould machinery safety

7.4.2.1. Where feasible, neck rings should be changed from the blank side of the machine to minimise risks to operators working across or over the machine conveyor. Where this is not possible, safety devices must be in place to minimise the risks to operators at the front of machinery.

7.4.2.2. The use of swab-free and auto-swabbing mould equipment is preferred. If this is not technically achievable, licensees must implement safe swabbing systems, and as a piece of mould equipment reaches the end of its life, modern replacements must be considered as part of ongoing HRA monitoring.

7.4.2.3. Safe swab procedures include:

a. clear safety systems must be implemented, always engaging the swab cycle;
b. visually checking that the blanks and moulds remain open before swabbing;

c. wearing gloves, using a swab of suitable length and keeping hands outside of the danger zone of the mould cavity, arc of the invert bar and take-out mechanism at all times;
d. always replacing swabs at the end of a shift and ensuring correct handling at the doping station.

7.4.2.4. Licensees must ensure full and effective fire safety reviews are performed at least annually with adequate measures in place to ensure the effectiveness of systems.
7.4.2.5. Effective cleaning and maintenance routines must be in place to ensure the machinery does not accumulate oil, dirt or other residues presenting a combustion risk.
7.4.2.6. Site monitoring must be performed according to a predefined schedule to ensure that work areas are safe and fit for purpose and that no risks exist, such as combustible materials stored in the machine area.

7.5. Ergonomics and manual handling safety

7.5.1. It is the duty of the licensee to ensure that workplaces and tasks are designed to minimise the risk of potential physical injury due to physical work and manual handling.
7.5.2. Regular audits must ensure that task design effectively manages frequency, duration and speed of tool usage, to avoid injury to workers.
7.5.3. Regular audits must ensure that workstations and tools are fit for purpose and designed effectively to avoid:

a. chronic disorders of the hand, wrist and forearm, which result in pressure on tissues or joints;
b. awkward wrist positions that mean a tool is held with the wrist bent, causing additional muscular effort during use;
c. static loading of arm and shoulder muscles, due to tool-holding positions that can lead to injury;
d. muscular effort in holding, operating and guiding tools due to poor design or heavy, poorly balanced and/or poorly maintained tools;
e. poorly maintained tools, which may compromise safety and increase the effort required for use.

7.5.4. Hazardous manual handling shall be kept to a minimum in processing. If not avoidable, effective precautionary measures must be in place to minimise risks from:

a. repetitive or sustained application of force;
b. repetitive or sustained awkward posture;
c. repetitive or sustained movement;
d. application of high force;
e. exposure to sustained vibration levels;
f. unstable or unbalanced loads;
g. loads or tools which are difficult to grasp or hold.

7.5.5. The employer has a legal duty to:

a. identify tasks involving hazardous manual handling and assess risks in the HRA, with particular attention to the potential risk of developing injuries due to the specific role or task;
b. implement processes and systems to ensure that risks are controlled or eliminated so far as is reasonably practicable;
c. implement regular review and audit processes to ensure that workers are safe and manual handling systems are effective;
d. if the HRA outcome suggests it is required, the licensee must alter the workplace or environmental conditions (e.g., height-adjustable work surfaces), the systems of work (e.g., regular maintenance on equipment, job rotation etc.), the object inducing risk (e.g., using hand tools that minimise hand-arm vibration or weight-bearing) and implement the use of mechanical aids (e.g., pallet lifters, adjustable trolleys, approved forklift attachments etc.).

7.6. Occupational noise exposure

7.6.1. Under no circumstances should workers be exposed to noise levels that exceed 85 dB averaged over an eight-hour period or a peak noise level of 140 dB without ear protection.
7.6.2. The licensee must eliminate noise sources or, if this is not feasible, implement substitute, quieter processes or implement engineering measures to limit noise exposure.
7.6.3. Hearing protection is required at noise level above 85 dB, with compulsory hearing tests implemented in the annual review for systems where hearing protectors are required, to ensure that noise exposure with protection is reduced to a safe level.

7.7. Combustible dust

7.7.1. Air sampling is a compulsory requirement, as outlined by the HRA, in all manufacturing environments where combustible dust may reasonably be expected to be generated to ensure that combustible dust concentrations are within the safe and approved limits.
7.7.2. OrganiTrust® requires that under no circumstances the working atmosphere ever have concentrations of combustible dust exceeding 5 g/m^3, even for a temporary period, to avoid a high risk of explosion, particularly in low-humidity environments.

7.8. Personal protective equipment

7.8.1. Protective clothing and equipment are an acceptable risk-control tool for employees exposed to chemicals, fumes, vapours or dust. As far as reasonably practicable, controls other than PPE should be applied to manage risks arising from the use of chemicals, fumes, vapours or dust, according to the BS or EN or EU standards.
7.8.2. Risks associated with the use of PPE should be fully considered in the HRA and reviewed at appropriate intervals.
7.8.3. If a need for PPE is identified by the HRA, processes should be implemented to avoid

any contamination risk to the product, with protective clothing effectively laundered at an appropriate frequency.

7.8.4. Disposable protective clothing should only be used where absolutely required, and its disposal must be documented and carried out in a controlled manner to avoid product contamination.

7.8.5. Based on the HRA outcomes on risks to product integrity, suitable footwear shall be worn within the factory environment.

7.8.6. To protect product integrity and avoid contamination, the processor shall have a policy on wearing jewellery in the production site area.

7.8.7. All cuts, grazes and wounds on exposed skin shall be covered by a contrasting-coloured plaster provided by the site's first aid representative, with monitoring to avoid contamination of product and records kept.

7.8.8. In sites where metal foreign body detection is in place, detectable plasters must be used, with regular testing.

7.8.9. In any environment where combustible dust is present, additional PPE management requirements for staff are:

a. staff must wear non-sparking clothing such as natural fibre (e.g., cotton);
b. staff should be hazard and risk-assessed and provided with flame-resistant clothing as appropriate.

Annex I: Organics Council® terms and definitions

https://organicscouncil.org/wp-content/uploads/2018/05/Terms-and-Definitions-12-05-2018.v2.pdf

Annex II: Product description report outline template

1. PDRs are mandatory and must be prepared prior to certification application, with HRAs and all other relevant data made available for audit.
2. PDRs must be prepared according to the defined format.
3. PDRs and all contributing data and information must be kept for a period of ten years following the date on which the last batch of the product was placed on the market.
4. The responsible person seeking certification must make available all required information for a full and transparent assessment; failure to disclose all required information will result in automatic certification audit failure.
5. A permanent data log must be maintained where all files and contributing data sources are logged with date of finalisation, date of review (if required) and name of the responsible person. This log must be a permanent and accurate record of all data and reports, including QA/QC data.
6. Deliberate attempts to withhold or remove data or evidence from PDR or any contributing data files will result in immediate audit failure or termination of current certification.

Product Description Report Outline Template (v.1.2.)	
Part I	**Product specifications**
I.	Product name and description
II.	Composition, including a detailed breakdown of all ingredients, materials or substances used at any point during production
III.	Annotated assembly diagrams
IV.	List of the legislation and product standards the products are manufactured to comply with
V.	Final technical product specifications, including all physical and/or chemical parameters of the product (established based on HRA and CCPs)
VI.	Packaging details, including packaging material, source, printing or labelling and packaging process

VII.	Intended product shelf life
VIII.	Example of final labelling, including warnings and instructions for use
Part II	**Annotated flow diagram of full product life cycle**
I.	Source of raw materials/ingredients
II.	Processes for receipt, QA/QC, handling and preparation of raw materials, substances and ingredients
III.	A detailed outline of each manufacturing process step
IV.	Details of production quality and conformity monitoring, in-line testing or any measuring systems or equipment
V.	Product construction, completion, filling or packaging steps
VI.	Onsite storage conditions
VII.	Process of dispatch to the primary customer
VIII.	Details of any subcontracted processes
IX.	Overview of product usage, target demographics and potential misuses
X.	End-of-life or disposal plan, with special emphasis on action taken to ensure safe and sustainable disposal methods.
XI.	Identify all areas where energy use may be improved via the implementation of: - improved procurement systems - implementation of BATs
XII.	Carbon footprint analysis: - GHG emissions must be calculated according to defined reporting schemes, such as ISO 14064-18 and the Carbon Trust Standard - carbon audits must also include PAS 20509 or ISO 1404010 for the assessment of the carbon footprint of

	products, although, until 2025, this does not apply to products with a sales volume lower than one million units per year - for small businesses with a sales volume below one million units per year, GHG emissions and carbon footprints should be calculated in-house using UK guidance [UK gov GHG calculations guidance]
Part III	**Product development data**
I.	Organics Council ® and material safety data sheets on all substances used
II.	Bill of materials for traceability and proof of source
III.	Pre-production HRAs for all identified risks to workers, users, the general public and the environment at any stage of production, transport and use or upon end of life; all identified CCPs and parameters to define acceptable control
IV.	Production trial report, where products made according to intended production methods are tested to ensure that the final product is safe, sustainable and of the required quality, forming the final product technical specification
V.	Description of conformity assessment procedures
VI.	Compliance test reports
VII.	Inspection reports (third-party, external or internal, where applicable)
VIII.	Product development corrective actions
IX.	Final product technical specifications
X.	CCP control procedures and surveillance
XI.	Approval held from by any statutory body, if applicable
XII.	Final product declaration of compliance

Annex III: Hazard risk assessment and critical control points template

Hazard and risk assessment and critical control points template

Template for a systematic approach to HRA and CCP formation, addressing physical, chemical and biological hazards.

- The licensee must complete this document as part of the certification application pack.
- The licensee must assess the risk of the product and any associated articles.
- The licensee must identify all potential hazards pertaining to processing safety, quality or sustainability during the full product life cycle.
- The licensing application must be accompanied by a Product Description Report (annex II).

III.I. Product intended use summary

Provide a detailed breakdown of the intended use of the product, with information on the demographics of previous purchasers or market group, including any vulnerable or at-risk groups.

III.II. Process flow diagram

Provide a flow diagram of the full production process, including:

a. sourcing of materials, ingredients and components;
b. all production steps;
c. inspection;
d. quality control;
e. packaging labelling/decoration;
f. packing;
g. storage;
h. distribution;
i. end-of-life recovery.

III.III. List of raw materials and incoming materials

Provide a detailed outline of the product composition, with ingredient, component or material concentrations or proportional abundance, including:

a. ingredients and raw materials;

b. processing aids and any substances used during manufacturing;
c. any known final residual NIAS;
d. all non-core ingredient substances, such as inks and outer label adhesives.

Process	Material	Description (including trade name)	Hazard	Supplier	Product/ Catalogue number

III.IV. Plant layout flow diagram with employee/product flow

In free form.

III.V. Physical, chemical and biological hazard identification

III.V.I. Identify all core use parameters, considering potential product safety, sustainability, conformity or quality issues which could occur at each stage, such as (but not limited to):
a. core functionality requirements;
b. maximum or minimum use temperatures and other use conditions and restrictions;
c. machine use and tolerances;

d. physical or chemical product contamination;
e. microbiological contamination;
f. end-of-life disposal hazard and sustainability.

III.V.II. Establish specifications for each core use parameter.

III.V.III. Describe the potential risk attached to each hazard identified and assess the likelihood of identified risks without controls using the risk matrix.

		Evaluation and action policy	Non-acceptable risk level	Critical control point: critical risk control system required (CCP)	Control point: non-critical risk control system required (CP)
	Effect	No human or environmental health impact	Minor human or environmental health impact	Moderate/ reversible human or environmental health impact	
Likelihood of hazard occuring	Not possible or expected to occur during product or facility life or no known affect on exposed individuals				
	Unlikely, but may possibly happen during product or facility life or unlikely, but could affect vulnerable exposed indviduals				
	Could occur several times during product or facility life or could affect vulnerable exposed individuals				
	Could occur at any point/on a regular basis during product or facility life or could affect exposed individuals				

III.V.IV. Product packaging must also be assessed for fitness for purpose and be suitable to protect the product from damage and maintain its integrity, protecting the consumer from injury, preventing contamination and ensuring sustainability.

III.VI. Critical control points

III.VI.I. Identify any CCPs, defined as those control points that are compulsory to prevent or avoid a serious product safety, sustainability, quality or integrity hazard and provide specifications or critical limits to identify whether correct controls are being maintained in the production process. Provide evidence of reasonable industrial or scientific rationale, where relevant legislation or codes of practice are absent.

III.VI.II. A fully documented control plan system must be established, ensuring product safety, sustainability and conformity to each critical use parameter.

a. Monitoring systems must be outlined ensuring compliance with critical limits, with records maintained and documented procedures for the monitoring of each CCP included in internal audits for standard compliance.
b. Procedures for validation, verification and annual review must be outlined to confirm that the system is working effectively, including auditing of the system.

Annex IV: Specific product technical guidance

1. Food contact material production guidance

1.1. Plastic food contact materials

1.1.1. Ventilation

1.1.1.1. Processors must ensure adequate ventilation in the production of both HDPE and PP as polymer dust particles are combustible and may be explosive.
1.1.1.2. Effective systems must be in place to avoid HDPE combustion or thermal decomposition, as this will generate toxic and irritant vapours (CO, olefinic and paraffinic compounds, organic acids, ketones, aldehydes and alcohols).
1.1.1.3. Effective systems must be in place to protect from the vapours in PP production, as vapours generated either under recommended processing conditions or thermal decomposition include hydrocarbons and carbon oxides.
1.1.1.4. Processors producing HDPE or PP FCMs must ensure adequate ventilation, appropriate breathing apparatus and/or PPE, as processing vapours may cause irritation to the eyes, skin and respiratory tract.
1.1.1.5. For both HDPE and PP polymer resins, workers must not be exposed to concentrations over 3.0 mg/m^3 respirable dust or 10.0 mg/m^3 total dust (American Conference of Governmental Industrial Hygienists) without the use of effective breathing apparatus.

1.1.2. Storage conditions

1.1.2.1. Plastic FCM storage temperatures should be below 50ºC, and both HDPE and PP polymers should never be exposed to temperatures above 300ºC, except during controlled incineration.
1.1.2.2. Plastic FCM materials and products must be stored in dry conditions.
1.1.2.3. Plastic FCM materials and products must be stored avoiding UV exposure.

1.1.3. Equipment maintenance

1.1.3.1.Lubricating oils may react with polymer materials for both HDPE and PP. Therefore, lubricating oils should not come into direct contact with plastic FCMs or any component materials.

1.2. Glass food contact materials

1.2.1. Ventilation requirements

1.2.1.1. Ventilation-controlled heat refuges must be provided close to areas of high ambient heat to ensure employees can take breaks from the heat, remove protective clothing and regulate their body temperatures.

1.2.1.2. Adequate ventilation and filtration systems must be in place to ensure safe working conditions with air quality in the premises meeting the OrganiTrust ® approved maximum exposure limit value for the emission of aerosols in industrial premises of 1 mg/m^3.

1.2.2. Storage conditions

1.2.2.1. Glass FCM storage temperatures for any glass material type should be below 100ºC to minimise breakage due to thermal shock during loading or moving. Glass FCMs should never be exposed to temperatures above 150ºC.
1.2.2.2. Glass FCMs and products should be stored avoiding direct UV exposure.

1.3. Wood food contact materials

1.3.1. Moisture content requirements

1.3.1.1. OrganiTrust® requires the water content of raw materials to be below the fibre saturation point for the specific wood species used. Under all circumstances, it should be below 19%.
1.3.1.2. To ensure that no compromise to strength or durability occurs due to increased moisture levels, the temperature and relative humidity in storage environments must be controlled at all times, both during production and storage.
1.3.1.3. The density, established as weight divided by volume, at a defined moisture content, must be fully established in the product description report.
1.3.1.4. Water content must be established based on pre- and post-drying weights and water activity.
1.3.1.5. Additional water gain assessment must allow soaking for one hour. Water activity levels must be below 0.5 to avoid growth of microorganisms and must be measured at ambient temperature.

1.3.2. Storage conditions and requirements

1.3.2.1. During storage, wooden FCMs and articles should always be kept at a constant temperature and humidity, using heating, ventilation and air conditioning systems, such as dehumidifiers, customizable thermostats and insulation, to manage temperature and humidity.
1.3.2.2. Temperatures should be maintained between 12.5°C and 29.5°C (55-85°F).
1.3.2.3. Humidity levels should be below 50% to prevent microbial growth.

1.3.3. Hygiene requirements

1.3.3.1. The natural pH of raw wood material should be below pH 6 in order to minimise the potential for microbial growth and contamination.
1.3.3.2. OrganiTrust® requires that all wooden FCMs must be smooth-surfaced, with a longitudinal orientation of wood fibres to minimise contamination and facilitate cleaning and sterilisation.

1.3.3.3. The natural microbial content of wood must be reduced by:

a. drying wood to a moisture content of below 19%;
b. performing heat and/or pressure sterilisation.

1.3.3.4. Approved pre-sterilisation measures for raw materials and wooden FCMs include:

a. heat treatment at 100°C for sterilisation
b. high-temperature drying in kilns with temperatures up to 110-115°C;
c. steam-heating brushing in combination with hot steam or hot water sprinkling with dispersion of water in micro droplets.

1.3.3.5. For sterilisation of reusable wood FCM equipment, products and articles, OrganiTrust ® approves the use of:

a. manual scrubbing/washing and high-pressure water at 85°C;
b. sterilisation by autoclaving.

1.3.3.6. Hygiene issues are of critical importance with tertiary wooden FCMs such as pallets and transport packaging.

a. The processor must ensure that clean, dry pallets are utilised. If the pallets are dirty or contaminated, these shall be removed.
b. Wooden pallets should not be stored outdoors unprotected in order to avoid biological, physical and chemical contamination.
c. A separated and protected store of pallets with hygienic zones, where applicable, should be maintained, with clear visible identification.
d. Pallet inverters should be used.
e. To avoid contamination, wooden pallets with an upper slip sheet should be utilised.
f. The licensee must have active systems in place for the control and elimination of dirt, toxic materials, debris, mould etc.

1.3.3.7. In cases where contamination of wooden FCMs or tertiary packaging occurs, a documented procedure must be in place for the proper identification of pest(s) or damage caused by the pest and location of the infestation(s), with thorough inspections and monitoring.

1.3.3.8. Specifications must be established with native background microbes and any other relevant microbes or pests, establishing tolerance levels and cut-offs for pests.

1.3.3.9. Effective functioning of the microbial monitoring process must be verified and validated at least annually during a review.

1.3.4. Ventilation requirements

1.3.4.1. Adequate ventilation is required to ensure air quality is safe within and around production facilities and sites. Breathing wood dust particles and aerosolised production chemicals may cause allergic respiratory symptoms, mucosal and non-allergic respiratory symptoms and cancer.

1.3.4.2. Sensitive individuals and individuals with respiratory impairments may be significantly affected by exposure to components in the processing vapours. The processor must have systems in place to ensure a rapid and acceptable response to any such scenario.

1.3.4.3. Processors must ensure production facilities are effectively cleaned, as production and processing vapour condensing on surfaces can cause irritation and injury to the skin.
1.3.4.4. Adequate ventilation and filtration systems must be in place to ensure safe working conditions with air quality in the premises meeting the OrganiTrust ® approved maximum exposure limit value for the emission of aerosols in industrial premises of 1 mg/m^3.
1.3.4.5. Adequate ventilation and filtration systems must be in place to ensure safe working conditions with air quality in the premises meeting the OrganiTrust ® approved maximum exposure limit value for total dust concentrations of 3 mg/m^3.
1.3.4.6. Adequate ventilation and filtration systems must be in place to ensure safe working conditions with air quality in the premises meeting the OrganiTrust ® approved maximum exposure limit value for inhalable dust concentrations of 1 mg/m^3.
1.3.4.7. Many harmful substances are contained within the breathable atmosphere in woodworking environments due to the number of processes being performed, such as from oils and lubricants, as well as components of wood dust etc. The upper limit concentration of any contaminating or potentially harmful substance is 0.1 mg/m^3, unless specific exposure limits have been specified by the Organics Council ®.
1.3.4.8. Certain types of wood dust have been identified as causing cancer (International Agency for Research on Cancer, 1995). A full HRA is required to ensure that no carcinogenic components exist in the wood dust or atmospheric environment of woodworking production facilities.
1.3.4.9. Occupational asthma may be caused by certain types of grain, flour and wood dust (e.g., African maple, red cedar, oak, mahogany etc.). A full HRA is required to ensure that no components exist in the wood dust or atmospheric environment of woodworking production facilities that may induce occupational asthma.

1.4. Stainless steel food contact material

1.4.1. Waste avoidance during stainless steel production

1.4.1.1. The by-products and residues generated during steel production make a valuable contribution to society, replacing natural resources that would otherwise be used by other industrial sectors such as:

a. blast-furnace slag;
b. basic oxygen furnace slag/electric arc furnace slag;
c. chemical compounds;
d. process gases.