Organics Council®

Organics Council® Circular Economy Non-food Goods Certification Regulation

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1.1. Certification body

1.1.1. All certification bodies certifying goods to Organics Council ® Regulations must be first accredited by the Organics Council ®, based on compliance with all specified Organics Council® Regulations.
1.1.2. Certification audits should be undertaken by certification bodies of non-governmental and independent nature, ensuring a transparent and independent audit to certify products and services that meet the Organics Council® Regulations.
1.1.3. A certification body must employ assessors that have a suitable level of training, education and expertise, to ensure that certification audits adequately assess the safety and sustainability of products and services.
1.1.4. The certification body shall conform at least to ISO 9001 document management requirements.
1.1.5. The certification body must be accredited to ISO 17020 or continuously progress towards attaining such accreditation.
1.1.6. Any substance or product tests shall be initiated by the certification bodies, with laboratory analysis carried out by institutions that are accredited to ISO 17025 to carry out such tests on the same or similar or associated products or substances.
1.1.7. The certification body's proprietary safety and sustainability certification and circular economy and organics standards must be in harmony with the Organics Council® Regulations.
1.1.8. Each certification body must have a whistle-blowing policy in place and publically available, with one of the addressees being the Organics Council®, and must carry out regular whistle-blowing policy implementation audits to ensure that transparency is never compromised.

1.2. Audit framework

1.2.1. Product information requirements

1.2.1.1. PDRs are mandatory and must be prepared prior to certification application, with HRAs and all other relevant data made available for audit.
1.2.1.2. PDRs must be prepared according to the format defined by the Organics Council®.
1.2.1.3. HRAs prepared for all known or feasible product risks must be kept for ten years after the date on which the last batch of the product was placed on the market.
1.2.1.4. PDRs and all contributing data and information must be kept for ten years after the date on which the last batch of the product was placed on the market.
1.2.1.5. 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.
1.2.1.6. 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 quality assurance and quality control (QA/QC) data.

1.2.1.7. Deliberate attempts to withhold or remove data or evidence from PDR or HRA files will result in immediate audit failure or termination of current certification.

1.2.2. Product description reports

1.2.2.1. All certified products must have a detailed PDR in the prescribed format:

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

1.2.3. Hazard and risk assessments

1.2.3.1. All certified products must undergo a regular HRA following the prescribed format:

a. product description: in 500 words or less, summarise the product's intended purpose of use, demographics of use, usage restrictions or limitations and any key safety and sustainability benefits;
b. process flow diagram: including all production steps, inspection, quality control, packaging labelling/decoration, packing, storage and distribution

Process	Material	Description	Hazard	Trade name	Supplier	Product/ catalogue number

c. list of product raw materials and incoming materials;
d. plant layout with employee/product flow;
e. physical, chemical and biological hazard identification;
f. establishing the likelihood of occurrence and severity of hazards and risks:

	Severity of consequences		
	Low	**Medium**	**High**
Likelihood of occurrence			
High	**Minor**	**Major**	**Critical**
Medium	**Minor**	**Major**	**Major**
Low	**Minor**	**Major**	**Minor**
Remote	**Minor**	**Major**	**Minor**

g. CCPs must be effectively identified to prevent or avoid hazards to product safety, sustainability, quality or integrity;
h. CCPs must have a documented control plan implemented to ensure risks are controlled effectively;
i. detailed specifications must be documented for all CCPs and other safety testing parameters to ensure compliance checks are validated, standardised and automatic

CCP	Description	Safe limit	Parameter to define risk (cut-off or limit)	Control plan/ preventative actions	Surveillance/ monitoring

1.2.3.2. Compliance requires a safety evaluation of any risks that a product may potentially pose to the consumer, the general public or the environment when it is used in the intended or a reasonably expected way during the full product life cycle.

1.2.3.3. Appropriate specifications or critical limits must be defined to identify whether risks are being mitigated, based on reasonable industrial and scientific rationale, and where present, on relevant legislation and codes of practice (clearly documented).

1.2.3.4. HRAs must ensure completeness in identifying all relevant considerations such as (but not limited to):

a. injury scenarios and potential injury severity;
b. likelihood of exposure;
c. affected subpopulations and variability within populations, particularly vulnerable subpopulations, which may be more susceptible and/or less resilient to exposure;
d. reasonably foreseeable misuses of the product;
e. hazard recognition and CCP identification;
f. interactions with other relevant products, substances or materials;
g. any sustainability aspects or potential negative impact on the environment.

1.2.3.5. The HRA must clearly communicate uncertainties, assumptions and descriptions of the parameters considered in the analysis. Sources of uncertainty can include (but are not limited to):

a. the quantity and quality of information;
b. non-validated assumptions;
c. the state of current scientific knowledge;
d. limitations of the risk assessment methodology.

1.2.3.6. For all CCPs identified, defined and tested systems must be in place to:

a. maintain consistent quality and conformity in final products via a defined programme of process control and quality control;
b. identify and control hazards to product safety and sustainability that are reasonably expected to occur at each step of the production process.

1.2.4. Audit of product description reports and hazard and risk assessments

1.2.4.1. HRAs rely 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 and use and upon end of life.

1.2.4.2. HRAs must be objective and ensure transparent methodology analysis, subject to confidentiality, privacy and legal constraints.

1.2.4.3. The assessment shall be undertaken by trained and competent internal or external resources, using a standardised and evidence-based risk assessment methodology, as well as evidenced scientific reasoning and judgment.

1.2.4.4. Transparent HRA reporting systems must be used, with records kept for a minimum period of ten years.

1.2.4.5. Where the company subcontracts analyses, the subcontracting must be approved and accredited in accordance with Organics Council ® requirements, and the company must provide proof of indemnity insurance or be ISO 17025 accredited for the test undertaken.
1.2.4.6. CCPs must be assessed as part of the certification inspection. Audits must ensure that detailed specifications are documented for all CCPs and safety testing parameters to ensure compliance checks are validated, standardised and automatic where feasible.
1.2.4.7. If the HRA determines that no control is required for a potential risk or hazard, the responsible person must provide a full justification for this, which is audited annually.
1.2.4.8. The responsible person shall have a product-in-use evaluation (internal or external), reliability trials and shelf-life tests performed by a validated body.

1.2.5. Critical control point monitoring and validation

1.2.5.1. The responsible person shall directly undertake or subcontract CCP audits; in the latter case, the third party must be duly accredited for this type of audit. The audit shall be carried out in conformity to these Regulations, and the audit process shall be indemnity, insurance and quality-assured or ISO 17025 accredited.
1.2.5.2. 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.
1.2.5.3. Procedures for validation, verification and annual review must be in place to confirm that the system is working effectively, including auditing of the system itself. Via an internal audit process, the company must show it has systems in place to verifiy the effectiveness of:

a. product safety and quality systems;
b. sustainability measures as per the Organics Council ® Circular Economy Standard.

1.2.5.4. Corrective and remedial actions must be taken and documented when monitored results indicate a failure to meet specified control limits, and the responsible person must ensure tested procedures are in place for all non-conforming or non-specification goods, including:

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

1.2.5.5. Evidence of review and investigation of all non-conformity issues that have arisen must be kept, with root cause analysis and a detailed outline of preventative and protective measures taken to mitigate risk.
1.2.5.6. Any non-conformities identified in final products are given a maximum of three months for corrective actions or product redesign or development.

1.3. Product audit

1.3.1. General requirements for all products

1.3.1.1. All certified products must be tested to ensure they meet Organics Council ® Regulations and all applicable certification body's proprietary standards, and to confirm that they are made of Organics Council ® ASL substances and materials, as well as being applied under appropriate usage conditions.
1.3.1.2. Certification bodies must perform transparent and impartial product sampling at the certifiee's premises, whilst upkeeping the records for at least ten years, as part of product audits, with samples collected and sent to an ISO 17020 accredited laboratory to be examined in accordance with Organics Council ® Regulations and certification body's proprietary standard requirements.
1.3.1.3. Quality checks must both guarantee and fully demonstrate that the finished product conforms to Organics Council ® Regulations standards for safety and sustainability:

a. The products must be made from safe and sustainable ingredients and materials approved by the Organics Council ®;
b. quality assurance must be in place to confirm that the products meet defined specifications and do not pose a risk to users and consumers;
c. quality assurance must be in place to confirm that no risk is posed to environmental health.

1.3.1.4. Internationally recognised methods must be used for all safety and conformity testing, with the benchmark being the methods approved by the European Committee for Standardization (CEN).
1.3.1.5. ISO-standard testing methods are also approved for use by the Organics Council ®, and EPA protocols may be applied alternatively if they are identified as being more applicable according to HRA outcomes.
1.3.1.6**.** The Organics Council ® may permit the use of other suitable validated methods for compliance, ensuring that processors have fully outlined in the HRA why the alternative method is more suitable than any available CEN, ISO or EPA alternative, and subject to approval by the Organics Council ® Certification Committee.

1.3.2. Food contact materials

1.3.2.1. Physical conformity

1.3.2.1.1. The product must be mechanically safety tested to ensure that products are fit for purpose and capable of providing a protective barrier to avoid contamination of contents.
1.3.2.1.2. The product must be capable of preserving contents effectively.
1.3.2.1.3. The product must not induce any organoleptic changes to the food contents.

1.3.2.2. Migration safety

1.3.2.2.1. Migrants transferred to a food simulant in terms of OM or SM must be determined as a requirement of these Regulations.
1.3.2.2.2. Migration must be assessed for each substance identified in HRAs which may possibly migrate, be converted to an intermediate or NIAS substance, or be released upon processing, use or disposal of the product.
1.3.2.2.3. The responsible person must ensure that any migration conforms to the Organics Council ® general OM limits for FCM requirement of less than 0.1mg/dm^2/ 0.01 mg/kg.
1.3.2.2.4. Migration tests must be performed under standardised conditions of simulant time, temperature and contact area, which correspond to the maximum foreseeable potential treatment of the stimulant product.
1.3.2.2.5. Conventional conditions for migration tests with food simulants, covering conditions of worst foreseeable use, are defined as:

Contact time	**Test time**
T ≤ 5 min	See conditions
5 minutes < t ≤ 0.5 hours	0.5 hours
0.5 hour < t ≤ 1 hour	1 hour
1 hour < t ≤ 2 hours	2 hours
2 hours < t ≤ 4 hours	4 hours
4 hours < t ≤ 24 hours	24 hours
t > 24 hours	10 days
Contact temperature	
t ≤ 5°C	5°C
5°C < t ≤ 20°C	20°C
20°C < t ≤ 40°C	40°C
40°C < t ≤ 70°C	70°C
70°C < t ≤ 100°C	100°C or reflux
100°C < t ≤ 121°C	121°C

121°C < t ≤ 130°C	130°C
130°C < t ≤ 150°C	150°C
t >150°C	175°C

1.3.2.2.6. For materials subjected to a combination of two or more times the amount of contact and varying temperatures, migration test should be carried out by successively subjecting the sample to all the applicable worst foreseeable conditions appropriate to use, using identical food simulants.

1.3.2.3. Approved food group categories for food contact material conformity testing

1.3.2.3.1. For the purposes of FCM conformity testing for all FCMs, food groups can be specified as (based on EU guidelines unless otherwise stated):

Type	Description	Classification	Relevant simulant
I.	Non-acid, aqueous products; may contain salt, sugar or both (pH > 5)	Aqueous	Simulant A = ethanol 10% (v/v) for aqueous food
II.	Acid, aqueous products; may contain salt, sugar or both, and including oil-in-water emulsions of low- or high-fat content	Acidic	Simulant B = acetic acid 4% (w/v) (+/- 10% ethanol as per FDA guidelines) for acidic food
III.	Aqueous, acid or non-acid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content	Fatty	Simulant D1 = fatty food, 50% (v/v) ethanol
IV.	Dairy products and modifications		
	A. Water-in-oil emulsions, high- or low-fat	Fatty	Simulant D1 = fatty food, 50% (v/v) ethanol

	B. Oil-in-water emulsions, high- or low-fat	Aqueous	Simulant D1 = fatty food, 50% (v/v) ethanol
V.	Low-moisture fats and oils	Fatty	Simulant D2 = vegetable oil Simulant D3 = food oil, HB307 Simulant D4 = miglyol 812
VI.	Beverages		
	A. Containing up to 8% alcohol	Low alcohol	Simulant C1 = 20% (v/v) ethanol for alcoholic product
	B. Non-alcoholic	Aqueous	Simulant A = ethanol 10% (v/v) for aqueous food
	C. Containing more than 8% alcohol	High alcohol	Simulant C2 = 50% ethanol for high alcoholic content products (as per FDA guidelines)
	D. 95% or absolute ethanol	Absolute alcohol	95% or absolute ethanol
VII.	Bakery products (other than those under types VIII or IX)		
	A. Moist bakery products with surface containing free fat or oil	Fatty	Simulant D1 = fatty food, 50% (v/v) ethanol Simulant D2 = vegetable oil Simulant D3 = food oil, HB307 Simulant D4 = miglyol 812

	B. Moist bakery products with surface containing no free fat or oil	Aqueous	Simulant A = ethanol 10% (v/v) for aqueous food
VIII.	Dry solids with the surface containing no free fat or oil	Dry	Simulant E = tenax (PPPO) for dry food
IX.	Dry solids with the surface containing free fat or oil	Fatty	Simulant D2 = vegetable oil Simulant D3 = food oil, HB307 Simulant D4 = miglyol 812

1.4. Processing audit

1.4.1. Premises and workforce

1.4.1.1. A certification body must visit the certifiee's premises to perform an audit and complete a site inspection report in order to establish if procedures and conduct conform to Organics Council ® Regulations, with a maximum of three months given to correct any procedures or processes failing standard requirements as a non-conformity.
1.4.1.2. Equipment verification, safety, suitability and maintenance must be audited, with responsible persons ensuring that production and processing facilities and machines have established, documented and annually tested safety and protection procedures as per the Organics Council ® HRA requirements, with continual validation of equipment effectiveness.
1.4.1.3. Process validation must be evidenced by regular internal audits and quality-control systems.
1.4.1.4. Layout, product flow and segregation, production site security and staff facilities must be assessed to ensure that production is safe and of the highest quality.
1.4.1.5. Hygiene and cleanliness must be assessed to ensure that the highest standards are maintained and that no product contamination risks or to workers exist.
1.4.1.6. Sanitation and pest control systems must be assessed to ensure that the highest standards are maintained and that no product contamination risk to workers exist, as well as ensuring that safe pest-control methods are in place.
1.4.1.7. Record-keeping must be effective and allow full traceability of stock, suppliers, equipment, ingredients and materials. Records must be kept for a minimum of ten years.
1.4.1.8. Personnel qualifications and training must be of an adequate level to ensure that production is safe and high-quality, with no risk to the product, general public or the workforce.

1.4.1.9. Complaint-handling systems must be adequate to ensure accountability and a proactive approach to complaint management, both internally and externally.
1.4.1.10. Health and safety within the workplace must be a priority for all responsible persons, ensuring maximum safety and protection for both the workforce and the local environment.

1.4.2. Energy

1.4.2.1. Compliance with sustainable energy use requirements defined by the Organics Council® may be certified based on implementation of the following:

a. incorporating energy efficiency considerations into all new factories or production lines;
b. energy efficiency of existing factories and production lines, applying best available techniques (BATs);
c. efficiency audit of local and regional procurement, trying to reduce reliance on non-sustainable energy.

1.4.2.2. Processors producing certified goods must embrace energy-saving technologies whenever possible during manufacturing, production, storage and dispatch.
1.4.2.3. 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.
1.4.2.4. Greenhouse gas (GHG) emissions must be calculated according to the defined international voluntary measuring and 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 of lower sales volume than 1 million units per year.
1.4.2.5. For small businesses with a sales volume below 1 million units per year, GHG emissions and carbon footprints should be calculated in-house using UK guidance [UK gov GHG calculations guidance].

1.4.3. Raw materials

1.4.3.1. Audits must assess the sustainability of material usage and the effectiveness of the systems in place to improve the sustainability of materials and inputs used.
1.4.3.2. Audits must perform traceability checks on randomly selected inputs to ensure that traceability systems are effective.
1.4.3.3. Audits must ensure that all inputs are ASL registered.

1.4.4. Pollution, waste and emissions

1.4.4.1. All emissions and waste produced must have monitoring data confirming that these comply with Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control).

1.4.4.2. The responsible person must have systems in place to show the use of BATs for the management of all emissions and waste generated.
1.4.4.3. The integrated audit must take into account the whole environmental performance of the plant, including but not limited to:

a. atmospheric emissions;
b. waste water generation;
c. solid waste generation;
d. noise pollution.

1.4.4.4. The HRA must assess the total volume of waste generated and evaluate the capacity of the processor to cope with treatment.
1.4.4.5. Audits must assess emissions and waste composition data to ensure that all nanoparticles generated during manufacturing and production are strictly controlled and do not contribute to nanoparticle pollution of the natural environment.
1.4.4.6. The Organics Council ® requires that manufacturers implement policies on waste production reduction based on following principles:

a. prevention of waste production;
b. recycling and recovery of waste;
c. non-recyclable waste to be compostable and degradable within 100 years;
d. use of renewable energy.

1.5. Social fairness audit

1.5.1. Employment

1.5.1.1. Full records must be maintained to show an annual review of all employees' continual development and training logs.
1.5.1.2. For internal workplace complaints and grievances, annually reviewed systems and logging shall be present.
1.5.1.3. A detailed policy and procedure must be in place for resolving internal workplace grievances, including complaint monitoring and logging, with supported systems in place for anonymous whistle-blowing to report bad practice.
1.5.1.4. Employers must ensure that all employees' and apprentices' living wages are reviewed annually based on:

a. https://wageindicator.org/main/salary/wages-in-context;
b. https://www.isealalliance.org/about-iseal/our-work/global-living-wage-coalition;
c. any other relevant tool, ensuring it has been prior agreed by the Organics Council®.

1.5.1.5. Where potential hazards may exist to employees' health, as identified by HRAs, protocolled and documented health checks must be performed at appropriate intervals to ensure adequate protection.
1.5.1.6. Equality and diversity policies and procedures must be in place and adequately reviewed, ensuring equality and diversity are maintained in the workplace, with assessments

performed as part of annual staff work reviews, and ensuring the policy is maintained throughout the recruitment processes.
1.5.1.7. Systems must be in place to ensure that staff can report any infringements on their equal opportunities in the workplace, without prejudice and with protocolled systems in place to undertake an objective and independent investigation into any reported infringements.
1.5.1.8. Evidence of meeting ISO 26000 guidelines is preferable but not in itself enough to ensure certification or conformity to these regulations.

1.5.2. Operations

1.5.2.1. Full disclosure is required for all operating practices during the audit process.
1.5.2.2. The licensee must provide evidence that all inputs are ASL approved and that sources are sustainable and not animal-tested.
1.5.2.3. An anti-corruption policy must be in place to ensure transparency and honesty in all aspects of business and production.
1.5.2.4. The PDR and all other information provided as a basis for product certification must completely and truthfully reflect all aspects of product design, production and sale. Any omitted or missing information will be considered a deliberate non-disclosure and will result in a non-compliance issue.
1.5.2.5. Any proven cases of corrupt activities will result in termination of certification approval, on the grounds of deliberate non-compliance, following an investigation by the Organics Council® approved certification body.

1.5.3. Customer Support

1.5.3.1. Annually reviewed systems must be in place for:
a. customer care services;
b. post-purchase support;
c. complaint and dispute resolution.

1.5.3.2. All complaint must be logged, and all management processes recorded as per protocolled systems.
1.5.3.3. 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.
1.5.3.4. 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.

1.6. Market safeguarding and surveillance

1.6.1. Transition period and requirement compliance degree

1.6.1.1. Compliance to Organics Council® regulations licence may still be granted despite the non-critical requirement failure, independently of the transition period, subject to those failures being addressed in a timely manner as if defined in Organics Council® accredited certification body audit schedule.
1.6.1.2. Transition periods may be used by the processor to adapt systems and processes so they are in compliance with the applicable Organics Council® regulations and, subject to the processor adequately proving they have a transition plan to implement all necessary changes to meet requirements defined in Organics Council® regulations. Inspections at defined periods will be made to ensure that transitions are completed in a timely manner.
1.6.1.3. The audit requirements which are critical, but not immediately mandatory to obtain the licence during the transition period, are defined in the Organics Council® accredited certification body audit schedule.
1.6.1.4. Artisan craftsmanship goods processing audit compliance to Organics Council® regulations must be subject to the simplified audit schedule.

1.6.2. Post-certification inspections

1.6.2.1. After an Organics Council® certification is granted, certification bodies must perform regular checks to ensure that the certifiee continues to meet Organics Council® Regulations and certification body standards.
1.6.2.2. Certification must be renewed annually, and each renewal requires the same audit robustness as each new certification.
1.6.2.3. Certification bodies must perform unannounced inspections at least once a year to monitor consistency of compliance.
1.6.2.4. Additional inspections must be carried out if any changes are made to product formulation or processes used, or if any other changes occur, such as in certification standards or risk assessment process, due to changes in legislation, regulations or current scientific knowledge.

1.6.3. Changes to product description report (PDR)

1.6.3.1. Any change in product processing systems or composition must be fully reassessed according to the HRA template.
1.6.3.2. In order for a certification licence to remain valid, the new PDR must be forwarded to the Organics Council® prior to the release of any stock batches containing the altered product, subject to certification body deciding whether a new audit is necessary.

1.6.4. Deliberate product compliance breaches

1.6.4.1. To dissuade any deliberate non-compliance practices, in case of substantiated non-compliance ascertained by the certification body, a penalty must apply in the form of a ban to reapply for Organics Council® licensing approval for two consecutive years.
1.6.4.2. 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.
1.6.4.3. Where the director of an entity applying for a new licence with a certification body 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 licensing standards conforming to Organics Council® Regulations, the new applicant entity is considered a contract-breaching entity.

1.6.5. Non-conformity mitigation

1.6.5.1. 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 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.

1.6.5.2. 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 QA/QC confirmed during the audit.
1.6.5.3. 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.

1.6.5.4. 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.
1.6.5.5. Annually tested procedures must be in place for product recall processes.

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v.1 to v.2 changes:

Term ‘manufacturer/s’ changed to ‘processor/s’;