Annex A16-2 Additional Rules for NPOP Input Approval

Chapter 10
Additional rules for the approval program- National Program for Organic Production-Inputs

Contents

Article 10.1 Administration 2
Article 10.2 Production/Processing 2
Article 10.3 Subcontracting 3
Article 10.4 Storage & Transport 4
Article 10.5 Record keeping 5
Article 10.6 Quality Analysis 5
Article 10.7 Traceability 6
Article 10.8 Samples for NPOP Inputs 6
Article 10.9 Classification of non-conformities for input approval programme 7
Article 10.10 For Traders/Marketing 8
Article 10.11 Conditions for publication and use of the Input Approved Logo 9

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Chapter 10: Additional rules NPOP Inputs

Article 10.1 Administration

10.1.1. The unit should have valid government registration, license to run the operation. like certificate of incorporation, factory license, MSME license, partnership deed, proprietorship documents etc. along with other applicable legal records.

10.1.2. The legal representative of the unit shall sign all the records concerned to certification body, if legal representative is not available, then the authorized person can sign (the authorization should be defined)

10.1.3. The unit under approval shall inform the CB for any changes that affects the scope of approval.

10.1.4. The unit shall have an organogram which defines the responsibilities of key person working the factory/department

10.1.5. The entity under approval shall submit to CU the process flow of products and product description sheet containing all the ingredients, percentage in the end product, active/inert specification, source of input etc. prior to audit for reviewing.

10.1.6. The Ingredients/raw materials shall be approved prior to the audit through a desk review of the Product description sheets

Article 10.2 Production/Processing

10.2.1. The unit shall have a site map showing the location of the factory and a Floor plan which shows the internal areas of the unit. The maps shall be made based on the nature of production.

10.2.2. The unit shall maintain the integrity of organic approved material, it shall not be contaminated with unallowed substances

10.2.3. Imported ingredients to be used in the final product can be approved based on the nature and shall follow all the 6 criteria's of NPOP

10.2.4. On request of the Inspector, the client shall prove the gene technology free origin of all products and raw materials for which gene technology is prohibited according to the applicable regulations by means of a declaration free of genetic

modification. The declaration free of genetic modification shall contain at least the information as mentioned in CUINP.GMO.D01. The declaration of the Non-GMO shall be obtained from the producer of that organism or strain line agricultural universities, culture collection centre or any industry from where the product is purchased

10.2.5. The unit shall maintain the list of the vendors with complete address, phone number and material, the list of these vendors shall be subjected to review whenever the supplier is changed. The approved list of suppliers shall be provided on request of the inspector.

10.2.6. A suitable cleaning process whose effectiveness has been checked shall be carried out; operators shall keep a record of such cleaning processes.

10.2.7. Pests should be avoided by good manufacturing practices. This includes general cleanliness and hygiene.

10.2.8. There shall never be direct or indirect contact between organic products and prohibited substances. (e.g. pesticides). In case of doubt, it shall be ensured that no residues are present in the organic product.

10.2.9. For Enzyme approvals, the agricultural products shall be from the organic source.

10.2.10. The Enzyme production units shall have the valid organic approved vendor certificates, if the product of agriculture in nature is not available as organic, conventional untreated product can be used.

10.2.11. If the unit is using untreated products, the lab analysis of such lot should prove no chemical/pesticide residue.

10.2.12. Ingredients other than agriculture in nature in the enzyme production shall be approved based on the normal input approval procedure

Article 10.3 Subcontracting

10.3.1. If the entity decides to subcontract work related to the processing/handling to a third party, it shall establish a documented system for overseeing the role and functions of the subcontracted party which shall address issues of confidentiality and conflict of interest.

10.3.2. The approval holder/entity shall take full responsibility for subcontracted work,

ensure that the subcontracted party complies with the requirements laid down in this document standard and the inspection regulation also ensure that the subcontracted party remains impartial in its functioning.

10.3.3. A list of the subcontractors with a description of their activities shall be made available during the application and in the processing plan.

10.3.4. Written agreement by the subcontractors that their holding will be subject to the inspection procedure laid down in this standard shall be made available

Article 10.4 Storage & Transport

10.4.1. Areas in which products are stored shall be managed in such a way that the stored batches or lots can be identified. Approved products must be protected at all times from co-mingling with unapproved products and from contact with materials and substances not permitted for use.

10.4.2. Where only part of the unit is approved and other products are unapproved, the approved products should be stored and handled separately to maintain their identity.

10.4.3. All necessary measures shall be taken to ensure identification of the products and to prevent any mixing or confusion with unapproved products; before approved products are stored.

10.4.4. The information of the product (name, lot number, consignee, consignor, vehicle details) may also be entered in an accompanying document. The accompanying document shall give details of the supplier and the transport operator.

10.4.5. Both consignor and consignee keep a record of these transport operations and make the records available to the inspector on demand

10.4.6. Only approved raw materials (complying to Chapter 3- Appendix-1-Annex- 3(2), Annex 3(3), Appendix 5- Annex 3 (17), 3(18), & Appendix 6- Annex 3(5), Annex 3(6) & Appendix 2- Annex 3(9) shall be stored, mixing of approved and unapproved raw materials are not allowed.

10.4.7. There shall be no contamination or substitution of products while transportation. The transportation of the approved product shall be done in clean and safe manner.

10.4.8. Approved and unapproved product processing shall not be combined, there shall be separation in all means throughout the process. No contamination of prohibited, unallowed substances allowed during processing.

Article 10.5 Record keeping

10.5.1. The unit shall maintain all records concerned with the process; the ingredients used with quantity shall be defined properly in the process record (production report/Batch manufacturing report) for the audit verification period (12 Months).

10.5.2. The unit shall maintain all the records concerned with the product like product license from the applicable authorities, process flow chart for the product, CCP plan, pollution control board records etc.

10.5.3. *Complaints record*

The entity shall have policies and procedures for dealing with complaints against its operation and products. It shall keep a record of all complaints and remedial actions relating to the product or process. When a complaint is resolved a documented resolution shall be made and forwarded to the complainant and the party concerned.

Article 10.6 Quality Analysis

10.6.1. The processing unit shall take and analyse samples for checking the quality of the product/detecting possible contamination by products not authorized for approved production.

10.6.2. The procedure of quality analysis shall be defined in the Process manual or SOP. If the internal quality analysis facility is not available, such companies shall do external lab analysis based on the applicable parameters.

10.6.3. The Inspector shall take sample of at least one product and carry out analysis based on the standard parameters. The inspector shall follow the sampling

procedures as defined in their working instructions.

10.6.4. Testing to be carried out in ISO 17025 accredited and preferably APEDA approved laboratories

Article 10.7 Traceability

10.7.1. At all processing stages, the operator shall introduce a traceability system that allows the allowed components of the product to be traced back to its raw material supplier(s).

10.7.2. The operator shall be able to demonstrate how the traceability system works and how it is possible to trace a final product from the shelf to its original approved input/ allowed raw material supplier and vice versa.

10.7.3. Producer shall maintain records, which clearly demonstrate input and output quantities along with stock balance at any given point of manufacture. That producer shall also be able to show explicitly the lot numbers/ batch numbers associated with those values.

10.7.4. The client shall keep records of the following information on approved incoming goods:
- Copies of packing lists and/or other transport documents;
- Invoices;
- Certificate of analysis as applicable.
- In case of Enzymes, Food/Feed based products, Copy of valid Certificates stating that the products have been produced according to the applicable organic regulation;

10.7.5. The client shall keep records of the following information on outgoing approved products:
- Copies from packing lists and/or other transport documents;
- Copies of the Invoices.

Article 10.8 Samples for NPOP Inputs

In case the result of any sample analyses for the organic programs NPOP shows residues of

disallowed materials in any amount above the detection level of the laboratory, the following procedure applies:
CU immediately starts an investigation. Dependent on the nature of the residue that has been found; the whole chain of custody from the processor till the point where the residue has been found may be subject of the investigation. The CU client receives a standard Incident Report Form from CU, in which the representative of the client is requested to describe the possible reasons of the disallowed material detection. The information supplied by the client in this document is an essential part of the investigation. Furthermore, the CU client is requested to inform his buyers about the found residue. CU has the right to suspend the concerned product/unit and to carry out unannounced visits at the project. The result of the investigation may cause changes in the approval status of the product and/or units.

Article 10.9 Classification of non-conformities for input approval programme

Non-conformities are classified as Minors and Majors:

10.9.1. A minor (also called as 'condition') is a non-conformity, related to working procedures of the concerned unit. The maximum deadline to rectify a condition is 2 months. If the client does not correct and does not show to the satisfaction of CU, that the condition is rectified before the deadline, CU shall grant a major with a maximum deadline of 1 month.

10.9.2. A major (also called as 'pre-condition') is a non-conformity, related to topics that endanger the status of the certified products coming from the concerned unit. The maximum deadline to rectify a major is 1 month. If the operator does not correct and does not show to the satisfaction of CU, that the major is rectified before the deadline, the Certificate is suspended for a given period determined by CU on a case by case basis. In case the NC is not corrected during the suspension period, Certificate shall be withdrawn.

10.9.3. In case of any non - conformity follow - up is needed. It is the responsibility of the client to take appropriate remedial actions. Whenever there is an outstanding NC, positive approval decision cannot be made, and Statement of Compliance cannot be issued for the concerned units/products.

10.9.4. Re-assessment can be done during an additional inspection or by administrative review (assessing documents, photos etc.).

10.9.5. During suspension, the product concerned cannot be sold with reference to the organic production method. In case the certification is withdrawn, the project needs to be re-inspected. All aspects of the standard need to be assessed during a new physical inspection.

Article 10.10 For Traders/Marketing

10.10.1. A certificate can have more than 1 brand name as part of marketing purposes, such names shall be entered in the certificate with a "/"

10.10.2. If a Marketing company wants to market any approved product and needs statement of compliance in its name, the marketing company shall be subject to audit with concern from the manufacturing company.

10.10.3. The manufacturing company and the marketing company shall be audited, an agreement of marketing shall be framed, all the technical sheets shall be filled by the manufacturing company. The manufacturing company shall be responsible for the standard integrity.

10.10.4. If the manufacturing company is already approved by CU then the marketing company alone shall be audited to check the compliance based on the approval certificate issued.

10.10.5. If the manufacturing company is already approved by other CB under APEDA, a full audit on behalf of CU shall be carried out both at manufacturing location and the marketing location. Also, the information about the audit shall be send to the concerned CB.

10.10.6. Any imported product can be approved based on the technical data sheet submitted and its proven that the manufacturing unit in the said country follows the Organic standard requirement. Such products after the sample analysis can be approved. The importing company shall be audited.

10.10.7. Every importer shall inform the Director of Agriculture of the State in which he intends to discharge the imported fertilizer, under intimation to the Central Government, before the import is made or within a period of 15 days after an indent for import is placed, the following details, namely
(i) name of fertilizer
(ii) name of country of import
(iii) name of manufacturer
(iv) quantity to be imported
(v) date of arrival of the consignment
(vi) name of the discharge port
(vii) other information

Annex A16-2 Additional Rules for NPOP Input Approval

Article 10.11 Conditions for publication and use of the Input Approved Logo

10.11.1. This document describes the conditions concerning publication and use of approved logo by customers of CU Inspections India Pvt. Ltd. (the Approval-holder) with a valid approval Certificate.

10.11.2. The Approval-holder can only publish those Approval-logos that are concerning the valid issued Approvals and does not make or permit any misleading statement regarding its approval, nor imply that the approval applies to activities that are outside the scope of approval.

10.11.3 The Approval--holder can use the CU approval logo, to be requested at the local office (for a specimen see below).

10.11.4. The approval logo permission should be taken before the use of same. The validity of the logo will expire with the approval; hence the same has to be renewed at applicable intervals.

10.11.5. The approval logo can be used in full colour, as well as in black and white.

10.11.6. The Approval - holder can use the approval logo on letterheads, brochures, products, packaging and other promotion material etc.

10.11.7. All labels of approved products with logo shall specify the manufacturing date, expiry date, batch number/lot number, price, quantity of packing and the ingredients of the product. On the label of Microbial formulated products, formulations and total Colony forming Units (CFU) should be mentioned

10.11.8. It is allowed to reproduce the logo in any other size.

10.11.9. The approved logo may never be bigger than the size of the company logo on the same document.

10.11.10. The logo needs to be reproduced completely (in one piece) always.

10.11.11. Operator shall not claim their approved products as “Only Organic, Certified organic or 100% organic fertiliser/pesticide/bio fertilizer/bio pesticide,” etc on the labels.

10.11.12. It is not allowed to use any accreditation logo.

10.11.13. The color-codes for the logo are the following:

Grey	PMS 5497
Blue	PMS 2985
Black	Process Black

10.11.14 When the Approval--holder does not respect these conditions for use of approval logo, the Approval--holder will stop immediately, without delay, the use against which CU has objected.

10.11.15. CU can take the following actions if found misuse of the logo:
a. suspension or withdrawal of the Approval.
b. publication of the non-compliance
c. juridical procedures

10.11.16. The action taken is depending on the severity of the non-compliance, the results of the non-compliance, and if the non-compliance was made intentionally.

10.11.17. The decision of CU Inspections India Pvt. Ltd. will in all cases be decisive.

10.11.18. In case the validity of the Certificate is ended, for whatever reason, the Approval-holder has to stop immediately with the use and/or distribution of promotion material on which the approval logo is printed

10.11.19. In case of not approval of label by Control Union, CU Inspections India Pvt. Ltd. shall not be responsible for any loss happened to the client in this regard.

10.11.20. It is not permitted to apply the logo to laboratory tests, calibration or inspection reports, as such reports are deemed to be products in this context.

Logo example:

CONTROL UNION
APPROVED INPUT for
National Programme for
Organic Production (NPOP)