#### **ZENITH Steps to Organic Certification**

#### Note in General:

 Language: The official language of ZENITH is English. Applicant or operator wishing to do certification business in another language must provide English translation for personnel and documentation. Production record may be maintained in native language provided documentation must be translated in English.

#### **Compliance Demonstration:**

- The Applicants and Certified operations can demonstrate compliance with the recordkeeping requirements under the NOP/EU/COR applicable regulations by ensuring that the records maintained are up to date and sufficiently document the practices, procedures, and inputs used by the operation. The records must fully disclose all activities in sufficient detail and in a format that can be readily understood, audited, and available for inspection. Certified operations must make records available for review by the ZENITH, Accreditation Authorities, the applicable State program's governing State official during normal business hours. The certified operations must submit annually Annual update form, an updated OSP, which includes documentation of any deviations in the practices, procedures, and inputs from what was specified in the previous year's OSP and any changes to the previous year's OSP that will be undertaken in the coming year. Documenting such changes allows ZENITH to verify an operator's compliance with the applicable standards requested for certification.
- Equity & Non Discrimination: ZENITH will not discriminate on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status. ZENITH will accept all production or handling applications that fall within its area(s) of accreditation and certify all qualified applicants, to the extent of its administrative capacity to do so without regard to size or membership in any association or group
- (NOP Programme): Agricultural products, including personal care products, that, by virtue of their organic agricultural product content, may meet the NOP standards and be labeled as "100 percent organic", "organic" or "made with organic" pursuant to the NOP regulations. A producer may substitute a Organic Management plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: Provided, That, the submitted plan meets all the requirements of this subpart.
- ZENITH here obliged to report violations of health or safety to the appropriate local, State, or Federal officials. A copy of all such reporting will be forwarded to the National Organic Program (NOP) in care of the NOP Compliance and Enforcement Branch (CEB), In India, report to APEDA, New Delhi. Further, organic certification will not be granted or continued when current health or safety inspections have not been granted or renewed for the facility.
- "Records must fully disclose all activities in sufficient detail and in a format that can be readily understood, audited, and available for inspection. Certified operations must make records available for review by the NOP, the applicable State program's governing State official, and the certifying agent during normal business hours (§ 205.103(c))."
- Organic certification shall not be granted or continued when current health or safety inspections have not been granted or renewed for the facility.

#### Who needs to be NOP certified?

Any grower or handler who wants to sell organic products on the US market must be certified according to NOP by a USDA accredited certifier. Also suppliers of organic ingredients must be NOP certified.

# Applicant/ operator must inform ZENITH of any COI (conflict of interest) identified with assigned inspector. Operator/ Applicant has the right to refuse the selected auditor in case of conflict of interest.

#### Exemptions (NOP):

a. Smallholders with less than 5,000 USD annual turnover from organic sales, who sell their products directly to the consumer (this is not relevant for producers outside the USA).

- b. Retailers
- c. A retail establishment that processes, at the point of final sale, agricultural products certified under this part as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."
- d. Operations, which handle agricultural products containing less than 70% of organic ingredients, or only identify some organic ingredients on the information panel.
- e. Operations which only handle packaged organic food (§ 205.101(e)&(f)).
- f. Customs broker (per 19 CFR 111.1) that only conducts customs business but does not otherwise handle organic agricultural products
- g. Operation that only arranges for the shipping, storing, transport, or movement of organic agricultural products but does not otherwise handle organic products.
- h. Recordkeeping by exempted operations (§ 205.101 {i}) and records must be maintained for no less than 3 years beyond their creation.
- i. Exempted operations, as described in above mentioned (a), (c)& (e) must make records available to representatives of the Secretary, upon request, that: Demonstrate that agricultural products identified as organic were organically produced and handled; and Verify quantities of organic agricultural products received and shipped or sold.

**Re-instatement of suspended certifications:** Any operator whose certification has been suspended by ZENITH may submit a request to the US Secretary of Agriculture for reinstatement of his/her certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with NOP, including a confirmation by an accredited certifier.

In case of COR (Re-instatement of Cancelled Certifications), Applicant have to submit an application for certification to ZENITH, Followed by completion of evaluation process and closing of all Non Conformities. Then ZENITH will request CFIA for removing the name of the holder of certificate from the list of cancelled holders of certificates posted on the CFIA web site. Then ZENITH will proceed further with granting of Certification after receiving confirmation from CFIA that concern operator is removed from CFIA website.

#### After Cancellation of Certification, Operator must not sell/Claim any produce as Organic.

**Penalties:** According to §205.662, a certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, except, that, the Secretary may reduce or eliminate the period of ineligibility.

In addition to suspension or revocation, any certified operation that:

- (1) Knowingly sells or labels a product as organic, which is not in accordance with the NOP requirements, shall be subject to a civil penalty of not more than amount specified in § 3.91(b)(1) (xxxvi) per violation.
- (2) Makes a false statement under the Act to the Secretary, a State organic program's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

**Complaints:** Complaints related to the certifier have to be addressed in writing to the Agricultural Marketing Service (AMS) of the USDA. For further details on complaints, please see § 205.680 in case of NOP & in case of EU & COR, Complaints must be submitted to ZENITH on id <u>cad@zenithcertifications.com</u>.

**Confidentiality** : ZENITH will handle confidentially all information obtained during the certification process unless, otherwise required by law. This is part of our certification contract, this also includes ZENITH will share information to accredited certified for complaint investigation purpose, (in this case too both ZENITH and other accredited certifier will maintain confidentiality). However, we have to inform the USDA, EU, COR, NPOP annually about the certified operations.

**Safeguarding Impartiality:** ZENITH safeguards the impartiality of certification activities. ZENITH takes responsibility for its management and certification activities at all levels of the organization to ensure certification is handled in an objective and transparent manner. ZENITH monitors the risk to impartiality, takes preventive actions and takes appropriate measures to minimize or eliminate any risk to the impartiality of services offered to its operator.

In case ZENITH granted certification, and in between ZENITH interprets the clarity on certain requirements implementation (with AB's) that affects integrity per Scheme requirement, then in such case ZENITH will indicate client to omit such activities along with justification.

	implementation.			
	ltems/Steps	Applicant or client or Operator	ZENITH Procedure	
1			<ul> <li>ZENITH Procedure</li> <li>The applicant receives a first package of information (Enquiry Form) from ZENITH, by e-mail, website, or often combined with individual additional information by phone as and when required. This package includes:</li> <li>Certification Steps/Procedure, a brief information concerning requirements in the respective area (e.g. crop production, group certification, wild collection, processing, Livestock, other G category).</li> <li>After receiving relevant information {No. of Products range, Area , No. of farmers (in case of GG)} Quotation will be raised , based on the operation activities (type, range, risk etc). You may Refer ZENITH Certification Fee structure for applicable certification cost Zenith Fee Schedule (NOP-EU-COR).pdf</li> <li>Once Quotation is Accepted by Applicant/client, Next Sequential Steps will be followed.</li> <li>Within 7/10 days working days, enquiry will be responded.</li> <li>QA or admin will review Scope and country list of concern operation (Approval status) for before further proceedings</li> <li>Application received within accredited scope and programme only</li> <li>Application received not within the accredited scope and programme</li> <li>Operator not working and understanding English language</li> <li>(EU): Certification withdrawn within past 2 years</li> <li>A geographical location that makes certification a technical impossibility or When unannounced inspection not possible in specific region or a risk for those involved outstanding payment</li> <li>When it is determined that ZENITH lacks the resources to perform the certification activity at point of time {Lack of qualified and competent staff (technical skills, language)}</li> <li>Repeated non-compliances and/ or complaints regarding the applicant or products, Identified health risk to consumer</li> <li>Proven open non-compliance with respect to</li> </ul>	
			applicable standard and local statutory and	

Along with requirements mentioned in guidelines, additional instructions/ memo to be followed for necessary implementation.

2	Formal application	Application Packets for certification Shared with Client.	<ul> <li>mandatory requirements, Prohibition of certification imposed by a local competent authority</li> <li>A conflict of interest that could undermine the impartiality of our decisions</li> <li>Upon acceptance of quote, Detailed application form will be sent.</li> </ul>
3	Working out the organic management plan	The applicant must return the completed Organic Management Plan (OMP) with OSP addendum and supporting documents to the ZENITH office with the required fee for certification. * In case of G category (products as listed in Annex I 848/2018) In addition to respective OMP, operator need to submit product specific detailed production, processing and handling method, flow chart as an attachment to main OMP	Application acknowledgement within 5 business days.
4	Application Review AND Preliminary Compliance Review		ZENITH reviews the OMP with essential Appendix and informs the client about the result of this review. All applications will be processed within approximately 4 weeks (15 working days, if expedited) of receipt of the complete application and paid deposit. *In case operation have Previous Non Compliances, Applicants may be asked for additional information and supporting documentation before moving forward with certification- Inspection Stage. Approved Input list, Non Organic seed/ingredient approval, label approval will be processed at this step and shared to operator with OSP approval letter. (Note: only approved input, label allowed, must request for approval prior to its application or use) * After the review is complete the applicant will be notified of any findings or additional information required. The applicant is notified in writing of the results of the initial compliance review. An application may be rejected. If so, the applicant will be notified in writing of the reasons. * If an applicant was previously certified by another certifier, then the applicant must provide their previous certification history, including documentation to support the correction of any preexisting non-compliances, and report any adverse actions (e.g., Notices of Proposed or Final suspension or revocation). ZENITH will contact previous certifier to provide operations control files (inspection report, certificates, non conformities, adverse action, derogations, complaints, residue analysis report (as applicable),any additional conditions if any with their closure status).

			ZENITH will ensure that all non-compliances and any subsequent adverse actions were correctly reported and successfully corrected. If a certified operation was previously suspended or cancelled for regulatory violations, the Re-instatement procedure will be followed (for NOP as per <u>NOP</u> 2605.) (COR operating manual: as per C.2.8) ZENITH may approve continuation of certification, only after the NOP approves the reinstatement request and in case of COR, after approval from CFIA and updation of cancellation status from portal. The information provided regarding previous certifications will be thoroughly verified, both during reviews and inspections. *In renewal case, *NOP§ 205.406(a) requires certified organic operations to only submit sections of its OMP and Addendum that have changed. But in case of EU & COR Operations, OMP need to submit as Full.
5	Audit Plan & On-Site Inspection/Ev aluation	Audit Plan will be notified to Applicant. The responsible person must be present, records must be prepared. The Exit Interview is signed by the client or an authorized representative who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. A copy of the Exit Interview form will be left with the applicant by the inspector.	<ul> <li>Within a reasonable time, Inspection will be scheduled as soon as practical after the initial review indicates the operation's ability to comply.</li> <li>Applicant/ operator must inform ZENITH of any COI identified with assigned inspector. operator/ Applicant has the right to refuse the selected auditor in case of conflict of interest.</li> <li>The inspector verifies, whether the management plan is consistent with the reality, may draw sample as per risk (group operation -mandatory 2 % member sampling), and identifies any findings (Observation, issue of concern, additional information request). Conclude audit/ exit meeting in the presence of authorized person, Team, /representative, as applicable. Inspector will share a copy of exit report with client along with sampling receipt form (if any). No charges applied for annual sampling requirement.</li> <li>ZENITH will share Feedback form to operator/applicant to submit audit &amp; auditor.</li> <li>(NOP requirement). The inspection may be delayed for up to six months when application receives in off season or lean period when organic production and handling practices could not be verified and plan audit within 6 month time frame so that the inspector can observe the relevant land, facility, or activities. For example, if the crop application received during the winter, the inspection may be delayed must the spring or summer when the production season is underway.</li> </ul>

		completed and mu receiving certificat	ust be paid in full prior to tion.
6	Inspection report		's operation is inspected, the an inspection report to the eview.
7	Final Certification Review and Certification Decision (initial certification Decision)	that: The applica organic syste The activitie are in compl The applicat in accordance	ed based on the determination ant is in compliance with its em plan and all procedures; es of the applicant's operation liance with the regulations; and nt is able to conduct operations ce with the plan. and Adverse Action will be logue and defined Procedure.
		addition, unit, area,	ddition request (crop/product farmer addition, processing line tion will require additional
		affect the Organic certification must b including changes products, product facilities to be certif immediately self-re violations of the org suspected contamina	y, any additions or changes that System Plan (OSP) during e communicated to ZENITH, to the program of services, formulations, acreage, or ied. Operators are required to eport any infringements or ganic regulations, including any ation or commingling of land, ituations that affect the organic
		There are basically	y three possibilities:
		a) Client fully complies with the standard	Certificate is issued and sent to client with a copy of the on-site inspection report, as approved by ZENITH
		b) Certification with conditions	Certification with conditions, if there are minor, non- violative issues. This will be verified during next renewal application or within the time line stated in certification letter (Minor Issue could be verified in Next Inspection)
		c) Client has non- compliances which need to be corrected. This may include missing documents, or	ZENITH issues Notice of Noncompliance. Certificate is issued once ZENITH has evidence of correction of non- compliances (in some cases, this may involve an

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	more substantial things.	additional/Follow up inspection depending upon severity).
	d) Client could not able to correct Non Compliances within specified time limit	Adverse Action Procedure will be followed, which may Lead to Certification Denial/ Suspension/Revocation (As applicable)
	suspended, or surrer discontinue (tempor certification, it shoul certification. Otherwi Note: A certified certification at any surrendered prior to adverse action, the and the process is cli its certification after adverse action, the and continues the	e valid until being revoked, adered. If an operation wants to rarily or definitely) with NOP d formally "surrender" the NOP se, ZENITH has to "suspend" it. operation may surrender its operation may surrender its of a ZENITH issuing a proposed ZENITH accepts the surrender osed. If an operation surrenders the ZENITH issues a proposed ZENITH accepts the surrender process for adverse action.
	USDA, not by a certifi After a "pro- revocation", arriving at a certifier (wir third party),	posed suspension" or "proposed the client has 30 days for either "settlement agreement" with the th or without mediation from a , or presenting an appeal to the re the suspension or revocation
	any time. The services provided the services provided the services of the serv	an withdraw their application at ney will be liable for the costs of ovided up to the moment of (§ 205.402 c).
		w.ams.usda.gov/sites/default/fi NCandAdvActionFlowChart.pd
	1. ZENITH res	ance / rejection criteria : erves the right to deny request on in following situation:
	<ul> <li>Untime crossed</li> <li>When uncorrect</li> </ul>	Non compliance is
	in following • Timely crossed	Mediation request (Due date

<ul> <li>Annual Update 6 Certification Renewal</li> <li>Annual Update 6 Certification Renewal</li> <li>Submitted by operation. A certified operation must submit an updated OSP and fees to its certifier at least once per year to continue its organic certification.</li> </ul>	<ul> <li>If the operation fails to submit its annual update and/or fees, then ZENITH will issue a Notice of Noncompliance.</li> <li>The annual update only requires to describe changes to the operation; it does not need to reiterate information that was previously submitted.</li> <li>The annual update must include a summary statement outlining any changes to the OSP that were made during the last year, as well as any changes planned for the coming year. ZENITH may ask client for the supporting documentation to verify these changes.</li> <li>Operations must also notify of any ongoing changes that may affect its compliance with the regulations.</li> <li>If an operation plans to add new products, fields, operations, or labels to its OSP, then the ZENITH will first review and approve these changes and may issue an updated certificate after determining satisfactory compliance.</li> <li>A request to add new fields, animal species, or facilities, production line, unique production equipment, animal herd, or animal facility to its certification would require an additional onsite inspection and sampling (as deem fit). Based on satisfactory inspection result and notify decision to client.</li> <li>ZENITH will inspect the operation annually to determine whether its certification should continue irrespective to the failure of an operation fails to submit an annual update prior to the onsite inspection, ZENITH will issue a Notice of Noncompliance.</li> <li>After inspection, certification decision process will be completed based on review of annual update and inspection report. Certification decision will be taken and protect the inspection report. Certification decision to the onsite inspection, the decision to continue certification decision in writing to the operation.</li> <li>As with the initial certification decision, the decision to continue certification may include new conditions for minor, non-violative issues. However, if an operation shows evidence of a repeated minor issue, ZENITH will elevate the violation to a</li></ul>
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Non-Organic Seed/Planting Stock Approval	It is Mandatory to have Non organic seed/Planting stock approval prior to Sowing. (Seed/ Planting stock Assessment, Organic Seed/ Planting stock Searches, Any Test Report {if available} must be Submitted for Evaluation) Per NOP, At least three Organic sources must be contacted prior to using a non-organic Seed or planting stock Per EU, Use of non-organic seeds/propagating material for more than one season at a time shall not be allowed.	su ir cc lc v E A V C C	Derator must submit documentation of each ubstance to be used as a production or handling nput. This should include the input's omposition and source, as well as the ocation(s) where and frequency with which it vill be used. ENITH will forward relevant information to valuator. Upon Analysis Completion, approval will be Confirmed Via Email. Will verify all inputs and ingredients listed in the DSP comply with the regulations. eview all multi-ingredient products before they re sold, labeled, or represented as organic to
Use of Non- organic agricultural ingredients for processed organic food	It is Mandatory to have Non organic agricultural ingredients approval prior to usage (Commercial Availability Search details must be Submitted for Evaluation, Refer OMP, Fill details in Section 3- ORGANIC INTEGRITY ASSURANCE). Applicant need to ensure access to certain agricultural ingredients, and where such ingredients are not available in appropriate form, Quality or in sufficient quantity. <u>NOP Rule:</u> Commercial Availability Search is required annually for non-organic material. <u>Per EU</u> , The authorization may be prolonged for a maximum of two times six months each.	e re ca v P a • re A re b	nsure that the product composition meets the equirements for the proposed labeling ategory. erify the use of any nonorganic ingredients or processing aids to determine that they are llowed. eview all retail product labels for compliance with the labeling requirements. All approvals, restrictions, disapproval (with eason) record of inputs, ingredients, labels will be kept at client file. During the onsite inspection, inspectors will eview a sample of these products to determine
Input Review	<ul> <li>All inputs intend to use require prior approval from ZENITH. See the list of inputs allowed &amp; prohibited to use in organic production and handling operation. The list helps operator to navigate and choose the appropriate input for use. Operators must go through the list of respective standards prior to request for input approval.</li> <li>You may Select the input from the OMRI – Organic Materials Review Institute for easy and Fast approval.</li> <li>NOP:</li> <li>Evaluation criteria for allowed and prohibited substances, methods, and ingredients. (*Operator/ applicant must submit details accordingly for necessary evaluation and approvals)</li> <li>Allowed and prohibited substances, methods, and ingredients in organic production and handling.</li> <li>Materials for Organic Crop Production</li> <li>COR :</li> <li>Organic Production Systems: Permitted substances lists (CAN/CGSB-32.311 - 2020)</li> <li>https://www.omri.org/sites/default/files/app materials/23CanStanMan-amended-June-2023.pdf</li> <li>EU :</li> </ul>	• N (2 to re p o y No any ZE per	ompliance. Note: An operation should consult its certifier ZENITH) prior to using any new input in order o ensure that the material complies with the egulations. The use of an unapproved material nay be considered an application of a prohibited substance, which would remove the operation's land from certification for three ears of that : Client can submit request for input at y time (i.e. During audit, in mid of the year), NITH will accept the request and evaluate input r standard requirement and approval status will intimated to client accordingly.

	<ul> <li>List of Authorized Substances</li> <li>Additional List, Amending to above list of Authorized Substance</li> <li>Note that All liquid fertilizers with a nitrogen analysis greater than 3% must be approved by ZENITH to be used in organic production.(NOP requirement)</li> </ul>	
	• <u>Micronutrient approval :</u> You must submit documentation in the form of a soil test, plant tissue test (from current crops), use of test strips, documentation of regional deficiency (research material or publications noting an area wide micronutrient deficiency), documentation from an agronomist or crop advisor that explains why the micronutrient use is needed.	
	• This documentation must be specific to the fields in which the micronutrient input is intended for use and be from within three years of the intended use date of the micronutrient product. If you intend to continue using the micronutrient input, they must re-submit documentation demonstrating the deficiency every three years.	
	Inert Ingredients : § 205.1 (Definitions): "Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m))." § 205.601 "Synthetic substances allowed for use in organic crop production (m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) (1) EPA List 4 - Inerts of Minimal Concern The official NOP guideline regarding inert ingredients, as communicated during numerous certifier trainings, is as follows:	
	<ul> <li>Inert ingredients others than those from List 4 are considered "non allowed substances". NOP does not make a distinction between active and inert ingredients in this regard.</li> <li>Land on which an non allowed inert ingredient has been applied, has to undergo a new three years conversion period.</li> <li>"If (an) operation used a material and full disclosure of ingredients is not obtained: in that situation, then operation must stop using the material, and the use of the material does not affect their certification."</li> </ul>	
	Information Disclosure:	

	<ul> <li>Operators requesting NOP/EU/COR certification are always informed at a very early stage about the importance of:</li> <li>Providing full information about inert ingredients contained in pesticides used in organic farming. The producer of the plant protection product must provide such information.</li> <li>Using only plant protection products, for which the inert ingredients are known and allowed, according to what is described above.</li> <li>Operators are required to include all relevant details about pesticides in their organic management plan (OMP), before the first inspection takes place. Operators are obliged to inform ZENITH beforehand, before using a new product. Using crop protection products without having submitted them previously to the certifier for approval, is a non-compliance (even in case the product as such turns out to be compliant).</li> <li>If you fails to mention a pesticide in the OMP or annual OMP update, but the pesticide, including its inerts, turns out to be compliant, this will be considered as a minor non-compliance. Repetition of the same minor non-compliance. In such cases, the crop may be decertified.</li> </ul>	
Product Addition in Mid of the Certification Cycle	Request for product addition, Per mentioned cases: Case-1 If the new products apply with the similar process, and the concern process was earlier approved during certification. Operator need to request product addition Followed by submission of Supplier List, Organic Product and Supplier Scope Certificate Case-2: If the new products apply with the different process, which was not approved during certification. Operator need to request product addition Followed by submission of Supplier List, Organic Product, Process Flow Chart and Supplier Scope Certificate (Note that Label must be approved, prior to usage, usage of unapproved labels may lead to Noncompliance).	For the product addition, Further proceedings will be done as per below mentioned Cases: <b>Case-1:</b> If the new products apply with the similar process, and the concern process was earlier approved during certification. Zenith will add products after verifying Supplier list, Organic Product list and Supplier Scope Certificate. <b>Case-2:</b> If operator apply for new products with different process, which was not approved during certification. Zenith will review the OMP Addendums (Supplier list, Organic Product list, Process Flow Chart and Supplier Scope Certificate) and then conduct onsite inspection for verification of new process. After the applicant's operation is inspected, the inspector forwards an inspection report to the ZENITH office for review. Final Product Addition Review and Decision will be done as per point 7 (Final Certification Review and Certification Decision).

Supply Chain Traceability and Fraud Prevention:	<ul> <li>Requires all certified operations to develop and implement improved recordkeeping and organic fraud prevention processes and procedures as applicable.</li> <li>Records must fully disclose all activities and transactions of the certified operation, in sufficient detail as to be readily understood and audited; records must span the time of purchase or acquisition, through production, to sale or transport and be traceable back to the last certified operation.</li> <li>External audit trail documentation must identify organic products as "100% organic," or "made with organic (specified ingredients or food group(s))," as appropriate.</li> <li>Operations may use abbreviations or acronyms to identify products, provided that the abbreviations or acronyms are easily understood. This information will clearly identify organic products, reduce the mishandling of organic products, and support traceability. ZENITH will conduct risk-based supply chain traceability audits between certifiers.</li> <li>Organic system plans must include verification practices for organic ingredients and all suppliers in the supply chain and describe how product is traced back clearly and completely to the last certified operation.</li> <li>The OSP must describe measures implemented to prevent fraud (i.e. fraud prevention plan). Such plans should include:</li> <li>A map or inventory of the operation's supply chain that identifies suppliers;</li> <li>Identification of critical control points in the supply chain where organic fraud or loss of organic status are most likely to occur;</li> <li>A vulnerability assessment to identify weaknesses in the operation's practices and supply chain;</li> <li>Practices for verifying the organic status of any product they acquire and/or use;</li> <li>A process to verify suppliers and minimize supplier risk to organic integrity;</li> <li>Mitigation measures to correct vulnerabilities and minimize risks;</li> <li>Monitoring practices and verification tools</li></ul>
Precautionary measures to avoid the presence of non- authorized products and substances	<ul> <li>Where an operator suspects, due to the presence of a product or substance that is not authorized for use in organic production in a product that is intended to be used or marketed as an organic or inconversion product, that the latter product does not comply with the Regulation, the operator shall: <ul> <li>(a) Identify and separate the product concerned;</li> <li>(b) Check whether the suspicion can be substantiated (where the suspicion of non-compliance concerns an incoming organic or in-conversion product, the operator shall check whether: i) the information on the label of the organic or in-conversion product and the information on the supplier relates to the product actually purchased; where there is a suspicion that the cause of the presence of the non-authorized products or substances lies under the control of the operator, the operator shall examine any possible cause for the presence of non-authorized products or substances lies under the product and not use it in organic product on the market as an organic or in-conversion product, and not use it in organic production unless the suspicion can be eliminated;</li> </ul> </li> <li>(d) Where the suspicion has been substantiated or where it cannot be eliminated, immediately inform the relevant control body, and provide it with available elements, <i>like :</i></li> </ul>

<ul> <li>information and documents about the supplier (delivery note, invoice, certificate of the supplier, Certificate of Inspection for organic products (COI));</li> <li>the traceability of the product with the lot identification, stock quantity, and quantity of product sold;</li> <li>laboratory results, from accredited laboratory when relevant and available;</li> <li>the sampling sheet detailing the time, place and method used to take the sample;</li> </ul>
<ul> <li>any information about any previous suspicion with regard to the specific non-authorised product or substance;</li> <li>every other relevant document to clarify the case);</li> </ul>
(e) Fully cooperate with the relevant control body, in identifying and verifying the reasons for the presence of non-authorized products or substances

# In case of positive detection or any suspected cases, Operator need to conduct investigation of same and submit results to ZENITH (NOP, EU, COR)

#### **Changes Affecting Certification:**

- 1. Certified operations shall immediately notify ZENITH in the event of emergency pest outbreak, a prohibited substance (including drift) has been applied to any field, production unit, site, facility or product that is part of the operation, as well as changes to an operation including but not limited to: new field, facility, production line, unique production equipment, animal herd, or animal facility to its certification, then the certifier will conduct an additional inspection before issuing an updated certificate. If the operation sells, labels, or represents products from fields or facilities that have not been inspected and that are not included on the certificate, then the operation is in violation of 7 CFR § 205.100(a). Similarly, any new retail labels developed for the operation's organic products must be approved by the certifier before being used. An operation should consult its certifier prior to using any new input in order to The certifier will determine whether and when documentation is required on a case by case basis. ZENITH will take appropriate steps to verify continued compliance with all applicable regulations and standards, including re-inspection when the change may affect the integrity of organic product, or as ZENITH deems necessary to confirm compliance. The certified operation shall not release certified products resulting from such changes until notified accordingly
- 2. In the event of changes significantly affecting a product's specification or changes in the standards to which compliance of the product is certified, or changes in the ownership, structure or management of the supplier, if relevant, or in the case of any other information indicating that the product may no longer comply with the requirements of the certification system, the scope of certification may be amended accordingly
- 3. If the operation sells, labels, or represents products from fields or facilities that have not been inspected and that are not included on the certificate, then the operation is in violation of standards

#### 4. Some examples of situations that would require operator to notification to the certifier (ZENITH) include following:

- a) Application of a prohibited substance to any field, production unit, product or site involved in organic production or handling, regardless of whether it was a direct application or drift from a neighboring area, and regardless of whether or not it was intentional. The operation must notify the certifier immediately of any such events;
- b) Damage to the site, e.g., damage by fire or natural disaster such as a flood
- c) Addition of acreage, a new field, product line, production facility, animal herd, or animal facility, new input or change in approved input formulation, change of input/ingredient/sub ingredient supplier (Approved earlier), new post harvest handling activity, new subcontracted activity (Note that in case operation subcontracted any of its activity, it must be certified by CB), to organic production;
- d) Change of legal entity, change of ownership, change or physical / mailing address
- e) Removal of a field or portion thereof from organic production;
- f) Removal/ sanction of group member from the group, Addition of group member, Major non-compliance identified by ICS affecting certification and affect the compliance with regulation
- g) Development of a new retail label for the operation's organic products, new label, change in label;
- h) New processing or handling of organic products, process or facility not already specified in the OSP; and
- i) Any change in the operation's practice, input, or procedure that may affect compliance with the regulations.

- 5. The operation must notify changes in writing. The notifications relevant to changes will be placed in client file, the concerned certification specialist will be notified of change notification received, so that the information may be reviewed and verified as part of the annual certification process, If necessary, ZENITH may require the operation to submit additional documentation at the time of notification. ZENITH will determine whether the documentation required at the time of review or during inspection. Operator will be notified for same.
- 6. Certification and certificates issued to certified Operations are not transferable to new owners in cases of mergers, acquisitions, or other transfers of ownership of the certified Operation. When there is a change in ownership of a certified Operation, the certified Operation must apply for and receive new certification from a ZENITH prior to selling, labeling, or representing products as organic. (EU requirement : In case Previous CB does not transmit the information as required by ZENITH or in case of doubts concerning the information transmitted, ZENITH will not issue certificate until the elimination of doubts, by means of verification)
- 7. ZENITH reserves the right to conduct special inspections (Additional audit, unannounced audit, follow up audit, additional monitoring audit and sampling as required in standard and certification procedure) during the course of the certification period, and as needed in response to changes/incidents. Where such changes may affect the conformity of the product(s) and/or the Operation's OSP, ZENITH as appropriate determines whether the announced changes require further investigation and schedules a special inspection as necessary.
- 8. The Supplier must not promote products, processes, and/or facilities/sites which have not been covered in the scope of certification as inspected and approved by ZENITH. Unauthorized promotion will result in the withdrawal of the Certificate.
- 9. Where Operation fails to notify ZENITH of any of the above changes, ZENITH may accordingly suspend or withdraw, as deemed appropriate, the Certificate and reserves the right to retroactively invalidate the Certificate effective as of the date the change occurred.

Additionally for any new addition request during audit, Inspector can collect request details with accompanying docs. A request to add new fields, input, animal species, or facilities etc would require an additional onsite inspection.

Note: A certified operation may surrender its certification at any time. When certification is surrendered prior to a certifier issuing a proposed adverse action, the certifier accepts the surrender and the process is closed. If an operation surrenders its certification after the certifier issues a proposed adverse action, the certifier accepts the surrender and continues the process for adverse action.

<u>**Requirement of Translator for Auditing:**</u> Will be required in case of the particular language barrier (other than english, hindi and known language). Ask ZENITH for translator/ Interpreter policy. The translator will be hired based on translator/ Interpreter policy.

ZENTH may hire translator independently by own or will notify operator for its requirement. ZENITH will have sole decision to approve or reject the identified translator by operator with reason (in case of rejection). Strict confidentiality and impartiality will be adhered throughout the process.

In the event of lack of essential communication (challenging situation) established (for any reason including medical issue by translator) for translation desired activity, ZENITH auditor will immediately report to ZENITH office and may abort the inspection there, notify abort this action to operator and ZENITH both with reason of audit abort, same to be reported in Exit Interview & inspection report for unsuccessful audit with reason. ZENITH will review the information and take appropriate action (disciplinary action) for translator and may execute next inspection with qualified translator. As a disciplinary action, ZENITH wont be approving concern translator is Future

Always ensure availability of Translator in good position to assist in scheduled inspection. An alternate qualified translator/interpreter will be arranged when circumstance requires for the same in sufficient time, else opt for aborting audit / cancelling audit and reschedule audit (additionally full audit) when appropriate measure or arrangements are ensured in place.

#### U.S. produced organic agricultural products outside the scope of the USCOEA:

- 1. Agricultural products produced with the use of sodium nitrate shall not be sold or marketed as organic in Canada
- 2. Agricultural products produced by hydroponic or aeroponic production methods shall not be sold or marketed as organic in Canada
- 3. Agricultural products derived from animals must be produced according to livestock stocking rates as set out in the most recent version of CAN/CGSB-32.310

#### US-Canada Organic Equivalence Arrangement (US-COEA) -FAQ

United States-Canada Organic Equivalence Arrangement (USCOEA) – Overview

See below link for all USDA NOP Trade Partners, export import requirements to be followed by operators: International Trade Partners | Agricultural Marketing Service (usda.gov)

Please be noted that, The Applicant will be responsible for the cost of follow-up inspections that are necessary to verify compliance. Random unannounced inspections may also be conducted to verify continued compliance with the regulations.

#### Frequency of annual inspection:

- NOP/COR Operations: At least once every calendar year (January to December)
- For EU Operations: At least once every calendar year from (January to December)
- Every year following types of inspection will be selected either randomly or selected based on results of the potential risk to organic integrity, and for other reasons deemed necessary.,
  - a minimum of 5% of ZENITH's operators (UA/AA/Sampling) in the NOP program ,
  - minimum of 5% of ZENITH's operators (UA/Sampling) in the COR program,
  - minimum of 5% of ZENITH's operators (Sampling) in the EU program (additional 5% sampling will be drawn from the positive detection cases)
  - Additional Inspection- 10% of the Annual inspection. ; Unannounced Inspection- 10% of (Announced+ Unannounced) Total Inspection {EU programme}
  - For the high-risk products referred to in EU, ZENITH shall carry out, at least, two physical on-the-spot inspections per year of operators or groups of operators. One of these physical on-the-spot inspections shall be without prior notice.

#### For NOP: In case of emergency situations, such as:

- 1. Natural disasters declared by the Secretary or declared by local government authorities;
- 2. Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption

The annual inspection can be delayed, and certification can be extended up to 6 months based on records submitted by operator/desk audit (only after the operator has applied for re-evaluation and paid the fee). Written notice is required from the concerned party, or it may be provided by telephone or email in urgent situations. For EU: Annual inspection cannot be delayed unless otherwise directed by the EU commission.

#### Transaction Certificate Checkpoints:

\*Please be aware that Operations outside the European Union, after issuing the certificate, have to obtain a transaction certificate (also called "certificate of inspection") for each shipment of organic products to the EU organic market. And For NOP, in case material is Export to US, it is mandatory to obtain <u>Import Certificate</u> This is issued by ZENITH. COI/ TC must be requested prior to shipment leaves the country. Failure to meet this requirement leads to non compliance. For COR, Refer <u>Canada Organic Regime Import Requirements.</u>

Along with requirements mentioned in guidelines, additional instructions/ memo to be followed for necessary implementation.

You may request NOP, COR & EU standard by writing email to ZENITH at <u>info@zenithcertifications.com</u> or may also find standard by following Link:

#### Regulatory References: NOP, EU & COR regulation can be referred and downloaded from the below link:

• <u>USDA organic regulations.</u> 7 CFR Part205 includes all USDA organic standards, including prohibited practices, requirements & the NOP <u>National List of Allowed and Prohibited Substances</u>.

- **NOP** <u>Program Handbook</u>. This compilation of guidance documents, policy memos, and instructions is intended to clarify policies and assist those who own, manage, or certify organic operations with complying with NOP regulations.
- EU Regulation 848/2018:
  - o <u>EU Regulation secondary acts cover organic production and labelling of organic products.</u>
  - o FAQ regarding the provisions of Regulation (EU) No 2018/848 and its secondary legislation.

#### • (Category includes for certification: A,D,E,G)

For COR Programme: Canadian Organic Standards. This includes:

- Organic Production Systems: General Principles and Management Standards (CAN/CGSB-32.310 2020). These are the National Standards of Canada which establish the production practices that must be followed by operators.
- Organic Production Systems: Permitted substances lists (CAN/CGSB-32.311 2020), This list identifies materials that may be used in the production of organic products under COR.
- <u>Canada Organic Regime operating manual</u>
- Offer Scope or category for certification includes: Crop Production Livestock Production, Plant & Animal Food Processing, Trading, Group Certification, Specialized Production).

#### Terms and conditions of certification

#### The parties must agree to the terms and conditions as follows:

- 1. Signing the Contract does not constitute certification by the ZENITH. Certification by the ZENITH is deemed granted when a scope of certification is issued by ZENITH
- 2. Must Provide complete and accurate information on organic system or management plan and other application materials representing my/our operation.
- 3. Comply with the Organic Production Rules and Regulation of (EU) 2018/848 and COR (Canadian Organic Regulation) including implementing appropriate changes whenever they are communicated by the ZENITH, Import Export trade arrangement requirements of respective regulatory requirements.
- 4. Provide description of the organic and/or in-conversion production unit and, where relevant, of the non-organic production units and of the activities to be performed in accordance with Regulation requested for certification.
- 5. Take the relevant measures to be taken at the level of the organic and/or in-conversion unit and/or premises and/or activities to ensure compliance with Regulation requested for certification
- 6. Take the precautionary measures to be taken in order to reduce the risk of contamination by non-authorised products or substances and the cleaning measures to be taken throughout the stages of production, preparation and distribution;
- 7. Confirm not being certified by another certification body in relation to activities carried out in the same third country regarding the same category of products, including in cases in which operators or groups of operators operate at different stages of production, preparation or distribution. Notify in application of any dual certification activities, failure to notify leads to appropriate Disciplinary and Adverse action
- 8. Confirm that members of a grower group are not certified on an individual basis for the same activity for a given product covered by the certification of the group of operators to which they belong;

- 9. Recognize that official language of doing business with ZENITH is English and submit all required documentation and communication in English. Some exceptions may apply where ZENITH accepts Operators submission in another language appropriate annotations in English provided for relevant parts.
- 10. Establish, implement, and update annually an organic production or handling system plan;
- 11. Submit the applicable fees charged by the ZENITH
- 12. Represent products as being "Certified by ZENITH" only when those products are listed on a current certificate issued by ZENITH.
  - a. Any use of the ZENITH name, logo, or certification mark, in communication media such as documents, brochures or advertising or anywhere else without current certification by ZENITH and written permission from ZENITH, is strictly prohibited and constitutes an infringement of the ZENITH trademark.
  - b. Should not use product certification in such a manner as to bring the ZENITH into disrepute and does not make any statement regarding its product certification that the ZENITH may consider misleading or unauthorized;
  - c. Upon surrender, suspension, withdrawn or revocation of certification, discontinue use of any labels or advertising materials that contain any reference to certification by ZENITH and return or destroy all certificates and packaging material containing references to ZENITH. Operator or Group of operators shall inform in writing the buyers of the product in order to ensure that the indications referring to the organic production method are removed from this production.
- 13. Reproduce ZENITH certification documents (such as certificates, Certificate of Inspection) in their entirety while providing to any other interested parties. The product certification will not be used in a manner as to bring ZENITH into disrepute.
- 14. Inform ZENITH in the event of certification with another agency for any other category or products, or if subcontractors are certified by another agency. Information and data related to activities of this operation may be shared with other certification agencies and government authorities as and when required.
- 15. Operator or Group or operators shall hereby give consent to:
  - i. Allow authorized representatives of ZENITH Certification Pvt Ltd (shortly named "ZENITH"), the officials of Accreditation Body, Regulatory body or other applicable government official (as applicable to certification request under standard or regulation) to observe the inspections and access to such records during normal business hours for review and copying to determine compliance with the regulations; and have an authorized representative knowledgeable about the operation present during the inspection;
  - ii. Permit on-site inspections and make necessary arrangements for evaluation with complete access to the production or handling operation, including noncertified production and handling areas, structures, accounts and relevant supporting documents, offices and subcontractors; as well as additional inspections, which may be announced or unannounced, additional monitoring control visit or as a part of complaint investigations as per the standard's requirements.
  - iii. Provide the control authority or control body with any information necessary for the purposes of the controls
  - iv. Inform immediately the control authority or control body in the event of withdrawal from organic production

- v. Accept the enforcement of the corrective measures established by ZENITH in the event of non-compliances, infringement or irregularities, complaints, residue analysis.
- vi. Investigate and keep record of all complaints (including INTC and relevant authroity) relating to compliance with certification requirements and make these records available to ZENITH when requested, and Take appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification and Document the actions taken.
- vii. Immediately notify the ZENITH concerning any:
  - a. Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and
  - b. Change in a certified operation or any portion of a certified operation that may affect its compliance with the regulations.
  - c. In the event of withdrawal from organic production.
- viii. Confirm that the EU certification is not withdrawn by previous certification body in last 2 years.
- ix. Submit, when requested by the control authority or control body, the results of its own quality assurance programmes
- x. Inform buyers of the products in writing and without undue delay, and to exchange relevant information with the control body, in the event that a suspicion of non-compliance has been substantiated, that a suspicion of non-compliance cannot be eliminated, or that non-compliance that affects the integrity of the products in question has been established
- xi. Allow the release of information as required by law or the applicable standard for which certification is granted. This includes the name of the operation, contact information, type(s) of operation, products produced, and the effective date of the certification.
- xii. Accept the transfer of the control file in case of a change of control authority or control body or, in the case of withdrawal from organic production, the keeping of the control file for 5 years by the last control authority or control body
- xiii. In the event that the subcontractors of the operators or of groups of operators are subject to controls by another certification body, to accept the exchange of information among those certification bodies.
- xiv. Consent to the use of subcontractors working under the direction and authority of ZENITH;
- xv. In the event that the subcontractors of the operators or of groups of operators are subject to controls by different control authorities or control bodies, to accept the exchange of information among those control authorities or control bodies
- xvi. When required for export purposes and transfer of certification, Accept transmission of control files to other control body and vice versa including :
  - a) The status and validity of certification, including cases of scope reduction, suspension and withdrawal as referred to in regulation and certification requirement
  - b) Reports of inspection carried out in the preceding 3 years
  - c) The list of non-compliances and the measures put in place to address them, and the fact that all noncompliances were addressed

- d) Derogations granted or requests for derogation being processed by the previous control authority or control body
- e) Information relating to any ongoing dispute relevant for the certification of the operators or groups of operators.
- f) Any other element that may be considered relevant.
- xvii. Hereby agrees, If the previous control body does not transmit the information as required in respective Regulation to ZENITH or in case of doubts concerning the information transmitted, ZENITH shall not issue the certificate to operators or groups of operators until the doubts has been eliminated by other means of ZENITH control system.
- xviii. To perform the activities in accordance with the organic production rules and maintain all records applicable to the organic operation (including in-conversion) for not less than 5 years beyond their creation;
- xix. Allow authorized representatives of ZENITH to take samples of plants, soil, crops, or other substances for testing to be used in the assessment of compliance to certification standards;
- xx. Comply with all requirements and/or conditions levied by ZENITH as a result of its review of our application file and associated documents including inspection information.

#### Rights of Operator: ZENITH shall,

- 1. Share the latest version of applicable Organic Standard, Licensing & Labeling Guide with operator.
- 2. Share the copy of Complaint Handling Procedure and Appeal Procedure with operator.
- 3. Inform applicable fee to operator.
- 4. Update operator regularly about the changes in the standards and new standards.
- 5. Share application procedure and renewal procedure with the operator.
- 6. Inform operator about required documents to be maintained depending on the risk assessment and type of operation of operator.

#### Duties of the ZENITH: ZENITH shall,

- Inform operator or applicant about regulation, changes to the regulation and certification requirements and of any substantial changes to the certification procedures through website, email circulation followed by advisories or instructions. Clarification on regulatory/ standard requirement may be explained through any means : virtual meetings, Email, Telephonic response as deem fit and necessary upon requested by operator
- 2. Permit the operator a reasonable period, being not less than three (3) months, unless otherwise determined by the scheme owner or regulatory body or authority, to implement any changes arising from updates to the applicable regulatory requirements and/or procedures that come into force during the period of this certification Agreement or Contract.
- 3. Conduct initial review, inspection, monitoring, sampling for residue and desired contamination analysis, complaint investigation and certification procedure for operator/ Applicant against accreditation certification scheme or programme requirements requested for certification.

- 4. Issue inspection report including observations with all non-compliances, requirements, additional information, analysis report found during the office evaluation and field inspection to operator or applicant and which require corrective action from operator.
- 5. Evaluate and respond to corrective actions which the operator takes and update and finalize the certification decision as necessary. When all necessary requirements are met, grant certification or proceed with adverse action as deemed fit to the applicable standard/ regulation and certification procedure.
- 6. Supply invoices to the operator for applicable fees due.
- 7. Respond to any request for appeal or complaints in accordance with the requirements of the ZENITH policy and Procedure.

#### Confidentiality:

- 8. During the contract period or after contract period any of the party, the operator and ZENITH will keep all the commercial and business information, circumstances, data and events of the other parties, Information obtained from sources other than the client (e.g. from the complainant or from regulators) are strictly confidential. This commitment covers all the staff and other persons of the parties concerned.
- 9. The followings are exempted from this :
  - a. Information to competent authorities in accordance with the regulations and standards to which ZENITH is accredited.
  - b. The Exchange of information (e.g. for the purpose of responding to complaints, control files) with any certification/inspection body, as required by applicable standards.
  - c. Release of the information to third parties on special request of the applicable accreditation body.
  - d. Information pertaining to the Listing of operators name, address and relevant certification status of the applicable regulation to be listed in public.

#### Force Majeure & Economic hinderences: Operator must agrees that;

- 1. ZENITH shall not be responsible or liable under any circumstances or events for any failure or delay in the performance of its obligations hereunder arising out of or caused by, directly or indirectly, forces beyond its control, including, without limitation, strikes, accidents, acts of war or terrorism, civil or military disturbances, natural catastrophes or acts of God, and interruptions, loss or malfunctions of system, communications services.
- 2. Reasonably unforeseeable changes to applicable regulations shall be considered a "force majeure" event for purposes of inspection & certification procedure, such as the imposition of adverse actions, non compliances, sanctions or export control restrictions that render performance economically impracticable.
- 3. Operator shall use all reasonable efforts which are consistent & appropriate practices to resume performance as soon as practicable under the circumstances and notify ZENITH for further certification process. ZENITH will review the details and may take appropriate decision under derogation or cancel or terminate certification contract as deem fit.

4. ZENITH shall not be liable for any loss of profit, use, revenues, business, goodwill or anticipated savings (whether direct or indirect), loss of or corruption to data, or any indirect, consequential or special damages, loss, costs, claims or expenses howsoever arising

#### Disputes & Arbitration

- 1. Any dispute between any of the ZENITH and operator, other affected parties if not resolved mutually, such disputes will be considered, investigated, and resolved as per ZENITH Procedures.
- 2. All legal disputes are subject to Lucknow Jurisdiction only.

#### Changes in applicable standards

Any changes in applicable standards are binding to all the parties.