

Submission Completeness Checklist for Research Authorizations

Documentation Required for all Research Trials – RN, RS, and RE (Categories A, B and C)	
<input type="checkbox"/>	A completed Application for Research Authorization CFIA/ACIA 5475 form.
<input type="checkbox"/>	Information as required in T-4-95: Signing authority, delegated representatives and Canadian agents , or written indication that information is unchanged from previously provided documentation.
<input type="checkbox"/>	A copy of the proposed research label (see T-4-103: Guidelines for research authorizations for testing of novel supplements , section 6b) for information that is mandatory on research labels).
<input type="checkbox"/>	Trial Maps, within 21 days of trial establishment
Additional Documentation Required for RN, and RS (Categories A and B)	
<input type="checkbox"/>	Description of trial design and the treatment regime for the trials. This should include specific details on the rates and method of application of the novel supplement.
<input type="checkbox"/>	Constituent materials: identification and description of <u>all</u> materials used in the production of the end-product, the source and proportion of these materials (include all extenders, carriers, etc.).
<input type="checkbox"/>	SDS for ingredients and/or final product, including precautions and protective measures.
<input type="checkbox"/>	For microorganisms: provide the purpose of the microbial strain; taxonomic identification of the microorganism to the genus and species level, subspecies, and strain; methodology used to identify all microorganisms found in the final product; relationship to known pathogens; and the origin/source from which they were obtained (environmental isolate or strain bank accession numbers, if the strain has been deposited in a recognized culture collection).
<input type="checkbox"/>	Method of manufacture and quality control procedures in place to ensure consistency in production and freedom of the final product from contaminants at levels which may be harmful to human health, plant health or the environment.
<input type="checkbox"/>	Detailed method(s) of crop disposal to be implemented following the trial period. As per T-4-103, crop destruction waivers are administered outside of the research authorization process and will not be accelerated to meet service delivery timelines associated with research applications.
Additional Documentation Required for RS (Category B)	
<input type="checkbox"/>	<p>Rationale for product safety: identify potential risks the supplement may pose towards human health and the environment, supported by data or literature.</p> <p>Hazard Characterization: Human, Terrestrial plants/crops, and Non-target species. Please refer to T-4-103 for more information.</p> <p>Exposure Characterization: Product use pattern, Natural occurrence, Description of life cycle, and Physiological properties. Please refer to T-4- 103 for more information.</p> <p>For additional guidance, please see Tab 5 of the Guide to Submitting Applications for Registration.</p>
<input type="checkbox"/>	Monitoring Plan and Procedure: A monitoring plan of the spread and establishment of the supplement in the environment throughout the duration of the trial must be provided.
<input type="checkbox"/>	Confinement Procedures: This includes but are not limited to descriptions of the packaging of the supplement during shipment and storage, timing and application methods, implementation of buffer zones (if required), research area entry restrictions, equipment cleanup and sterilization, etc.
<input type="checkbox"/>	Contingency Plan: This includes a detailed description of cleanup and disposal procedures in cases of accidental spill or release of the product, treated plant material or growing medium contaminated with the supplement
The Fertilizer Safety Section reserves the right to require additional information, data, rationale or results of analysis to support the issuance of a research authorization for any novel supplement as regulated under the <i>Fertilizers Act and Regulations</i> .	