

# 10 STEPS to Ensure a Seamless Regulatory Process



**Richard Shaw**  
AgriThORITY® Product Development  
Manager and Regulatory Expert

## STEP ONE

**Establish a coherent strategy.** Strategy is a must for any product but especially biologicals, specifically microbials (in the field of fertilization), or microbial plant protection products. Commitments of time and costs also impact the choice of the “appropriate” regulatory pathway. Recognize that regulatory strategies will change across geographies, so when a product is planned globally, it is advantageous to devise a global strategy from the start, as **strategy in the first country may affect others.**

**Do a deep study** into the stakeholder expectations, classification of the technology product(s) and the stage of development. That’s essential to fit into the appropriate regulatory framework.

## STEP TWO

## STEP THREE

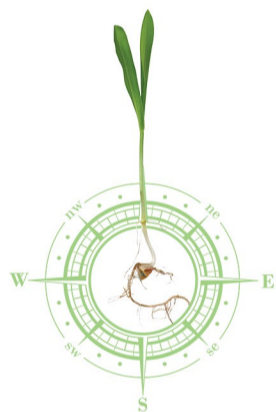
**Classify the product** (fertilizer, inoculant or plant protection product). Correctly classifying goods with all the necessary papers can avoid delays in clearing goods through customs and incurring additional duties or penalties. In the case of Europe, consider the registration and harmonization of the process is different in EU countries. The complexity and variability of the process depends upon whether you work through a harmonized regulatory framework (which would be the case for a plant protection product), or through a partially harmonized regulatory framework (which would be the case for a fertilizer product).

**Determine the first country of origin and target countries.** The process may require one country to license and then the product dossier be sent to other countries. Occasionally, special studies are required for additional registrations.

## STEP FOUR

## STEP FIVE

**Determine time and cost range.** Time and cost can’t be fully defined at the beginning, but a “range” will be more accurate as the product advances in the development phase. Consider conservative timeframes (theoretical vs. practical) and establish a solid data package according to the claims on the label of your product. Importing agricultural products into the U.S. for evaluation or sales can require as many as a dozen documents to assure compliance with regulations of four or more regulatory agencies.



**Prepare and submit import documents.** In some cases, additional approval is required by every state in which the product is intended for testing. Complete preparation, submission and approval of necessary import documents usually requires a minimum of 8 weeks. The most common enforcement action reported on EPA’s website is failure to file the necessary paperwork for importation prior to arrival at the port of entry. Filing documents after the shipment arrives may not be viewed as a serious violation, but this can result in extreme fines, especially if the agency investigates and

## STEP SIX

## STEP SEVEN

**Define product composition.** Products to be imported must be defined in specific detail. In most countries, chemical pesticides must declare the active ingredients as well as every other ingredient in the formulation. In the U.S., this is required by the EPA. Microbial pesticides must identify all ingredients and microbes must be identified by strain as well as genus and species. Purity of culture and absence of potential plant or animal pathogens must also be documented.

**Define Intended use:** To legally import a microbial pesticide into the US, it is necessary to obtain an import permit from USDA as well as EPA approval prior to arrival at customs. Both agencies must approve the intended experimental plan including trial locations, responsible researchers at each location, area to be treated and total area to be treated. Modifications in plans require submission of an amended experimental plan to each agency for approval before proceeding. Microbial pesticide trials with imported products also require review and approval by every state in which you plan to test. Chemical pesticides for evaluation only require approval of the testing plan by EPA. finds multiple instances of the same violation.

## STEP EIGHT

## STEP NINE

**Complete Labeling Requirements.** Experimental pesticides for import must bear labeling compliant with defined EPA standards. Labels must be reviewed and approved by EPA before shipment arrives at the port of entry. Labels on containers at time of customs inspection must be identical to labels previously approved by EPA. Even those agricultural products that do not require EPA registration, such as fertilizers, many inoculants, soil amendments and 25B exempt products are required to bear labels compliant with EPA and/or state regulations. Many US states do not require registration of inoculants, but most want to review the labeling before sales occur in their state.

**Set up Production and Packaging by EPA Establishment:** Products imported for testing as a pesticide or Plant Growth Regulator (chemical or biological) must be produced and packaged in an EPA approved establishment. The EPA establishment number must appear on the label submitted to EPA. To obtain an EPA establishment number, if the manufacturer does not already have one, adds at least two weeks to the importation timeline.

## STEP TEN

**Add AgriThORITY® to your team for technical depth and business breadth. Trust our native guides to fuel your growth into uncharted territory.**

Join in our conversation on business, market and product development insights. Contact Richard Shaw at 1-888-891-0511, or at [Richard.Shaw@AgriThORITY.com](mailto:Richard.Shaw@AgriThORITY.com)