



Factors for IR-4 Public Interest Finding

February 21, 2013

Under the Pesticide Registration Improvement Extension Act (PRIA 3) (FIFRA Section 33(b)(7)(E)), the Administrator shall exempt an application from the registration service fee if the Administrator determines that the application meets both of the following criteria:

- (i) the application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR-4) as described in Section 2 of Public Law 89-106 (7 U.S.C. 450i(e)), and
- (ii) the exemption is in the public interest.

An application will be presumed to be in the public interest if it is for a biopesticide or if the following criteria are met:

1. The data submitted have been developed by IR-4; and
2. The active ingredient, for which the data are developed, must have been already registered for use on a food commodity; and
3. The active ingredient/crop combination has been pre-screened by EPA prior to the Food Use Workshop, and EPA has discussed any risk concerns that might hinder registration or the establishment of tolerances with IR-4; and
4. The use is for:
 - 4.1 a minor crop ($\leq 300,000$ acres), or
 - 4.2 a major crop that is a representative commodity for a crop group/subgroup that is being submitted to establish tolerances for the minor uses in the crop group/subgroup, and where the accompanying label amendment adds at least one new minor use from that crop group to the label; or
 - 4.3 control of a niche pest on a major crop (where the most likely # of acres treated is $\leq 300,000$ acres at the time the application is submitted), or
 - 4.4 control of a public health pest on the List of Pests of Significant Public Health Importance [http://www.epa.gov/PR_Notices/pr2002-1.pdf], or
 - 4.5 control of a pest identified as critical by the Federal government National Plant Disease Recovery System (NPDRS) as called for in Homeland Security Presidential Directive # 9 (HSPD-9)
<http://www.ars.usda.gov/Research/docs.htm?docid=14271>, or

- 4.6 control of a pest identified as critical by the USDA OPMP or APHIS Plant Protection and Quarantine (PPQ) Program Pests
http://www.aphis.usda.gov/plant_health/plant_pest_info/index.shtml, or
- 4.7 pesticide/crop combination associated with a Section 18 and there likely is insufficient economic incentive for the registrant to generate the data.

For other actions that do not meet the above criteria, EPA will determine if a fee exemption is warranted on a case-by-case basis using a weight-of-evidence approach considering the following factors:

- insufficient economic incentive for the registrant to support the use for which IR-4 is generating the data;
- pesticide provides a new mode of action for the proposed use;
- pesticide plays a significant role in integrated pest management program – pesticide has characteristics that other registered alternatives do not have [including but not limited to the following: pesticide provides an entirely new method of control, or more effectively targets critical pest life stages, or avoids use of prophylactic treatments, or is easier on beneficial insects, or allows for different timing intervals or novel placement where pests are found and is compatible with other IPM methods];
- insufficient efficacious alternatives;
- reduced risk compared to existing alternatives for the proposed crop use.

Background information regarding EPA input on IR-4 candidate list of AI/crop combinations:

IR-4 develops residue field trial data for projects based on requests from growers, grower groups and state/federal research and extension agents. In order for a project to be considered, a request is made through the IR-4 website by completion of an IR-4 Minor Use Project Clearance Request Form [<http://IR4.rutgers.edu/fooduse/foodrequestform.cfm>]. Each year IR-4 receives more requests for projects than there are resources, so the potential researchable projects are prioritized by various stakeholders each year at the annual IR-4 Food Use Workshop. The workshop is usually held during the month of September.

Prior to the IR-4 Food Use Workshop, OPP is sent a list of all project requests that have been submitted to IR-4. OPP reviews these candidates and identifies if there are any risk concerns that would likely prevent the registration of the proposed use and the establishment of its tolerance (i.e., full risk cup for the active ingredient, cumulative risk concerns for the class of chemicals that share a common mechanism of toxicity). OPP provides feedback to IR-4 on any risk concerns with the proposed projects.

Once the Food Use Workshop is done, and IR-4 has determined their list of projects, EPA encourages IR-4 to discuss with the Agency any projects that may not clearly meet the criteria described in this document before IR-4 commits any resources to these projects. While responsibility for providing an adequate public interest rationale rests with the submitter, EPA retains the final responsibility for approving a public interest finding.

The policies stated in this document will be implemented in considering project proposals to be evaluated at the IR-4 September 2013 Food Use Workshop. If the funding for an IR-4 project occurred before this policy was implemented, where the project doesn't meet the criteria listed above, the fact of such funding will be taken into serious consideration by EPA in their weight-of-evidence deliberation regarding the public interest finding.