

BPPD New Product/Non-Registered AI Source Readiness Screen

Date:

Review Date:

File Symbol No.:

Reviewers:

BPB/MPB:

Comments: *note if any calls to the registrant were made*

Pass/Fail:

Hours Worked:

	Checklist Item	Yes	No	N/A	Comments
1.	<u>Forms</u>				
a.	8570-1: Application for Registration				
b.	8570-4: CSF				
c.	8570-27: Formulator's Exemption				
d.	8570-34: Certification with Respect to Data				
e.	8570-35: Data Matrix				
2.	<u>Confidential Statement of Formula (CSF)-review for alternate formulations too</u>				
a.	Signed and dated				
b.	Food-use? (If no, skip to 1e.)				
c.	All inerts cleared for food-use				
d.	Active cleared for food-use				<i>List exemption</i>
e.	All inerts cleared for nonfood-use (skip if food-use)				
f.	Conventional or antimicrobial actives present?				
g.	CSF accurately reflects label				
h.	Active(s) + Inert(s) = 100%				
i.	CAS #s for all inerts				
j.	Chemical names provided for inerts				
k.	Units in all applicable boxes				
l.	Proprietary inerts? If so, is info. on file with the Agency?				

m.	Supplier information adequately listed				
n.	Certified limits correct?				
o.	If certified limits are outside recommended range, explanation provided?				
p.	Microbial: culture collection reference				
q.	Microbial: strain designation for a.i.				
r.	Microbial: potency provided with a.i.				
s.	Alternate formulations?				
t.	Are alternate formulations actually alternate and not a new product?				
3.	Data Matrix-ACTIVE INGREDIENT				
a.	Separate data matrix for the source of AI				
b.	All product chemistry data requirements addressed (guideline by guideline)				
c.	All toxicology data requirements addressed (guideline by guideline)				
d.	All nontarget toxicology data requirements addressed (guideline by guideline)				
e.	Reflects info. reported on CSF (e.g.: identity of AI)				
Note for 3b.-d. above: if not addressed in data matrix, may be addressed in elsewhere in submission					
4.	Data Matrix-MP or EP				
a.	Separate data matrix for the product				
b.	All product chemistry/product analysis data requirements addressed (guideline by guideline)				
c.	All mammalian/human health toxicology/ pathogenicity data requirements addressed (guideline by guideline)				
d.	All Tier 1 nontarget organism toxicology/ pathogenicity data requirements addressed (guideline by guideline)				

e.	Efficacy data (if public health pests on label)				
f.	HSRB review required?				
5.	<u>Data Requirements-Guideline Studies</u>				
Note: This section is for submitted guideline studies only. See below for waivers and rationales.					
a.	Product chemistry: do all submitted studies appear to satisfy the data requirements?				
b.	Toxicology: do all submitted studies appear to satisfy the data requirements?				
c.	Nontargets: do all the submitted studies appear to satisfy the data requirements?				
d.	Other (residue data, special studies, etc.)				
6.	<u>Data Requirements- Waivers</u>				
Note: This section is for waivers only. This does not apply to rationale submitted to satisfy the data requirements.					
a.	Are there any requests for waivers? Please note.				
b.	For each applicable data requirement, does the waiver request have a separate scientific rationale justifying why testing is not applicable?				
c.	Does each waiver request seem reasonable and justified?				
7.	<u>Data Requirements- Rationales/Literature</u>				
Note: This section is for rationales only. This does not apply to requests submitted to waive the data requirements.					
a.	Have rationales been submitted in lieu of guideline studies? Please note.				
b..	Does each rationale have scientific literature citations where applicable?				
c.	Are the rationale and scientific citations organized in reasonable order to facilitate timely review and is each guideline addressed individually?				
d.	Are copies of cited scientific literature included in the package?				

e.	Does the rationale appear to be reasonable and scientific?				
8.	<u>Label</u>				
a.	Restricted Use Pesticide statement (If applicable)				
b.	Product name, brand or trademark				
c.	Ingredient statement correct? Microbial: strain designation Microbial: potency designation				
d.	"Keep Out of Reach of Children" (KOOROC) Statement				
e.	Signal word				
f.	First aid statement				
g.	Net contents/net weight				
h.	EPA Reg. No. and Establishment No.				
i.	Company name and address				
j.	Precautionary statement: hazards to human and domestic animals Microbial: dusk mask statement				
k.	Environmental hazards				
l.	Physical and chemical hazards (if app.)				
m.	Directions for use				
m.	Storage and disposal				
o.	Warranty statement				
p.	Worker protection				
q.	Batch code				