Release Permits Checklist

Permit 08-014-101rm

Reviewer L.W. Handley

Date of Review 4/18/08

**** Reminder that ePermits does not use the APHIS 2000 box numbers.**

Information Required	Reference/ resources	Complete/comments
CBI formatting. If applicant is submitting a CBI, check to make sure the CBI and CBI-deleted versions are attached. Also check for CBI justification letter attachment.	Users Guide http://www.aphis.usda.gov/brs/pdf/usersguide.pdf	OK
Quantity of regulated article to be introduced and proposed schedule and number of introductions—Should indication how much is being released into the environment (acres, number of plants, etc.)		OK
Port of arrival, destination, or specific location of release(s)	Users Guide	OK
A description of the anticipated or actual expression of the altered genetic material in the regulated article and how it differs from expression in the non-modified parental organism: For example: - Phenotypic difference (desired/actual phenotype) - physiological processes and activities (function of the protein) - numbers of copies (or loci) of inserted DNA (description of inheritance or Southern or PCR analysis results) - nuclear, organellar, or extrachromosomal insert, if known - products and secretions (what is the gene product or its reaction products and is it secreted) and how the product is to be used - growth confinement characteristics, if relevant (e.g., more seeds, phenology, flowering, dispersal, etc) For PMP/PMI – See separate checklists for these products….	Users Guides for permits or PMP/PMI permits -	Yes Yes Yes No No No Yes
Molecular biology – genetic construct can be notification style, provide description or map of the plasmid vector, all genetic elements must list donor organisms, **check to see if donors are select agents**, description of the transformation process, etc.	Users Guide and letter to permit applicant – See also box in the Users Guide at III-15.	Yes
Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced. Check for description.	Users Guide	

Information Required	Reference/ resources	Complete/comments
Purpose and detailed description of experimental and production design, For PMP/PMI – see separate checklists.	Users Guide	Yes
A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).		Yes
A detailed description of the proposed procedures, processes, and safeguards that will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.		Yes
A detailed description of the proposed method of final disposition of the regulated article		Yes
Check for pharma/industrial intent		OK
For microorganism releases: For microorganisms – is consult with PPQ required? Is microbe widely prevalent? What strain, isolate or pathovar is being used? For GH work: What are containment measures for transport of microbe between lab and greenhouse? Secondary spread of organism: Is secondary spread possible? If so, how is secondary spread controlled? Can the microbe be vectored by an insect? If so, what control measures are in place to prevent insect contamination? Can the organism be transmitted via seed? If so, how are seeds maintained and disposed of? Is disposition appropriate given the organism's life cycle? Will plants be inoculated? Will plants be transformed?		
Generally, only release of pathogens that are widely prevalent in field test area.		
What are containment measures for transport of microbe between lab (or GH) and field? Only release pathogens that are the same or less virulent than the wild-type. Virulence test is required What is host range of organism? Host range test required? How is inoculation conducted in the field? How is the microbe transmitted and what control measures are required to conduct a confined field test?		