

Intragovernmental Select Agents and Toxins Technical Advisory Committee

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Agricultural Select Agent Program



Select Agent Program Workshop Series



History

- ISATTAC was first formed by CDC in May 2005
- ISATTAC's role is to enhance the Federal Select Agent Program due to events of Anthrax letters to Congress and the events of September 11, 2001.
- ISATTAC is co-chaired by HHS and USDA



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Membership

Technical Members of ISATTAC are from several Federal agencies:

- USDA, APHIS
- USDA, ARS
- HHS, CDC
- HHS, NIH
- DOT
- DHS
- DOD



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Defined Role

ISATTAC's role is to make technically based recommendations to the APHIS/CDC Select Agent and Toxin Program on:

- Exclusion of SA&T
- Exemption of SA&T
- Restricted Experiments of SA&T
- Biannual review of the SA&T List for HHS and overlap SA&T



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Exclusions (7 CFR, 9 CFR, 42 CFR 73.3(d); 73.4(d))

- SA&T in their natural environment
- Non-viable or non-functional SA&T
- Toxins below a specific threshold
- Attenuated strains
- Seizure by Federal law enforcement agencies
- All requests must be in writing and submitted either to APHIS or CDC for consideration



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Exemptions

(7 CFR, 9 CFR, 42 CFR 73.5; 73.6)

- Clinical and diagnostic labs (with stipulations)
- Proficiency testing
- Specific activities regulated under Food Drug and Cosmetic Act, Public Health Service Act, Virus, Serum, Toxin Act, Federal Insecticide, Fungicide, and Rodenticide Act

All requests must be in writing on APHIS/CDC Form 5 and submitted to either APHIS or CDC



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Restricted Experiments (7 CFR, 9 CFR, 42 CFR 73.13)

- Recombinant genetic manipulations that give drug resistant traits of the primary therapy for humans, animals or agriculture to Select Agents
- Recombinant DNA for Toxins with a LD50 < 100ng/KG bw
- Any experiment or manipulation that gives a Select Agent new traits or functions that the SA would not acquire naturally
- Enhancing the pathogenicity or toxicity of SA&T

**All requests must be in writing and submitted
either to APHIS or CDC for consideration**

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Biannual Review

Public Health Security and Bioterrorism Preparedness and Response Act of 2002, SEC. 351A (a)(B)(2); SEC. 212 (a)(B)(2)

Duties:

- Reviews, recommends, and analyzes criteria and ranking factors for SA&T addition or removal from the regulated lists
- Recommends a list of HHS and Overlap SA&T for the approval of the HHS Secretary and the APHIS Administrator



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Questions ?



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