

Select Agent Program: Lead Agency Concept

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ABSA Annual Meeting
6 October 2007



Briefing Topics

- Background and Context
- Lead Agency
 - Definition
 - Operation: APHIS and CDC Roles and Responsibilities
 - Effect on Regulated Entities
 - Revised List Implementation



Lead Agency

- Agency (CDC or APHIS) responsible for entity services (*e.g.*, registration, inspections)
- Serves as primary point of contact for entity
- All correspondence and information exchange is through lead agency regardless of agent(s) involved



Determination of Lead Agency

Type of Agent(s)	CDC	APHIS	Either, but not both (Entity Choice)
HHS only	X		
USDA only		X	
Overlap			X
Mixture			X

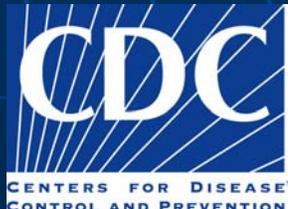
- An entity is required to register with either APHIS or CDC, but not both
- Registration is based on the types of agents the entity will be using, transferring, or possessing



Lead Agency

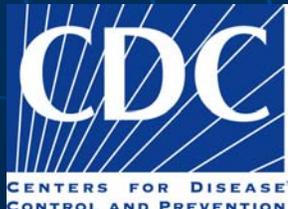
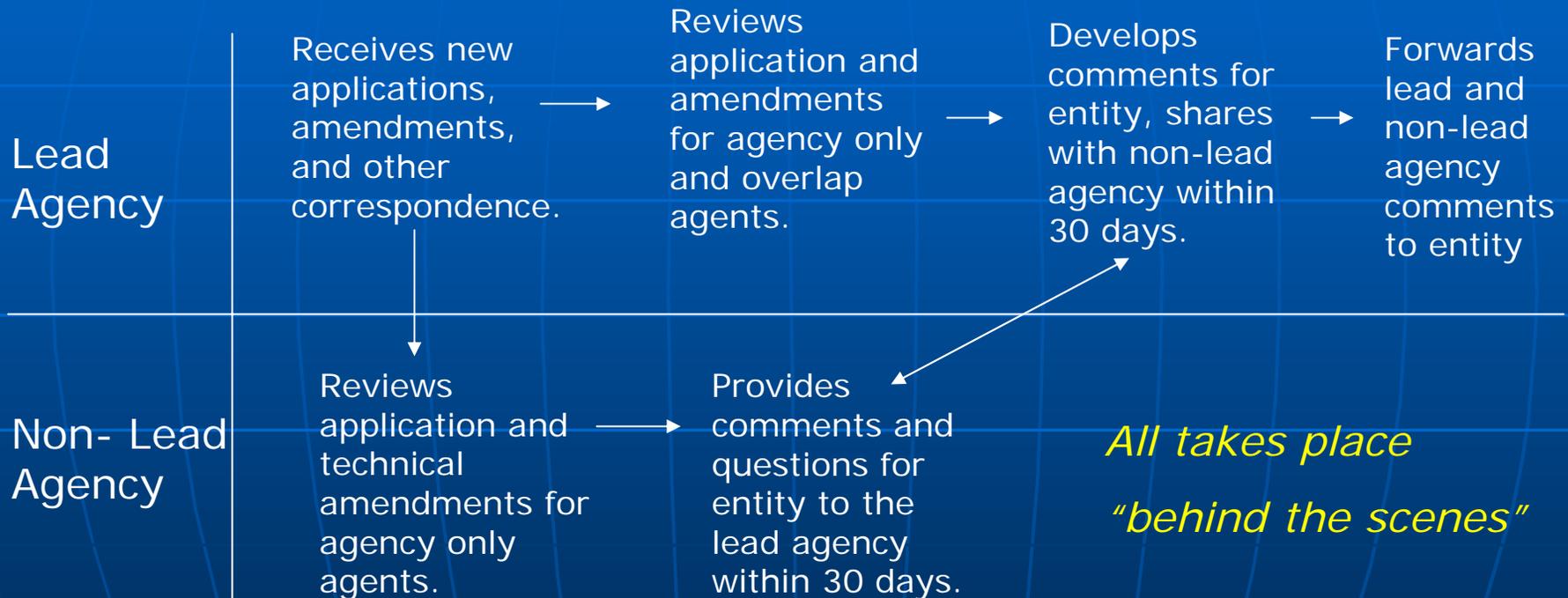
Roles and Responsibilities

- Lead Agency will coordinate all application reviews, inspections, and appropriate material with the non-lead agency
- Reduces burden on entities
- Increases clarity and understanding of Select Agent Program Requirements



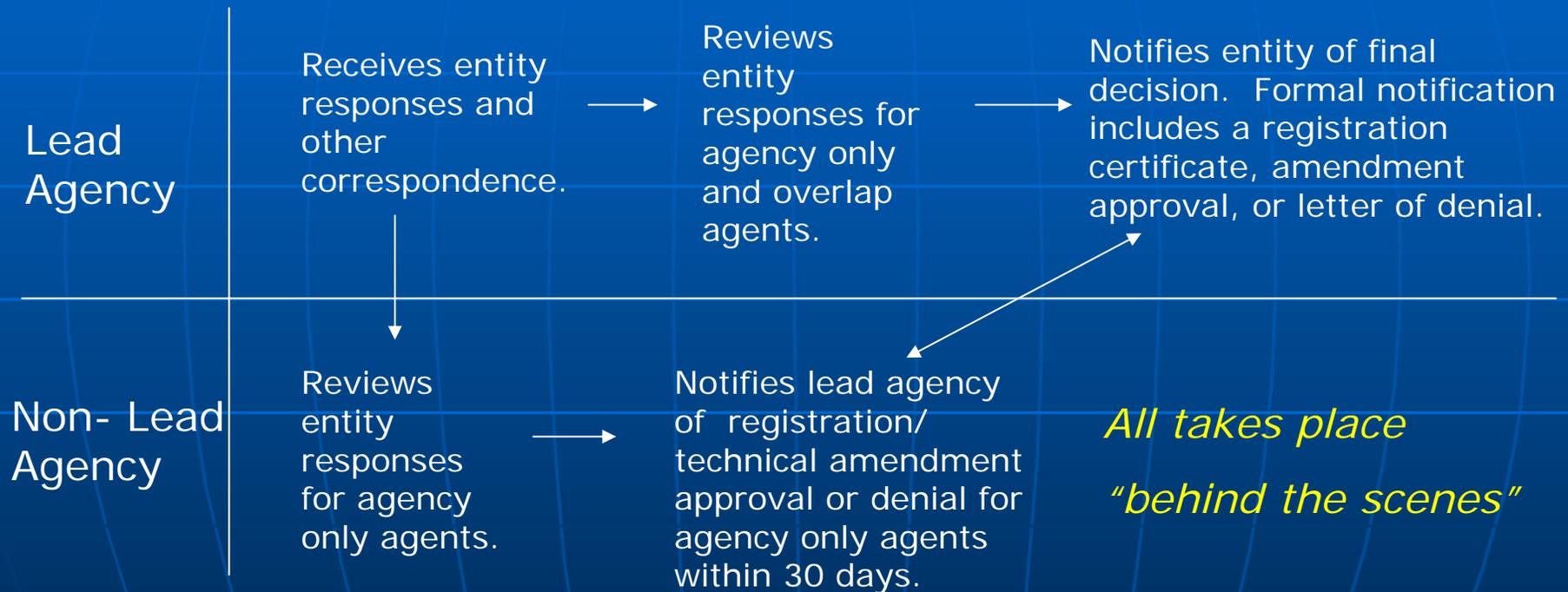
Operational Roles & Responsibilities

For example: Application, or Technical Amendment Review



Operational Roles & Responsibilities

For example: Application, or Technical Amendment Review (cont'd)



Benefits to Entity of “Lead Agency” Protocols

- Entities have a single point of contact—their lead agency—for all select agent issues, regardless of agent(s)
- CDC/APHIS Coordination of application/amendment review, inspections, transfers, and security risk assessments is conducted *“behind the scenes”*



Upcoming “Lead Agency” Challenge for CDC, APHIS and Entities

CDC and APHIS have published Proposed Rules that if finalized, will change all four lists of select agents and toxins (CDC-only, VS-only, Overlap, PPOQ-only)

This would change the “Lead Agency” determination for some entities



Revised List Implementation

If the proposed changes become final...

- Entities registered with APHIS who are now in possession of only CDC-only agents or toxins will become registered with CDC
- Will be accomplished **“behind the scenes”**
- Entities will be officially notified of Lead Agency/point of contact changes



Questions ?

