Endpoints and Protection Goals

The Legal Framework

Warren Lehrenbaum
Crowell & Moring LLP
wlehrenbaum@crowell.com
Topics

- ESA Nuts and Bolts
- The FIFRA-ESA Disconnect
- Very Brief History of FIFRA-ESA Litigation
- Recent Efforts to Resolve the Disconnect
- Fitting the Pieces Together
ESA Nuts and Bolts
Overview of the Act

• Enacted in 1973; amended several times; codified at 16 U.S.C. 1531-44; implementing regulations at 50 C.F.R. Part 402
• Administered by two “Services” -- National Marine Fisheries Service (NMFS) and U.S. Fish and Wildlife Service (FWS).
• Supreme Court’s decision in *TVA v. Hill*, 438 U.S. 153 (1978) established ESA as an uncompromising statute.
  ▪ Court: ESA makes protection of listed species the highest priority for all federal agencies.
  ▪ Completion of Tellico Dam enjoined despite $100’s M of prior federal funding b/c expected to cause extinction of the endangered snail darter.
Key Provisions of ESA

- **Section 7(a)** -- Establishes substantive and procedural obligations for Federal agencies to protect listed species

  *Each Federal agency shall, in consultation with the Services, “insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence” of any endangered or threatened species or result in destruction or adverse modification of critical habitat*  
  § 7(a)(2)

  - The agency action cannot be likely to jeopardize the continued existence of a listed species; cannot adversely modify critical habitat of a LS
  - The action agency must ensure compliance with these substantive requirements “in consultation with” the Services
Consultation -- Procedural obligations for “consultation” are spelled out in the Services’ regulations.

- Consultation required if action agency concludes in an effects determination that its action may affect listed species or critical habitat. 50 C.F.R. 402.03 and 402.14(a).

- Informal consultation is allowed if action agency and Services agree the proposed action is “not likely to adversely affect listed species or critical habitat” (“NLAA”). 50 C.F.R. 402.13.

- Otherwise, formal consultation is required. Resource and time intensive; concludes with Service’s written biological opinion (“BiOp”) on whether the proposed federal action meets ESA § 7(a)(2)’s substantive constraints.
Low Bar for “May Affect” Determination:

- The regulatory preamble to 50 C.F.R. 402.14(a) states that “[a]ny possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement, as suggested by one commenter.” 51 Fed. Reg. 19926, 19949-50 (June 3, 1986).

- Thus, the ESA regulations (and their interpretation by the Services) almost guarantee that approval of any nationwide pesticide registration “may effect” a listed species – triggering the requirement for consultation.
The FIFRA Disconnect
FIFRA Registration Standard

- Unreasonable adverse effects on the environment (Will perform intended function without . . . When used according to wide-spread practice will not generally cause . . . )

  • “. . . any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits . . .”
  • i.e., risk-benefit analysis
FIFRA vs. ESA

Unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits.

Insure action is not likely to jeopardize the continued existence of endangered or threatened species or result in destruction or adverse modification of critical habitat.
How Real is the Conflict?

• Standards are different; but not necessarily incompatible
  – e.g., “benefits” don’t trump “risks” under FIFRA
  – Also, non-target effects are already evaluated under FIFRA . . . but at a higher taxa level, not an individual species level

• The basic concept of risk assessment is the same for both statutes
What’s the Disconnect?

• For decades EPA/OPP ignored the ESA § 7 consultation provisions. . . . until it was sued

• First major ESA-FIFRA Case: *Washington Toxics*
  - Brought in 2001 to force ESA consultation on several dozen a.i.’s with respect to listed Pacific salmonid species.
  - District court found EPA violated ESA -- had not made effects determinations nor initiated consultation on 54 pesticides.
  - Affirmed by Court of Appeals (9th Cir) – established the principle that FIFRA registration actions are subject to ESA § 7
Aftermath of *Washington Toxics*

- Eighteen more years of litigation, and counting
- Tribal warfare between EPA and Services over how to conduct risk assessment
- Services spend huge resources to prepare BiOps for first groups of Wash. Toxics a.i.’s
- First BiOp (OPs) challenged by registrants and overturned by the court (4th Cir.)
Efforts to Resolve The Disconnect
Development of the “Interim Approaches”

• National Academy of Sciences (NAS) report on ESA-FIFRA issued in 2013, in response to a joint request from EPA, the Services and USDA.
  – The NAS Report largely agreed with EPA’s approach to risk assessment;
  – Provided recommendations for how the Services and EPA could develop a common risk assessment framework

• November 2013, EPA and the Services rolled out their “Interim Approach” to implementing the NAS recommendations.
  – EPA explained that Interim Approaches would be implemented in the context of registration review
  – EPA also asserted that new registrations would be evaluated under ESA on a “case-by-case” basis
The OPs and Carbamates were the “beta” test cases for development of nationwide ESA assessments using the Interim Approaches

- EPA’s Biological Evaluation (BE) for Malathion: “may affect” 99% of LS; “likely to adversely affect” 97%
- EPA’s BE for Diazinon: “may affect” 94% of LS; “likely to adversely affect” 85%
- EPA’s BE for Chlorpyrifos: “may affect” 99% of LS; “likely to adversely affect” 98%

Maybe EPA is looking at the wrong endpoints?
Memorandum of Agreement

• January 31, 2018 Memorandum of Agreement (MOA) between EPA, DOI, Commerce and DOA established an Interagency Working Group on ESA Consultations for Pesticide Registration and Registration Reviews

• Purpose:
  • Provide recommendations on improving the ESA Consultation Process for Pesticide Registrations and Registration Reviews
  • Record and formalize a new process.

• Formalized in Farm Bill
Path Forward

• Opportunity to develop and formalize new approaches to ERA – including the use of more appropriate endpoints.
• Substantive challenge – achieving consensus on appropriate endpoints
• Procedural challenge – formalizing that consensus in guidance or regulation, to ensue that it’s durable
• Filtering
• User community as a stakeholder