ENVIRONMENTAL CONSIDERATIONS FOR TOBACCO PRODUCT APPLICATIONS SUBMITTED TO CTP

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AGENDA

- Introduction to National Environmental Policy Act (NEPA)
- 21 CFR Part 25 and 21 CFR 1107.1
- Basic Elements of an EA
- FDA Review

WHAT IS NEPA?

NEPA is the National Environmental Policy Act, signed into law on January 1, 1970

A national policy which will encourage productive and enjoyable harmony between man and his environment

~ National Environmental Policy Act, Sec. 2

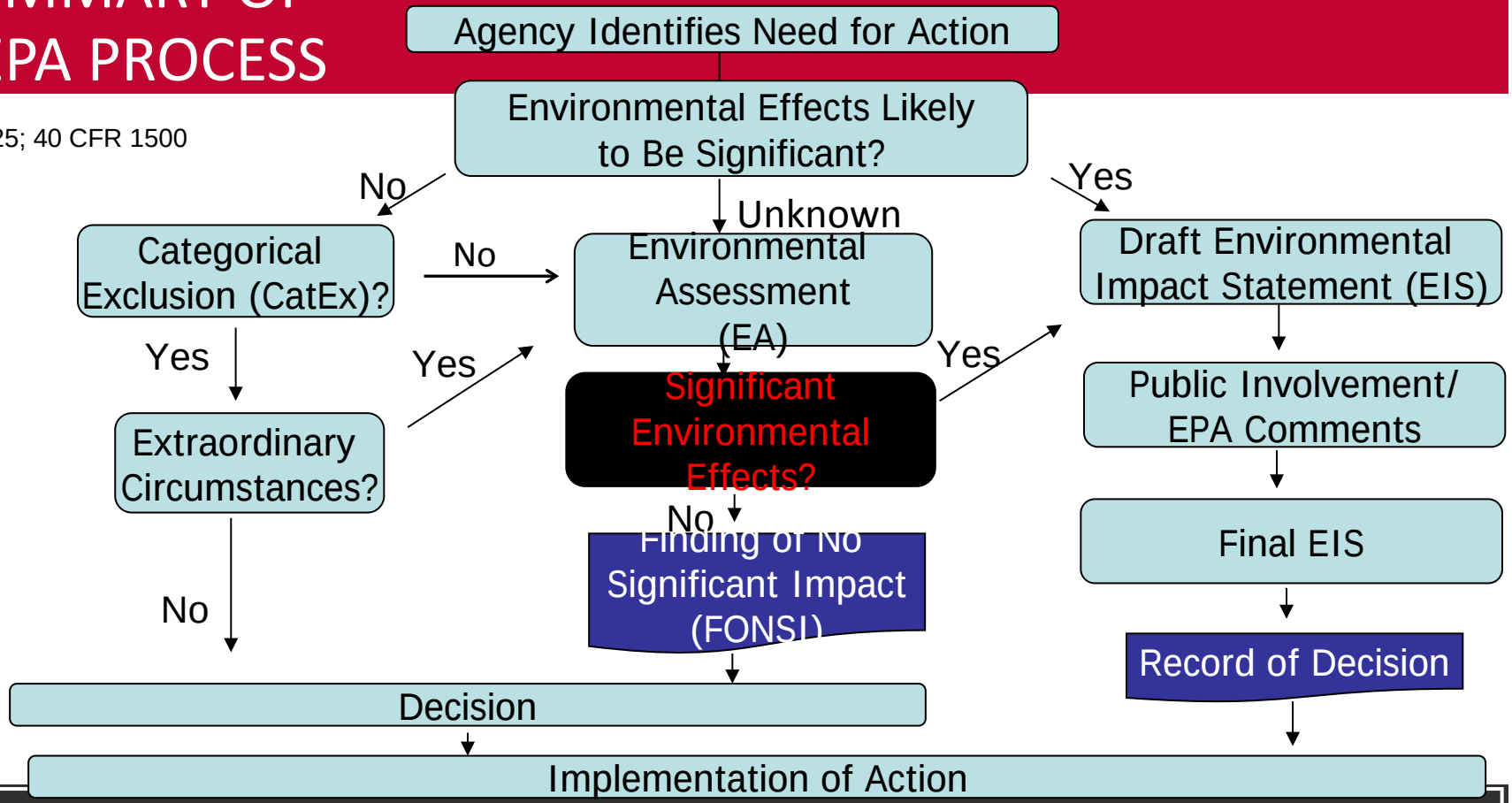
THE PURPOSE OF NEPA

- To PROMOTE efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man
- To ENRICH the understanding of the ecological systems and natural resources important to the Nation
- To ESTABLISH a Council on Environmental Quality

Abstract from National Environmental Policy Act of 1969

SUMMARY OF NEPA PROCESS

21 CFR 25; 40 CFR 1500



FDA ACTIONS SUBJECT TO NEPA

- Promulgation of new regulations
- Requests for private action
  - Market authorizations* for product applications

*Also applies to denials of authorizations which have a CatEx

CTP'S NEPA PROCESS (21 CFR 25.15)

21 CFR 25.15 (a)

- All applications or petitions requesting agency action require the submission of an EA or a claim of categorical exclusion
- A claim of categorical exclusion shall include a statement of compliance with the categorical exclusion criteria and shall state that no extraordinary circumstances exist

In addition, for SE EX Requests, 21 CFR 1107.1(b)(9) provides that EX Requests must contain an EA prepared in accordance with the requirements of 25.40

CTP’S NEPA PROCESS (21 CFR 25.15)

21 CFR 25.15(a)

- Failure to submit an adequate EA for an application or petition requesting action by the agency of a type specified in 25.20, unless the agency can determine that the action qualifies for exclusion…, is sufficient grounds for FDA to refuse to file or approve the application or petition.

WHAT DOES THIS MEAN FOR A TOBACCO PRODUCT?

- All tobacco product applications must contain either an EA or a claim of categorical exclusion
  - If a claim of categorical exclusion is provided, manufacturers should cite the criteria and state no extraordinary circumstances exist
  - Currently the only authorization orders with an applicable CatEx are SE findings for provisional SE Reports
  - Authorizations on regular SE Reports, SE EX Requests, PMTAs and MRTPAs do not currently have an applicable CatEx

WHAT DOES THIS MEAN FOR A TOBACCO PRODUCT?

- Failure to include an adequate EA (if the action does not qualify for CatEx) may result in FDA refusing to file (RTF) or authorize the application
  - For applications that do not have a filing stage, FDA may refuse to accept (RTA) or authorize the application

BASIC ELEMENTS OF AN EA

- 21 CFR 25.40(a) sets forth some of the basic elements of an EA:
  - Brief discussion of the need for the proposal
  - Alternatives as required by section 102(2)(E) of NEPA
  - Environmental impacts of the proposed action
  - Environmental impacts of alternatives
  - Environmental issues relating to the use of the tobacco product
  - Environmental issues relating to the disposal from use of the tobacco product
  - Listing of the agencies and persons consulted

BASIC ELEMENTS OF AN EA

- Brief discussion of the need for the proposal:
  - What is the applicant seeking?
    - Premarket authorization so that a new tobacco product may be introduced into interstate commerce
    - Authorization to market a modified risk tobacco product
- Alternatives as required by section 102(2)(E) of NEPA:
  - No-action alternative
  - Denial

BASIC ELEMENTS OF AN EA

- Environmental impacts of the proposed action and alternatives:
  - Environmental impacts of the proposed action (i.e., if the product is authorized and subsequently marketed)
  - Environmental impacts of the alternatives (e.g., no action, denial)
  - What is the product for which the EA must assess the impact?
    - The product for which the applicant is seeking authorization
    - Not a comparator product (e.g., predicate)

BASIC ELEMENTS OF AN EA

- Environmental issues relating to use and disposal from use of the tobacco product:
  - What is the product for which the EA must assess the use and disposal from use?
    - The product for which the applicant is seeking authorization
    - Not a comparator product (e.g., predicate)
  - Discuss disposal from use of packaging

- Listing of the agencies and persons consulted:
  - List of agencies and persons consulted in the preparation of the EA
  - If none consulted, a statement that no agencies or persons were consulted

FDA REVIEW

- Recently FDA published a regulation regarding tobacco products and the NEPA process (the National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions)
- With this regulation the burden is with the applicant to meet 21 CFR 25.15(a) in their application.

FDA REVIEW

- FDA found that once this rule became effective, many of the applications received did not include some of the basic elements discussed in this webinar.
- Because industry has still been gaining experience with NEPA and 21 CFR Part 25, FDA has recently accepted some applications it could have refused to accept/file.
- However, we have issued RTA letters when an application is entirely lacking an EA.

FDA REVIEW

- To aid with the understanding of what is required, FDA has posted EAs that support NEPA requirements for all actions posted on our website.

- These EAs include not only the basic elements discussed today, but also sufficient information for authorization.
  - A future webinar will be held to discuss information that has been included in EAs to support a finding of no significant impact (FONSI), which would support an order

THE END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