

PART 601 – Regulatory Development and Publication

Subpart E – Required Analyses and Consultation for Rules

Amended March 2024

601.40 Benefit-Cost Analysis

- A. Economic and Policy Analysis Division (EPAD) develops the benefit-cost analysis (BCA). The summary below details regulatory requirements for the BCA.
- B. EPAD, with advice and oversight by NRCS, should follow the below process in the production of a BCA:
 - 1. Establish a program baseline for comparison purposes.
 - 2. Collaborate with regulation writers to consider discretionary as well as mandatory options.
 - 3. Determine the correct approach or type of analysis to conduct (standard BCA or a cost-effectiveness analysis).
 - 4. Assemble the support team for developing the analysis.
 - 5. Conduct the analysis where the economist documents findings, writes the preliminary draft, and reviews the assessment with others in the regulatory group. Preliminary drafts must be published with proposed or interim rules.
 - 6. Complete the final written BCA based on comments and feedback received during the review process. Final BCAs must be published with final rules.
- C. BCAs must be drafted in accordance with Executive Order 12866, which requires that a regulatory BCA be performed on each significant and economically significant regulatory action. The Office of Management and Budget (OMB) has also issued guidance for completing BCAs (see OMB Circular A94). Public Law 104-121 also requires that a regulatory BCA be prepared for all major regulations.
- D. Review and Clearance
 - 1. Following an internal agency review, NRCS submits the BCA as part of the regulatory package to the appropriate USDA offices for review (see Subpart F). The Office of Risk-Assessment and Cost-Benefit Analysis in the Office of the Chief Economist provides specific review of the document. Once all applicable USDA offices have approved it, OMB must approve the BCA.
 - 2. When made available or published in conjunction with a rule, the BCA is placed in the clearance package along with the rule, environmental analysis,

civil rights analysis, and any other supporting documentation and clearance sheets. The package goes through the internal and external review process, as applicable, with editing conducted at each stage.

E. Comment Review and Response

Any comments received from other agencies and the public on the BCA during the open comment period are forwarded to EPAD for review and response. Any comments received outside of regulations.gov must be forwarded to the Federal Docket Management System (FDMS) administrator to be uploaded into FDMS.

601.41 Risk Assessments

- A. The Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, Pub. L. No. 103-354 Title III, Section 302, established certain analysis requirements that address risk assessment. A risk assessment must be conducted on all proposed regulations that meet the act's definition of major (i.e., rules primarily regulating issues of human health, human safety, or the environment).
1. The risk assessment must include an analysis with as much specificity as practicable of—
 - a. The risk, including the effect of the risk, to human health, human safety, or the environment, and any combination thereof, addressed by the regulation, including, where applicable and practicable, the health and safety risks to persons who are disproportionately exposed or particularly sensitive.
 - b. The costs associated with the implementation of, and compliance with, the regulation.
 - c. Where appropriate and meaningful, a comparison of that risk relative to other similar risks regulated by USDA or another federal agency resulting from comparable activities and exposure pathways (such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks and the preventability or non-preventability of risks).
 - d. The quantitative and qualitative benefits of the regulation, including the reduction or prevention of risk expected from the regulation.
 2. The analysis must also contain a statement that the Secretary of Agriculture evaluated—
 - a. Whether the regulation will advance the purpose of protecting against the risk, including the effect of the risk to human health, human safety, or the environment, and any combination of those risks and, where applicable and practicable, the health and safety risks to persons who are disproportionately exposed or particularly sensitive.
 - b. Whether the regulation will produce benefits and reduce risks to human health, human safety, or the environment, and any combination thereof, in a cost-effective manner because of the implementation of and compliance

with the regulation, by local, state, and Federal governments, and other public and private entities, as estimated.

B. Review and Clearance

1. The risk assessment goes through an internal and external review process, with editing conducted at each stage. Following an internal agency review, NRCS submits the risk assessment as part of a regulatory package to the Department for review. ORACBA in the Office of the Chief Economist provides specific review of the document. Once cleared by the Department, OMB must approve it.
2. When made available or published with a rule, the risk assessment is placed in the clearance package along with the rule, environmental analysis, civil rights analysis, and any other supporting documentation and clearance sheets. The package goes through the internal and external review process, as applicable, with editing conducted at each stage.

601.42 Environmental Review

- A. The National Environmental Policy Act (NEPA) requires federal agencies to prepare an environmental review for “major Federal actions significantly affecting the quality of the human environment” (42 U.S.C. § 4332) to aid in decision making. Agency rulemaking may be considered a major federal action (40 CFR § 1508.18) depending upon whether a regulatory decision is non-discretionary under the agency’s statutory authority. Thus, if NRCS has discretion on a decision about a regulatory provision, NRCS must review that discretionary decision under NEPA to determine if it is a major Federal action that significantly affects the quality of the human environment. The NRCS National Environmental Handbook sets forth procedures and policies relating to NRCS compliance with NEPA and the Endangered Species Act. A condensed summary of the environmental assessment preparation and review is presented below.

B. Determination of Applicability of NEPA

For NEPA to apply, NRCS must have some discretion in developing regulations. The enabling legislation (e.g., the Agriculture Improvement Act of 2018 (2018 Farm Bill)) is carefully reviewed to determine what decisions have been delegated to the Department and agency through the Secretary. If Congress has not delegated any decisions about how the program will be carried out, then NRCS has no discretion and further environmental review is not necessary for rulemaking. However, this decision is subject to review and approval by OMB.

C. Determination of Whether to Prepare an Environmental Assessment (EA) or Environmental Impact Statement (EIS) for Rules

1. Regulation writers and environmental specialists must collaborate early in the rule development process. Once it has been determined that NEPA applies, the designated regulation writer or other people from the Programs deputy area and the technical specialists from the Science and Technology deputy

area must work together to determine the scope of the discretionary decisions and of the related analysis.

2. Once the scopes are well-defined, NRCS considers how significant the impacts of the discretionary decisions are based on their anticipated context and intensity. If the agency expects that impacts will be significant, it must prepare an EIS; otherwise, an EA is sufficient. The decision on whether an EA or EIS is to be prepared must be made by the responsible federal official (i.e., the Chief of NRCS). The environmental review is then prepared by either Science and Technology technical specialists or a contractor.

D. Use of a Contractor

Conducting an environmental review and producing an EA or EIS may take several months to several years depending on whether an EA or EIS is prepared and requires extensive financial and other resources or NRCS staff time. The agency must decide whether to make funds available for a contractor to develop the EA or devote staff time and other resources to this effort. The approval of the Chief is required for contracting.

E. Determine Team (Internal Agreements or Contract Process)

After deciding whether to prepare an EA and whether to contract the work, the work then needs to be assigned. Contractors must be hired through the contracting process. The national environmental compliance specialist will obtain assistance from Ecological Sciences Division and central ecologists for review of work products. If the EA is to be developed in-house, states and national technology support centers may request help from NRCS technical specialists. Approvals must be provided by the technical specialists' supervisors.

F. Conduct Training Sessions

Contractors or NRCS technical specialists must attend training sessions on the proposed rules and program requirements that must be considered in the environmental review process. NRCS technical specialists must also attend additional training on writing NEPA documents if the EA is developed in-house. The Chief must approve of all funding for training sessions, and attendees must have supervisory approval.

G. Collaboration with Regulation Writers to Identify Requirements

Information regarding program requirements and how the program will be carried out under the rules is essential to accurately reflect the potential impacts of implementing a program rule. As such, rule writers must be constantly engaged with the drafters of the EA in the process of developing the EA. The contractors or specialists developing the EA must have access to information from those developing the rules. Contact between these groups is necessary throughout the EA and rule development.

H. Information Collection and Analysis

1. The national environmental coordinator provides oversight for acquisition of data and information when contracted out. Otherwise, data collection is conducted by teams of NRCS technical specialists with guidance from the environmental coordinator. For an NRCS program, information to be gathered should include:
 - a. Program requirements.
 - b. The current or baseline condition of natural, economic, and social resources that may be impacted (requires consultation with economist developing benefit-cost analysis).
 - c. Current agricultural practices.
 - d. NRCS conservation practices and potential effects.
 - e. Past NRCS programs, practices implemented under them, number and extent of implementation, and past impacts.
 - f. Applicable laws, regulations, Executive orders, and policies.
2. A comprehensive analysis of the program's potential direct, indirect, and cumulative impacts must be conducted, including impacts to natural, economic, and social resources, as well as potential impacts to socially disadvantaged farmers and protected resources. This information and analysis must be documented in the EA.

I. Write Assessment

Once adequate information has been gathered, the actual writing of the EA or EIS document can begin. An EA, if prepared, is the basis for decision making and must provide sufficient documentation of the evidence and analysis to show whether a finding of no significant impact (FNSI) is appropriate (40 CFR § 1508.9). If the drafting of an EA is contracted out, the bulk of the work would be done by the contractor with oversight by the national environmental coordinator. Otherwise, the work is done by teams of NRCS technical specialists. The national environmental coordinator must approve the draft EA.

J. Review and Clearance

1. When the EA has been completed, the Chief must decide based on the analysis whether an EIS is required or an FNSI may be issued.
2. The EA goes through an internal and external review process, with editing conducted at each stage. The goal is to produce a document that is accurate, defensible, transparent, and easily understood by the public. Following an internal agency review, the EA or EIS is provided to the Office of Budget and Program Analysis (OBPA) for review. Once cleared by OBPA, OMB must approve it.
3. When published with a rule, the EA is placed in the clearance package along with the rule, benefit-cost analysis, civil rights analysis, and any other supporting documentation and clearance sheets. The package goes through the internal and external review process, as applicable, with editing conducted at each stage.

K. Publish for Comment

A notice of availability for the final EA and associated FNSI are published in the Federal Register for public comment. This provides an opportunity for other agencies and the public to review the NRCS analysis and decision over 30 days. The 30-day comment period must occur before an interim rule is effective, unless otherwise allowed by law. For example, the responsible federal official (the Chief) may determine that a reduced comment period for an EA would be in the best interest of the Government (40 CFR § 6.203). In that case, the notice of availability can be published within the regulatory certifications section of proposed or interim rules.

L. Comment Review and Response

Any comments received from other agencies and the public on the EA or FNSI during the official review period are sent to the national environmental coordinator. Any comments received outside of regulations.gov must be forwarded to the FDMS administrator to be uploaded into FDMS. Each comment is reviewed to determine if it is substantive or not (i.e., whether it could impact the decision). Substantive comments must be addressed and may result in a supplemental EA or FNSI.

M. Environmental Impact Statements

The EIS follows the same development process as an EA. However, the EIS is a more detailed document with public review periods for both the draft and final EIS documents. The draft EIS is made available for a 45-day public review once published in the Federal Register and the final EIS is subject to a 30-day public review before a record of decision by the Chief may be issued. As with an EA, the preparation of an EIS is covered in detail in the National Environmental Compliance Handbook.

601.43 Civil Rights Analysis and Tribal Impact Statements

- A. A civil rights impact analysis (CRIA) is required for all rulemakings by DR 4300-004. The FPAC Business Center Civil Rights and Equal Opportunity Division (CREOD) prepares a CRIA subject to necessary requirements.
- B. CREOD will prepare a CRIA within 4 to 6 weeks of receiving notice for proposed, interim, and final rules as follows.
 - 1. The Chief, deputy chief for Programs, or other responsible official notifies CREOD that a rule is being developed and an associated CRIA is needed.
 - 2. The responsible official forwards copies of legislation and program changes along with the proposed, interim, or final rule changes to CREOD.
 - 3. Under the USDA Action Plan for Tribal Consultation and Collaboration, the NRCS Outreach and Partnerships Division is responsible for preparing a separate tribal impact statement. The tribal impact statement and supporting documentation is forwarded to CREOD for certification.

4. CREOD reviews the program and rule to determine the scope of the analysis and the type of data that is needed.
5. A formal request for data from CREOD is sent to EPAD.
6. CREOD staff analyzes the rule and data for potential disparate treatment.
7. CREOD relies on a stipulated statement as it relates to the BCA of the rule and drafts the report in accordance with policy.
8. The CRIA goes through the following internal review process:
 - a. A copy of the draft CRIA is forwarded to the responsible official to ensure programmatic consistency with proposed legislated changes.
 - b. The responsible official returns the draft to CREOD, who makes any required revisions. The CRIA is submitted to the CREOD director for certification.
 - c. Once the CREOD director certifies the CRIA, it is forwarded to the USDA Office of the Assistant Secretary for Civil Rights (OASCR) for preliminary clearance.
 - d. Upon clearance of the CRIA from the OASCR, the certified original copy of the CRIA is returned to the responsible official and added the rule package.

601.44 Tribal Consultation

Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments,” requires that any time an agency develops a new rule, policy, or directive or takes any action directly impacting one or more tribes, the agency must consult with tribes early and often during the decision-making process. A statement on tribal consultation must be included in the regulatory certifications section of all rules. The NRCS tribal relations liaison also works closely with CREOD when drafting tribal impact statements and is responsible for developing and writing tribal policy under DR 1350-001.