By George G. Misko, Esq.

FDA Demand for FCN Environmental Assessments Is a Solution Looking for a Problem

Tougher standards, more demanding requests make for even stickier red tape

Completing an environmental assessment (EA) for a food contact submission to the U.S. Food and Drug Administration (FDA) has always been a nuisance task. This was true with food additive petitions and threshold of regulation (TOR) submissions and is no less true today with food contact notifications (FCNs). Although no one disputes FDA's interpretation of the National Environmental Policy Act (NEPA) of 1969 as requiring the agency to review the potential environmental impact of its actions, the last 40-plus years have borne out the significance of this inquiry: *de minimis*, at best. An environmental issue has only once prevented a clearance for a food packaging material from proceeding.[1]

Notwithstanding the rather meager significance of this work on the agency's part, a noteworthy development took place in 2015 and has not let up since. Starting that summer, submitters of FCNs saw a significant increase in the number of questions FDA asked related to EAs. These additional questions and the Council on Environmental Quality's (CEQ) August 2016 Final Guidance on Greenhouse Gases and Climate Change–which recommends, among other things, that federal agencies quantify greenhouse gas (GHG) emissions in documents required under NEPA, such as EAs for food contact substances (FCSs)–have impacted how submitters must prepare EAs, taking more time and resources with no net benefit to the environment.

National Environmental Policy Act

The requirement to conduct an EA stems from NEPA, which specifies that all federal agencies must consider environmental factors in their decision making and examine the environmental impacts of major and final actions. It also established the CEQ in the Executive Office of the President, which oversees NEPA implementation and issues regulations and other guidance to federal agencies regarding NEPA compliance. CEQ issued implementing regulations for NEPA in 1978[2] and guidance documents on NEPA implementation.

Under NEPA, all federal agencies are required to prepare an Environmental Impact Statement (EIS) for any major action significantly affecting the quality of the environment. EISs must include a detailed analysis of the potential environmental impact, any adverse environmental effects that cannot be avoided and alternatives to the proposal. If it is unclear whether an anticipated environmental impact will be significant, then an EA is prepared. An EA is a "concise public document that serves to provide sufficient evidence and analysis for an agency to determine whether to prepare an EIS or a Finding of No Significant Impact."[3]

Federal agencies may establish categorical exclusions (CATEXes) for actions that have no significant effect on the environment. More specifically, CATEXes are:

- Categories of action that do not individually or cumulatively have a significant effect on the environment
- Generally established based on agency experience
- Narrowly defined and precisely worded to fit very specific actions

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In addition, NEPA regulations require all federal agencies to "provide for extraordinary circumstances in which a normally excluded action may have a significant environmental effect."[4] Therefore, if a CATEX is not applicable or an extraordinary circumstance exists, then an EA is required.

FDA and EAs

Since NEPA establishes a baseline standard without dictating the specific actions an agency must take, many federal agencies have developed their own NEPA procedures that supplement the CEQ NEPA regulations. Importantly, NEPA supplements FDA's authority under the Federal Food, Drug, and Cosmetic Act of 1938 and other statutes but does not supersede it. Regulations specific to FDA's environmental review of FCNs can be found in 21 C.F.R. Part 25.

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With respect to environmental reviews, an FCN must contain information to address FDA's responsibility under NEPA in the form of either a claim of exemption based on a CATEX or an EA. When an FCN is for multiple uses and the entire action does not qualify for a CATEX, then an EA must be prepared. As noted previously, even actions that are ordinarily categorically excluded must have an EA if extraordinary circumstances indicate that the action may nonetheless have a significant environmental effect, such as:

- Potential for serious environmental harm
- Adverse effects on a federally protected species or its habitat
- It is highly uncertain or involves unique or unknown risks
- It is precedent setting
- Unique characteristics, such as an ecologically critical area
- It threatens a violation of laws imposed for environmental protection

In 2006, FDA issued a guidance on CATEXes and EAs entitled *Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition*. The guidance outlines that a claim of CATEXes must cite the CATEX claimed; include a statement of compliance with the criteria of that CATEX; and include a statement that, to the applicant's knowledge, no extraordinary circumstances exist that would require the preparation of an EA. In some instances, FDA may require that a CATEX claim be substantiated with supporting data so the FDA reviewer can determine whether the claim is warranted.

All FCNs must include an EA or claim for an exemption based on a categorical exclusion.[5] FDA adopted the same exclusions for FCNs that apply to food additive petitions and TOR submissions. These CATEXes include food packaging substances that compose 5 percent or less of the finished article, provided the substances are intended to remain with the finished packaging material throughout use by consumers or when the substances are a component of a coating or repeated-use article, where no extraordinary circumstances exist.[6]

The most commonly claimed CATEXes for packaging components other than coatings fail because:

- FCS use level for noncoatings is not indicated in the submission or exceeds 5 percent by weight
- FCS is a processing aid and less than 95 percent is retained in the finished package
- Retention of the FCS through use and disposal is not supported[7]

The other CATEXes established by FDA include:

- CATEX 25.32(j): When the FCS is used as a component of a food contact surface of permanent or semipermanent equipment or another article intended for repeated use. Service lifetime and market volume are often useful in determining if this CATEX claim is warranted.
- CATEX 25.32(k): For substances directly added to food that are intended to remain in food through ingestion by consumers and are not intended to replace macronutrients (carbohydrates, proteins, fats). This exclusion is primarily for food and color additive petitions and rarely applicable to FCSs.
- CATEX 25.32(q): For an FCS registered by the U.S. Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act for the same use requested in the petition.
- CATEX 25.32(r): For a substance that occurs naturally in the environment, and "when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or its degradation products in the environment."

If a claim for a CATEX is not available and an EA is required, it must include brief discussions of the need for the proposal, the available alternatives, the environmental impacts of the proposed action and the alternatives, and a listing of agencies and persons consulted. An EIS is required only when significant impacts are potentially present. FDA has never completed an EIS for a food packaging material.

Since 2006, CEQ has issued three guidance documents with relevance to reviews conducted by FDA's Center for Food Safety and Applied Nutrition:

- *Final Guidance on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews,* August 2016
- *Improving the Process for Preparing Efficient and Timely Environmental Review (Relevant for Preparation of EAs),* March 2012
- *Establishing, Applying, and Revising Categorical Exclusions,* November 2010

FDA readily acknowledges that the November 2010 guidance needs updating and is apparently working on an updated version.[7]

Guidance on GHGs

The guidance on GHGs and climate change recommends, among other things, that federal agencies quantify GHG emissions in documents required under NEPA, including EAs for FCSs. The guidance was intended to clarify when and how federal agencies should conduct GHG analyses as part of NEPA reviews. Among other things, it pointed out that even minor activities should get some GHG emission analysis. Significantly, because of the guidance, FDA began requiring more detailed environmental information in FCN submissions, even when a CATEX applies.

CEQ defines GHGs as carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, nitrogen trifluoride and sulfur hexafluoride. The common unit of measurement for GHGs is metric tons of CO_2 equivalent. CEQ's final guidance related to GHG emissions in NEPA documents includes the following recommendations:

- An agency action's projected direct and indirect GHG emissions should be quantified whenever the necessary tools, methodologies and data inputs are available, taking into account available data and GHG quantification tools that are suitable for the proposed action
- Agencies should use projected GHG emissions (to include, where applicable, carbon sequestration implications associated with the proposed agency action) as a proxy for assessing potential climate change effects when preparing a NEPA analysis for a proposed action
- When an agency does not quantify a proposed action's projected GHG emissions because tools, methodologies or data inputs are not reasonably available, the agency should include a qualitative analysis in the NEPA document and explain the basis for determining that quantification is not reasonably available
- Agencies should consider alternatives that would make an action and affected communities more resilient to the effects of a changing climate

The final guidance does not include the annual 25,000 metric tons CO_2 equivalent threshold that was in the draft guidance. However, the threshold is still applicable because it is legally the reporting threshold for municipal solid waste (MSW) combustion facilities, and, in general, the GHG emissions that would occur from disposal of a food contact material are related to combustion in MSW combustion facilities.

More Information Requested

FDA first-phase reviews of FCNs almost invariably request additional environmental information or clarifications now that were passed on in years past. In addition to new requirements associated with GHGs, the standards for assessment are becoming increasingly stringent. In some cases, additional information on a CATEX claim is being requested. For example, FDA has asked for examples of possible repeat-use applications to demonstrate compliance with the length-of-service-life conditions described in the preamble to the regulation.

In many instances, FDA is returning an EA for revisions just to modify the wording used. This sometimes includes the rejection of language that FDA found acceptable for years and now finds inadequate. In these circumstances, FDA reviewers will often provide the submitter with specific wording to be used in the revision. Although none of this is difficult or likely to endanger the clearance of an FCN, it does tend to be annoying.

The Future

The guidance on GHG emissions with respect to the NEPA and CEQ regulations refers to the relationship between GHG emissions and climate change. In the introduction, CEQ states, "Analyzing a proposed action's GHG emissions and the effects of climate change relevant to a proposed action—particularly how climate change may change an action's environmental effects—can provide useful information to decision makers and the public."

President Donald Trump has indicated that his energy policy will focus less on climate change, in addition to calling for a reduction in federal regulations. Consequently, the GHG memo has been removed from CEQ's website.

Despite the current administration's emphasis on reducing regulations related to climate change, FDA still requires FCN submissions to include more specific, detailed information in the environmental review section. So for now, preparation of an FCN will continue to require the submission of an EA, or at least a GHG assessment, to support a claim of categorical exclusion. ■

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