

Draft Guidance for Preparing Environmental Reports

NEPA Pilot Project

July 2011

Biotechnology Regulatory Services

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Purpose of this Guidance Document

This guidance provides information on how to prepare an environmental report (ER) for submission to Biotechnology Regulatory Services (BRS) as part of the NEPA pilot project. ERs can be submitted as part of the petition package when filing a petition under the regulations at 7 CFR 340.6. Petitioners can submit the ER up until the time that APHIS initiates the NEPA analysis. Be sure to contact APHIS to discuss when you plan to submit the ER. Submission of an ER is voluntary.

This guidance provides a general overview of the contents of an ER. It also presents some technical guidance on formatting and packaging the report for delivery to the agency.

Throughout this guidance the term “crop” is used. Crop should be interpreted to mean an agricultural crop: field crops, ornamental plants, orchard trees, forestry, cover crop, or any other way that plants are used for agricultural purposes.

Introduction

What is an Environmental Report?

An ER is not an Environmental Assessment (EA). It is a technical document that provides the basis for preparing a NEPA analysis. It describes the subject of the petition and how it will be used in the environment. It compares the current agroecosystem with one that includes the use of the GE organism that is the subject of the petition. ERs should include enough background information about the GE crop and affected environment associated with the crop for the reader to fully understand where the crop is typically produced and the practices used to produce the crop in U.S. agriculture, and how the crop will interact with the environment. The report should be prepared using a balanced approach (providing both pros and cons of the subject/issue) and should not contain excessive background details or analysis which does not contribute to the overall understanding of how the crop will interact with the environment.

Scoping the Issues

Each petition is unique in itself and therefore all issues identified in this guidance document may or may not be applicable in all situations. An issue considered in an EA for a previous petition may not be applicable in

your current ER. It is important to consider which issues are relevant for the new petition and to supply this information in your ER.

To identify which issues are relevant, you need to scope the issues. Some ways to scope are:

- Use the market data that prompted you to develop that product.
- Look at previous petitions for similar products. What was covered in the EA? What types of public comments were received?
- Read the literature. What issues are being raised in the scientific community? Are any of these issues controversial within the scientific community?
- Talk to growers, processors, extension agents, or other people who may be interested in using the product or may have concerns about its use.
- Read the news, blogs, websites, etc. to gauge public interest in the product.

Developing the Environmental Report

A typical ER may contain the following sections. As you work through each section, strive to present a balanced view of the issues supported by current scientific data and literature.

Purpose and Need for the GE Organism

This section identifies and describes the GE organism for which the petition is being submitted and establishes the rationale for why the specified GE organism is needed. Describing the purpose and need of a GE organism can help to identify how the organisms will be used in the human environment.

In the ER, briefly describe the “problem” that the GE organism was designed to address and how the organism helps to solve that “problem.” Make sure that enough information is presented to understand the issues or concerns driving the need.

Questions to consider include: Does the GE organism help growers manage weeds or pests? Is it resistant to an economically important disease? Does the GE organism have unique characteristics that fill a market niche in which the non-GE organism is not used? Can the GE organism be grown in areas that the non-GE organism cannot be grown? Is the GE organism intended to replace or supplement what is currently on the market? If intended as a replacement, why is the replacement product needed?

Action

An important part of any NEPA analysis is clearly describing the action that the agency is proposing. APHIS is considering whether or not to approve your petition. By describing the action that you are seeking APHIS to perform, you begin to define the scope of the analysis. Clearly stating the action will also help to define the types of information that you should include in your ER. If you are seeking for APHIS to approve a petition for two different events, then your data should include information about both events.

Describe the action for which you have petitioned APHIS. Are you seeking the deregulation of a particular event and all of its progeny? Are you seeking the deregulation of multiple events and their progeny? Clearly identify what action you are seeking from the agency.

Action Area

Defining the action area is an important first step in conducting an environmental analysis. By clearly identifying the geographic area of the action, you can identify the potential resources that may be affected.

Start by identifying where the non-GE crop or deregulated similar GE crop is typically grown. Is the crop only grown in certain areas of the country, or is it grown in all states? On what types of land is the crop grown? What are the geographic limits of crop production? For example, are there only certain planting zones or soil types in which it can be planted? Once you have established where the non-GE plant can be grown, determine if the GE plants will be grown in the same areas. Does the GE trait expand the areas where the plant can be cultivated? Does the GE trait restrict where the plant can be cultivated? Is the GE plant intended for a specialty market that is dependent on proximity to certain types of infrastructure (e.g., processing plants or refineries)?

In the ER, briefly describe where the GE plants can be grown, highlighting any differences from where the non-GE crop is typically cultivated.

Affected Environment

The affected environment is a description of the receiving environment where the GE organisms will be grown. The affected environment is not an analysis of impacts. It includes all of the resources with which the GE organism will interact directly and indirectly. When describing the affected environment, consider the present prevailing conditions. Do not focus on how conditions were in the distant past or how conditions might be in the future.

For most crop plants, the affected environment can be divided into six main areas: agricultural production, the physical environment, biological resources, human health, livestock health, and socioeconomic. Each of these sections is described briefly below. The level of detail used to describe each section depends on how that resource area is affected by producing and marketing products of the proposed GE organism. The more environmental interactions there are, the more detailed the description should be. Think about how the GE organism that is the focus of the report will interact with each resource area. Be sure to think about direct and indirect interactions. Be sure to include important local or regional differences in your descriptions.

The following sections are typically included in the affected environment. Place extra emphasis on those areas where the interactions will change as a result of the use of the GE organism. Only briefly discuss those areas where there will be no change in the interactions. Use the action area that you defined, above, to help to bound your discussion of the affected environment.

Agricultural Production

Land use

This section should include a discussion of the area where the crop is grown and the acreage of the crop. This information can be presented in a table or a figure. Give some context to the area where the crop is grown. Is it major crop of the area or a minor crop? Have the number of acres been increasing or decreasing over time? How much (percent/proportion) of the land in the area where this crop is grown is agricultural land? Are the seed crop and the commodity crop grown in separate regions? If so, identify the different areas.

If the subject of the petition is a new GE crop (first of its kind), or the GE trait will allow the crop to be grown in a new area, describe how the land is used now. What types of crops are grown? If it is not cropland, how is it used?

General production

Describe the life cycle of the conventional plant. Is it grown as an annual or as a perennial? When is the crop typically planted? When is it typically harvested? Does planting or harvesting time vary by region? What are typical yields? What types of cultivation practices are used? Do these vary by region? Are cover crops used? What are the typical rotation crops? Do these practices vary by region? Are the seed crop and the commodity crop produced differently? If so, explain how there are different.

Tillage

This section describes the tillage practices associated with the crop. Only include tillage as a separate section if the GE crop is likely to result in a change in tillage practices. If the GE crop does not result in a change in tillage, discuss briefly in the general section. Discuss how tillage is currently used. Is conservation tillage employed? On what percent of the acres is conservation tillage used? What types of conservation tillage are used?

Pesticide use

This section describes pesticide use on the currently available (conventional and/or GE) varieties. Only include pesticide use as a separate section if the GE crop is likely to result in a change in pesticide use. If the GE crop does not result in a change in pesticide use, discuss briefly in the general section.

Disease or pest management

In this section, discuss management practices used to control pests and diseases focusing on the target pest or disease as is appropriate. Only include disease or pest management as a separate section if the GE crop is likely to result in a change in these management practices. If the GE crop does not result in a change in management practices, discuss briefly in the general section.

Specialty markets

If the GE crop is for a specialty market then be sure to describe the current production practices and post-harvest isolation and processing protocols for that market. Include common methods for managing gene flow in the crop, if applicable. Discuss any differences in the land use associated with the specialty crop.

Organic markets

If an organic market exists for the crop, describe the acreage grown, the land use associated with organic production, and techniques used in organic production, including buffers.

Any other relevant topics

Add any additional topics that are important to the agricultural production practices associated with the production of the non-GE organism.

Physical Environment

This section describes the physical environment with which the GE organism will interact. It includes soil, water, and air resources. Climate change is typically discussed in this section as well.

Soil

How do soil resources interact with the currently available varieties of the crop plant? Are only certain types of soils suitable for growing the plant? Is soil erosion an issue with growing the currently available varieties? Are there regional differences in soil types that influence or change the cultivation practices for the currently available varieties of the crop?

Water

Discuss water resources that may interact with the currently available crop. Consider direct and indirect interactions with surface water and groundwater. How is water used as a resource for growing the crop? Consider regional differences.

Air

Discuss the interaction of the crop and its production practices with air quality. Do any particular production practices influence the quality of the air? For example, does tillage cause local issues with increased particulate matter in the air? Does the crop directly affect air quality? Are there known issues of pesticide volatilization and drift associated with current production procedures? If so, use this section to frame the air quality issues that may be affected by the GE crop.

Climate change

Discuss anthropomorphic climate change and the interaction with the currently available varieties of crop or the crop that the GE organism may displace. Some things to think about are farm equipment use, petroleum based products, or carbon sequestration.

How might climate change interact with the production of the crop? Some things to think about include shifts in weather patterns, shifts in pest populations, or shifts in weed populations. Describe the relevant factors.

Biological Resources

The section describes the plants, animals, and microorganisms with which the GE organism is likely to interact.

Animals

Focus on the types of animals that are typically associated, directly or indirectly, with the production of the crop. If the GE organism will extend the range of where a crop can be grown, be sure to discuss the biological resources in the new cultivation areas. If the GE crop is likely to displace a different crop, discuss the biological organisms that interact with that crop. Look at both vertebrates and invertebrates. Discuss pest organisms, beneficial organisms, and any other organisms that can be found in the area. How do these animals use the crop? Do they eat it? Live in it? Hunt in it? Include animals that might use surrounding areas that are affected by the production of the currently available varieties of the crop (or will be newly affected by the practices associated with the GE organism). When identifying the appropriate resources, consider impacts

from pesticide use, tillage, or irrigation. Put emphasis on those biological resources that might change with the planting and production of the proposed product.

Plants

What plants are typically associated with the currently available varieties of the crop? Which are weeds? What plants may be found around the periphery of the crop? Does this vary by region? Which plants may be directly or indirectly affected by current management practices?

Be sure to identify any plants with which the GE organism and its respective non-GE organism may be able to interbreed that occur within the action area. Describe the frequency of crossing under common management practices.

Microorganisms

Microorganisms can have beneficial, detrimental, or neutral interactions with crop plants. Describe those that have important interactions with the currently available varieties of the crop plant that is the subject of the petition. Focus on those whose interactions may change when planting the proposed product. Also, focus on important interactions that may change as a result of changes in management practices.

Biological diversity

Agricultural production can affect the biodiversity of an area. The crop and the production methods can both influence biodiversity. Describe the biodiversity typically associated with the crop. Focus on local or regional difference of note. Look at within field biodiversity and adjacent land biodiversity. Think about stable and transient interaction of organisms in the agricultural ecosystem.

Human Health

This section describes both consumer health and worker health. Consumer health should focus on direct and indirect exposure to the products of the crop. Worker health should focus on the agricultural workers and processors that interact with the crop.

Consumer health

Describe how people are exposed to the currently available varieties of the crop that is the subject of the petition. Is it eaten? Is it used for fiber? Is it used for fuel? How frequently are people exposed to it? How much do consumers typically eat or use the crop? Look at both direct and indirect exposure.

Worker health

When discussing worker health, look at both direct (e.g. dermal contact, inhalation) and indirect (e.g. pesticide use) exposures related to the production of the crop. Are there certain types of injuries associated with the production of the crop or its products? Pay special attention to possible adverse changes workers with the use of the GE crop.

Livestock Health

Many products of agricultural are used as components of livestock feed. Describe crop use in livestock feed (if applicable). Which livestock? How is it fed: whole or processed? Is only a component of the product used? If so, how is it processed? How important is it to livestock diets? Is its use regional or is it used nationally?

Socioeconomic

Domestic socioeconomic environment

Describe how the crop is typically incorporated into commerce. Is it sold for domestic use? What are the values of these markets? Are there specialty markets for the crop? Where are those markets located? Is there an organic sector? Where is it located? What is its value? What is its structure? Are there social or cultural preferences associated with the crop? Are there regional or demographic differences in specialty markets associated with the crop?

Export markets

Is this crop exported? What is the value of the market? Is the GE crop approved in other countries? Are there major export markets in which it has not been approved? Are there markets that are sensitive to GE traits? Are there practices currently used to address those sensitivities?

Alternatives

For the ER, the preparer should examine two alternatives: approving the petition and denying the petition. APHIS will use the plant pest risk assessment to identify the full range of reasonable alternatives. The preparer should not attempt to identify the full range of reasonable alternatives, as the APHIS plant pest risk assessment for the petitioned regulated article will not be complete during the completion of the ER.

Environmental Consequences

The environmental consequences section should compare the potential impacts from approving the petition to the impacts from not approving the petition. The analysis of impacts should be discussed relative to each of

the areas described in the affected environment. The methods and the assumptions for the analysis need to be clearly identified and supported with references and data.

As you work through this analysis, think about how the GE crop is different from the currently available crops. Focus on those issues that are likely to be different between the subject of the petition and the currently available varieties. If the GE crop is a replacement product, a brief analysis may be all that is necessary

Agricultural Production

Land use

Analyze the trends for agricultural practices under the alternative to deny the petition (no action). This is the baseline for your analysis. Look at the trends in the production of the crop. Has acreage been increasing, decreasing, or staying the same? What factors are influencing this trend? Are these trends likely to continue under the no action alternative? If land use is changing, what is happening to the land? Is it being converted from agriculture to another use? Is it being converted from another use to agriculture? Is the type of agricultural production changing? Compare the alternative (i.e., to approve the petition) to the baseline alternative. Do the trends change? If so, how do they change? What is the magnitude of the change? Will the change be local, regional, or national in scale? If the trends do not change, explain why the GE crop does not influence the current trends.

If the GE crop will be grown in a new area, look at the crop production trends in the area under the no action alternative. Are those trends likely to continue under the no action alternative? What is influencing the trends? How will the introduction of the GE organism into this area change these trends? Identify the land use changes. Describe the scale of the changes. Describe the magnitude of the changes at the appropriate scales.

General production

Look at the general production characteristics associated with the no action alternative. Use cause and effect analysis or trend analysis to identify the influences of the non-GE or currently available GE varieties (no action alternative) on production practices. Look at trends in harvest time, age to maturity, yield, fertilizer use or other important characteristics. These are the baseline for your analysis. How does the

introduction of the new GE variety affect these characters? Does it reduce time to harvest? Does it increase yield per acre? Does it require less fertilizer? Does it require less irrigation? How do these changes influence other production practices? Work your way through the causes and effects to identify the changes in production. Do these changes vary by region? Look at scale. Is the effect local, regional, or national? What is the magnitude of the difference?

Tillage

Include this section only if the GE trait influences tillage practices. Begin by establishing the current tillage practices.

Analyze the tillage trends under the no action alternative. This is the baseline for your analysis. What types of tillage are used? On what percent of the acres is each type of tillage used? Does this vary by region? Has conservation tillage been increasing, decreasing, or staying the same? What is influencing these trends?

Compare the alternative, to approve the petition, to the baseline alternative. How will the trends change? What will influence these changes? Is there a difference among regions? Discuss the scale of the effects (local, regional, or national) and the magnitude of the effect.

Pesticide use

Only include pesticide use as a separate section if the GE crop is likely to result in a change in pesticide use. If the GE crop does not result in a change in pesticide use, analyze as appropriate in the general agricultural production section.

Begin by establishing current pesticide use for the currently available varieties of the crop. Which pesticides are typically used? Has their use been increasing or decreasing. What influences are driving these trends? Are there regional differences in pesticide use? Are there any production considerations associated with the use of the pesticides (e.g., rotation crop restrictions)?

How will the introduction of the new GE crop change pesticide use? Will the use of certain pesticides decrease? Will others increase in use? Will the GE crop allow the use of a pesticide that is not currently labeled for use on the crop? If so, how will it be used?

Disease or pest management

Only include disease or pest management as a separate section if the GE crop is likely to result in a change in these management practices. If the GE crop does not result in a change in management practices related to controlling pests or disease, discuss briefly in the general section.

Begin by establishing the current pest or disease pressures for the available varieties. Have these pressures been increasing, decreasing, or remained relatively stagnant? What is influencing the trend? Are there regional or local differences? What factors play into these differences? What are the management outcomes if the current trends continue?

How do the trends change with the introduction of the subject of the petition? Are there regional or local differences? What other factors influence the trend? Are these influences the same or different than the no action alternative? How will the management outcomes compare to the no action alternative?

Specialty markets

If the GE crop is for a specialty market, establish the current production trends for the crop used in this market. Analyze the effectiveness of production practices for meeting the desired goal. Will the production practices associated with the GE crop change with respect to the current practices for the specialty market. If they will not change, will the current practices be adequate to meet the desired goals? If the practices will change, how will these changes contribute to meeting the desired goal?

If it is a new specialty market, how will production practices compare to current production trends?

Organic markets

If an organic market exists for the crop, analyze the current trends for land use for organic production. Is the acreage growing, shrinking, or remaining the same? Are there certain regions where organic acreage is more prevalent? Examine trends in production practices.

How will the introduction of the subject of the petition affect the trends described for the no action alternative? Are there regional differences? What factors might affect the trends?

Any other relevant topics

Add any additional topics that are important to the agricultural production practices associated with the production of the non-GE organism that may

change with the introduction of the GE organisms. Be sure to compare the no action alternative with the alternative to approve the petition.

Physical Environment

Soil

Analyze how the currently available varieties of the crop (conventional and/or GE) impact soil. Include both direct (the plant) and indirect effects (cultivation). Include discussions of erosion, tillage, mineral fertility, or health of soil communities, as is relevant. This establishes the baseline for the no action (deny the petition) alternative. Then examine how soil resources will change if the petition is approved? If the GE crop will be grown in a new area, explain how existing crops impact the soil. Consider both direct and indirect effects. Will there be a change in erosion, tillage, or soil communities? Will changes in production practices affect (indirectly) soil or soil communities? Include analysis of the impacts on soil of those production characteristics that change as a result of using the GE crop. For example, changes in tillage practices can affect soil health or erosion potential.

Water

Analyze how the currently available varieties of the crop (conventional and/or GE) impact water resources, including indirect effects such as possible pesticide and nitrogen runoff, if relevant. Include both direct (the plant) and indirect effects (production practices). Include discussions of water use for irrigation, indirect effects on surface water from erosion or pesticide use, or impacts of cultivating the crop on groundwater, as relevant. This establishes the baseline for the no action (deny the petition) alternative. If the GE crop will be grown in a new area, explain how current crops in the action area impact the water resources. How will impacts on water resources change if the petition is approved? Consider both direct and indirect effects. Will there be a change in water use? Will changes in production practices affect (indirectly) runoff to surface water or groundwater?

Air

Analyze how the varieties of the crop (conventional and/or GE) currently available impact air quality, including indirect effects, such as to greenhouse gases and particulates. Include both direct (the plant) and indirect effects (production practices). Include discussions of impacts from erosion or pesticide use, or other impacts, as relevant. This establishes the baseline for the no action (deny the petition) alternative. If

the GE crop will be grown in a new area, explain how land use in the action area impacts the air quality. How will impacts on air quality change if the petition is approved? Think about both direct and indirect effects.

Climate change

Climate change needs to be examined from two perspectives. The first is how the introduction of the organism will impact climate change. The second is how climate change might affect where or how the organism is produced.

Begin by establishing trends in climate change and the uncertainties in forecasting their impacts. Discuss the relationship of the varieties of this currently available crop to climate change. Will climate change result in the proposed GE crop being grown in a new area? Discuss the impacts of crops currently grown. Do current production practices contribute to the release of greenhouse gases? Compare the new GE variety to the baseline. Does the introduction of the new GE crop change the contribution to climate change with respect to the baseline? Consider production practices as well as the plant itself. Be sure to characterize the scale and magnitude of the impact.

Look at how changes in climate may affect the production of the currently available varieties. If the GE crop will replace a different crop, discuss the effects of climate change on that production. Compare the new GE organism to the baseline. Discuss any changes. Characterize the scale and magnitude of the impact.

Biological Resources

Animals

Establish a baseline for how animals that interact with the crop are impacted by the currently available varieties of the crop. This is effectively the no action alternative for this analysis. Consider both direct effects and indirect effects. If the GE crop extends the range of the crop or changes where it can be grown, discuss the impacts of crop production on animals in those areas. Make sure to discuss the vertebrate and invertebrate animals that you identified in the affected environment section. Include impacts on beneficial, neutral, and pest animals associated with the current state. Analyze the impacts of production practices (pesticide use, tillage, irrigation, etc.) on these organisms. Focus on impacts to the populations of these organisms. Compare the impacts of

the use of the proposed product to the baseline. How do the impacts change? Consider both the direct effects of the new GE variety on each animal class, as well as the indirect effects of its production or processing. Be sure to characterize the scale of the impacts and magnitude of the effects.

Plants

Establish a baseline for how plants that interact with the crop are impacted by the currently available varieties of the crop. Consider both direct and indirect effects. If the GE crop extends the range of the crop or changes where it can be grown, discuss the impacts of crop production in those areas on plants. Make sure to cover the effect on any native or naturalized plants with which the crop can interbreed. Analyze the impacts of production practices (pesticide use, tillage, irrigation, etc.) on plants associated with the crop. Focus on impacts to the populations of these organisms. Compare the impacts of the use of the subject of the petition to the baseline. How do the impacts change? Consider both the direct effects of the new GE variety on each group of plants identified, and the indirect effects of production or processing of the crop. Be sure to characterize the scale of the impacts and magnitude of the effects.

Microorganisms

Identify the baseline for the impacts of the currently available varieties of the crop on microorganisms. Focus on what is known about important interactions, such as possible pesticide impacts on microorganisms. Analyze both direct and indirect effects. Direct effects are those associated with the plant, while indirect effects are those associated with production or processing. Compare the effects of the new GE variety to the currently available varieties. Describe any changes in impacts. Be sure to describe the scale and magnitude of the impacts.

Biological diversity

Analyze the impacts of the available varieties on biodiversity in the agricultural ecosystem. Look at direct and indirect effects on vertebrate and invertebrate animals and plants. A cause/effect analysis may be helpful for assessing the impacts on biodiversity.

Analyze the impacts of the new GE variety, comparing these impacts to the baseline. How does the introduction of the new organism change the impacts? Consider both direct and indirect impacts. Be sure to describe the scale and magnitude of the impacts.

Human Health

Consumer health

Begin by establishing the baseline under the no action alternative. How do the currently available varieties directly affect consumer health? Think about how people interact with the crop and its products. How will the introduction of the new GE variety change these effects? Are there local, regional, or national effects? What is the magnitude of the effect at each level?

Analyze the indirect effects of the production of the currently available crop varieties on consumer health. Include in this relevant processing or production practices that affect consumer health. Give special attention to those aspects of processing or production that may change with the adoption of the subject of the petition. Analyze how the introduction of the new GE variety indirectly impacts human health. If its use changes processing or production practices, focus on how those changes might impact consumer health. Are there local, regional, or national effects? Characterize the magnitude of the effect.

Worker Health

Begin by establishing the baseline under the no action alternative. How do the currently available varieties directly affect worker health? Consider how workers interact with the crop. Are allergies an issue? How will the introduction of the new GE variety change these effects? Are there local, regional, or national effects to worker health? What is the magnitude of the effect at each level?

Analyze the indirect effects of the production of the currently available crop varieties on worker health. Include in this analysis relevant processing or production practices that affect worker health. Give special attention to those aspects of processing or production that may change with the adoption of the subject of the petition. Analyze how the introduction of the new GE variety indirectly impacts worker health. If its use changes processing or production practices, focus on how those changes might impact worker health. Are there local, regional, or national effects? Characterize the magnitude of the effect.

Livestock Health

Establish a baseline based on the no action alternative for how the currently available varieties of the crop impact livestock health. If the new GE crop has altered composition, specifically discuss the existing

varieties with respect to those components that will change. Look at both direct and indirect effects on livestock health. Compare the new GE organism to those that are currently available. How does the genetic modification in the plant affect livestock that might consume it? How do indirect effects (changes in production practices, processing, stability of stored products, etc.) impact livestock feed? Be sure to characterize the magnitude of any effects.

Socioeconomic Effects

Domestic socioeconomic environment

Begin by analyzing the trends associated with the use of the currently available crop varieties in commerce. Pay special attention to those areas that will change with the introduction of the new GE variety. This is the baseline or no action alternative. Then consider any new phenotype of the variety and analyze how (if at all) these uses will change.

Look at trends in the values of the markets with available varieties. Analyze how these trends might change with the addition of the new GE variety. Consider how to present this analysis. You may want to focus on overall value, net return to grower, or reductions in input costs. Use the measure that is most appropriate to the analysis.

If you identified an organic industry associated with the crop, analyze the current trends in that market. How much of the crop is organic, looking at regional differences in the production and marketing. Analyze how the addition of the new GE crop to agriculture will affect the organic market. If seed and commodity crop production are regionally segregated, be sure to look at the effect of each on the organic sector.

If you identified a specialty market associated with the crop, analyze the current trends in that market. How much of the crop enters that market? Look at regional differences in the production and marketing. If there are demographic or regional preferences associated with the specialty market, include a discussion of those trends. Analyze how the addition of the new GE crop to agriculture will affect the specialty market.

If you identified social or cultural preferences associated with the use of the crop, analyze the impact of the current varieties on those preferences. If appropriate, look at regional differences in these preferences. Analyze how the introduction of the new GE variety influences the current preferences. Look at regional differences where appropriate. Characterize the magnitude of any effects.

Export markets

Characterize the export markets for the crop and currently available varieties. To what regions is the crop exported? What are the trends in the markets? If any of the markets are GE sensitive identify any processes or procedures used by these markets or thresholds used in testing for the markets. This is your no action alternative or baseline. Analyze how the new GE variety may impact the important export markets. Characterize the magnitude of the impact. Be sure to include a discussion of applications for regulatory approvals and for those received in other countries and the effect of these approvals on exports.

Cumulative Impacts

The cumulative impacts section should follow the order of topics covered in the direct and indirect impacts analysis above. CEQ defines cumulative impacts as:

"Cumulative impact" is the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time. (40 CFR 1508.7)

To begin the cumulative impacts section, first identify the impacts that you discussed in each section of the environmental consequences thus far. If you did not find any impacts under a given topic, there is no need to discuss the cumulative impacts of that topic. Wherever there are impacts (even minor ones), identify the baseline related to that impact. Look at the past, present, and future actions that have contributed to the impact. It does not matter who has taken the action, just that the actions together are causing the impact. Once you have established the baseline, ask how the addition of the subject of the petition will change the impact? Look at the impact at different scales (local, regional, national), if appropriate. Be sure to characterize the magnitude of the impact as well.

Format and Document Preparation

Document

A Microsoft Word template is available in your packet.

Margins are 1 inch all around.

Headers at level 1 are in Arial 16 point bold font.

Headers at level 2 are in Arial 14 point bold font.

Headers at level 3 are in Arial 11 point bold font.

Use Times New Roman 12 pt. text for the body of the document.

All figures should be formatted to fit within the above margins.

Deliverables

- APHIS uses Endnote bibliographic software. If possible, include all references organized and cataloged in an Endnote library. Additionally, if possible, ensure that all citations and the bibliography within the ER are formatted by Endnote.
- Please submit ERs as a doc, docx, or rtf file and also as a pdf file. The pdf file of the ER will be posted on the internet along with the petition file.
- Include an electronic (preferred) or hard copy of all references used to prepare the ER. Highlight relevant data in references.
- Please submit separate files for all figures and tables that are included in the ER in the original format. Include all supporting data that was used to create the table or figure. Do not flatten the image in the original file.
- If claiming supporting data as CBI, a CBI and a CBI deleted version should be submitted with the references.