

Guidance to Industry for Foods Derived from New Plant Varieties

Text Version of Figures

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Statement of Policy: Foods Derived From New Plant Varieties

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Action: Notice.

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Figure 1. Safety Assessment of New Varieties: Summary

Figure 1 shows a flow chart for two different aspects of the evaluation: one for unexpected or unintended effects, and one for expected or intended effects. These are summaries that reference Figures 2-6 in this document.

1. Unexpected or unintended effects

- a. Safety assessment: the host plant (Figure 2)
 - i. Have safety concerns about host-associated toxicants and donor-associated toxicants been addressed?
 1. If no: New variety not acceptable.
 2. If yes: Are the concentration and bioavailability of important host-associated nutrients within range?
 - a. If no: Consult FDA.
 - b. If yes: No concerns.
- b. Safety assessment: the donor(s) (Figure 3)
 - i. If food from the donor is commonly allergenic, can it be demonstrated that the allergenic determinant has not been transferred to the new variety?
 1. If no: Consult FDA.
 - a. Have safety concerns about host-associated toxicants and donor-associated toxicants been addressed?
 - i. If no: New variety not acceptable.
 - ii. If yes: Are the concentration and bioavailability of important host-associated nutrients within range?
 1. If no: Consult FDA.
 2. If yes: No concerns.
 2. If Yes: Have safety concerns about host-associated toxicants and donor-associated toxicants been addressed?
 - a. If no: New variety not acceptable.
 - b. If yes: Are the concentration and bioavailability of important host-associated nutrients within range?
 - i. If no: Consult FDA.
 - ii. If yes: No concerns.

2. Expected or Intended Results

- a. Safety assessment: Introduced proteins in new variety (Figure 4).
 - i. If food from the donor is commonly allergenic, can it be demonstrated that the allergenic determinant has not been transferred to the new variety?
 1. If yes: Is there any reported toxicity, or does the biological function raise any safety concern?
 - a. If yes: Is there any reported toxicity, or does the biological function raise any safety concern?
 - i. If yes: Consult FDA.

- ii. If no: Is the introduced protein likely to be a macroconstituent in the human or animal diet?
 - 1. If yes: Consult FDA.
 - 2. If no: No concerns.
 - b. If no: Consult FDA.
 - i. Is there any reported toxicity, or does the biological function raise any safety concerns?
 - 1. If yes: Consult FDA.
 - 2. If no: Is the introduced protein likely to be a macroconstituent in the human or animal diet?
 - a. If yes: Consult FDA.
 - b. If no: No concerns.
- b. Safety assessment: new or modified carbohydrates, fats or oils in new variety (Figure 5 and 6).
 - i. Are there any unusual or toxic components? Are there any alterations that could affect nutritional qualities or digestibility in a macroconstituent of the diet?
 - a. If no: No concerns.
 - b. If yes: Consult FDA.

Figure 2. Safety Assessment of New Varieties: The Host Plant

Figure 2 is a flow chart beginning with “Does the host species have a history of safe use?”. Following the paths, and answering the questions, the end will be either “No concerns” or “Consult FDA”. It references notes 1-5c, which follow in the document text.

1. Does the host species have a history of safe use? (See Note 1.)
 - a. If yes: Do characteristics of the host species, related species, or progenitor lines warrant analytical or toxicological tests? (See Note 2.)
 - i. If yes: Do test results provide evidence that toxicant levels in the new plant variety do not present a safety concern? (See Note 3.)
 1. If no: New variety not acceptable. (See Note 5b.)
 2. If yes: Is the concentration and bioavailability of important nutrients in the new variety within the range ordinarily seen in the host species? (See Note 4.)
 - a. If yes: There are no concerns. (See Note 5a.)
 - b. If no: Consult FDA. (See Note 5c.)
 - ii. If no: Is the concentration and bioavailability of important nutrients in the new variety within the range ordinarily seen in the host species? (See Note 4.)
 1. If yes: There are no concerns. (See Note 5a.)
 2. If no: Consult FDA. (See Note 5c.)
 - b. If no: Do test results provide evidence that toxicant levels in the new plant variety do not present a safety concern? (See Note 3.)
 - i. If no: New variety is not acceptable. (See Note 5b.)
 - ii. If yes: Is the concentration and bioavailability of important nutrients in the new variety within the range ordinarily seen in the host species? (See Note 4.)
 1. If yes: There are no concerns. (See Note 5a.)
 2. If no: Consult FDA. (See Note 5c.)

Figure 3. Safety Assessment of New Varieties: The Donor(s)

Figure 3 is a flow chart beginning with “Is food from the donor commonly allergenic?” Following the paths, and answering the questions, the end will be either “No concerns” or “New variety not acceptable.” It references notes 6-9b, which follow in the document text.

1. Is food from the donor commonly allergenic? (See Note 6.)
 - a. If yes: Can it be demonstrated that the allergenic determinant has not been transferred to the new variety of host plant? (See Note 6.)
 - i. If yes: Do characteristics of the donor species, related species, or progenitor lines warrant analytical or toxicological tests? (See Note 7.)
 1. If no: No concerns. (See Note 9a.)
 2. If yes: Do test results provide evidence that toxicant levels in the new plant variety do not present a safety concern? (See Note 8.)
 - a. If yes: No concerns. (See Note 9a.)
 - b. If no: New variety not acceptable. (See Note 9b.)
 - ii. If no: Consult FDA on protocols for allergenicity testing and/or labeling. (See Note 9c.)
 1. Do characteristics of the donor species, related species, or progenitor lines warrant analytical or toxicological tests? (See Note 7.)
 - a. If no: No concerns. (See Note 9a.)
 - b. If yes: Do test results provide evidence that toxicant levels in the new variety do not present a safety concern? (See Note 8.)
 - i. If yes: No concerns. (See Note 9a.)
 - ii. If no: New variety not acceptable. (See Note 9b.)
 - b. If no: Do characteristics of the donor species, related species, or progenitor lines warrant analytical or toxicological tests? (See Note 7.)
 - i. If no: No concerns. (See Note 9a.)
 - ii. If yes: Do test results provide evidence that toxicant levels in the new plant variety do not present a safety concern? (See Note 8.)
 1. If yes: No concerns. (See Note 9a.)
 2. If no: New variety not acceptable. (See Note 9b.)

Figure 4. Safety Assessment of New Varieties: Proteins Introduced from Donor(s)

Figure 4 is a flow chart beginning with “Is the newly introduced protein present in food derived from the plant?” Following the paths, and answering the questions, the end will be either “No concerns” or “Consult FDA.” It references notes 10-17e, which follow in the document text.

1. Is the newly introduced protein present in food derived from the plant? (See Note 10.)
 - a. If no: No concerns. (See Note 17a.)
 - b. If yes: Is the protein derived from a food source, or substantially similar to an edible protein? (See Note 11.)
 - i. If no: Does the biological function of the introduced protein raise any safety concern, or is the introduced protein reported to be toxic? (See Notes 14, 15.)
 1. If yes: Consult FDA (See Note 17d, e.)
 2. If no: Is the introduced protein likely to be a macroconstituent in the human or animal diet? (See Note 16.)
 - a. If no: No concerns. (See Note 17a.)
 - b. If yes: consult FDA. (See Note 17d, e.)
 - ii. If yes: Is food from the donor commonly allergenic? (See Note 11.)
 1. If yes: Can it be demonstrated that the allergenic determinate has not been transferred to the new variety of host? (See Note 11.)
 - a. If yes: Is the Introduced protein reported to be toxic? (See Note 12.)
 - i. If yes: Consult FDA (See Note 17c.)
 - ii. If no: Will the Intake of the donor protein in new variety be generally comparable to the intake of the same or similar protein in donor or other food? (See Note 13.)
 1. If yes: Is the introduced protein likely to be a macroconstituent in the human or animal diet? (See Note 16.)
 - a. If no: No concerns (See Note 17a.)
 - b. If yes: Consult FDA. (See Note 17d, e.)
 2. If no: Does the biological function of the introduced protein raise any safety concern, or is the introduced protein reported to be toxic? (See Note 15.) (See continuation note below** for further decisions.)
 - b. If no: Consult FDA on protocols for allergenicity testing and/or labeling. (See Note 17b.)
 - i. Is the Introduced protein reported to be toxic? (See Note 12.)

1. If yes Consult FDA (See Note 17c.)
2. If no: Will the Intake of the donor protein in new variety be generally comparable to the intake of the same or similar protein in donor or other food? (See Note 13.)
 - a. If yes: Is the introduced protein likely to be a macroconstituent in the human or animal diet? (See Note 16.)
 - i. If no: No concerns (See Note 17a.)
 - ii. If yes: Consult FDA. (See Note 17d, e.)
 - b. If no: Does the biological function of the introduced protein raise any safety concern, or is the introduced protein reported to be toxic? (See Note 15.) (See continuation note below** for further decisions.)
2. If no: Is the introduced protein reported to be toxic? (See Note 12.)
 - a. If yes: Consult FDA,
 - b. If no: Will the intake of the donor protein in new variety be generally comparable to the intake of the same or similar protein in donor or other food? (See Note 13.)
 - i. If yes: Is the introduced protein likely to be a macronutrient in the human or animal diet (See Note 16.)
 1. If yes: Consult FDA (See Note 17d, e.)
 2. If no: No concerns (See Note 17a.)
 - ii. If no: Does the biological function of the introduced protein raise any safety concern, or is the introduced protein reported to be toxic? (See Note 15.) (See continuation note below** for further decisions.)

** Continuation after “Does the biological function of the introduced protein raise any safety concern, or is the introduced protein reported to be toxic? (See Note 15.)”

1. If yes: Consult FDA (See Note 17d, e.)
2. If no: Is the introduced protein likely to be a macroconstituent in the human or animal diet? (See Note 16.)
 - a. If no: No concerns. (See Note 17a.)

b. If yes: consult FDA. (See Note 17d, e.)

Figure 5. Safety Assessment of New Varieties: New or Modified Carbohydrates

Figure 5 is a flow chart beginning with “Has there been an intentional alteration in the structure, composition, or level of carbohydrates in the new variety?”. Following the paths, and answering the questions, the end will be either “No concerns” or “Consult FDA”. It references notes 18-20b which follow in the document text.

1. Has there been an intentional alteration in the structure, composition, or level of carbohydrates in the new variety?
 - a. If no: No concerns.
 - b. If yes: Have any structural features or functional groups been introduced into the carbohydrate that do not normally occur in food carbohydrates? (See Note 18.)
 - i. If yes: Consult FDA. (See Note 20b.)
 1. Have there been any alterations that could affect digestibility or nutritional qualities in a carbohydrate that is likely to be a macroconstituent in the diet? (See Note 19.)
 - a. If no: No concerns. (See Note 20a.)
 - b. If yes: Consult FDA. (See Note 20b.)
 - ii. If no: Have there been any alterations that could affect digestibility or nutritional qualities in a carbohydrate that is likely to be a macroconstituent in the diet? (See Note 19.)
 1. If no: No concerns. (See Note 20a.)
 2. If yes: Consult FDA. (See Note 20b.)

Figure 6. Safety Assessment of New Varieties: New or Modified Fats or Oils

Figure 6 is a flow chart beginning with “Has there been an intentional alteration in the identity, structure, or composition of fats or oils in the new variety?” Following the paths, and answering the questions, the end will be either “No concerns” or “Consult FDA”. It references notes 21-23b, which follow in the document text.

1. Has there been an intentional alteration in the identity, structure, or composition of fats or oils in the new variety? (See Note 21.)
 - a. If no: No concerns. (See Note 23a.)
 - b. If yes: Have intentional alterations been in a fat or oil that will be a macroconstituent in the diet? (See Note 21.)
 - i. If yes: Consult FDA. (See Note 23b.)
 1. Are any unusual or toxic fatty acids produced in the new variety? (See Note 22.)
 - a. If no: No concerns. (See Note 23a.)
 - b. If yes: Consult FDA. (See Note 23b.)
 - ii. If no: Are any unusual or toxic fatty acids produced in the new variety? (See Note 22.)
 1. If no: No concerns. (See Note 23a.)
 2. If yes: Consult FDA. (See Note 23b.)