

# American Chestnut

Specialty Crop Regulatory Assistance  
“Nuts and Bolts” Workshop  
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Views and considerations presented on these slides are intended for discussion purposes only and do not reflect formal agency opinion.

# What we know...

FDA has participated in several meetings with the developers

- We understand that the developers' intention is to **restore forests** rather than **provide a source of food**
- However, it remains that chestnuts have a history of food use in the United States

We had a meeting with the developers in 2015

- We are aware that the oxalate oxidase protein introduced **may** be viewed as a PIP by EPA
- If so, FDA's purview is limited

However, there remains a significant regulatory issue

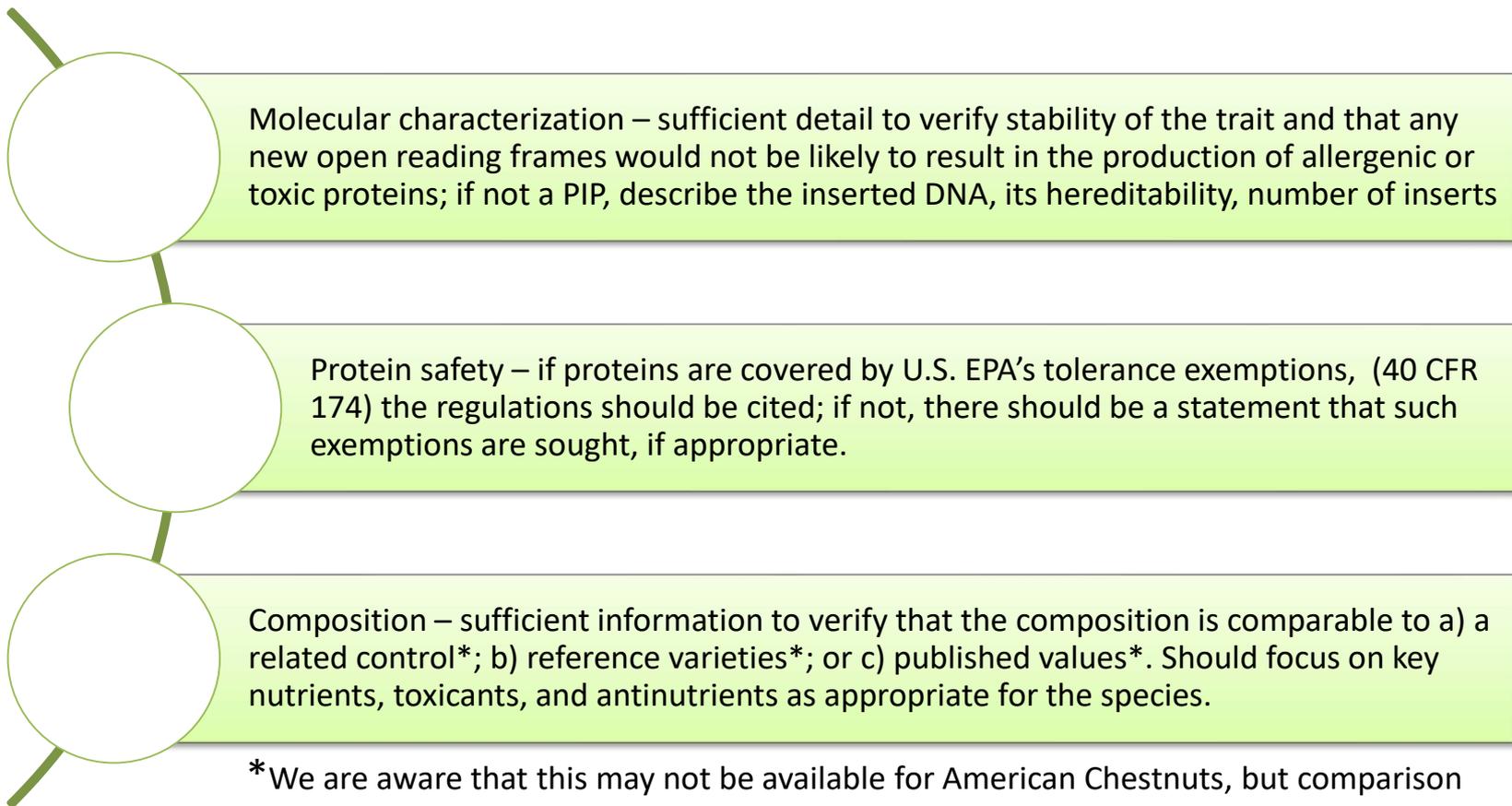
- The oxalate oxidase protein is from wheat



An interesting combination

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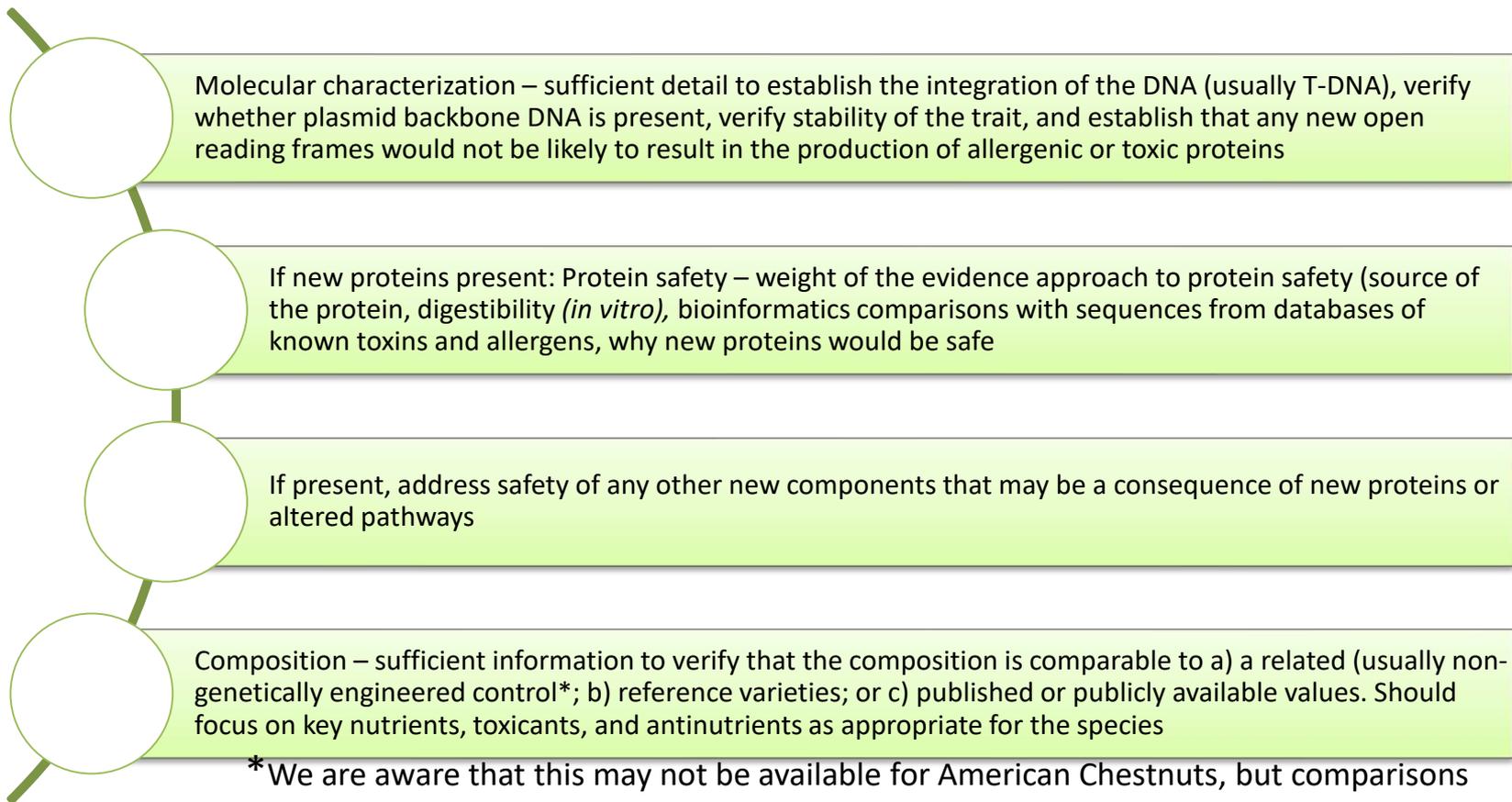
# Door No. 1: What we typically expect in consultations on PIPs



\*We are aware that this may not be available for American Chestnuts, but comparison to related species should serve

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# Door No. 2: What We Typically Expect in consultations without PIPs



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# Information that developers likely have

- Given the unusual nature of the project, we think this might warrant a different approach.

## Molecular Characterization

Presume this would be well-characterized for further progress under any circumstances

## Safety of New Proteins

We don't expect this would be an issue (for an enzyme), but if EPA considers this as a PIP, it wouldn't be under our purview

## Composition

Presume that most consumption would be by forest animals, that it would not comprise a major dietary component for humans or domesticated animals, this could warrant further discussion – proximates??

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# Chestnuts in (human) food

High tannic acid  
content requires  
roasting

Not a major  
component  
of the diet

Largely used to  
impart flavors,  
sweet flavor

American Chestnuts  
reputed to be smaller,  
sweeter than others

# Chestnuts in food for animals

1

Some evidence that tannins have effects against microbial pathogens

2

Some use of chestnuts in feeding pigs

3

Trials in other animals

# What about...

## Intended Uses

Even if it's **not intended for food** use or unlikely to enter interstate commerce, given historical uses, it could end up in the food supply.

## Responsibility

**If likely to be present** in the food supply, it would be **prudent** to consult FDA. Responsibility for food safety lies with the purveyors of food, so food should meet safety standards

# The 2004 Food Allergen Labeling and Consumer Protection Act (FALCPA)

## What is FALCPA?

- 2004 amendment to the Federal Food, Drug and Cosmetic Act
- Requires that label of food containing ingredient that is or contains protein from major food allergen declare the presence of the allergen

## What is a major food allergen?

- The law defines milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans as major food allergens

# FALCPA Exemptions

Raw Agricultural  
Commodities

Highly refined oils

Petition if the ingredient  
does not cause an  
allergenic response that  
is a risk to human health

Notification if the  
ingredient does not  
contain allergenic  
protein

# Potential challenges

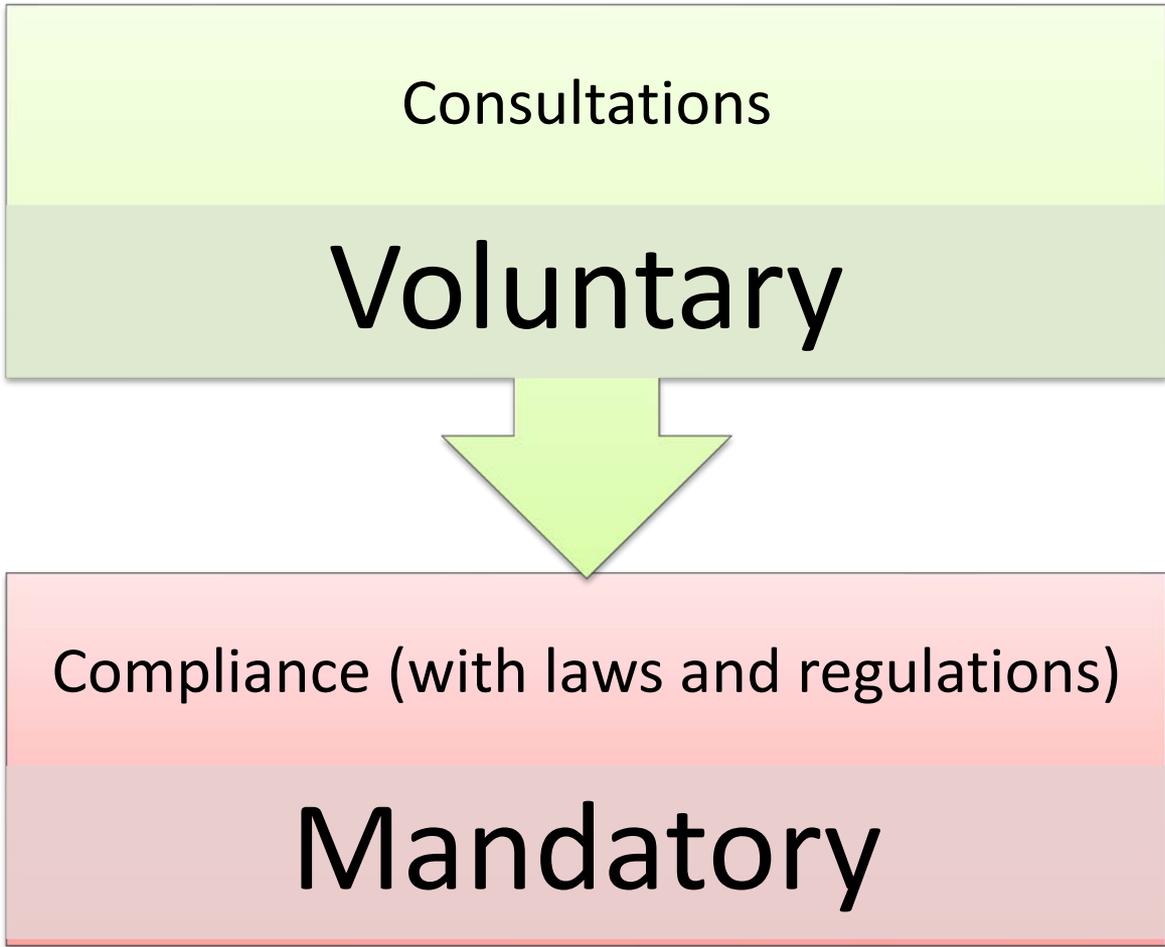
## Composition

- Existing varieties are different from American Chestnuts, but may provide some relevant information – no nearly isogenic comparators likely
- Not likely to be a significant source of nutrition for humans or domesticated animals – primary consumers may be forest animals

## Allergen Labeling

- Wheat is one of the allergens specified in 2004 legislation requiring labeling of certain allergens
- Protein derived from wheat would require labeling if present in food
- Is there sufficient information for an exemption?
  - What info would be needed?

However...



# Conclusions?

The GE American Chestnut faces interesting regulatory challenges

The safety of added oxalate oxidase from wheat may be under EPA's purview

However, if present in the food supply it should be labeled as "contains wheat"

We would suggest that the developers and those with interest in commercializing the nuts consult FDA

If used in animal feed, a compositional assessment would be needed



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