Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

From Chart 2

Does the research involve only* a taste and food quality evaluation or a food consumer acceptance study?

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

YES

Are wholesome foods without additives consumed?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(6) from 45 CFR part 46 requirements. Other Federal, State, and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]

NO

Is food consumed that contains a food ingredient, agricultural chemical, or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture?

YES

Research is not eligible for exemption under 45 CFR 46.101(b)(6).

NO

Go to Chart 8

February 16, 2016