The Grocery Reform And Safety Act

introduced by:

Rep. Frank Pallone Jr.

Section 1. The Grocery Reform And Safety Act, or "GRAS" Act

Section 2. Removal of GRAS Exemption from Food Additive Definition

This section removes the loophole in the food additive definition which allows companies to market food substances as generally recognized as safe (GRAS) without notifying the Food and Drug Administration (FDA) or providing scientific evidence of safety.

Section 3. GRAS Notifications

This section requires any person that manufactures, introduces, delivers for introduction, or receives a food substance intended to be marketed as GRAS, including any new use of such a substance, to provide notice to the Secretary of the conditions under which they will use the substance. It also lists the requirements and procedures that must be met prior to marketing such substance. Specifically, the section:

- Requires publicly available scientific evidence supporting the determination that a substance is GRAS to be submitted in the notice;
- Specifies the form of the notice;
- Requires a written response from the FDA that the agency does not object to use of the substance as GRAS, prior to it being used as GRAS;
- Outlines criteria under which the FDA shall object to the use of a substance as GRAS;
- Specifies the timeline under which the FDA shall respond to the notice;
- Allows the FDA to correct a written response that the agency does not object to use of the substance as GRAS if new evidence is subsequently presented or discovered;
- Requires an opportunity for public comment on the notice and public listing of the FDA's responses to object or not object to the use of the substances as GRAS on the FDA's website; and
- Authorizes appropriations to ensure timely responses.

Section 4. Reassessments

This section requires that every 3 years, the FDA systematically reassess the safety of certain substances or classes of substances, including food additives, substances considered GRAS prior to enactment, color additives, prior sanctioned substances, and food contact substances. The section authorizes the FDA to require industry to submit updated safety evaluations of the substances the agency is reassessing.

The section also provides the FDA with authority to revoke a previous written statement to not object to a determination that the substance is GRAS and to require submission of a notice for substances marketed as GRAS prior to enactment. The section authorizes assessment of civil monetary penalties and appropriations to ensure timely reassessments.

Section 5. Food additive and GRAS substance fees

This section authorizes the FDA to collect user fees to ensure that the agency responds to notifications and conducts reassessments in a timely manner.