How Safe is Safe – Chemical Perspective

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Historical Perspective

1970s: Negligible Residue (0.1 ppm)

1980s: Sensitivity of Method (defining "no" residue in Delaney clause in 512(d)(1)(I) as level that would not cause more than one additional tumor in a million people over their lifetime of 70 years)

1990s: Threshold of regulation for substances used in food contact articles (0.5 ppb)

Federal Food, Drug, and Cosmetic Act, Section 402

A food shall be deemed to be adulterated --

(a)(1) If it bears or contains any [added] poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health

Federal Food, Drug and Cosmetic Act Section 406 (Tolerances)

406. Tolerances for poisonous or deleterious substances in food; regulations

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

Federal Food, Drug and Cosmetic Act Section 408 (Pesticides)

408. Tolerances and exemptions for pesticide chemical residues

(a) Requirement for tolerance or exemption

(1) General rule

Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 342(a)(2)(B) of this title unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

Federal Food, Drug and Cosmetic Act Section 409 – Food Additives

(a) Unsafe food additives; exception for conformity with exemption or regulation

A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 342(a) of this title, unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (j) of this section;

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

(3) in the case of a food additive as defined in this chapter that is a food contact substance, there is—

(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

(B) a notification submitted under subsection (h) of this section that is effective.

Federal Food, Drug, and Cosmetic Act, Section 512(d)(1)(I) (Delaney Clause)

(d) **Grounds for refusing application; approval of application; factors; "substantial evidence" defined; combination drugs**

(1) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that—

(I) such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h) of this section), in any edible portion

Chemical Safety Program Review

- **Focus**: Scientific capacity and the management of the program's multiple elements across CFSAN and CVM

Chemical Safety Program Review

- **Goal**: Determine overall program needs and then determine not only how to meet the needs but also how to further improve our chemical safety program

Chemical Safety Program Review

- **Process**: Contractor has completed interviews of employees in CFSAN and CVM as well as interviews of CFSAN alumni, colleagues in other agencies, and stakeholders outside the U.S. government

Chemical Safety Program Review

Current Status:

- Two reports are being finalized – the consultant's report based on the internal interviews, and our report based on the listening sessions
- We will send the two reports to four external consultants for their review and recommendations, grounded in the reports, on how to best improve the program
- After we have the consultants' recommendations, we will share the reports internally with employees working in the chemical safety assessment program to get their views on how to best make program improvements

Chemical Safety Program Review

Outcome:

- Implementation of recommendations to help improve the program to better meet today's chemical safety challenges
- We will be asking that recommendations include both resource neutral and resource light solutions, and may include solutions, with tiers, that would require substantial increases in resources

Signal Detection of Chemicals in Food

- Goal is to improve detection of signals of problems with the safety of chemicals in the food (including dietary supplements) and cosmetics supplies
- CFSAN work group will make recommendations in ~ 4 months
- We are planning a Food Advisory Committee (FAC) meeting on this issue in the fall

Signal Detection of Chemicals in Food

Examples of issues we may ask the FAC to address:

- Sources of data and information on chemical hazards that might best identify emerging chemical hazards or newly recognized risks from known chemical hazards
- Criteria FDA should use in evaluating data from the sources
- Criteria FDA should use to move something off the emerging issues list - either as no longer an issue or as something FDA needs to be working on right now

Thanks for listening