What has Changed Since November 3, 1984?

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1984 - FQPA

- Part 158 Rule Promulgated
- 1984 – All pesticides registered prior to November 3 subject to reregistration (FIFRA '88).
- Mid-1980s – Separate ecological fate and hazard assessments performed.
- 1986 – The Standard Evaluation Procedure for Ecological Risk Assessment issued.
- 1986 – Coordinated Framework for the Regulation of Biotechnology.
- Late-1980s – Agency began requiring ground water testing => to more case-by-case prospective groundwater monitoring.
- Late 1980s – Part 158 Subdivision U (handler exposure) guidelines developed.
- 1989 – Independent Laboratory Validation
- 1989 – Part 158 Subdivision M guidelines updated to tailor data requirements for biopesticides.
- Early-1990s – Current RQ/LOC approach implemented (LOC terminology became official policy in 1992).
- 1990 - Spray Drift Task Force formed.
- 1991 – Developmental neurotoxicity guidelines completed.
- 1991- PHED becomes available for handler risk assessments.
- 1993 – New Risk Paradigm (ecological) - implementation plan reiterating the LOC approach for high acute risk and restricted use pesticides.
- 1993 – Added or modified chemistry requirements as result of rejection rate analysis (860.1340 – multi-residue method testing, 1360 independent lab validation, 1380- storage stability).
- 1994 – Modified requirement for field trial studies with respect to regional representation (860.1500).
- Mid-1990s – Began using aquatic exposure modeling.
- 1995 – Refined modeling for estimated concentrations in aquatic environment.
- 1995 – Added short-term and intermediate-term endpoints for all human health assessments.
- 1995 - Agricultural reentry DCI issued.
- 1995 - Turf DCI for occupational and residential exposure.
- 1995 - Full implementation of WPS
- 1996 – Independent Laboratory Validation for ecological studies
- Crop grouping guidance revised.
- 1996 – Policy on plant incorporated protectant (codified July, 2001)

Post-FQPA - Present

- 1996 – Antimicrobial Division formed.
- 1996 – Biological and Pollution Prevention Division formed.
- 1996 – Begin considering groups of pesticides for cumulative assessment.

- 1996 - Routinely begin considering aggregate risks from food, water and residential exposures.
- 1996 – Sanitizers and food contact disinfectants moved from FDA to EPA.
- 1996 – Indirect food additive - dual jurisdiction between EPA and FDA (2bb)
- 1996 – GRAS not sufficient to set 408 tolerance.
- 1997 – Residential exposure assessment SOPs created.
- 1997 – Began using aquatic exposure models for drinking water assessments. (DWLOC approach)
- 1997- Higher tier studies for surface water performed more frequently.
- 1997 – Began reconsidering older data waiver to accommodate needs of more refined water models; therefore, additional water related data are required.
- 1997- Higher tier ecological studies performed more frequently.
- Guidelines for Ecological Risk Assessment standardizes methods and procedures for conducting ecological risk assessments.
- Risk Assessment Oversight Committee formed to deal with antimicrobial exposure issues.
- 1998 – Regulatory authority for liquid sterilants on equipment transferred from EPA to FDA.
- 1998 – Immunotoxicity guidelines implemented as needed.
- 1998 – Change protocol for two generation study.
- 1998 – Begin performing probabilistic dietary risk assessments
- 1998 – Final 6(a)(2) Guidance issued
- 1999 – Proposed 152/156 rule for antimicrobial chemicals.
- 2000 – Science Policy Council Handbook – Risk characterization.
- 2000 – Protocol for Hepatitis B Virus testing for disinfectant products released.
- 2001 – Eliminate phenol resistant testing for disinfectant products.
- 2001 – Published 40 CFR part 174 to codify 1996 policy on plant incorporated protectant.
- 2002 - Antimicrobial Division Toxicity End-Point Committee formed.
- 2004 – Joint Counterpart Endangered Species Consultation process implemented (yellow book).
- Dose Analysis Procedure modified dealing with database uncertainty factor to account for the lack of a DNT.
- 2004 – Begins to use probabilistic models for aggregate risk assessments.

Looking Ahead

- Endocrine testing program implemented.
- 2005-6 – Broaden use of probabilistic risk assessment model.
- Update of 158.690 (biochemical data requirements) & 740 (product analysis data for microbial pesticides).
- Promulgate antimicrobial guidelines (158 W).
- Revising crop groupings allowing for field trial data from high consumption commodity to be translated to lower consumption commodities.
- Part 158 Subdivision W guideline requirements for antimicrobial pesticides.