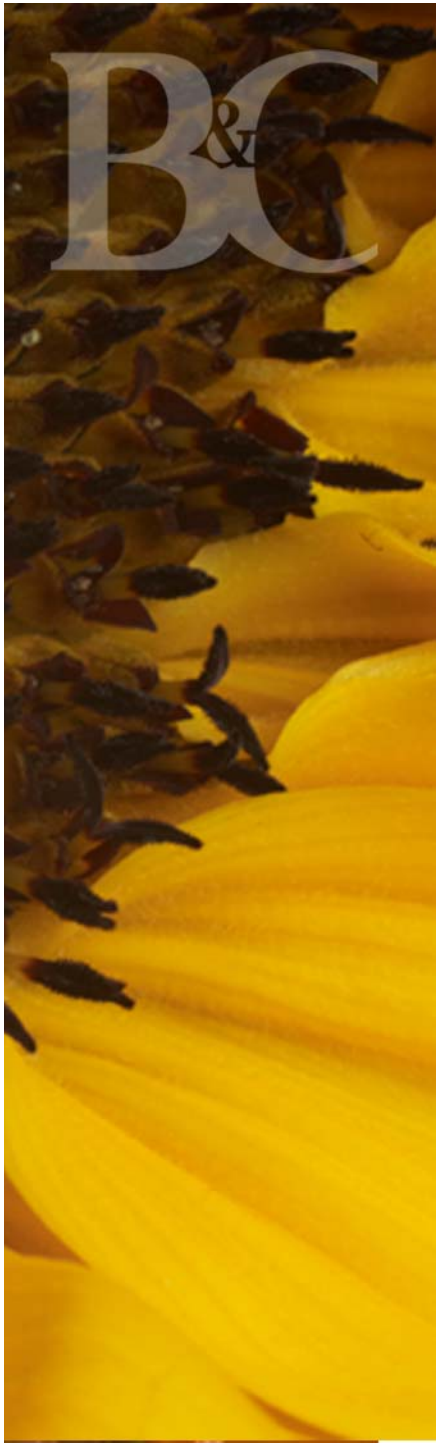

BERGESON & CAMPBELL PC

American Spice Trade Association 2020 Annual Meeting

Chemical Product Issues of Note

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Pesticide Regulation: FIFRA and FFDCA

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - Implemented by the U.S. Environmental Protection Agency (EPA) -- Pesticides must be "registered" (licensed) prior to sale
  - FIFRA standard for approval is that use of the pesticide "will not generally cause unreasonable adverse effects on the environment" [including human health]

Pesticide Regulation: FIFRA and FFDCA

- Federal Food, Drug, and Cosmetic Act (FFDCA)
  - Regulates safety of pesticide residues found in food
  - Human dietary risk from pesticide residues in food must be "safe" -- EPA determines the maximum level allowed – a "tolerance" level
  - Safe is defined as a "reasonable certainty of no harm"
    - The 1996 Food Quality Protection Act (FQPA) added various new safety criteria requirements
- Pesticide residues in food must meet both standards
- The Food and Drug Administration's (FDA) role is to enforce the tolerance level EPA sets
  - FDA conducts enforcement sampling of food
  - Domestic and imported food must meet the same standard

EPA Review and Requirements

- EPA requires extensive data on potential human health and environmental effects for each pesticide
  - EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency, manner, and timing of its use; and storage and disposal
    - EPA evaluates possible risks to the applicator, workers, bystanders, water, eco-systems, pollinators. EPA must determine residues in food are safe to consume
    - EPA follows government-wide risk assessment methods: evaluate animal data, find level where no effect is seen, add standard safety factors
- Residues on food evaluated under the 1996 FQPA
  - EPA looks at exposures from all sources, including all foods, water, different crops (**aggregate risk**)
  - EPA considers if different pesticides have the same mechanism of activity (**cumulative risk**)
  - Special consideration of possible risks to children from residues -- default "extra **10x safety factor**" added to evaluation
  - EPA is also reviewing data regarding possible "**endocrine effects**" -- aka "environmental hormones," "endocrine disrupting chemicals"

EPA Risk Assessment

- EPA follows government-wide assessment practices
  - Like FDA and other federal agencies: risk estimate is function of hazard and exposure
- EPA evaluates risk to both human health and the environment
- EPA hazard review based on extensive data required to be submitted
- FDA market-basket survey of food consumption is used to calculate exposure ranges
- Safety factors are considered to account for sensitive populations (children, pregnant women)
- Evaluates risk via multiple routes (inhalation, oral, skin) and sources (air, water, food)

EPA calculates maximum allowable exposure -- the “risk cup” -- sum of exposures must be at or below this level

Typical Issues

- Critics of pesticide use often disagree with EPA (or FDA) conclusions
- Controversies about specific products or policies
  - Products: Chlorpyrifos, Glyphosate
  - Policies: Genetically Modified Organism (GMO) approvals, FDA enforcement sampling program
- EPA approval decisions are increasingly subject to litigation
- EPA pesticide registrations are routinely subject to legal challenge under the Endangered Species Act (ESA)
  - Topic for another time

Pesticide Registration Review

- FIFRA requires EPA to re-review (reregister) a pesticide every 15 years
  - Allows product approvals to meet any newer EPA requirements (usually new studies) and updated policies
- Policies and research may cause "minor" uses, such as spices, to come under scrutiny
  - Review can decide a spice needs a changed or new tolerance
  - EPA revising crop grouping designations to establish "minor use" tolerances for some uses based on representative crops
    - Expanded existing crop groupings likely to facilitate agricultural trade
  - Review can result in changed crop grouping designation
- Knowledge of and ability to track supply chain can avoid residue "surprises"
  - Advanced detection technologies can "discover" previously undetected pesticides

Agency Resources and Personnel

- Federal budget for EPA (and FDA)
  - Cuts to budget affect ability to meet statutory deadlines or scheduled review times
    - Example: EPA Registration Review for pesticides is to be completed by October 2022
- Federal workforce demographics
  - Aging federal workforce has high percentage of workforce eligible for retirement
- Federal agency recruitment is difficult
  - Pay and morale affect ability to fill vacant slots
  - Demographic shifts will see large loss of institutional memory

International Issues

- Globally sourced products are sensitive to regional and national policies
- Trade agreements include phytosanitary provisions
  - One country's vigilance is another's non-tariff trade barrier
  - Even pesticides banned in the United States can be exported to other countries
  - U.S. trade policy supports Codex/MRL review process
- EU policies based on the "precautionary principle" may affect pesticides used in U.S. food production
  - Domestic restrictions on use in EU countries might lead to virtual zero-tolerance policy for U.S. food exports
  - Other trading partners may adopt similar policies
    - Current proposal by Mexican government could have similar impact

Labeling and Consumer Warnings

- Consumer "right-to-know" provisions might include incidental/*de minimis* exposures
- Terms like "no artificial ingredients" or "natural" can be subject to litigation
- FDA or EPA approval can be insufficient to gain consumer confidence in food ingredients
- Product de-selection pressures can come from advocacy groups, social media, or campaigns unrelated to food safety
  - "Save the bees"

California Proposition 65

Prop 65 and Pesticides -- Background

Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop 65) - Warning requirements for more than 900 listed chemicals

Warning requirements differ depending on type of exposure:

- Consumer product = interpreted broadly but must be from a reasonably foreseeable use of a consumer product
- Occupational = exposure to any employee at place of employment for facilities in CA
- Environmental = exposure from environmental source (*e.g.*, ambient air, drinking water, running water, soil, manmade or natural substances or objects) in CA

Warning not required if safe harbor exemption established

Note: There are no threshold or *de minimus* concentrations below which a substance listed under Prop 65 is not subject to warning requirements, so exposure assessment required

Prop 65 Warnings for Pesticides

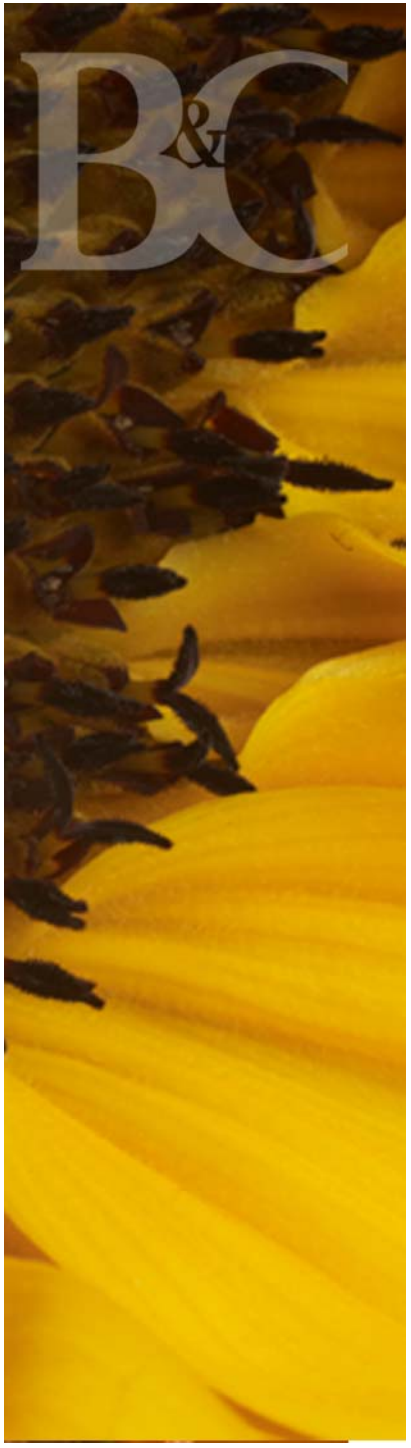
FIFRA does not preempt Prop 65 warning requirements, but recent glyphosate case illustrates the controversy concerning the application of OEHHA's Prop 65 warning requirements to FIFRA-regulated pesticide labels

- OEHHA: Listed glyphosate based on International Agency for Research on Cancer (IARC) classification as "probably carcinogenic to cancer"
- EPA: Sent a letter to glyphosate registrants that it would consider a Prop 65 warning on a glyphosate label to constitute a false and misleading claim

If warning required, OEHHA's warning requirements regulations were significantly amended and in effect since August 30, 2018

Final Thoughts

- Consumer product companies face ever-changing operating environment
  - Demanding and informed customers
  - Social media and press coverage can present unpredictable “crises”
- Divisive, bitter partisanship makes consensus over policy issues unlikely
  - Food safety law implementation, agency budgets, and Congressional oversight are increasingly rancorous
  - Regardless of 2020 election result, partisanship expected to continue
- After long hiatus, Congress considering legislation on specific pesticides
  - Science/risk issues difficult for members to evaluate
- Consumer-driven initiatives at state and local level will continue
  - State and local officials have fewer review resources
- Efforts outside of political process will pressure product de-selection
- Litigation will also continue over appropriate scientific basis of decisions by federal agencies



Thank You

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