

# Alternative Assessments in Personal Care: A Case Study

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Personal Care  Products Council  
Committed to Safety,  
Quality & Innovation

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## How does Industry Identify a Chemical of Concern?

- **Trained staff continuously review study results and monitor current and new information on cosmetic ingredients**
  - “ Literature
  - “ Consumer complaints/opinions
  - “ Press
  - “ Internal consumer or safety studies
  
- **Human Safety Assessments also conducted under CIR, industry-sponsored safety evaluation program**
  - “ Cosmetic Ingredient Review (CIR) Mission: To thoroughly review and assess the safety of ingredients used in cosmetics in an *open, unbiased, and expert* manner, and publish the results in the peer-reviewed scientific literature
  - “ CIR meetings are open to the public
  - “ Seven CIR Expert Panel voting members, publicly nominated by consumer, scientific, and medical groups, government agencies, and industry
  - “ Expert Panel members must meet the same conflict of interest requirements as individuals serving on FDA advisory committees
  - “ Three liaison members, which serve as nonvoting members, include representatives from FDA, the Consumer Federation of America, and PCPC

## What Types of Information are Reviewed When Assessing Safety of a Chemical?

- **Exposure analysis**
  - “ Possible routes of exposure
  - “ Quantitative exposure estimates
- **Chemical structure information**
  - “ Structural alert identification
  - “ Information on chemical class
- **Human health study results**
  - “ Genotoxicity
  - “ Dermal irritation/sensitization
  - “ Reproductive hazards
  - “ Ocular irritation
- **Environmental study results**
  - “ Biodegradability
  - “ Ecotoxicity

# What Questions need to be answered in conducting a Scientific Safety Assessment of a Product?

- **Does a hazard exist?**
  - “ Study quality
  - “ Complaint analysis (types, frequency)
  - “ Statistical analysis
  - “ Scientific plausibility
  
- **Risk-benefit analysis**
  - “ If hazard exists, is risk in the formulated product meaningful?
  - “ Relevance of exposure
    - “ Biodegradability/ecotoxicity results for leave-on products
    - “ Results of oral testing for topical products
    - “ Extent of absorption
  - “ What are benefits of substitution?
  - “ Are there unexpected/unintended consequences?
  
- **Timing for substitution of an ingredient, if warranted**
  - “ Immediate
  - “ Long-term

## How do we ensure products comply with regulations?

Personal care products and ingredients are assessed to ensure compliance with regulatory requirements:

### Federal:

- “ FDA
- “ OSHA
- “ EPA
- “ DOT
- “ Other (FTC, CPSC)

### State:

- “ Myriad (and differing) state requirements

### International:

- “ EChA (R.E.A.C.H.)
- “ EU Cosmetics Regulation

## Case Study: *Geranyl Nitrile (GN)*

- **Common fragrance ingredient**
- **Longstanding history of safe use**
- **Required testing (OSHA, EChA) revealed genotoxicity**
  - “ Follow-up studies indicate absorption and metabolism
- **“Prohibited” under IFRA standards in 2006**
  - “ *No government prohibitions to date*
- **IFRA members voluntarily began reformulating out of GN in 2006-2007**
  - “ Thousands of products reformulated or discontinued
  - “ Not determined to be immediate hazard, full reformulation took 1+ year
- **Environmental Assessment: determined as environmentally safe**
  - “ Assessed by conventional risk assessment methodologies known to and used by industry and the USEPA
  - “ GN is not acutely toxic to representative aquatic organisms
  - “ Volumes discharged into the aquatic environment are quite low, thereby limiting exposure to aquatic life.

## Generic Outline of Process to Substitute One Fragrance

**Step 1:** Identify formulations with a fragrance containing that ingredient

“ Fragrance Supplier provides information to customers

**Step 2:** Determine when proposed substitutes will be available

“ Approximately 1-3 months while fragrance house develops, evaluates, tests alternatives

“ Identify whether alternative ingredient needs to be reported under California Safe Cosmetics Act of 2005



## Generic Outline of Process to Substitute One Fragrance (continued)

### **Step 3:** Prepare and evaluate products with substitute

- i. Initial Laboratory and Pilot Plant work commences**
- ii. Stability Work commences**
  - a. Typically 3 months minimum @ high temperatures
  - b. Room Temperature Controls for up to 3 years
  - c. Consumer Tests
  - d. Safety Assessment of new formulation
  - e. Small Scale Gross Negative Tests
  - f. Extensive Testing for Products in which Fragrance is critical selling point
- iii. Advertising Claims and Regulatory Support**
  - a. Ensure previous claims are still valid
    - “ Additional product testing and evaluation may be needed
- iv. Failure? = Back to Beginning**

## Generic Outline of Process to Substitute One Fragrance (continued)

### Step 4: Manufacture

- i. Scale-up production trials
  - ” Comparison with standards
- ii. Full Manufacture
  - ” Up to 3 Months before product gets into stores

### Step 5: Post-Launch Activity

- i. Monitor Consumer Hot-Lines & Adverse Events (as normal)

## Immediate Impact on Industry

The substitution of just one chemical, Geranyl Nitrile, significantly impacted personal care products companies, affecting *hundreds* of fragrances and *thousands* of products.

## Product Reformulation with Modified Fragrances: P&G Experience

- For P&G, approximately 800 perfume formulations were impacted by the Geranyl Nitrile re-formulation
- Involved the cooperation of 5 R&D sites on 3 continents, 3 manufacturing sites where formulations are produced, and numerous supplier sites
  - P&G estimated 2 FTEs for 1.5 years simply to manage the information for GN (e.g, approval of new formula cards, entry into regulatory and product development database, development of new disclosures for future reformulations, etc.)
    - This does not include Perfume R&D, Product Development R&D, or Purchasing, which involved significant effort as well
- **Estimated Cost for One Ingredient Change: approximately \$4.5 million**

## P&G Product Reformulation with Modified Fragrances: Cost and Resource Implications

- **Perfume Raw Material (PRM)**
  - Significant Resource and Costs associated with identification of substitute PRM(s) – identifying appropriate replacement material(s)
- **Fragrance Formulation**
  - Qualification of the new PRM(s) in the fragrance formulation
  - Qualification of the new fragrance formulation itself
- **Product Formulation**
  - Qualification of the new fragrance in product formulations
  - Reformulation of products as a result of qualification studies
- **Ancillary Product Issues**
  - Change in product labels/ingredient statement modifications/re-registration of products
  - Disposal of unused perfumes

## Conclusions

### Industry is Committed to Safety

- “ Industry is committed to ensuring that all products are safe for use by consumers and comply with appropriate regulations
  - “ FDA requires cosmetic manufacturers to assess safety of product formulations
- “ Personal care industry has a long and successful history of identifying and evaluating chemicals of concern
  - “ Continuous monitoring and evaluation using state of the art test protocols
  - “ Scientific analysis
  - “ Timely action
  - “ Above and beyond significant global regulatory requirements
- “ Safety assessments, which evaluate hazards of specific chemicals and their exposure to relevant populations , are periodically reviewed as new data become available
- “ Industry takes proactive initiatives when warranted, without waiting for regulations to catch up

## Conclusions

### Need for Flexibility in Regulations

- “ Must allow flexibility to keep up with current developments
- “ Prescriptive requirements will hamper innovation

### Substitution Will Have Major Repercussions

- “ Performing Alternatives Assessments and making any resulting changes is a complex operation and is done by manufacturers of products on a global basis
- “ Substitution process may be costly and time-consuming
  - “ Want to insure appropriate risk-benefit ratio
  - “ Scientific analysis crucial to determining course of action