CRODA

SCC Spring Regulatory Update

Canada - March 20, 2012

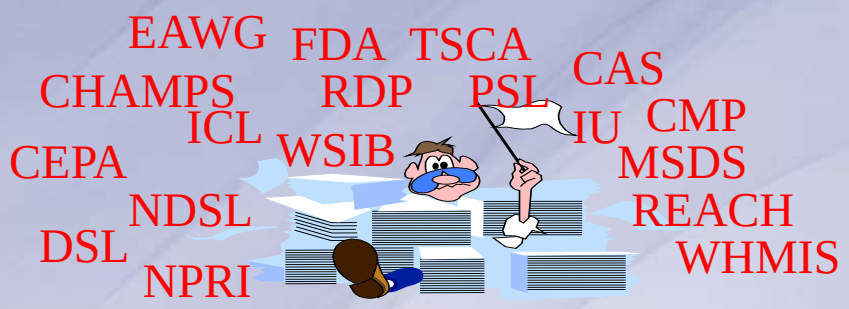
CACD

CRODA

Teena Warrin

Product Safety and Regulatory Affairs Manager

- Member CACD Regulatory Affairs Committee
- Member CCTFA Environment Committee
- EAWG Co-Chair, CACD Representative
- Member ICL Sub-Committee
- Member Sub-Committee 2 - Cosmetics



CACD

CRODA

Topics

- *CEPA 1999*
- *In Commerce List*
- *New Regulations for FDA Substances*
- *Chemicals Management Plan*
- *Other Issues*
- *Meeting the Challenges*

CACD

CRODA

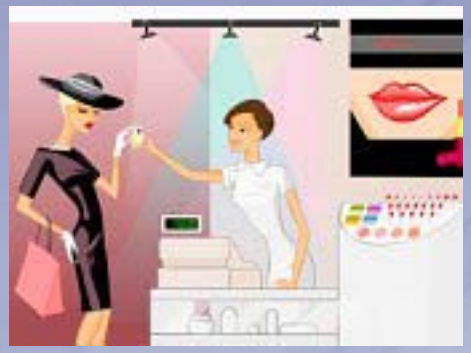
The Good Ol' Days - BC

Regulatory Decision Making

safety

Europe COSMETICS CIR

F&DA



was

Relatively Simplistic

CACD

CRODA

After CEPA 1999

Regulatory Decision Making

Nanotechnology Provisions (NSNR)

Industry Challenge (High Priorities, Batches 1-12)

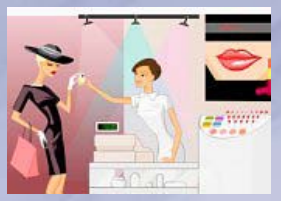
Rapid Screening (low priorities)

CEPA 1999

SARs and RM considerations

DSL deletions

ICL 'Categorization and Screening'



has become

REACH

Significantly More Complex

CACD

CRODA

NSNR Challenges

- *Two lists*
- *No polymer exemption*
- *Animal Testing*
- *Tiered Process*

CACD

CRODA

Inventory Considerations

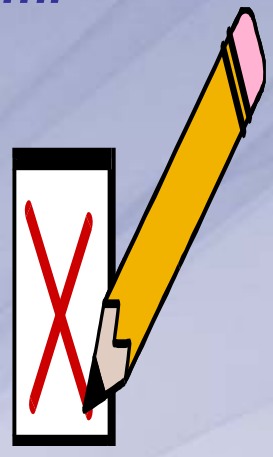
- *DSL*
- *NDSL*
- *In Commerce Lists*

CACD

CRODA

What is the ICL?

- *In Commerce List (imported '87 -01)*
  - *Must be assessed in some manner*
  - *Five lists available via web-site*
  - *http://www.hc-sc.gc.ca/ewh-semt/contaminants/person/impact/list/index_e.html*
  - *Lists 1 and 2 have CAS Numbers*
  - *Lists 3 and 4 do not*
  - *DSL Identity Conventions are not used*
- *Revised ICL has CAS name and number*
- *Policy is ICL = NSN Not Required*

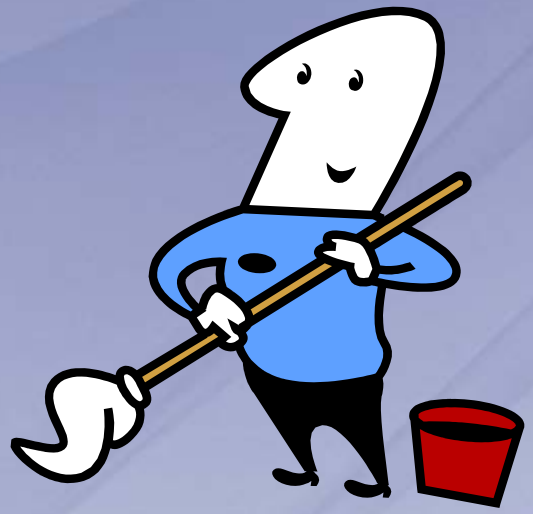


CACD

CRODA

What Needs to Be Done?

- *ICL Substances Need*
  - *Revision/Update (cleaning up)*
  - *Categorization (prioritization)*
  - *Risk Assessment (post market screening)*
  - *Risk Management Considerations*
- *New Substances Need*
  - *Appropriate Environmental Assessment Regulations*



CACD

CRODA

Who Is Doing What?

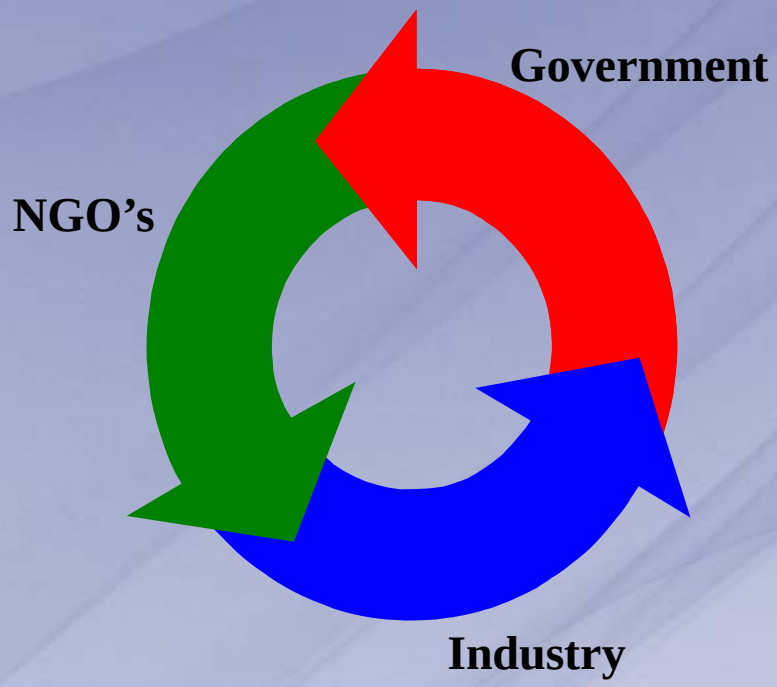
- *Environmental Assessment Working Group - EAWG*
  - *Multi-stakeholder group established by Health Canada to seek input on creating appropriate environmental assessments for Food and Drug Act Regulated products*

CACD

CRODA

Environmental Assessment Working Group

Provide broad, strategic advice on policy, technical, operational and regulatory issues regarding the development of appropriate environmental assessments for new substances contained in products regulated under the F&DA and the revision, prioritization and management of substances on the In Commerce List (ICL)



CACD

CRODA

EAWG ICL Subcommittee

- *Secretariat (HC in Commerce Substances Unit 1)*
- *Health Canada (Environmental Impact Initiative)*
- *Environment Canada (new and existing substances)*
- *Associations (CACD, CCSPA, CCTFA, FCPC, COPA, CNMA, Rx&D)*
- *Industry/Association members [9]*
- *Non-Governmental Organization members [2]*

CACD

CRODA

EAWG ICL Subcommittee

- *Current Focus – Revising the List ("doing the laundry")*
  - confirming identity of Current ICL substances
  - process to nominate other substances

CACD

CRODA

Revising the List

- **CAS contracted to "verify" 2497 substances**
  - **334 substances (13%) are already on the DSL**
  - **1725 substances (70%) now verified**
  - **438 substances (17%) could not be verified**
  - Will require nomination along with all substances on sub lists 2 and 3

- Phase I – Voluntary Nomination Process in 2010
- Phase II – Final Call In – February 14, 2012

CACD

CRODA

Current ICL/Verified Substances

Phase 1 Volunteer Nominations (key importers, distributors, manufacturers)

Phase 1 Revised ICL Published

Phase 2 Open Nominations (all importer, manufacturers, users, and others)

Phase 2 Revised ICL Published

CACD

CRODA

Originating in Nature (OiN)

- Expansion of "Naturally Occurring" definition
  - Original CEPA definition is limited to substances isolated by manual/physical/gravitational means or extraction with water
  - For the purposes of Phase 2 ONLY exemption extends to all forms of extraction

= Reduced Regulatory Burden

CACD

CRODA

OiN Web-Site Statement

- For Phase 2 of the nomination process, they are substances, other than medicinal ingredients in a drug product regulated by the Food and Drug Regulations, that meet the following description:
  - is a natural source material or an extract or isolate from a natural source material; and
  - the primary molecular structure is unaltered from its original form (regardless of processing method); or
  - the substance is a salt or derivative of a substance which meets 1) and 2) provided that the structural alterations are reversible under environmentally relevant conditions.
- For (b), it should be noted that:
  - guidance on the description is not available at this time;
  - this description applies exclusively to phase 2 of the ICL nomination process; and
  - these substances may become subject to notification requirements at a later time and their nomination to the revised ICL may be required at a future date.

CACD

CRODA

What Else Is the EAWG Doing?

- Environmental Assessment Regulations (EAR's)
  - A "New" New Substance Assessment Scheme
  - Specific to FDA substances
  - New regulatory framework
  - Different data requirements
- Is this necessary?
  - No specific legislative requirement
  - This is a choice to be made

CACD

CRODA

EARs

- What we have heard from EII
  - Detection of pharma/personal care ingredients in the environment
  - Current system may not be sensitive enough for substances in FDA regulated products
  - Current triggers result in insufficient data early enough in the process

ADAMANT THAT A NEW PARADIGM IS NEEDED

CACD

EARs

- Industry is NOT convinced!!
  - 1 pre-market system for most new substances
  - Unless there is scientific need (ie: API's)
  - Does the fish care?
- But we press on…..
  - SC1 – Approved framework for API's
  - PEC Based
  - ? SC2 – All other ingredients (NHP's, Food Additives, Cosmetics, non-medicinal ingredients in drugs)

CRODA

EARs

- Proposed Framework has Pros and Cons
- Unresolved Issues
  - Dual Use Substances
  - New vs Existing Inventories
  - Implementation
  - Cost/Benefit

What Next???????

CACD

CRODA

Chemicals Management Plan

- ***Challenge to Industry (High Priority)***
  - ***Additions to the hotlist***
  - ***Risk Management Decisions***
  - ***Siloxanes***
- ***CMP 2 Funding Announced at CCSPA***

Government Interface

  - ***Medium Priorities MUST be addressed***
  - ***Grouping Initiatives***
  - ***Polymers***
  - ***http://www.chemicalsubstanceschimiques.gc.ca/plan/index_e.html***

CACD

Significant New Activity Notices

- *SNAc's*
- *Management Tool CEPA Section 80*
- *Used when a concern arises with a potential new use*
  - *Usually hazard driven*

CRODA

SNAc Attack

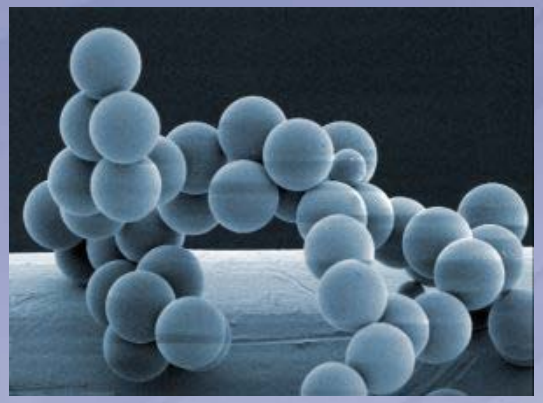
- *Increased Use*
  - Between 2001 – 2007 approx. 55 issued, 2008 approx 25 issued
- *Advisory Note 2009-01 Clarifies max quantity*
  - As specified or 0-kg default
- *Potential for instant non-compliance*
- *Additional data may be cost prohibitive at low volumes*
- *Impossible to predict*

CACD

CRODA

SIZE MATTERS!!!

- ***Nanomaterials***
- *Wide range of possible materials*
- *Silica, TiO2, Zinc Oxide, Alumina*
- *Section 71 survey expected*



- ***Health Canada definition***
  - *http://www.hc-sc.gc.ca/sr-sr/pubs/nano/index-eng.php*
  - *1-100 nm*
  - *Unique structure or molecular arrangement*
- ***Using SNAc provisions***

CACD

CRODA

Other Issues

- *GHS Labeling and MSDS*
- *NGO Activity – Predicting what's on their radar*
  - *Dirty Dozen*
  - *Heavy Metals*
  - *DEA*
- *Ontario Toxics Reduction Plan*
- *Update to cosmetic notifications*

http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/require-exige/index-eng.php

CACD

CRODA

Managing the Challenges

- *Information You Can Count On*
  - *– accurate composition information is essential*
  - *– international cooperation is required*
- *Keeping Informed*
  - *– Industry trade publications and associations*
  - *– CCTFA Regulatory Workshops*
- *Get Involved*
  - *– SCC, CCTFA*

CACD

CRODA

Useful Web Sites

- *Environment Canada – CAS Search*
  - **www.ec.gc.ca/substances/nsb/search/eng/cp_search_e.cfm**
- *Health Canada – In Commerce Lists*
- **www.hc-sc.gc.ca/ewh-semt/contaminants/person/impact/list/index_e.html**
- *CCTFA*
  - www.cctfa.ca
- CACD
  - www.cacd.ca

CACD

Questions

Acknowledgements

- *Beta Montemayor, CCTFA and SC2 Co-Chair*
- *Robert Cash, ADM and ICL Co-Chair*
- *Environment Canada (New Substances Division)*
- *Environment Canada (Existing Substances Division)*
- *Health Canada (New Substances Division)*
- *Health Canada (Existing Substances Division)*
- *Health Canada (Environmental Impact Initiative)*