Identifying Tools to Rapidly Characterize & Prioritize Chemicals in Commerce for Prevention

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Overview

- The need to apply HPV information to decision-making
- The need for tools to rapidly prioritize HPV chemicals for action that can be used for lower volume chemicals
- Ways to move forward

Starting points

- Data serves little purpose if not in a usable format or is used for decision-making
- Chemical by chemical risk assessments are slow, costly, and few have been completed
  - EPA will never be able to conduct detailed risk assessments on all HPV chemicals
  - For most chemical information users, full risk assessments are unnecessary when there is an urgent need for good information
  - Yet premise of HPV is hazard information alone is generally considered an insufficient basis for the initiation of risk management
- HPV data set does not include exposure data
- Data are limited for non-HPV chemicals
- Uncertainty favors more study – inaction – data collection slow
- Risk management measures often come only after years of regulatory analysis

Using the HPV data for decision-making

- Early years – no clear idea of how it would be used
- Still questions as to how data will be presented in a user friendly way
- Further questions about how HPVIS will be linked to other data sources to enhance decision-making
  - IURA
  - TRI
  - Other country analyses – eg. Canada, Sweden
  - REACH dataset when it comes into being.

NPPTAC Recommendation on Screeningfor HPV data, Feb 2005

- **Process – Tier I and Tier II**
  - Tier I is an automated process whereby key elements of a submitted data set are screened against predetermined criteria (GHS) to establish a logical order in which OPPT should review the chemicals/ categories
  - Submissions taken at face value with no review of quality or completeness
  - Results categorized into three review groups for Tier II (first group up to 55% of submissions)
  - Results do not provide a final judgment of hazard or risks, if any, of a chemical/category.

Risk Management after screening – Cases where Tier II raises questions/ concerns

- Gathering additional information on uses (e.g., by use function, category, release potential, or benefit) and exposure (to humans and/or the environment);
- Gathering additional information on hazards to support a more in-depth characterizations;
- Identifying existing risk management programs and practices;
- Evaluating existing Federal and State regulatory controls (e.g., occupational exposure limits);
- Providing information referrals or recommendations for actions to other EPA program other Federal or State agencies;
- Initiating a risk assessment led by EPA, another agency, industry, etc.;
- Referring the chemical to another program or agency for assessment; or
- Deciding after closer examination that no further action is needed at this time.

HPV review process – NPPTAC recommendation

- **Tier II (2-4 years)**
  - OPPT would conduct a more in-depth review of the data in the Challenge Program submissions for quality and completeness; develop a screening level hazard assessment based on SIDS and non-SIDS hazard data provided by the sponsors; and inform the sponsors and the public of its finding
  - Any use and exposure information in the submission should be described to assist in any further information gathering, assessment, or management activities that OPPT deems appropriate.
  - Tier II is not an evaluation of the exposure potential or risks of a chemical.
  - The key outputs of a Tier II review are a determination as to the adequacy of the submitted data and a screening-level hazard characterization that is posted in the public HPVIS database.

A new approach

- Rapid prioritization based on hazard characteristics (using HPV and structure analog tools) and use category (as a surrogate for potential exposure), IURA data, etc.
- Voluntary/regulatory actions on chemicals (or categories/classes) raised as higher concern
- Use of existing, well recognized EPA tools and processes for new chemicals in addition to HPV and other sources of data for both HPV and non-HPV (mid-production volume) chemicals.
- Key questions: Are there sufficient data to determine whether there might be a problem or if there is low concern?; What are key uncertainties and data gaps and to what extent do these need to be filled in before proceeding?; Should risk management techniques be applied and are there opportunities for pollution prevention?

Goal: EPA is more effectively able to rapidly assess, categorize, prioritize, and act on chemicals that should be addressed through pollution prevention and other voluntary/regulatory measures, as well as those that appear to not need any regulatory or voluntary action based on existing knowledge. EPA finds more efficient ways to use data collected under the HPV challenge (and other testing programs) combined with other EPA tools such as the P2 Framework to avoid chemical impacts early on while avoiding unwarranted actions and stimulating the development of safer processes and substances.

Goals of a new process

- Develop a set of flexible considerations/a process flow (though not pre-defined method) for EPA to more effectively and efficiently link data collection with assessment and voluntary and regulatory prevention actions. Avoid a “straightjacket” process that doesn’t allow EPA to adapt tools to the particular data and nuances of a specific case.
- Better integration of successful rapid assessment tools (and multidisciplinary review processes) currently used for new chemicals review and to encourage safer syntheses and chemicals – P2 Framework, SMART analysis – with data being generated on existing chemicals (HPV, OECD, S. 4, IURA).
  - This would help strengthen and validate the new chemicals tools, provide tools for rapid assessment and prioritization of existing chemicals (not just chemicals in processes but also in products), as well as provide additional information for characterizing substances that have properties that make them potentially safer or greener.

More goals of a new process

- To outline tools and processes by which EPA can recommend or proactively move preventive actions when warranted (before the S. 6 thresholds have been met) while avoiding unnecessary actions.
- To encourage broader consideration of potentially safer or greener chemicals and design at the design stage of chemicals and for existing chemicals when concerns are raised.
- Avoid unnecessary, expensive and protracted risk assessments and use existing resources more efficiently to identify chemicals needing risk management actions and those that do not need such actions at the time being.
- Increase the ability of the agency to more effectively screen, assess, and manage larger numbers of chemicals.
- Integrate consideration of availability of alternatives and p2 options in the discussion of chemical risk and appropriate actions.

Step I – Initial Data Collection

- Gather existing data (hazard and exposure or use category) – this should include all data developed through testing programs such as (SIDS data set from HPV program or § 4 or IUR and New Chemicals PMNs). A voluntary data call in for mid-production level chemicals could be initiated.
- Fill data gaps and validate when possible using P2 Framework/New chemicals assessment tools (SAR, etc.).
- Make data available to the extent it is not Confidential Business Information (e.g. electronic data base for HPV chemicals, § 4, § 8 e, and IUR)
- Take data collected and update SARs/other models.

Step II data screening

- **Hazard/Use Category (or if available use/exposure data) Screening**
  - **Take existing data (exposure and hazard) and information from SAR and other models to screen and categorize chemicals based on hazard and exposure potential/use category**
    - **Screening processes and principles would need to be outlined – for example examine exposure and hazard data separately to identify opportunities for pollution prevention.**
    - **Determine set of hazard, physiochemical property or exposure triggers (eg P&B or reprotoxicty, developmental toxicity or carcinogenicity or high/consumer exposure or GHS category) and develop set of categories to determine next steps. Categories could include high concern, medium concern, low concern or potentially safer chemical**

More data screening

- Determine whether additional hazard or exposure data is needed to make a reasoned determination and who needs to provide that data – ie if there are no data, should a conservative value be assumed until data are provided?
- Next steps would be based on concern levels which could be further broken down by use categories or type of exposures. These could include: further study, no further action needed (eg potentially safer chemical), and risk management action needed.
  - A question here is whether P&B or some key hazard data combined with some use category data is enough to categorize a chemical as one of potential concern and in need of pollution prevention activities?
  - Can EPA provide guidelines such as those for new chemicals of types of chemicals and structures that may result in problems?
  - Can chemicals be grouped into categories for additional efficiency in review at this stage?

Outcomes of screening

- Further study
- A list of higher concern chemicals and possibly categories of concern – ie Nordic Observation lists
- Design for Environment or Pollution Prevention initiative
- R&D into substitutes – challenge program
- Voluntary action program (e.g., PFOA/PFOS)
- Address under other regulatory regimes?
- Risk management regulation (unlikely after only screening level)
- No action

Next step options following categorization

- **Further Study**
  - **Develop additional hazard data**
    - **Are rules needed to gather data (timelines)**
    - **Are there additional screens using SAR approaches that could be used**
  - **Develop additional exposure data**
    - **If exposure data is available, consider whether more is needed?**
    - **Are existing exposure models adequate – do they consider issues such as cumulative effects, sensitive subpopulations, etc.**
    - **Are better supply chain data needed to understand downstream uses?**
  - **Based on further data collection**
    - **Are there still important data gaps that must be addressed before action**
    - **Are risk management measures needed or can the process stop – ie the chemical is reasonably safe or greener and no further actions are needed.**
    - **Is there to conduct a more detailed risk assessment and what are the trade-offs between conducting such assessments and continued exposure. Is there a rapid risk assessment that could be made**
  - **Are there additional on-going data requirements, etc. that are needed – ie data requirements as production levels rise, etc.**

Considerations after further study

- Are alternatives or p2 options readily available?
- How widely used is the substance and are major market players working towards alternatives?
- Will the agency want to undertake a regulatory action – S. 6 in which case higher standards of evidence will be necessary.
- After further study is there a need for risk management or is the substance reasonably safe?
- What risk management measures are needed
  - Regulatory
  - Pollution Prevention/DfE initiative

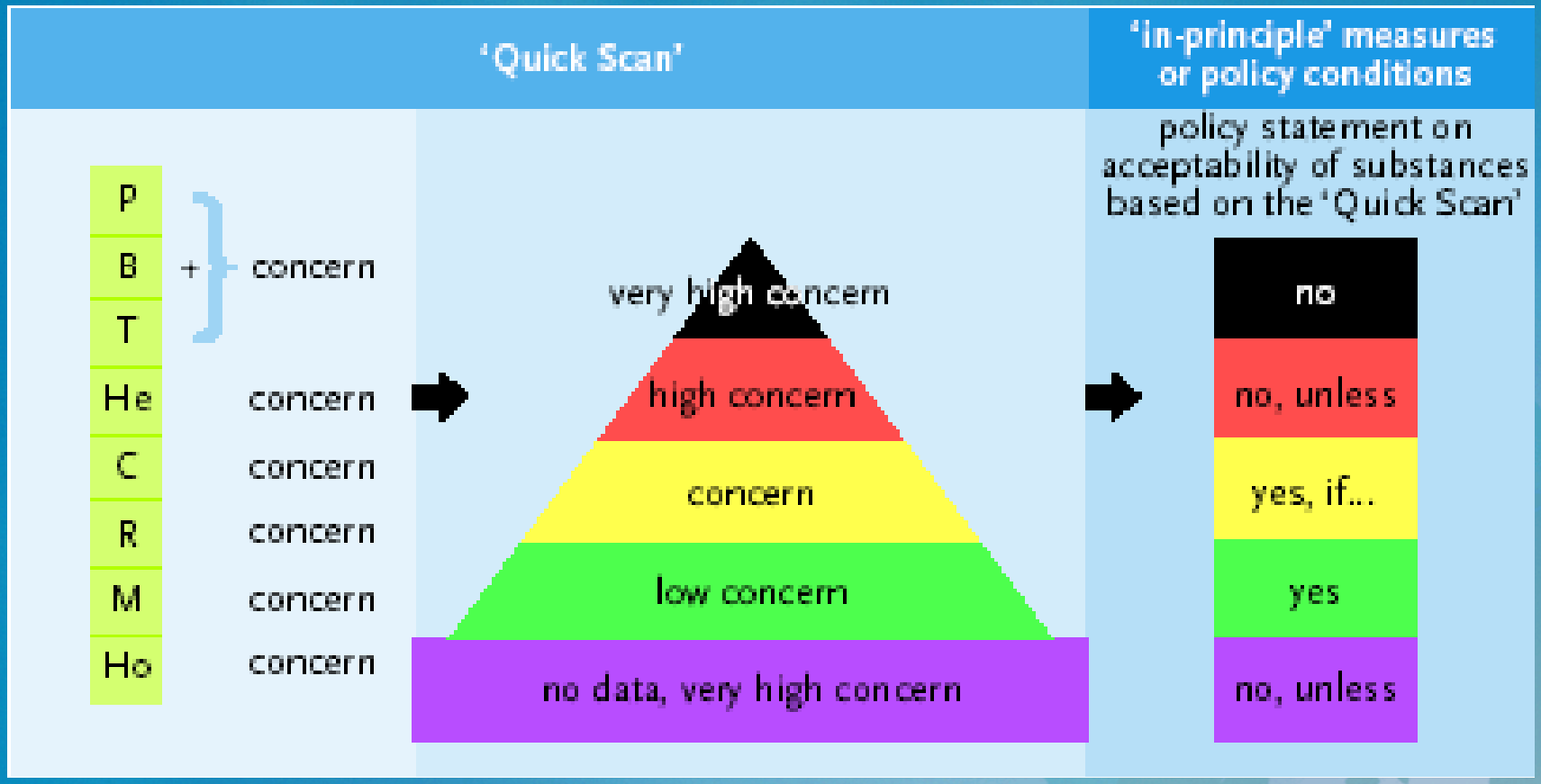
Muir (1994) Use Category Scheme

A generic scheme outlined by Muir is as follows:

	Closed System	Controlled Use	Dispersive Use	Direct Exposure
1. Research Chemical				
2. Raw Material				
3. Reagent				
4. Product Ingredient				
5. Essential Processing Agent				
6. Non-specific Processing Agent				
7. Waste by-product				
8. Indoor Consumer Use				
9. Outdoor Consumer Use				

Producers and users of chemicals should be provided with guidance on reasonable uses of chemicals and that this guidance should form the basis of EPA's prioritization of chemicals for prevention activities

Dutch Quick Scan Screening Method



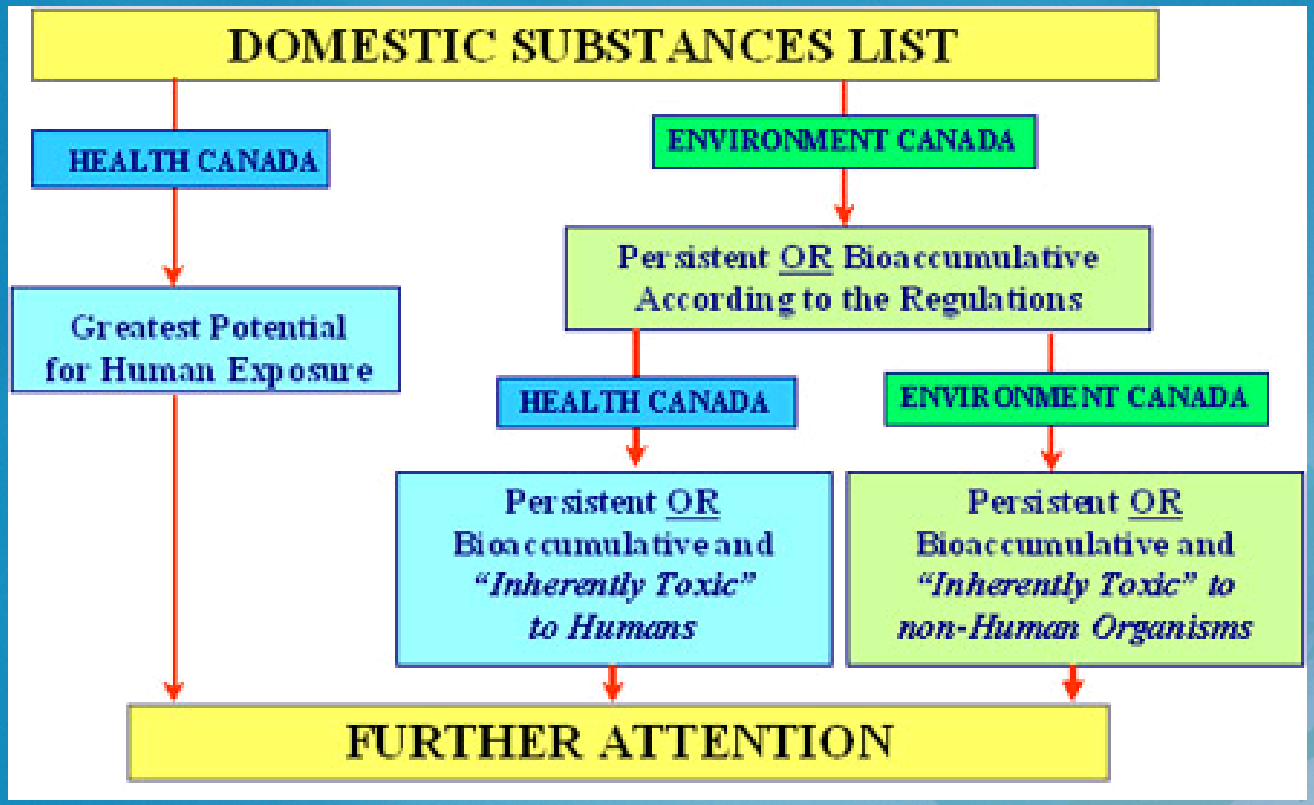
*Dutch Strategy on Management of Substances, 2001

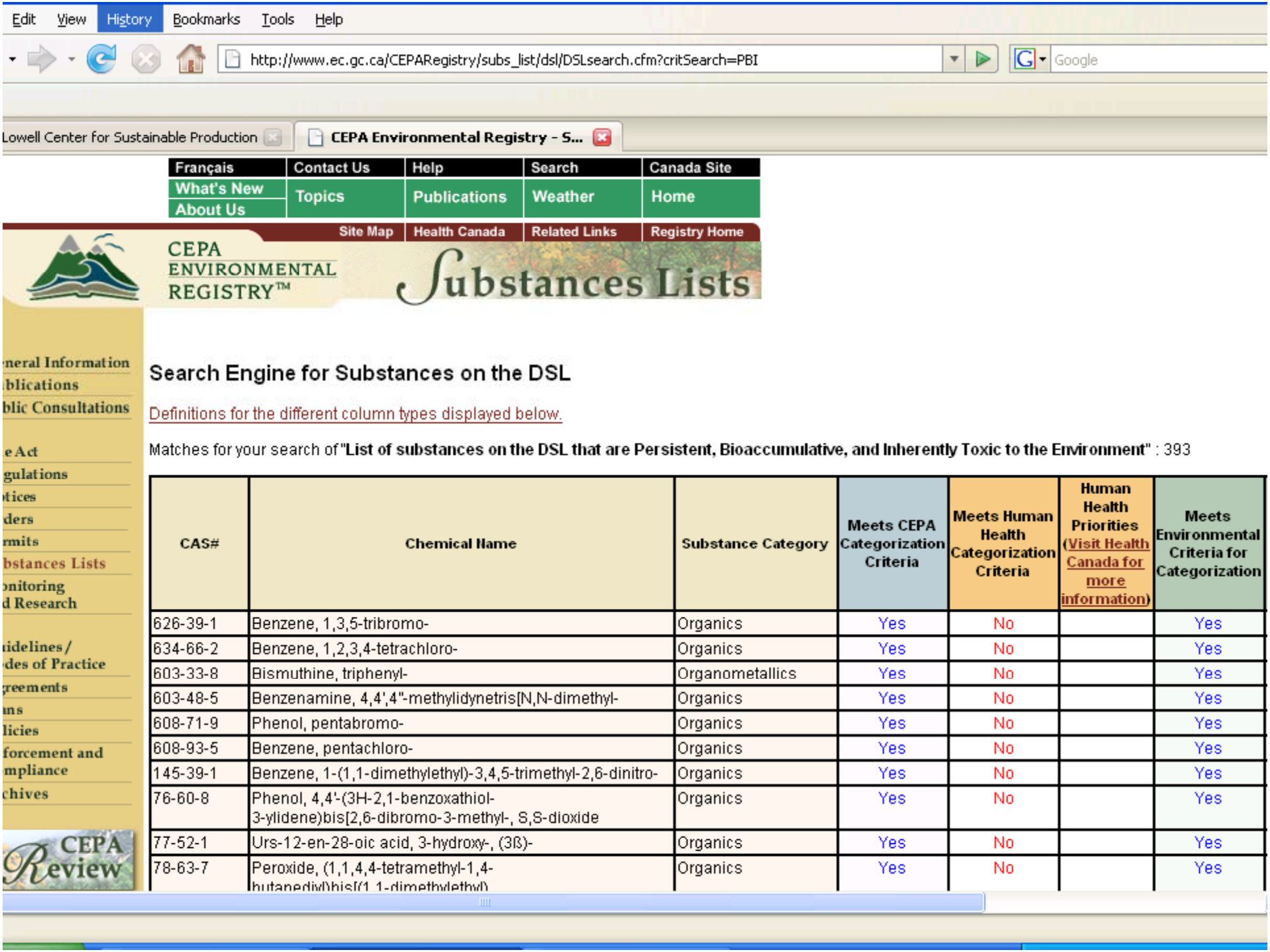
Dutch Quick Scan - 2002

Substances in concern category on basis of hazard and use[23]

CONCERN ON BASIS OF HAZARD / EXPOSURE ON BASIS OF USE	Use of substances as indication of exposure			
	Site limited intermediate substances	Substances in industrial applications	Open professional use of substances	Substances in consumer applications
	Low Exposure	Exposure	High exposure	Very high exposure
Very high concern	High concern	High concern	Very high concern	Very high concern
High concern	Concern	Concern	High concern	High concern
Concern	Concern	Concern	Concern	High concern
Low concern	Low concern	Low concern	Low concern	Concern
No data, very high concern	Very high concern	Very high concern	Very high concern	Very high concern

Canadian DSL Categorization





CAS#	Chemical Name	Substance Category	Meets CEPA Categorization Criteria	Meets Human Health Categorization Criteria	Human Health Priorities (Visit Health Canada for more information)	Meets Environmental Criteria for Categorization
626-39-1	Benzene, 1,3,5-tribromo-	Organics	Yes	No		Yes
634-66-2	Benzene, 1,2,3,4-tetrachloro-	Organics	Yes	No		Yes
603-33-8	Bismuthine, triphenyl-	Organometallics	Yes	No		Yes
603-48-5	Benzenamine, 4,4',4"-methylidynetris[N,N-dimethyl-	Organics	Yes	No		Yes
608-71-9	Phenol, pentabromo-	Organics	Yes	No		Yes
608-93-5	Benzene, pentachloro-	Organics	Yes	No		Yes
145-39-1	Benzene, 1-(1,1-dimethylethyl)-3,4,5-trimethyl-2,6-dinitro-	Organics	Yes	No		Yes
76-60-8	Phenol, 4,4'-(3H-2,1-benzoxathiol-3-ylidene)bis[2,6-dibromo-3-methyl-, S,S-dioxide	Organics	Yes	No		Yes
77-52-1	Urs-12-en-28-oic acid, 3-hydroxy-, (3ß)-	Organics	Yes	No		Yes
78-63-7	Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl)	Organics	Yes	No		Yes

Other prioritization/categorization schemes

- TRI rapid risk review – Univ of TN
- MA Toxics Use Reduction Inst. Delphi Process for Categorization
- Danish review of existing chemicals using SAR analysis
- PRIO - Sweden

Benefits of such a process

- Relatively rapid review to facilitate decision-making and remove barriers (e.g. lack of knowledge)
- Use existing tools, processes, expertise, and data
- Can promote implementation of safer chemicals in a timely and thoughtful manner – supports innovation
- Can be applied to non-HPV chemicals to rapidly screen the entire chemical universe
- Focuses on how much information do we need to make informed decisions – not “perfect” knowledge

Conclusion

- Rapid screening processes and prioritization and action processes are critical to the success of the HPV program
- It is what the public thinks government and industry are already doing – confidence
- We will not be able to sustainably manage chemicals without such processes.