# SVHC in Articles: Practicalities for Industry and Enforcement

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# Why REACH?

1990s Conflicting pressures for change:

- Industry concerns over burden of chemicals legislation, but
  - Pressure from consumer groups
  - Pressure from green NGOs
  - Pressure to replace substance of concern

Need to know what chemicals are in products and what risk is there to user

# Risk from chemicals

- The original plans for REACH in 1990 emphasised the need to identify risk and ensure risk management
- Risk = Hazard X Exposure

- Consumer products seen to be high exposure and therefore potentially a high risk

# Where does REACH fit in?

- REACH aims to make the link between chemical substances and the products they end up in
- REACH has some exemptions where higher standards are imposed elsewhere and arrangements are equivalent
  - e.g. Medicines
- But same product can be subject to more than one law and standards may differ
  - e.g. WEEE, RoHS, tobacco, end use cosmetics, food contact etc
- Big gaps in current legislation relating to chemical risk
  - General products in the home (flame retardants, plasticisers etc)
  - Recovery and recycling (trace metals, preservatives, pigments etc)

# Defining an article

- REACH Article 3(3): definition of an article

***“an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”***

# “Article” vs. “Chemical”

- **“Chemical”** when chemistry is primary function
  - e.g. ink, photocopy toner
  - Chemicals in containers
    - e.g. shampoo in a bottle, paint in a can
  - Chemicals on carriers
    - e.g. wet wipes

**May have Registration obligation for chemical**

- **“Article”** when **physical form** more important:
  - Beads in cuddly toys
  - Textiles
  - Components, nuts and bolts
  - Furniture, plastics etc

**SVHC obligations**

# Borderline cases

- Processed materials into articles
  - Sheets of metal and plastic to be cut
  - Products intended to be melted or burned
- Candles, desiccant bags, fragranced products
  - Combinations of article and substance/mixture
  - Wick is carrier of fuel (and scent)

Suppliers need to justify their opinions

In all cases, SVHCs must be identified

# SVHC - define

Article 59 of REACH

- Carcinogens, mutagens, toxic for reproduction (CMR)
- Persistent, bioaccumulative and toxic (PBT)
- Very persistent and very bioaccumulative
- Anything else that might be nasty.....
  - A clause allows other stuff like nano-particles, endocrine disruptors etc a chance to join the list

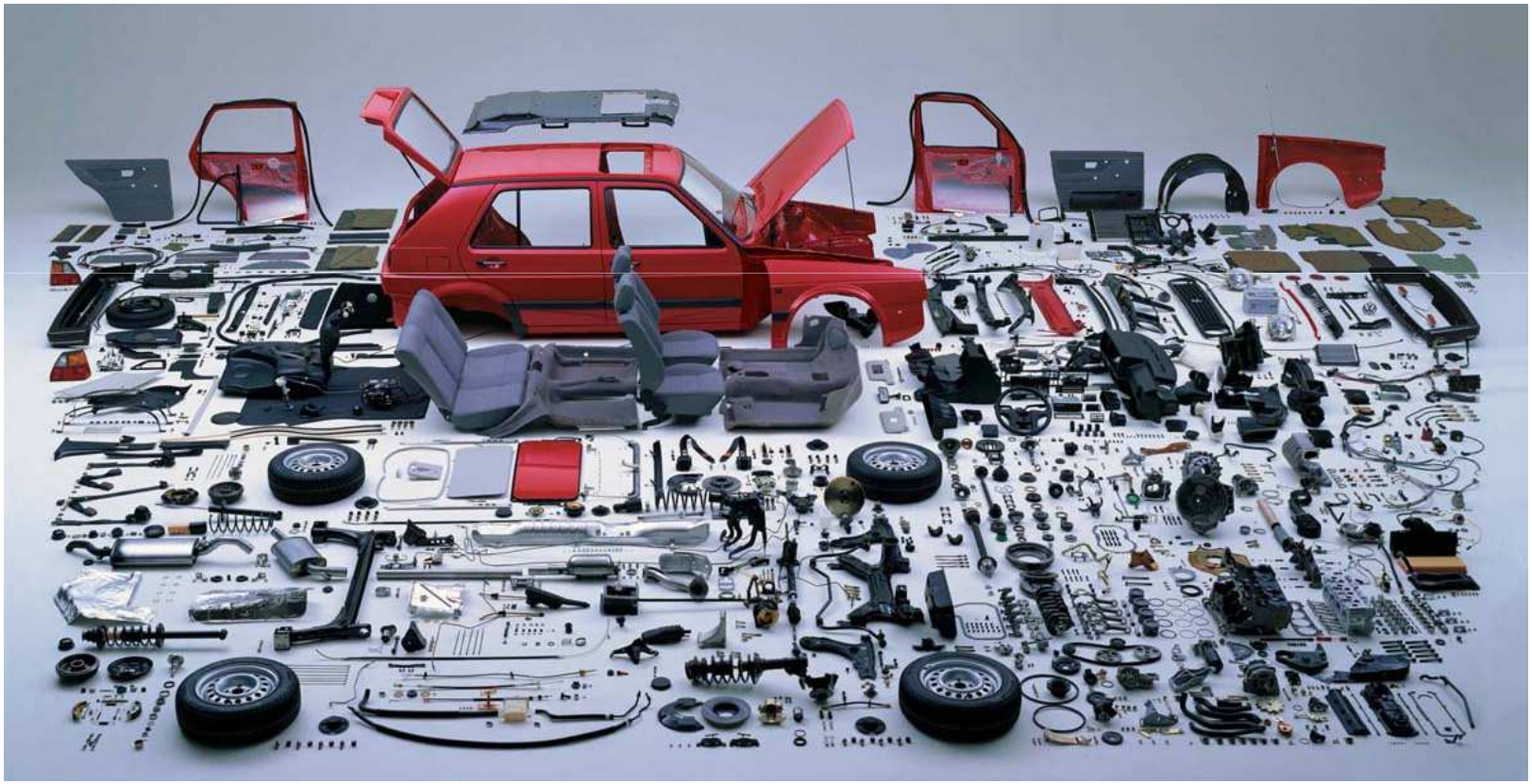
# Articles and SVHC

EEA producers of articles must pass on to customers details of any SVH present in the products, if > 0.1% and if there is a risk of exposure*

Importers must have a good level of confidence from non-EEA producers and need to pass on any information to customers if SVHC > 0.1% and if there is a risk of exposure*

* Very hard to prove there is no exposure

# Identification of SVHC - % of component or whole article?



Courtesy Volkswagen

# Challenges for industry

- Gaining information from suppliers
  - More difficult with non-EU suppliers
- Managing communication
- Obtaining and verifying data received on SVHCs
  - Can suppliers be trusted ?
  - Do they need to analyse samples of materials ?
  - Is there a paper-trail to demonstrate regulatory compliance ?

# Customer reactions


GUARDIAN
02/07/98

Europe set to torpedo 'lethal' bath-time ducks

A plastic duck . . . cute, but scientists say it could be deadly

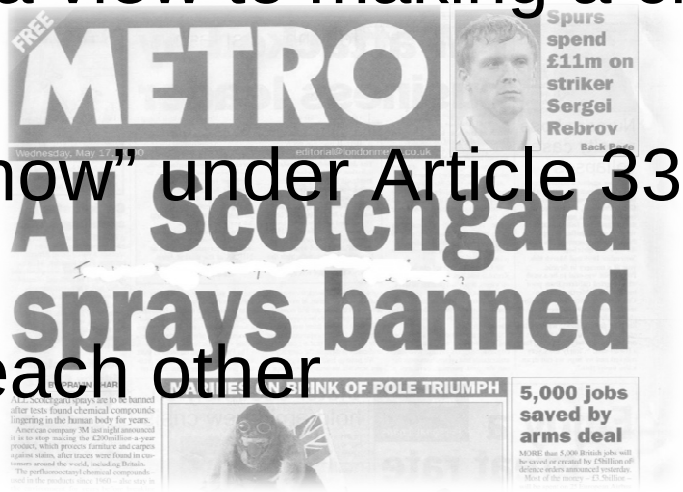
Stephen Bates in Brussels


Some stores in Europe are withdrawing soft PVC plastic toys

Children 'put at risk from chemicals in toys'

Teething troubles: there is particular concern over risks to babies chewing on teethers

- Many consumers already asking about the presence of Candidate List Substances in the products they buy with a view to making a choice of not to buy
- Citing “Public right to know” under Article 33 of REACH
- Competitors reporting each other


FREE METRO

Spurs spend £11m on striker Sergei Rebrov

All Scotchgard sprays banned

INK OF POLE TRIUMPH

5,000 jobs saved by arms deal

# Supply chain enforcement

- Customers
  - Looking for compliant suppliers
  - Impact on business reputation
- Public pressure
  - More public scrutiny

Confidence in regulatory control ?

Industry wants a level playing field

# Candidate list

- List of substances facing scrutiny as SVHC
  - May not be found ‘guilty’, but very likely to lead to banning or at least restrictions
- Check for regular updates on ECHA web-site
  - 161 substances at last revision
  - http://echa.europa.eu/candidate-list-table
- May be ‘promoted’ to Annex XIV as priority substances
- Candidate substances > 0.1% must be identified for supply of articles, but no restrictions on use
  - Consumers can demand information

# Annex XIV

- Priority Candidate list substances move on to Annex XIV
  - 31 substances currently listed
  - http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list
- Some exemptions may be applied for, but unless specific permission (Authorisation), substance cannot be used in Europe after sunset date

# Articles and sunset date

- Articles containing Annex XIV substances at over 0.1% can be supplied, but substance must be identified
- New articles cannot be made in Europe (unless Authorised or Exempt)
- New articles can be imported, but ‘Notification’ of uses may be needed if no valid Registration in place for the substance present
  - Expect future restrictions and customer resistance

# Annex XIV status – the 1st 6

| Substances added 21 Feb 2011 | EC Number | Sunset date | Apply By date |
|---|---|---|---|
| 4,4'-Diaminodiphenylmethane (MDA) | 202-974-4 | 21/08/2014 | 21/02/2013 |
| 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) | 201-329-4 | 21/08/2014 | 21/02/2013 |
| Benzyl butyl phthalate (BBP) | 201-622-7 | 21/02/2015 | 21/08/2013 |
| Bis(2-ethylhexyl) phthalate (DEHP) | 204-211-0 | 21/02/2015 | 21/08/2013 |
| Dibutyl phthalate (DBP) | 201-557-4 | 21/02/2015 | 21/08/2013 |
| Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane | 221-695-9, 247-148-4 | 21/08/2015 | 21/02/2014 |

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# Some of their common uses

- 4,4‘-Diaminodiphenylmethane
  - Flexible rubber products
- Dibutyl phthalate
  - Soft plastics, adhesives, inks
- DEHP
  - PVC goods, novelty products
- HBCDD
  - Flame-resistant polystyrene, clothing, textiles
- Benzyl butyl phthalate
  - PVC goods, artificial leather

# Annex XIV status – the 2nd set of 8

| Substances added February 2012 | EC Number | Sunset date | Apply By date |
|---|---|---|---|
| Diisobutyl phthalate | 201-553-2 | 21/02/2015 | 21/08/2013 |
| Diarsenic trioxide | 215-481-4 | 21/05/2015 | 21/11/2013 |
| Diarsenic pentaoxide | 215-116-9 | 21/05/2015 | 21/11/2013 |
| Lead chromate | 231-846-0 | 21/05/2015 | 21/11/2013 |
| Lead sulfochromate yellow (C.I. Pigment Yellow 34) | 215-693-7 | 21/05/2015 | 21/11/2013 |
| Lead chromate molybdate sulphate red (C.I. Pigment Red 104) | 235-759-9 | 21/05/2015 | 21/11/2013 |
| 2,4-Dinitrotoluene | 204-450-0 | 21/08/2015 | 21/02/2014 |
| Tris(2-chloroethyl)phosphate | 204-118-5 | 21/08/2015 | 21/02/2014 |

Courtesy REACHReady

# Some of their common uses

| | |
|---|---|
| • 4,4‘-Diaminodiphenylmethane | Flexible rubber products |
| • Dibutyl phthalate | Soft plastics, adhesives, inks |
| • Musk xylene | Fragranced toilet blocks |
| • DEHP | PVC goods, novelty products |
| • HBCDD | Flame-resistant polystyrene, clothing, textiles |
| • Benzyl butyl phthalate | PVC goods, artificial leather |

# Action for EU manufacturers

## EU manufacturers of articles

- Ensure purchasing, ensure substances are registered for uses
- Ensure that these substances are not of high risk to workers, consumers or the environment during use of the article
- Monitor Candidate List / Annex XIV etc to ensure substances are listed as SVHC
- If SVHC, communicate to customers

# Action for importers of articles

Import of components or finished articles

- Ensure purchasing systems are in place that ensure any SVHC are reported by the supplier
- If SVHC and registered for the uses of your article, communicate to customers
- If SVHC and not registration existes for your uses, Notify ECHA
- Monitor Candidate List / Annex XIV etc to ensure substances are listed as SVHC

# Analysis of articles ?

## Those importing articles

- Accepted that it is impossible to check every batch of material
- Certification and assurance from supplier important
- For high exposure products (eg toys, packaging, medical devices etc), trading standards checks may be needed
  - Note ‘higher’ legislation
- Consumer rights to ask if SVHC present
  - Advised to have answers ready

# Trust in suppliers

For all those sourcing articles (components)

- Ensure good relationship with suppliers and help them understand issues regarding SVHC (especially if importing)
- EU suppliers should be aware and may have their own systems for their own suppliers in turn
- Do not hassle and make unnecessary demands on suppliers (will put up their costs)
- Consider analysis as final step if not confident with supplier assurances

# Summary

- Keep up to date with lists and guidelines
- Have SVHC present been identified and if necessary, communicated
- Consider where potential for exposure is greatest
- Consider the risk from the presence of SVHC
- Understand uses