



Alles „gewaivt“? Und wo sind die besonders besorgniserregenden Stoffe?



Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

Umsetzung der
umweltbezogenen Anforderungen von REACH

Umwelt
Bundes
Amt 
Für Mensch und Umwelt

REACH
in der Praxis

*Dr. Christoph Schulte, Umweltbundesamt Dessau
Fachgebiet Chemikalien (IV 2.3)*

25. 10. 10
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BGA | Am Weidendamm 1A | 10117 Berlin

An Herrn
Jochen Flasbarth
Präsident des Umweltbundesamtes
Postfach 1406
06813 Dessau-Roßlau

UMWELTBUNDESAMT
- Präsidialbereich -
Eing.: 18. OKT. 2010 *[Handwritten mark]*
Gesch.Z.:

Bundesverband
Großhandel, Außenhandel,
Dienstleistungen e.V.

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2) P. sil. 10/10
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iv. P. H. B.
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→ IV 11. 1. 10
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→ Original an 11. 10. 10

Konferenzreihe „REACH in der Praxis“

14. Oktober 2010

Sehr geehrter Herr Flasbarth,

die vom Umweltbundesamt veranstaltete Informationsreihe „REACH in der Praxis“ ist mit einer Abschlusskonferenz am 28. September 2010 zu Ende gegangen. Ich nehme dies zum Anlass, Ihnen für die fachliche Tiefe und den zugleich praxisorientierten Informationsgehalt dieser Veranstaltungsreihe zu gratulieren.

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UBA chief: strengthen burden of proof on firms under REACH

The president of the German Federal Environment Agency (UBA), **Jochen Flasbarth**, speaks to chemicals journalist **Dr Ralph Heinrich Ahrens** on his expectations of REACH, his criticisms of many registration dossiers already submitted and the resource limitations of German authorities. He further makes a radical call to amend REACH to place all suspected substances of very high concern (SVHCs) on the candidate list immediately.

RHA: Mr. Flasbarth, what do you think about REACH?

JF: The REACH Regulation is a huge step forward. Before REACH, we didn't know much about the chemicals used in Europe. That was intolerable and everyone knew it.

RHA: What is the objective of REACH?

JF: Ultimately, we would like to find those critical chemicals which really harm people and the environment. For that, the authorities will evaluate registration dossiers. To make precise evaluations, the dossiers should contain correct and sound data. Companies should be able to

also accumulate in the environment. Or take anthracene – a very stable molecule. In the EU it is acknowledged as an SVHC. Some companies appear to have played down this hazard – and refer to other interpretations of the Regulation when, in fact, the substance is included in the candidate list.

We also have doubts about whether companies have correctly described the properties of nanomaterials in their dossiers.



conditions for the application of them. To give more specific examples: Some in silico results were evaluated as being more reliable than experimental data; in almost all cases only the best favourable value from the point of view of the registrant (eg the lowest prediction value for bioaccumulation) was used, without any scientific explanations. Moreover, the documentation of these computer modelling studies was insufficient in terms of REACH. That means the predictions are not reproducible – and could, therefore, be wrong.

In many other cases, if you look more carefully you find that companies have avoided tests – intentionally or unintentionally. In effect, those companies could underestimate the risk for the environment or could avoid regulatory threshold values.

Of course, companies are allowed to waive tests which are not useful. That is sensible. For example, it would be useless to check how a substance could be a danger for daphnia or fish if there is no likelihood of exposure in the aquatic environment. But in reality companies use this waiving mostly as a loophole in order to avoid carrying out tests. An example: companies claim very few substances that are extremely harmful

I

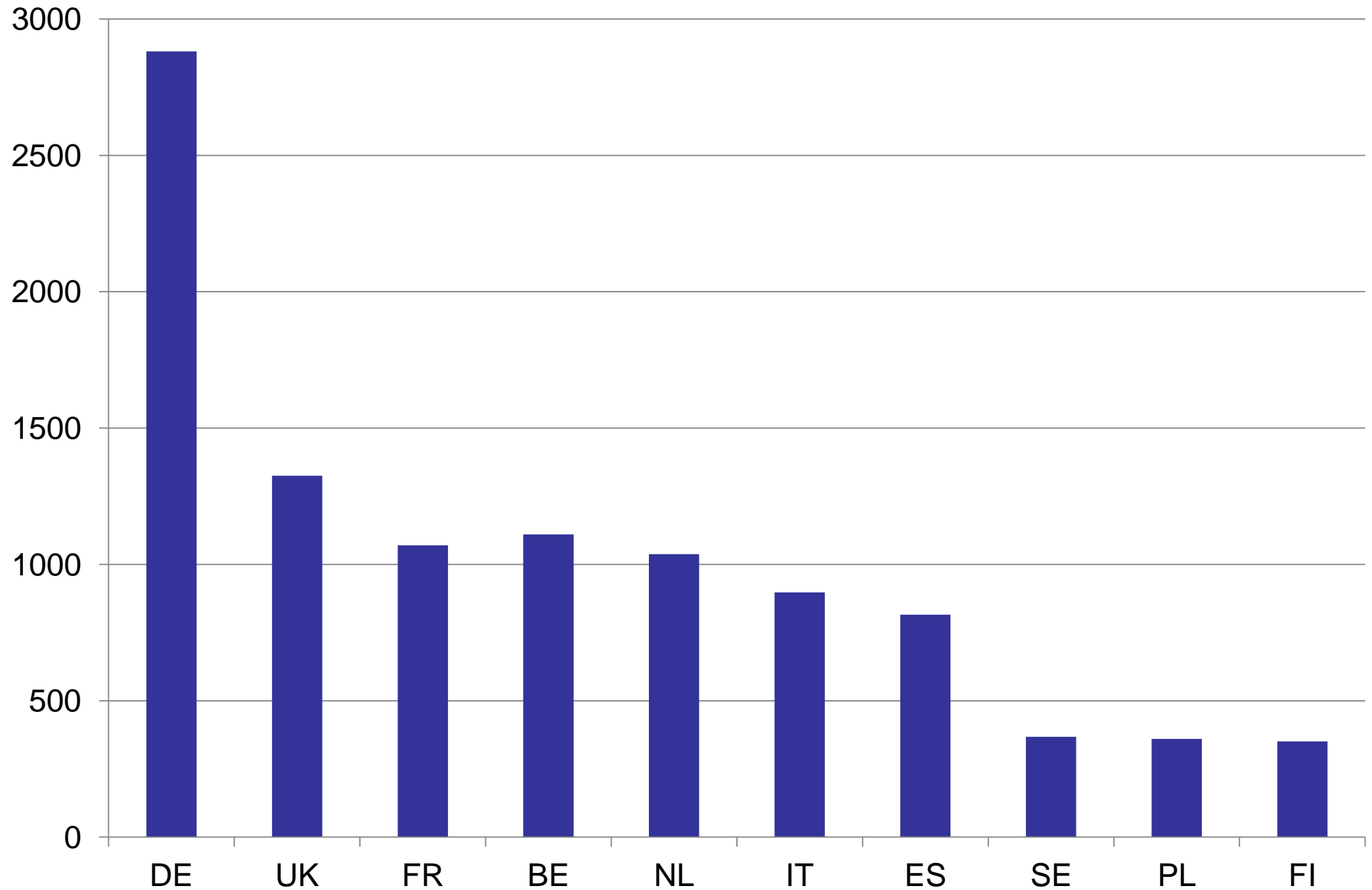
(Veröffentlichungsbedürftige Rechtsakte)

VERORDNUNG (EG) Nr. 1907/2006 DES EUROPÄISCHEN PARLAMENTS UND DES RATES

vom 18. Dezember 2006

**zur Registrierung, Bewertung, Zulassung und Beschränkung chemischer Stoffe (REACH),
zur Schaffung einer Europäischen Agentur für chemische Stoffe, zur Änderung der
Richtlinie 1999/45/EG und zur Aufhebung der Verordnung (EWG) Nr. 793/93 des Rates, der
Verordnung (EG) Nr. 1488/94 der Kommission, der Richtlinie 76/769/EWG des Rates sowie
der Richtlinien 91/155/EWG, 93/67/EWG, 93/105/EG und 2000/21/EG der Kommission**

Registrierte Stoffe



Erste Erfahrungen

327 begonnene Dossierbewertungen, davon:

- 95 in Bearbeitung durch ECHA
- 232 abgeschlossen
 - 117 „Final Decisions“
 - 59 „Quality observation letters“
+ (54 zusätzlich zu „Decisions“)
 - 56 abgeschlossen ohne Maßnahmen

Stand 31.01.2012

- ECHA; Bewertungsaktivitäten gemäß REACH – Fortschrittsbericht 2010 (jährlich)
- ECHA; ECHA's report on operation of REACH (REACH Art. 117 (2)); 2011
- Auswertung ECHA Zwischenprodukte
- Auswertungen Bundesoberbehörden
 - UBA Analyse Dossiers potentieller PBT-Stoffe
 - UBA Analyse Dossiers PAK-haltiger UVCB-Stoffe

Qualität Registrierungs dossiers

- Hohe Beanstandungsquote in der Dossierbewertung (nicht repräsentativ)
- Eindruck unserer Stichproben zeigt Verbesserungsbedarf, z.B.
 - Kaum PBT-Stoffe identifiziert (trotz teilweise bekannter PBT-Eigenschaften)
 - Kaum Nanomaterialien identifiziert
 - Waiving überstrapaziert
 - QSAR falsch angewandt

Gemeinsame Bewertung der Bundesregierung,
VCI und IG BCE des Konsultationsentwurfs REACH
der Kommission vom 21.08.2003...

IV. Qualitätssicherung

Für die von der Industrie im Rahmen der
Registrierung vorzulegenden Unterlagen sollte
ein angemessenes, wirksames System der
Qualitätssicherung begründet werden. In Betracht
kommen



UBA Schwerpunkte unter REACH

UBA Schwerpunkte unter REACH

- Methodenkompetenz „Stoffbewertung“ erhalten und Bewertungskonzepte weiterentwickeln – als verlässlicher und kompetenter Partner von BMU, BAuA, ECHA und Unternehmen
- Stoffe identifizieren, die hinsichtlich ihrer Auswirkungen auf Mensch und Umwelt oder ihres inhärenten Gefährdungspotenzials regulierungsbedürftig sind und angemessene Maßnahmen einleiten
- Chemikalienmanagement und Erfolgskontrolle an den Schnittstellen zu Anlagenrecht und medialem Recht verstärken



UBA Schwerpunkte unter REACH

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(Ein) Ziel von REACH

„ ...die von besonders besorgniserregenden Stoffen ausgehenden Risiken ausreichend beherrscht werden oder dass diese Stoffe schrittweise durch geeignete Alternativstoffe oder –technologien ersetzt werden, sofern diese wirtschaftlich und technisch tragfähig sind.“

Artikel 55

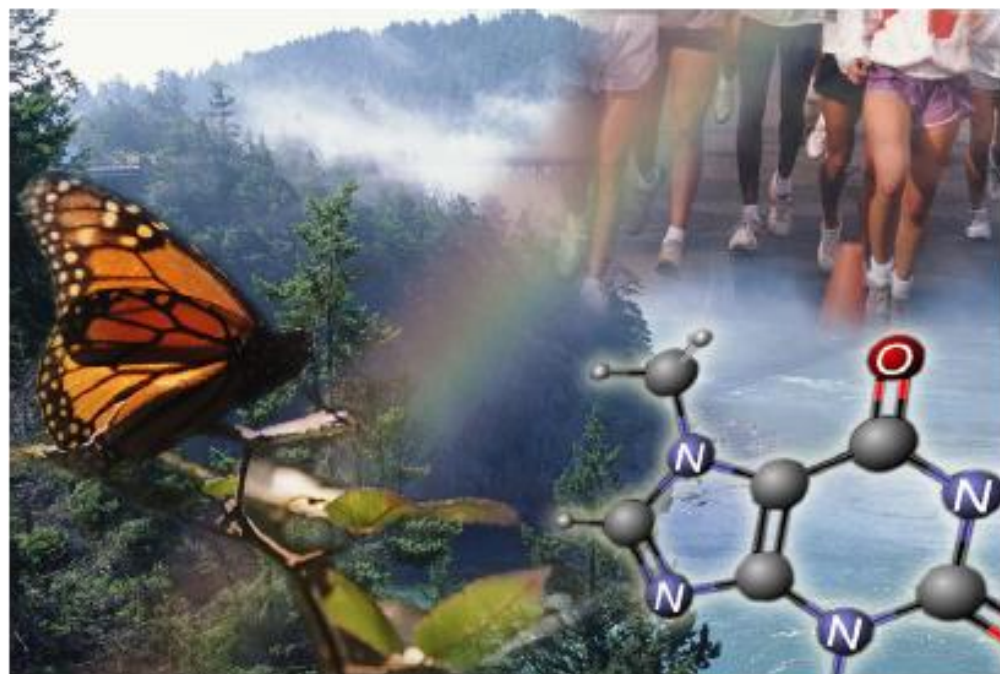
Besonders besorgniserregende Stoffe

- kanzerogene, mutagene, reproduktionsschädigende Stoffe (CMR Kategorie 1a und 1b)
- persistente, bioakkumulierende und toxische Stoffe (PBT)
- sehr persistente, sehr bioakkumulierende Stoffe (vPvB)
- gleichermaßen besorgniserregende Stoffe, z.B.:
 - Stoffe mit endokrinen Eigenschaften
 - Stoffe, die nicht PBT/vPvB-Kriterien erfüllen, aber persistent, bioakkumulierbar und toxisch sind **und** schwerwiegende und irreversible Wirkungen auf Mensch und Umwelt haben

Beispiel: PBT-Screening

 ECHA

Guidance on information
requirements and chemical safety
assessment
Part C: PBT Assessment

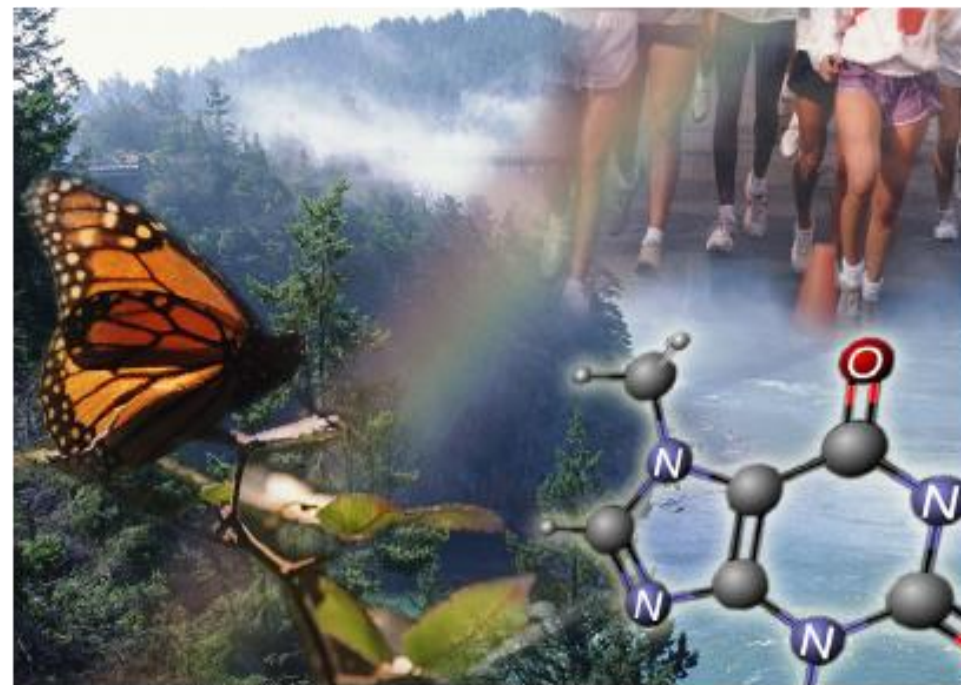


May 2008

Guidance for the implementation of REACH

 ECHA

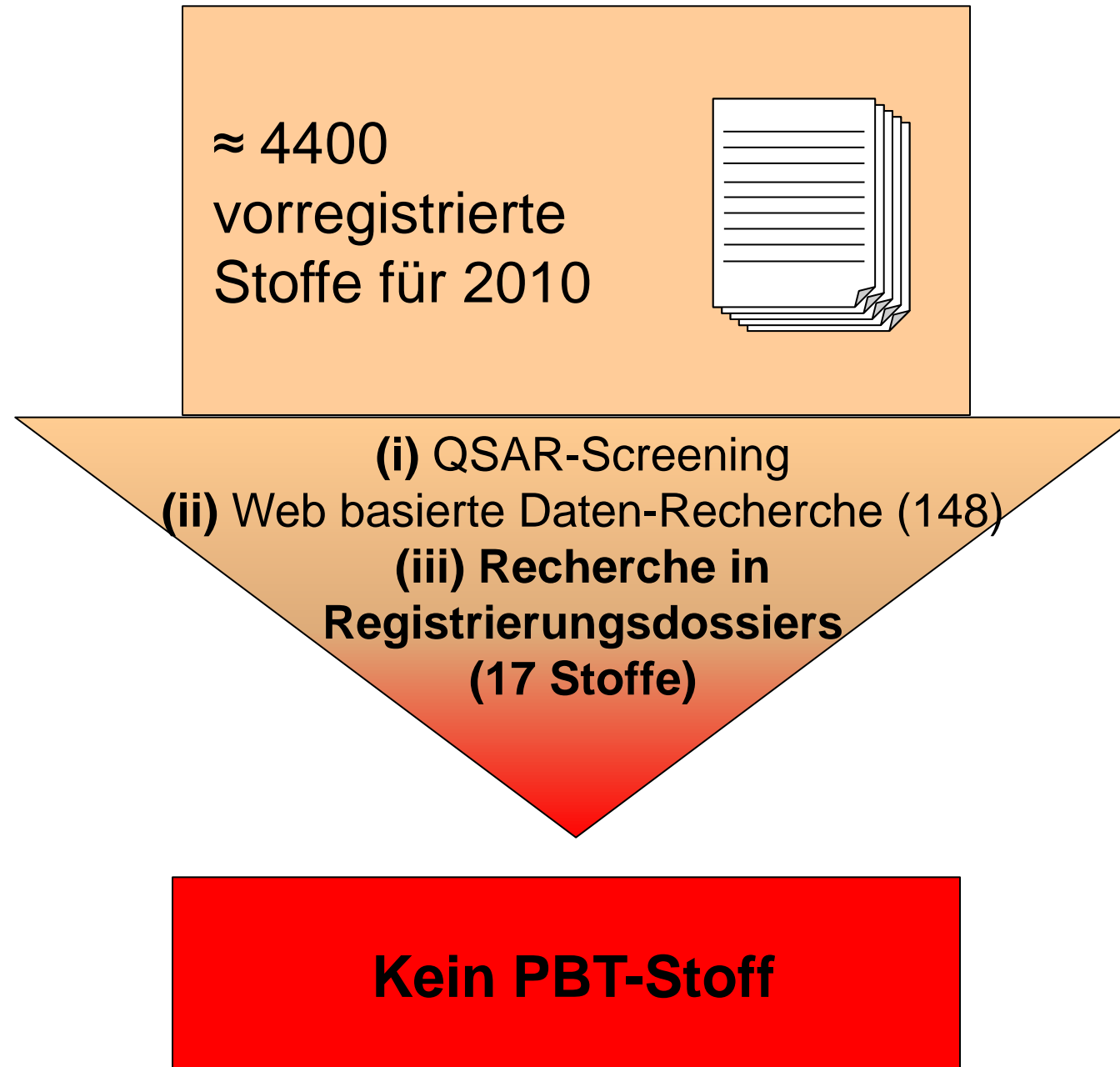
Guidance on
information requirements and
chemical safety assessment
Chapter R.11: PBT Assessment



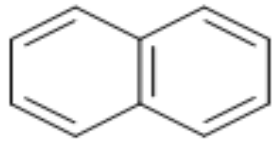
May 2008

Guidance for the implementation of REACH

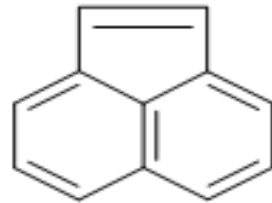
Beispiel: PBT-Screening



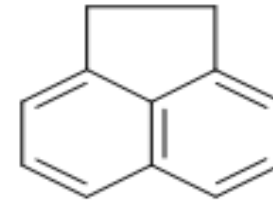
Beispiel: PAK



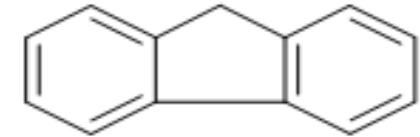
Naphtalin



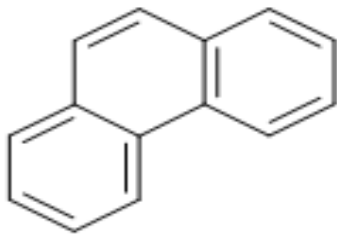
Acenaphtylen



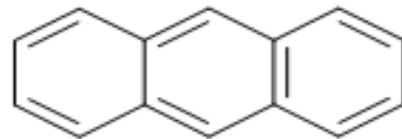
Acenaphten



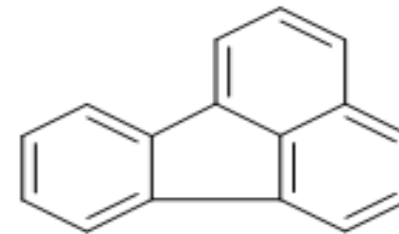
9H-Fluoren



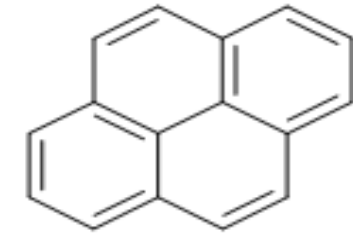
Phenanthren



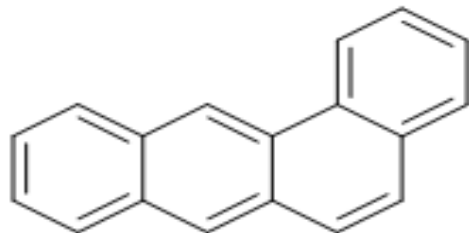
Anthracen



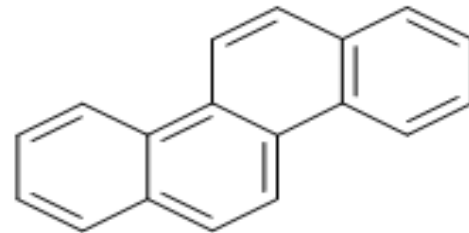
Fluoranthen



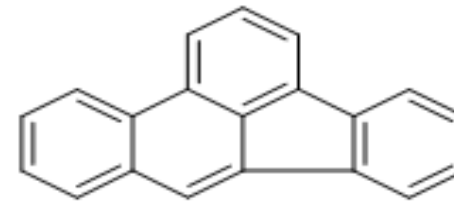
Pyren



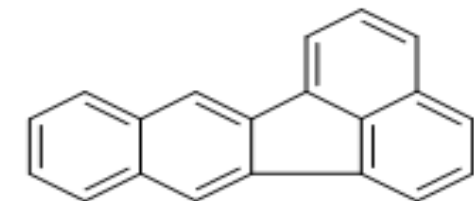
Benz[a]anthracen



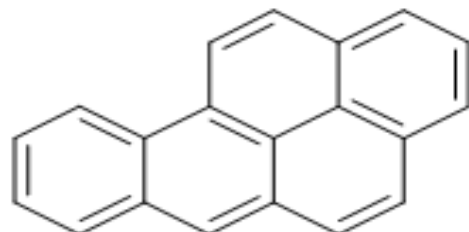
Chrysen



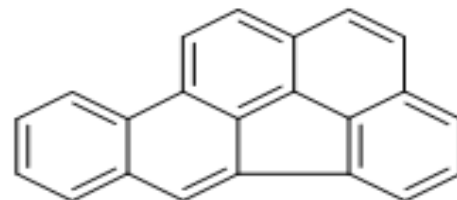
Benzo[b]fluoranthen



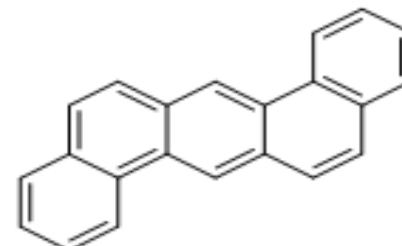
Benzo[k]fluoranthen



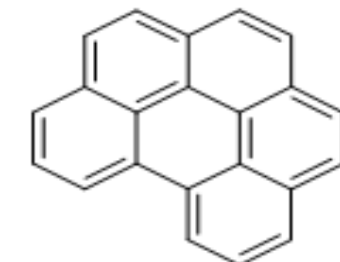
Benzo[a]pyren



Indeno[1,2,3-cd]pyren



Dibenz[ah]anthracen



Benzo[ghi]perylen

Beispiel: PAK

Auswertung von 22 Registrierungs dossiers zu PAK-haltigen UVCB-Stoffen

[UVCB = Substances of Unknown or Variable
composition, Complex reaction products or Biological
materials]

Fakten:

- UVCB aus der Kohle- oder Petrochemie
- Registrierung meist durch große Unternehmen,
überwiegend in SIEFS organisiert
- Geprüft: PBT-Eigenschaften und Stoffidentitäten

Beispiel: PAK

Ergebnis: PBT-Bewertung in allen Dossiers negativ

= > sind PAK eine unproblematische Stoffgruppe?

Probleme:

– Keine Gesamtschau bekannter Studien, sondern
Auswahl tendenziell entlastender Studien

– Keine Berücksichtigung bereits getroffener
regulatorischer Entscheidungen zu Einzel-PAK
(bspw. Anthrazen)

= > Bekannte PBT/vPvB–Stoffe werden verharmlost

Beispiel: QSAR und read-across

Observations from registration dossiers



- Insufficient documentation why adaptation of standard testing regime can be justified
- Reporting does often not address applicability domain and whether the result is adequate for risk assessment and/or classification and labelling
- Model reporting is lacking or used model is different to the one reported
- Substance is outside applicability domain
- QSAR is used only for one constituent of a substance
- Reliability score 1 used; common practice would be max. score 2
- Using QSAR as a supporting study without a key study

top

<http://echa.europa.eu>

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ADP Results
Print  Save Results  Copy  Remove Window  Help

SMILES : c1ccc(Cl)cc1Cl
CHEM   : Benzene, 1,2,4-trichloro-
MW     : C6 H5 Cl3
MWL VI : 181.45

----- SUMMARY (ADP v1.02): HYDROXYL RADICALS (25 deg C) -----
Hydrogen Abstraction - 0.0000 E-12 cm3/molecule-sec
Reaction with H, S and OH - 0.0000 E-12 cm3/molecule-sec
Addition to Triple Bonds - 0.0000 E-12 cm3/molecule-sec
Addition to Olefinic Bonds - 0.0000 E-12 cm3/molecule-sec
Addition to Aromatic Rings - 0.2817 E-12 cm3/molecule-sec
Addition to Fused Rings - 0.0000 E-12 cm3/molecule-sec

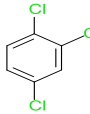
OVERALL OH Rate Constant = 0.2817 E-12 cm3/molecule-sec
HALF-LIFE = 37.1867 Days, 432.107 hr, 1.564 DRYDAYS

----- SUMMARY (ADP v1.01): OZONE REACTION (25 deg C) -----
***** NO OZONE REACTION ESTIMATION *****
(OH, HO2, H2O2, and Acetylperoxides are Estimated)

Experimental Database Structure Match:
Chem Name : 1,2,4-Trichlorobenzene
CAS Number: 88817-82-1
Exper OH rate constant : 0.55 E-12 cm3/molecule-sec
Exper OH Reference:  SMAC/SC 0 RISK/INRA (1994)
Exper Ozone rate constant: --- cm3/molecule-sec
Exper HO2 rate constant: --- cm3/molecule-sec
  
```



Beispiel: QSAR und read-across

1,2,4-TCB



1,2,3-TCB

Model valide?
(QMRF)

	QMRF identifier (JRC Inventory): to be entered by JRC QMRF Title: AOPWIN for k _{OH} Printing Date: 04.05.2010	
---	--	---

EC number 204-428-0 201-757-1

CAS number 120-82-1 87-61-6 108-70-3

Modell für Stoff
anwendbar?(QPRF)

1. QSAR identifier

1.1. QSAR identifier (title):

AOPWIN for k_{OH}

1.2. Other related models:

AOPWIN method for estimating k_{O3} (the rate constant for the gas-phase reaction between ozone and olefinic/acetylenic compounds)

1.3. Software coding the model:

EPISUITE Freely available software from the US EPA and the Syracuse Research Corporation. <http://www.epa.gov/epaosopr/ceqtoxic/exposure/pubs/contact.htm>

Read-across begründbar?
(reporting format)

QSAR Prediction Reporting Format (QPRF) (version 1.1, May 2008)

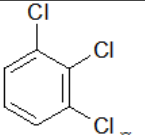
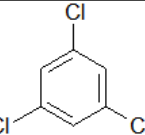
1. Substances

1.1 → CAS number: 87-61-6 and 108-70-3

1.2 → EC number:

1.3 → Chemical name: 1,2,3-Trichlorobenzene and 1,3,5-Trichlorobenzene

1.4 → Structural formula:

1,2,3-Trichlorobenzene	1,3,5-Trichlorobenzene
	
CAS 87-61-6	CAS 108-70-3

Reporting Format for the analogue approach for 1,2,3-Trichlorobenzene and 1,3,5-Trichlorobenzene

CHEMICALS: → 1,2,3-Trichlorobenzene and 1,3,5-Trichlorobenzene

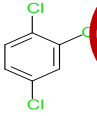
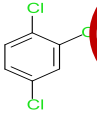
EC No: → → 201-757-1 and 203-608-6

CAS No: → → 87-61-6 and 108-70-3

1. Hypothesis of the analogue approach

The analogue approach is mainly based on the structural isomer 1,2,4-trichlorobenzene, which was already evaluated in the EU Risk Assessment and the PBT Working Group. For 1,2,3-trichlorobenzene, read-across to 1,2,4-trichlorobenzene was already carried in the PBT

Beispiel: QSAR und read-across

1,2,4-TCB	1,2,3-TCB	
		
EC number 204-428-0	201-757-1	
CAS number 120-82-1	87-61-6	108-70-3

Model valide? (QMRF)

Suchen

QMRF identifier (JRC Inventory): to be entered by JRC

QMRF Title: AOPWIN for k_{OH}

Printing Date: 04.05.2010

1. QSAR identifier

1.1. QSAR identifier (title): AOPWIN for k_{OH}

1.2. Other related models: AOPWIN method for estimating k_{O3} (the rate constant for the gas-phase reaction between ozone and olefinic/acetylenic compounds)

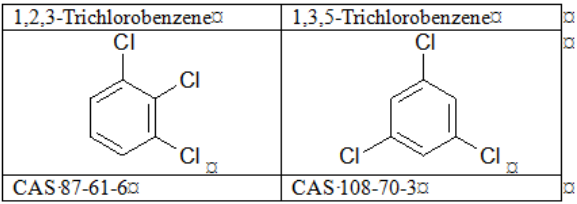
1.3. Software coding the model: EPISUITE Freely available software from the US EPA and the Syracuse Research Corporation. <http://www.epa.gov/epaosopr/qa/qacontact/exposure/pubs/contact.htm>

Modell für Stoff anwendbar? (QPRF)

Dokumentation verbessern!

[\(version 1.1, May 2008\)](#)

- 1. Substances
 - 1.1 → CAS number: 87-61-6 and 108-70-3
 - 1.2 → EC number:
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Reporting Format for the analogue approach for 1,2,3-Trichlorobenzene and 1,3,5-Trichlorobenzene

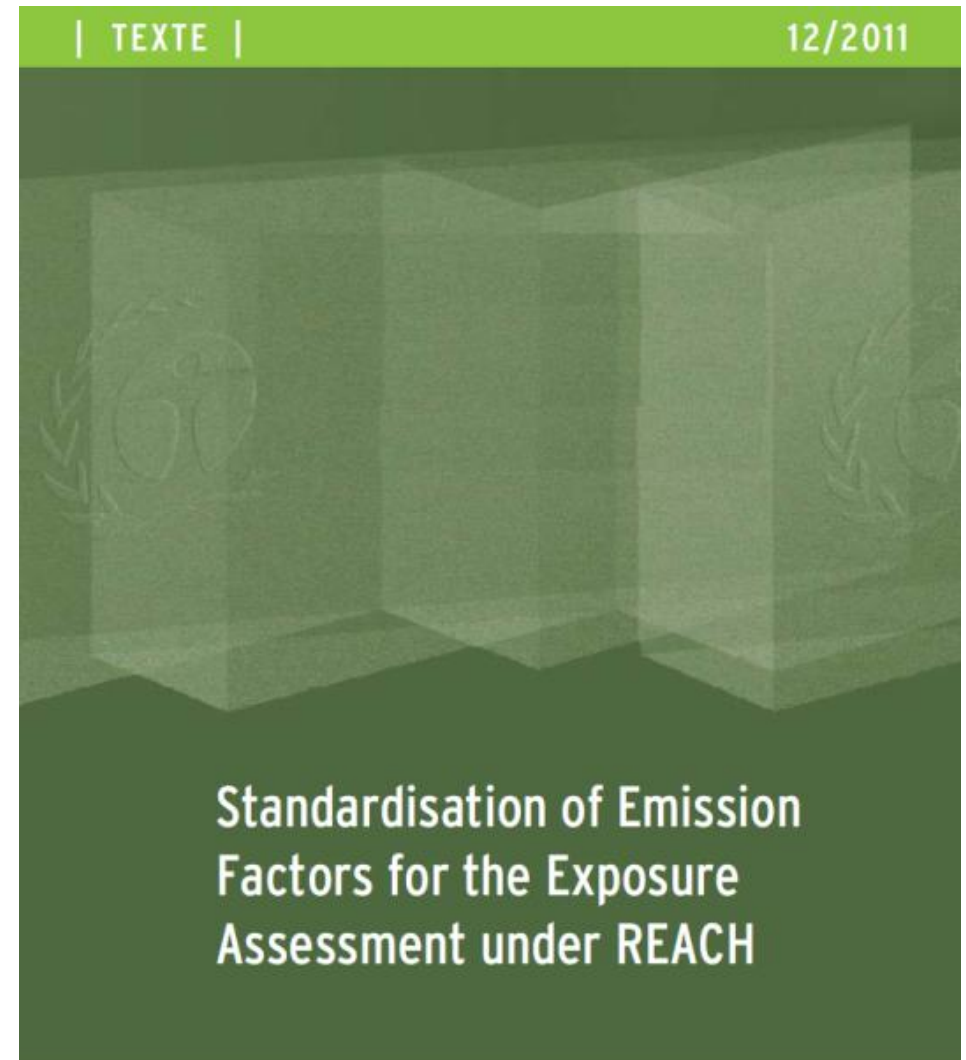
- CHEMICALS: → 1,2,3-Trichlorobenzene and 1,3,5-Trichlorobenzene
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Beispiel Expositionsanalyse

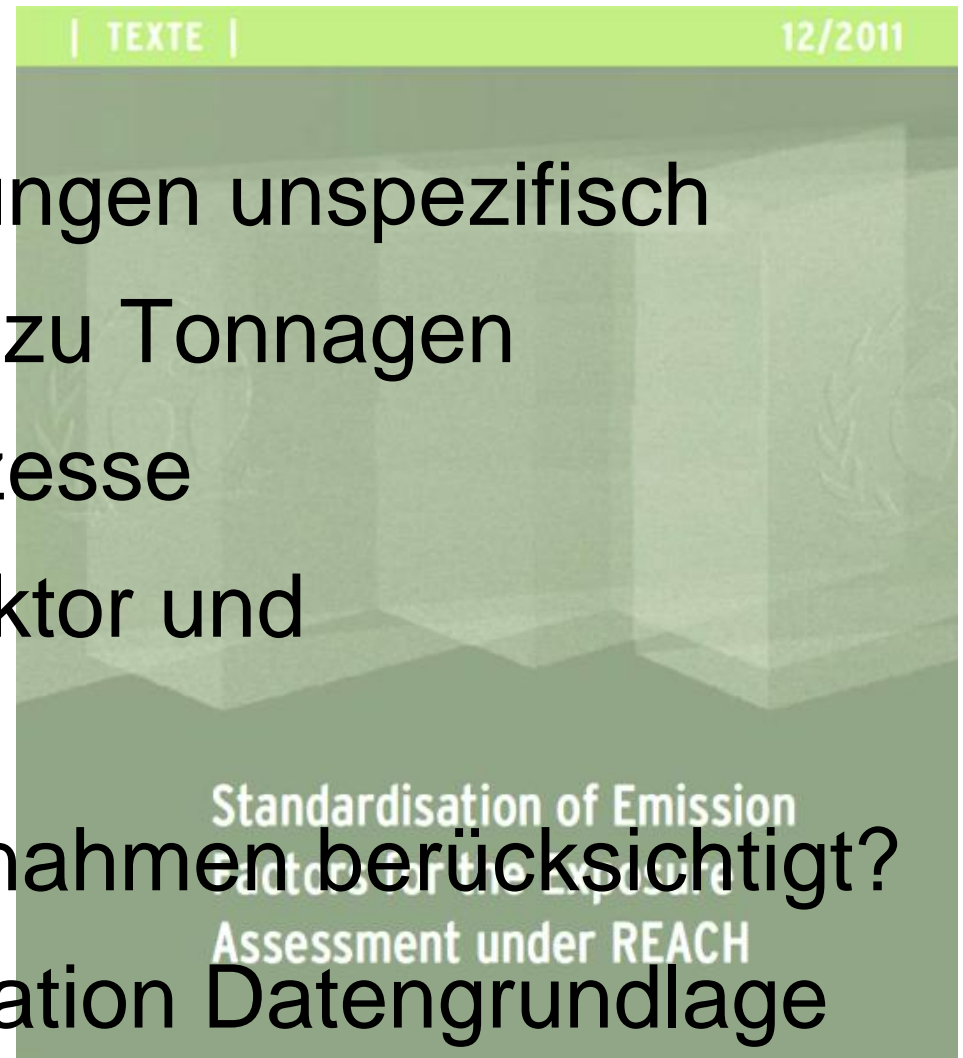
- Gutachten zur Standardisierung der Emissionsfaktoren
- Workshop mit Behörden der Mitgliedstaaten, Cefic, ECHA und EU-Kommission
- Veröffentlichung in IEAM in Vorbereitung



Beispiel Expositionsanalyse

Defizite:

- Beschreibung der Verwendungen unspezifisch
- Fehlende /unklare Angaben zu Tonnagen
- Definition der erfassten Prozesse
- Dokumentation Emissionsfaktor und Verwendungsbedingungen
- Sind Risikominderungsmaßnahmen berücksichtigt?
- Transparenz und Dokumentation Datengrundlage
- Abfallphase nicht bewertet




Verbesserung der Registrierungen




Verbesserung der Registrierungen


- Stärkere Unterstützung der Registranten
 - Verbesserung der Leitfäden (wo nötig)
 - Übersetzung Leitfäden
 - Identifizierung von Best-Praxis-Beispielen
 - ...
- Erhöhung der Quote Dossierbewertungen
- Einführung von Rechtsfolgen für Registranten mit mangelhaften Dossiers – Aberkennung der Registrierung durch ECHA als Option

Die Kandidatenliste

An Agency of the European Union 

English ▼



 Contact |

European Chemicals Agency

HOME

SIEF

REACH

DATA SHARING

ENFORCEMENT

CONSULTATIONS

ECHA CHEM

Registry of intentions

Pre-Registered substances

Registered substances

Identified substances for registration in 2010

Authorisation

Candidate List

Annex XIV Recommendations

Evaluation

Substances of Interest

Transitional measures

REACH-IT

CLP

GUIDANCE

LEGISLATION

HELP

SMES

NEWS AND EVENTS

ABOUT ECHA

Candidate List of Substances of Very High Concern for authorisation

The identification of a substance as Substance of Very High Concern and its inclusion in the Candidate List is the first step of the [authorisation procedure](#). Companies may have [immediate legal obligations](#) following such inclusion which are linked to the listed substance on its own, in preparations and articles.

Further documentation or more detailed information on the identification process of substances of very high concern can be found on the [web pages of ECHA's Member State Committee](#).

You can download this Candidate List as XML or CSV file from the below links.













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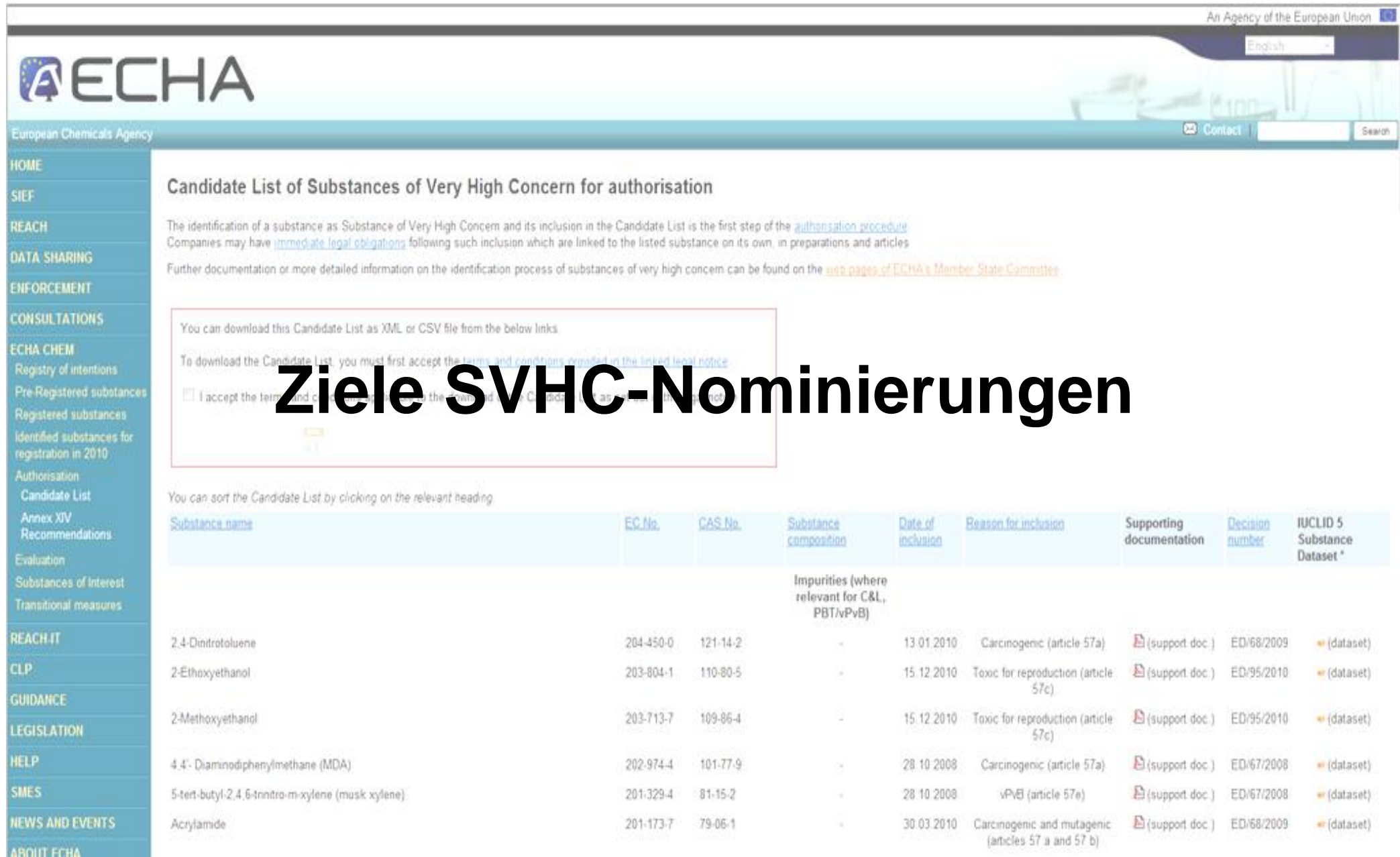
[Download in XML format \(XML\)](#)

[Download in CSV format \(CSV\)](#)

You can sort the Candidate List by clicking on the relevant heading

Substance name	EC No.	CAS No.	Substance composition	Date of inclusion	Reason for inclusion	Supporting documentation	Decision number	IUCLID 5 Substance Dataset *
			Impurities (where relevant for C&L, PBT/vPvB)					
2,4-Dinitrotoluene	204-450-0	121-14-2	-	13.01.2010	Carcinogenic (article 57a)	 (support doc.)	ED/68/2009	 (dataset)
2-Ethoxyethanol	203-804-1	110-80-5	-	15.12.2010	Toxic for reproduction (article 57c)	 (support doc.)	ED/95/2010	 (dataset)
2-Methoxyethanol	203-713-7	109-86-4	-	15.12.2010	Toxic for reproduction (article 57c)	 (support doc.)	ED/95/2010	 (dataset)
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	-	28.10.2008	Carcinogenic (article 57a)	 (support doc.)	ED/67/2008	 (dataset)
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	81-15-2	-	28.10.2008	vPvB (article 57e)	 (support doc.)	ED/67/2008	 (dataset)
Acrylamide	201-173-7	79-06-1	-	30.03.2010	Carcinogenic and mutagenic (articles 57 a and 57 b)	 (support doc.)	ED/68/2009	 (dataset)

Die Kandidatenliste



Ziele SVHC-Nominierungen

Candidate List of Substances of Very High Concern for authorisation

The identification of a substance as Substance of Very High Concern and its inclusion in the Candidate List is the first step of the [authorisation procedure](#). Companies may have [immediate legal obligations](#) following such inclusion which are linked to the listed substance on its own, in preparations and articles.

Further documentation or more detailed information on the identification process of substances of very high concern can be found on the [web pages of ECHA's Member State Committees](#).

You can download this Candidate List as XML or CSV file from the below links.

To download the Candidate List, you must first accept the [terms and conditions provided in the linked legal notice](#).

I accept the terms and conditions of the Candidate List as published on the ECHA website.

You can sort the Candidate List by clicking on the relevant heading.

Substance name	EC No.	CAS No.	Substance composition	Date of inclusion	Reason for inclusion	Supporting documentation	Decision number	IUCLID 5 Substance Dataset *
2,4-Dinitrotoluene	204-450-0	121-14-2	Impurities (where relevant for C&L, PBT/vPvB)	13.01.2010	Carcinogenic (article 57a)	(support doc.)	ED/68/2009	(dataset)
2-Ethoxyethanol	203-804-1	110-80-5		15.12.2010	Toxic for reproduction (article 57c)	(support doc.)	ED/95/2010	(dataset)
2-Methoxyethanol	203-713-7	109-86-4		15.12.2010	Toxic for reproduction (article 57c)	(support doc.)	ED/95/2010	(dataset)
4,4'-Diaminodiphenylmethane (MDA)	202-974-4	101-77-9		28.10.2008	Carcinogenic (article 57a)	(support doc.)	ED/67/2008	(dataset)
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	81-15-2		28.10.2008	vPvB (article 57e)	(support doc.)	ED/67/2008	(dataset)
Acrylamide	201-173-7	79-06-1		30.03.2010	Carcinogenic and mutagenic (articles 57 a and 57 b)	(support doc.)	ED/68/2009	(dataset)

Ziele SVHC Nominierungen

- Exposition Mensch und Umwelt minimieren
- EU-gemeinschaftliche Bewertung als PBT/vPvB/ED
- Signal an Unternehmen, Eigenverantwortung wahrzunehmen (Risikominderung, Substitution)
- Informationen über Verwendungen und Exposition komplettieren - Art. 7(2):
- Transparenz in der Lieferkette - Art. 33:
- Andere Rechtssetzungsbereiche unterstützen
- Ausstrahlung auf andere Staaten

Gründe für Priorisierung

1. Hohe Wahrscheinlichkeit für besonders besorgniserregende Eigenschaften
2. Priorisierung nach Relevanz
(Verwendungen, Umweltexposition, angemessene Risikominderung)
3. Regulierungsbedarf, weil Unternehmen Eigenverantwortung nicht ausreichend wahrnehmen

Zusammenfassung

1. Hoher Anteil der Registrierungen aus 2010 sind mangelhaft (Identität, Expositionsschätzung, Waiving, QSAR, PBT-Identifizierung, ...)
2. Registrierungspflichtige sind aufgefordert
 - a) für 2013 daraus zu lernen
 - b) bestehende Registrierungen zu aktualisieren
3. Wenn Eigenverantwortung nicht wahrgenommen wird, sind regulatorische Maßnahmen erforderlich
4. Wir schlagen vor, die Handlungsoptionen der ECHA zu erweitern

BGA | Am Weidendamm 1A | 10117 Berlin

An Herrn
Jochen Flasbarth
Präsident des Umweltbundesamtes
Postfach 1406
06813 Dessau-Roßlau



Bundesverband
Großhandel, Außenhandel,
Dienstleistungen e.V.

Gerhard Handke
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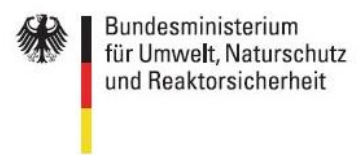
Konferenzreihe „REACH in der Praxis“

14. Oktober 2010

.....

Gerade vor dem Hintergrund, dass fast alle Wirtschaftsstufen in unterschiedlicher Intensität von den Pflichten aus REACH betroffen sind, würden wir die Fortsetzung der Veranstaltungsreihe – evtl. in abgewandelter Form – außerordentlich begrüßen.

.. und ab heute
geht es weiter !





Vielen Dank für Ihre Aufmerksamkeit

UBA chief: strengthen burden of proof on firms under REACH

The president of the German Federal Environment Agency (UBA), **Jochen Flasbarth**, speaks to chemicals journalist **Dr Ralph Heinrich Ahrens** on his expectations of REACH, his criticisms of many registration dossiers already submitted and the resource limitations of German authorities. He further makes a radical call to amend REACH to place all suspected substances of very high concern (SVHCs) on the candidate list immediately.

RHA: Mr. Flasbarth, what do you think about REACH?
JF: The REACH Regulation is a huge step forward. Before REACH, we didn't know much about the chemicals used in Europe. That was intolerable and everyone knew it.

RHA: What is the objective of REACH?
JF: Ultimately, we would like to find those critical chemicals which really harm people and the environment. For that, the authorities will evaluate registration dossiers. To make precise evaluations, the dossiers should contain correct and sound

also accumulates in the environment. Or take anthracene – a very stable molecule. In the EU it is acknowledged as an SVHC. Some companies appear to have played down this hazard – and refer to other interpretations of the Regulation when, in fact, the substance is included in the candidate list.

We also have doubts about whether companies have correctly described the properties of nanomaterials in their dossiers.



conditions for the application of them. To give more specific examples: Some in silico results were evaluated as being more reliable than experimental data; in almost all cases only the best favourable value from the point of view of the registrant (eg the lowest prediction value for bioaccumulation) was used, without any scientific explanations. Moreover, the documentation of these computer modelling studies was insufficient in terms of REACH. That means the predictions are not reproducible – and could, therefore, be wrong.

In many other cases, if you look more carefully you find that companies have avoided tests – intentionally or unintentionally. In effect, those companies could underestimate the risk for the environment or could avoid regulatory threshold values.

Of course, companies are allowed to waive tests which are not useful. That is sensible. For example, it would be useless to check how a substance could be a danger for daphnia or fish if there is no likelihood of exposure in the aquatic environment. But in reality companies use this waiving mostly as a loophole in order to avoid carrying out tests. An example: companies claim very

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