

The “E” and “A” in REACH: Context of the SIN List 1.0

Just enough information to get into trouble

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In 30 Minutes

- Outline REACH
- Relationship between the SIN List 1.0 and the REACH Candidate List
- What are Substances of Very High Concern (SVHC), and how did they come to be that way?
- What happens to SVHCs under REACH (ie what can we expect for SIN List chemicals?)

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)



REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 18 December 2006

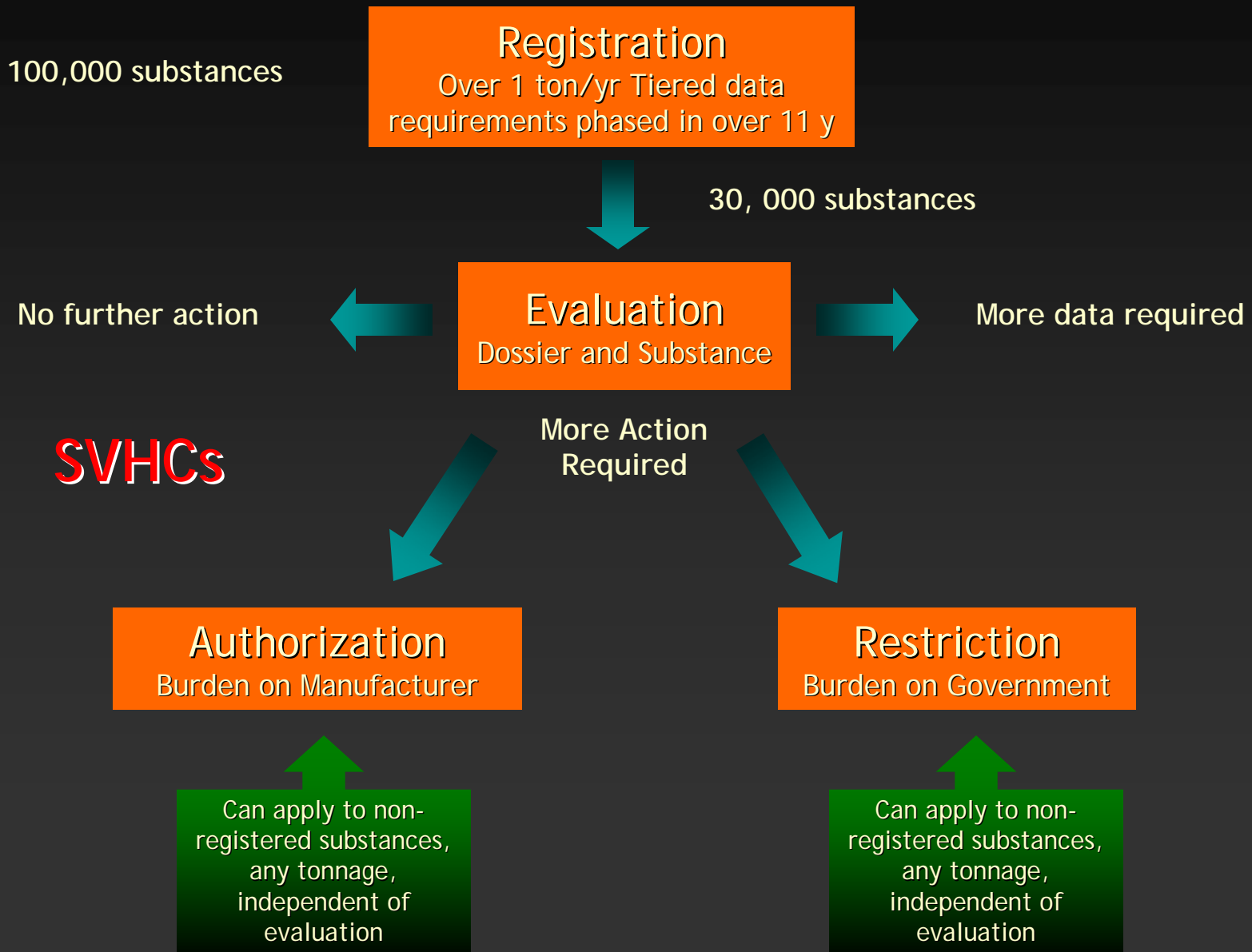
concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

- Went into force June 1, 2007
- First deadline December 1, 2008 (pre-registration)
- Europe's response to a similar situation as ours

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Overview of REACH Process



Evaluation

1. Dossier Evaluation (Art. 40-41)

- Completeness check
- Compliance check
- Testing proposals

2. Substance Evaluation (Art. 44-48)

- Aim: “clarify a concern that a substance constitutes a risk to human health or the environment”
- Mechanism for requesting more info from producers
- Selection based on hazard, exposure and tonnage
- Possible outcomes: recommend for designation as SVHC, labeling or restriction



Substances of Very High Concern (SVHC)

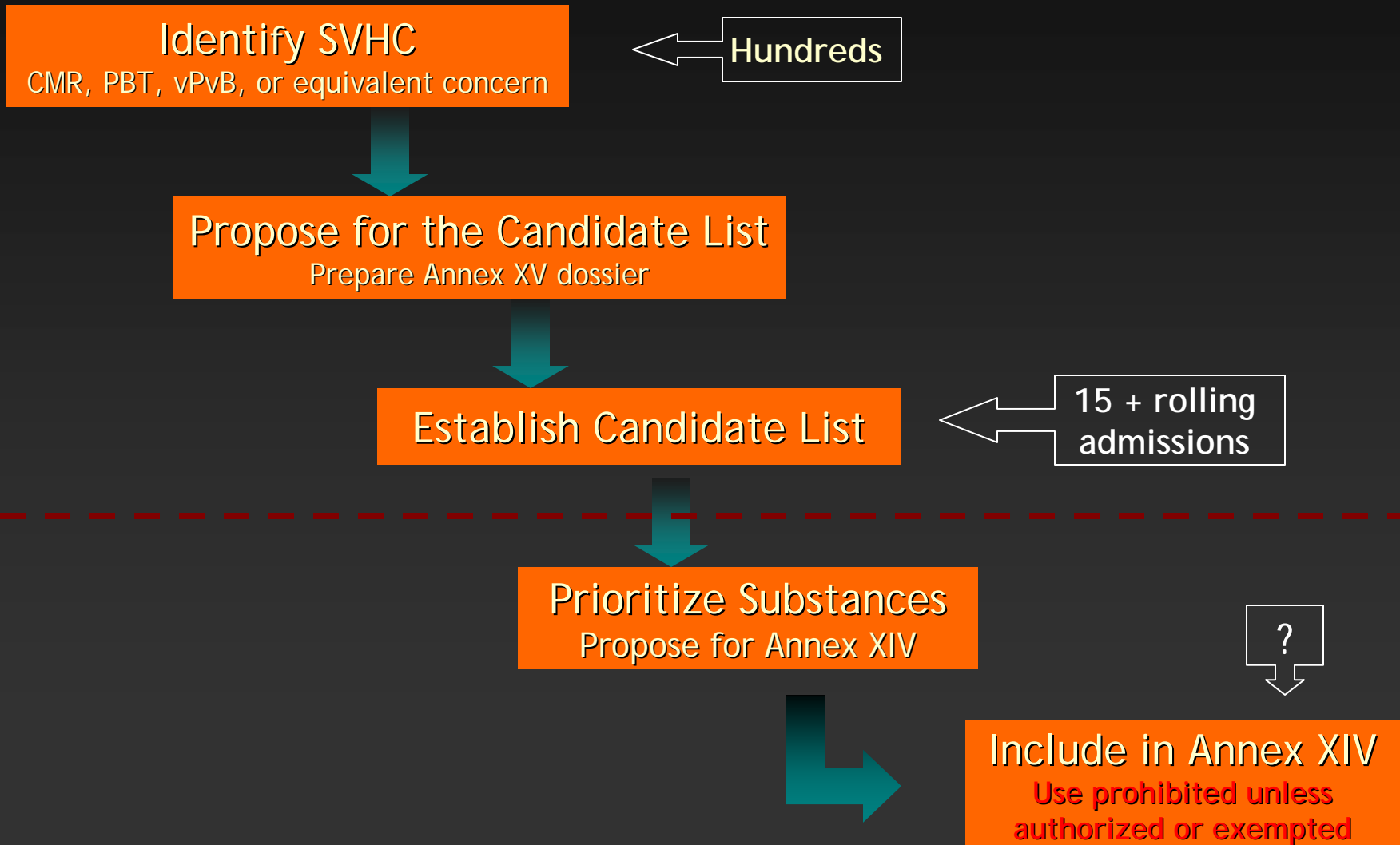
Substances which are (Art. 57):

- a) Carcinogenic
- b) Mutagenic
- c) Toxic for Reproduction
- d) Persistent, Bioaccumulative and Toxic
- e) very Persistent and very Bioaccumulative
- f) Substances of equivalent concern

SVHC = CMRs, PBTs, vPvBs and equivalent concern

Establishing Annex XIV

Substances Subject to Authorization



Authorization

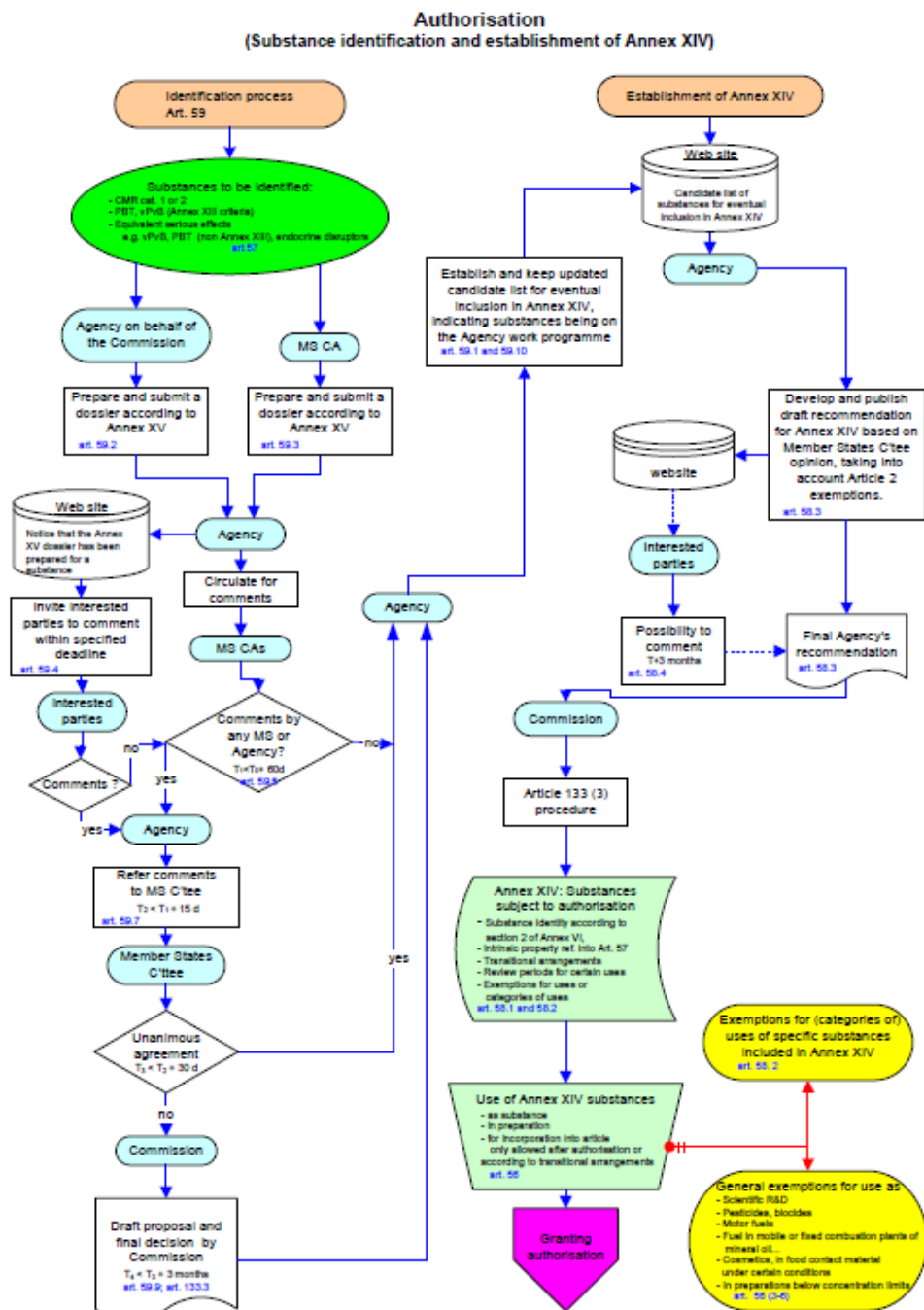
1) Identification and prioritization

- Identified as SVHC (Art. 57)
- Placed on Candidate List
- Substances chosen for Annex XIV = list of substances subject to authorization

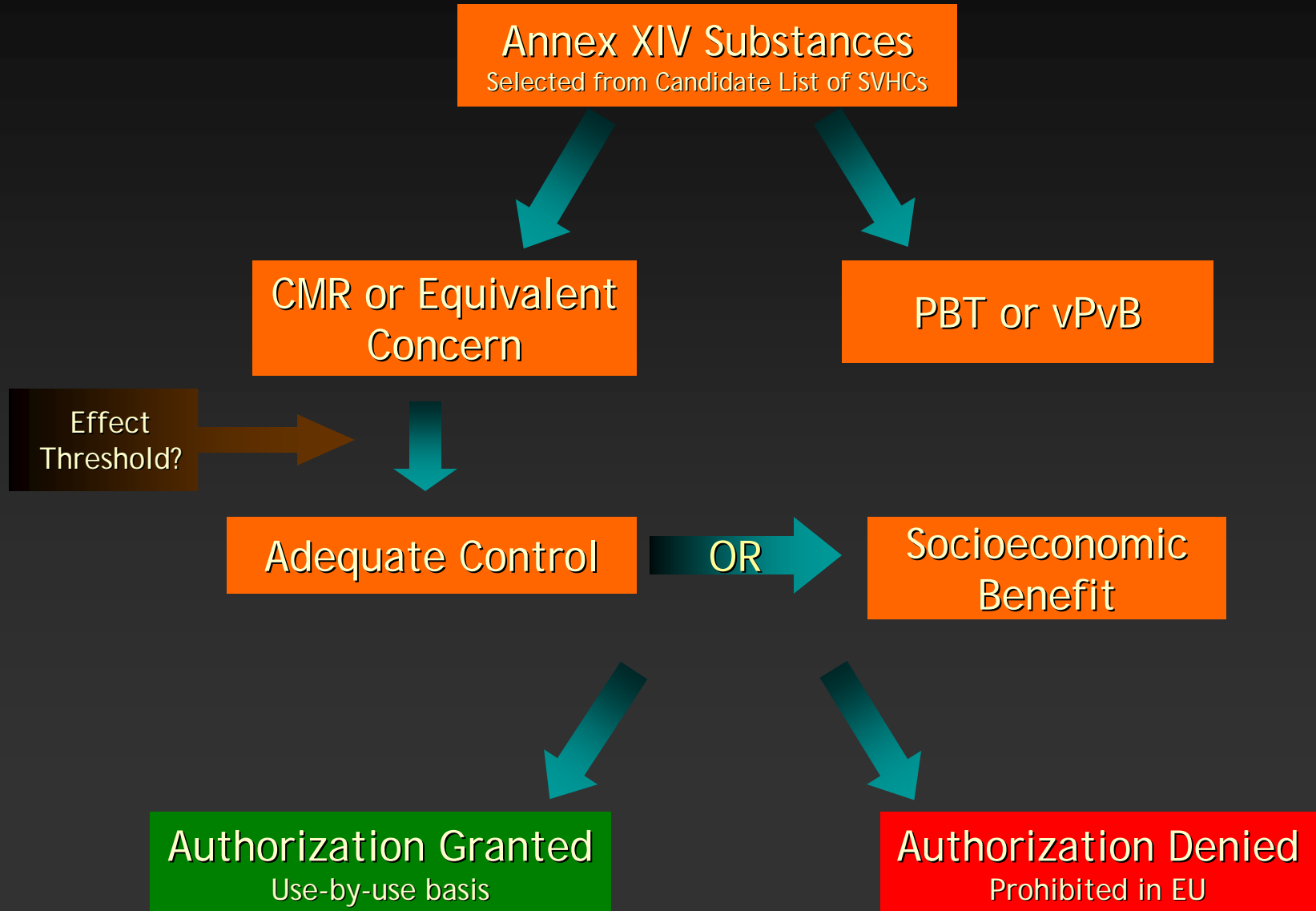
2) Application for Authorization

- Manufacturers apply for use-specific authorization
- Based on “adequate control” or “socio-economic necessity”
- Cannot claim “adequate control” for PBT, vPvB, or if there is no effect threshold established

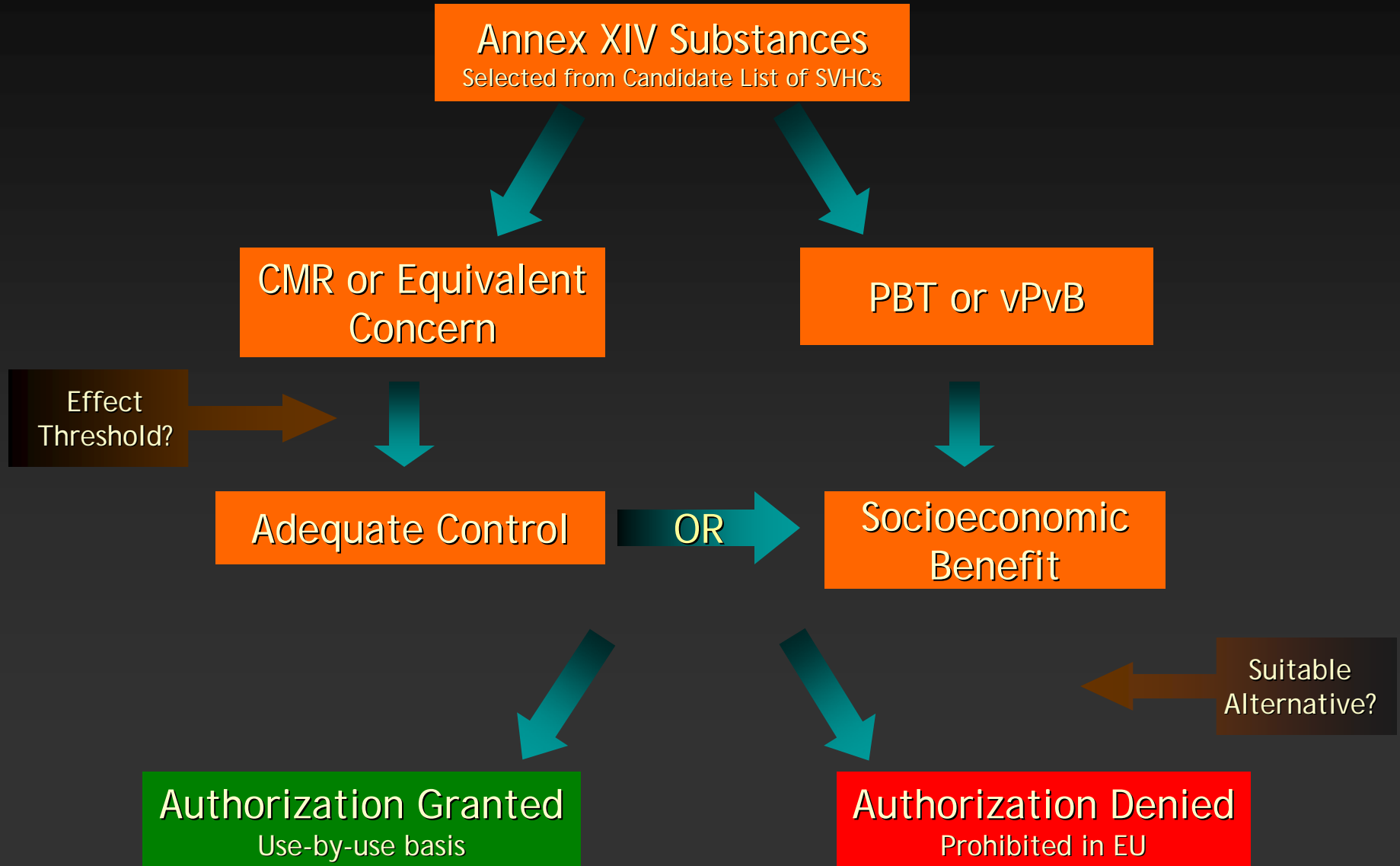
Figure 1 Substance identification and establishment of Annex XIV



Authorization Procedure




Authorization Procedure



ECHA Candidate List : 15 Substances

ECHA Website - Candidate list

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HOME

PRE-REGISTRATION

REACH

CONSULTATIONS

ECHA CHEM

Registry of Intentions

Pre-Registered Substances

Candidate List

Substances of Interest

REACH-IT

CLASSIFICATION

PRESS AND EVENTS

ABOUT ECHA

PUBLICATIONS

WORKING WITH US

APPEALS

Candidate List of Substances of Very High Concern for authorisation

The identification of substances as Substances of Very High Concern and its inclusion in the Candidate List is the first step in the [procedure concerning authorisation](#).

There are [immediate obligations](#) for companies linked to the substances on the Candidate List.

Substance identification	Substance composition	Date of inclusion	Reason for inclusion	Supporting documentation	Decision number
Substance name	EC (CAS No.) Impurities (where relevant for C&L, PBT/vPvB)				
Triethyl arsenate	427-700-2	-	28.10.08 Carcinogenic (article 57a)	(annex XV resp.)	ED/67/2008
Anthracene	204-371-1	-	28.10.08 PBT (article 57d)	(support doc.)	ED/67/2008
4,4'-Diaminodiphenylmethane (MDA)	202-974.4	-	28.10.08 Carcinogenic (article 57a)	(support doc.)	ED/67/2008
Dibutyl phthalate (DBP)	201-557-4	-	28.10.08 Toxic for reproduction (article 57c)	(support doc.)	ED/67/2008
Cobalt dichloride	231-589-4	-	28.10.08 Carcinogenic (article 57a)	(support doc.)	ED/67/2008
Diarсениc pentaoxide	215-116-9	-	28.10.08 Carcinogenic (article 57a)	(support doc.)	ED/67/2008
Diarсениc trioxide	215-481-4	-	28.10.08 Carcinogenic (article 57a)	(support doc.)	ED/67/2008
Sodium dichromate	234-190-3 (7789-12-0 and 10589-01-9)	-	28.10.08 Carcinogenic, mutagenic and toxic to reproduction (articles 57a, 57b and 57c)	(support doc.)	ED/67/2008
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	-	28.10.08 vPvB (article 57e)	(support doc.)	ED/67/2008
Bis (2-ethylhexyl)phthalate (DEHP)	204-211-0	-	28.10.08 Toxic to reproduction (article 57c)	(support doc.)	ED/67/2008
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified.	247-148-4 and 221-695-9	-	28.10.08 PBT (article 57d)	(support doc.)	ED/67/2008
Alpha-hexabromocyclododecane	(134237-50-6)	-			

[http://echa.europa.eu/chem_data/candidate_list_table_en.asp\[1/25/2009 8:48:34 PM\]](http://echa.europa.eu/chem_data/candidate_list_table_en.asp[1/25/2009 8:48:34 PM])

ECHA Website - Candidate list

Beta-hexabromocyclododecane	(134237-51-7)	-	28.10.08 PBT and vPvB (article 57d - e)	(support doc.)	ED/67/2008
Gamma-hexabromocyclododecane	(134237-52-8)	-	28.10.08 PBT and vPvB (article 57d - e)	(support doc.)	ED/67/2008
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	-	28.10.08 PBT (article 57d)	(support doc.)	ED/67/2008
Bis(tributyltin)oxide (TBT O)	200-288-0	-	28.10.08 Carcinogenic and Toxic to reproduction (articles 57a and c)	(support doc.)	ED/67/2008
Lead hydrogen arsenate	232-084-2	-	28.10.08 Carcinogenic and Toxic to reproduction (articles 57a and c)	(support doc.)	ED/67/2008
Benzyl butyl phthalate (BBP)	201-622-7	-	28.10.08 Toxic to reproduction (article 57c)	(support doc.)	ED/67/2008

Last update 15/1/2009 12:56 (EET)

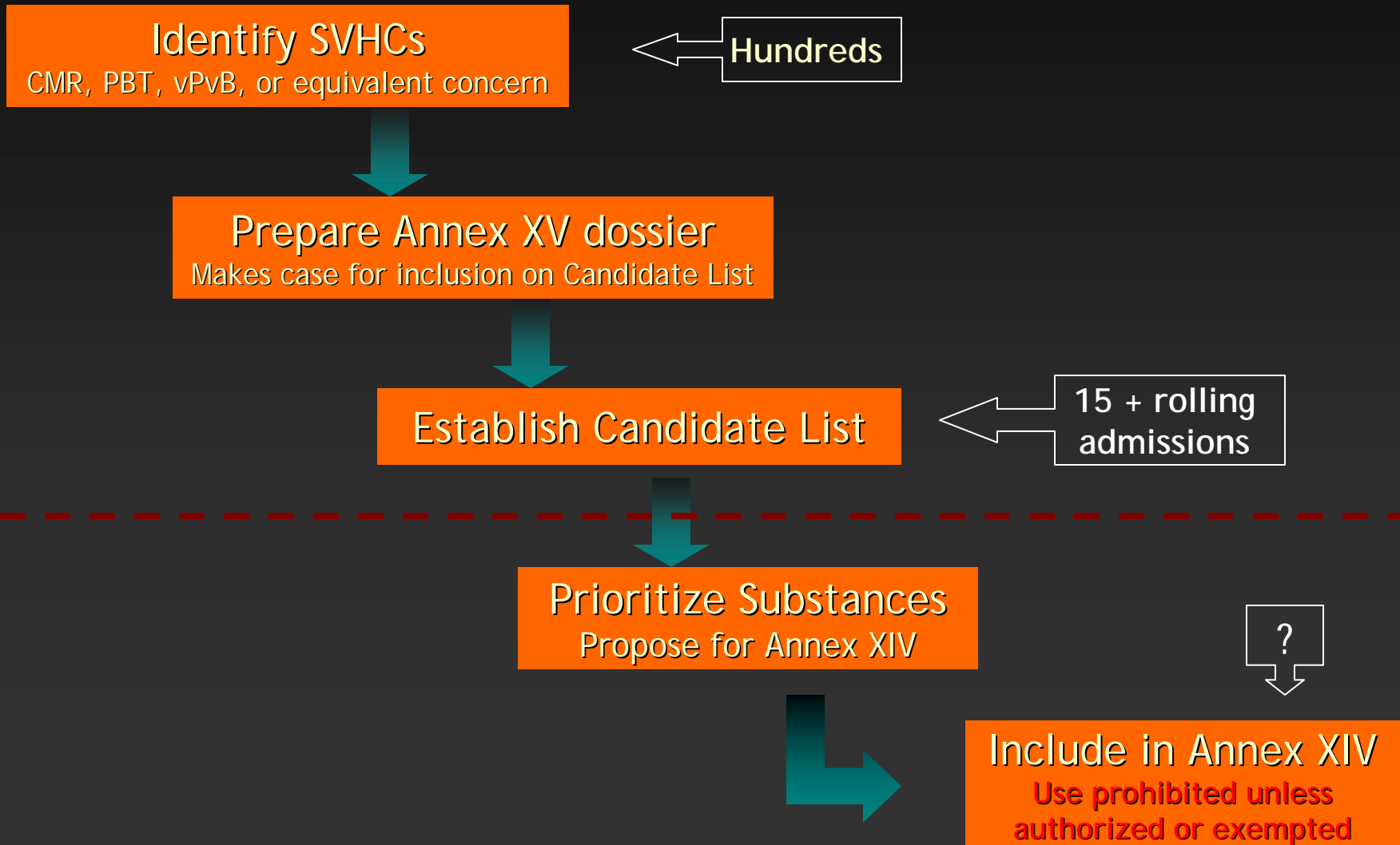
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SIN List 1.0: 267 Substances

REACH SIN* List 1.0 ("Substitute It Now")			
Substance name	EC No.	CAS No.	Substance type
1	001-001-001	001-001-001	Substance A
2	002-002-002	002-002-002	Substance B
3	003-003-003	003-003-003	Substance C
4	004-004-004	004-004-004	Substance D
5	005-005-005	005-005-005	Substance E
6	006-006-006	006-006-006	Substance F
7	007-007-007	007-007-007	Substance G
8	008-008-008	008-008-008	Substance H
9	009-009-009	009-009-009	Substance I
10	010-010-010	010-010-010	Substance J
11	011-011-011	011-011-011	Substance K
12	012-012-012	012-012-012	Substance L
13	013-013-013	013-013-013	Substance M
14	014-014-014	014-014-014	Substance N
15	015-015-015	015-015-015	Substance O
16	016-016-016	016-016-016	Substance P
17	017-017-017	017-017-017	Substance Q
18	018-018-018	018-018-018	Substance R
19	019-019-019	019-019-019	Substance S
20	020-020-020	020-020-020	Substance T
21	021-021-021	021-021-021	Substance U
22	022-022-022	022-022-022	Substance V
23	023-023-023	023-023-023	Substance W
24	024-024-024	024-024-024	Substance X
25	025-025-025	025-025-025	Substance Y
26	026-026-026	026-026-026	Substance Z
27	027-027-027	027-027-027	Substance AA
28	028-028-028	028-028-028	Substance AB
29	029-029-029	029-029-029	Substance AC
30	030-030-030	030-030-030	Substance AD
31	031-031-031	031-031-031	Substance AE
32	032-032-032	032-032-032	Substance AF
33	033-033-033	033-033-033	Substance AG
34	034-034-034	034-034-034	Substance AH
35	035-035-035	035-035-035	Substance AI
36	036-036-036	036-036-036	Substance AJ
37	037-037-037	037-037-037	Substance AK
38	038-038-038	038-038-038	Substance AL
39	039-039-039	039-039-039	Substance AM
40	040-040-040	040-040-040	Substance AN
41	041-041-041	041-041-041	Substance AO
42	042-042-042	042-042-042	Substance AP
43	043-043-043	043-043-043	Substance AQ
44	044-044-044	044-044-044	Substance AR
45	045-045-045	045-045-045	Substance AS
46	046-046-046	046-046-046	Substance AT
47	047-047-047	047-047-047	Substance AU
48	048-048-048	048-048-048	Substance AV
49	049-049-049	049-049-049	Substance AW
50	050-050-050	050-050-050	Substance AX
51	051-051-051	051-051-051	Substance AY
52	052-052-052	052-052-052	Substance AZ
53	053-053-053	053-053-053	Substance BA
54	054-054-054	054-054-054	Substance BB
55	055-055-055	055-055-055	Substance BC
56	056-056-056	056-056-056	Substance BD
57	057-057-057	057-057-057	Substance BE
58	058-058-058	058-058-058	Substance BF
59	059-059-059	059-059-059	Substance BG
60	060-060-060	060-060-060	Substance BH
61	061-061-061	061-061-061	Substance BI
62	062-062-062	062-062-062	Substance BJ
63	063-063-063	063-063-063	Substance BK
64	064-064-064	064-064-064	Substance BL
65	065-065-065	065-065-065	Substance BM
66	066-066-066	066-066-066	Substance BN
67	067-067-067	067-067-067	Substance BO
68	068-068-068	068-068-068	Substance BP
69	069-069-069	069-069-069	Substance BQ
70	070-070-070	070-070-070	Substance BR
71	071-071-071	071-071-071	Substance BS
72	072-072-072	072-072-072	Substance BT
73	073-073-073	073-073-073	Substance BU
74	074-074-074	074-074-074	Substance BV
75	075-075-075	075-075-075	Substance BW
76	076-076-076	076-076-076	Substance BX
77	077-077-077	077-077-077	Substance BY
78	078-078-078	078-078-078	Substance BZ
79	079-079-079	079-079-079	Substance CA
80	080-080-080	080-080-080	Substance CB
81	081-081-081	081-081-081	Substance CC
82	082-082-082	082-082-082	Substance CD
83	083-083-083	083-083-083	Substance CE
84	084-084-084	084-084-084	Substance CF
85	085-085-085	085-085-085	Substance CG
86	086-086-086	086-086-086	Substance CH
87	087-087-087	087-087-087	Substance CI
88	088-088-088	088-088-088	Substance CJ
89	089-089-089	089-089-089	Substance CK
90	090-090-090	090-090-090	Substance CL
91	091-091-091	091-091-091	Substance CM
92	092-092-092	092-092-092	Substance CN
93	093-093-093	093-093-093	Substance CO
94	094-094-094	094-094-094	Substance CP
95	095-095-095	095-095-095	Substance CQ
96	096-096-096	096-096-096	Substance CR
97	097-097-097	097-097-097	Substance CS
98	098-098-098	098-098-098	Substance CT
99	099-099-099	099-099-099	Substance CU
100	100-100-100	100-100-100	Substance CV
101	101-101-101	101-101-101	Substance CW
102	102-102-102	102-102-102	Substance CX
103	103-103-103	103-103-103	Substance CY
104	104-104-104	104-104-104	Substance CZ
105	105-105-105	105-105-105	Substance DA
106	106-106-106	106-106-106	Substance DB
107	107-107-107	107-107-107	Substance DC
108	108-108-108	108-108-108	Substance DD
109	109-109-109	109-109-109	Substance DE
110	110-110-110	110-110-110	Substance DF
111	111-111-111	111-111-111	Substance DG
112	112-112-112	112-112-112	Substance DH
113	113-113-113	113-113-113	Substance DI
114	114-114-114	114-114-114	Substance DJ
115	115-115-115	115-115-115	Substance DK
116	116-116-116	116-116-116	Substance DL
117	117-117-117	117-117-117	Substance DM
118	118-118-118	118-118-118	Substance DN
119	119-119-119	119-119-119	Substance DO
120	120-120-120	120-120-120	Substance DP
121	121-121-121	121-121-121	Substance DQ
122	122-122-122	122-122-122	Substance DR
123	123-123-123	123-123-123	Substance DS
124	124-124-124	124-124-124	Substance DT
125	125-125-125	125-125-125	Substance DU
126	126-126-126	126-126-126	Substance DV
127	127-127-127	127-127-127	Substance DW
128	128-128-128	128-128-128	Substance DX
129	129-129-129	129-129-129	Substance DY
130	130-130-130	130-130-130	Substance DZ
131	131-131-131	131-131-131	Substance EA
132	132-132-132	132-132-132	Substance EB
133	133-133-133	133-133-133	Substance EC
134	134-134-134	134-134-134	Substance ED
135	135-135-135	135-135-135	Substance EE
136	136-136-136	136-136-136	Substance EF
137	137-137-137	137-137-137	Substance EG
138	138-138-138	138-138-138	Substance EH
139	139-139-139	139-139-139	Substance EI
140	140-140-140	140-140-140	Substance EJ
141	141-141-141	141-141-141	Substance EK
142	142-142-142	142-142-142	Substance EL
143	143-143-143	143-143-143	Substance EM
144	144-144-144	144-144-144	Substance EN
145	145-145-145	145-145-145	Substance EO
146	146-146-146	146-146-146	Substance EP
147	147-147-147	147-147-147	Substance EQ
148	148-148-148	148-148-148	Substance ER
149	149-149-149	149-149-149	Substance ES
150	150-150-150	150-150-150	Substance ET
151	151-151-151	151-151-151	Substance EU
152	152-152-152	152-152-152	Substance EV
153	153-153-153	153-153-153	Substance EW
154	154-154-154	154-154-154	Substance EX
155	155-155-155	155-155-155	Substance EY
156	156-156-156	156-156-156	Substance EZ
157	157-157-157	157-157-157	Substance FA
158	158-158-158	158-158-158	Substance FB
159	159-159-159	159-159-159	Substance FC
160	160-160-160	160-160-160	Substance FD
161	161-161-161	161-161-161	Substance FE
162	162-162-162	162-162-162	Substance FF
163	163-163-163	163-163-163	Substance FG
164	164-164-164	164-164-164	Substance FH
165	165-165-165	165-165-165	Substance FI
166	166-166-166	166-166-166	Substance FJ
167	167-167-167	167-167-167	Substance FK
168	168-168-168	168-168-168	Substance FL
169	169-169-169	169-169-169	Substance FM
170	170-170-170	170-170-170	Substance FN
171	171-171-171	171-171-171	Substance FO
172	172-172-172	172-172-172	Substance FP
173	173-173-173	173-173-173	Substance FQ
174	174-174-174	174-174-174	Substance FR
175	175-175-175	175-175-175	Substance FS
176	176-176-176	176-176-176	Substance FT
177	177-177-177	177-177-177	Substance FU
178	178-178-178	178-178-178	Substance FV
179	179-179-179	179-179-179	Substance FW
180	180-180-180	180-180-180	Substance FX
181	181-181-181	181-181-181	Substance FY
182	182-182-182	182-182-182	Substance FZ
183	183-183-183	183-183-183	Substance GA
184	184-184-184	184-184-184	Substance GB
185	185-185-185	185-185-185	Substance GC
186	186-186-186	186-186-186	Substance GD
187	187-187-187	187-187-187	Substance GE
188	188-188-188	188-188-188	Substance GF
189	189-189-189	189-189-189	Substance GG
190	190-190-190	190-190-190	Substance GH
191	191-191-191	191-191-191	Substance GI
192	192-192-192	192-192-192	Substance GJ
193	193-193-193	193-193-193	Substance GK
194	194-194-194	194-194-194	Substance GL
195	195-195-195	195-195-195	Substance GM
196	196-196-196	196-196-196	Substance GN
197	197-197-197	197-197-197	Substance GO
198	198-198-198	198-198-198	Substance GP
199	199-199-199	199-199-199	Substance GQ
200	200-200-200	200-200-200	Substance GR
201	201-201-201	201-201-201	Substance GS
202	202-202-202	202-202-202	Substance GT
203	203-203-203	203-203-203	Substance GU
204	204-204-204	204-204-204	Substance GV
205	205-205-205	205-205-205	Substance GW
206	206-206-206	206-206-206	Substance GX
207	207-207-207	207-207-207	Substance GY
208	208-208-208	208-208-208	Substance GZ
209	209-209-209	209-209-209	Substance HA
210	210-210-210	210-210-210	Substance HB
211	211-211-211	211-211-211	Substance HC
212	212-212-212	212-212-212	Substance HD
213	213-213-213	213-213-213	Substance HE
214	214-214-214	214-214-214	Substance HF
215	215-215-215	215-215-215	Substance HG
216	216-216-216	216-216-216	Substance HH
217	217-217-217	217-217-217	Substance HI
218	218-218-218	218-218-218	Substance HJ
219	219-219-219	219-219-219	Substance HK
220	220-220-220	220-220-220	Substance HL
221	221-221-221	221-221-221	Substance HM
222	222-222-222	222-222-222	Substance HN
223	223-223-223	223-223-223	Substance HO
224	224-224-224	224-224-224	Substance HP
225	225-225-225	225-225-225	Substance HQ
226	226-226-226	226-226-226	Substance HR
227	227-227-227	227-227-227	Substance HS
228	228-228-228	228-228-228	Substance HT
229	229-229-229	229-229-229	Substance HU
230	230-230-230	230-230-230	Substance HV
231	231-231-231	231-231-231	Substance HW
232	232-232-232	232-232-232	Substance HX
233	233-233-233	233-233-233	Substance HY
234	234-234-234	234-234-234	Substance HZ
235	235-235-235	235-235-235	Substance IA
236	236-236-236	236-236-236	Substance IB
237	237-237-237	237-237-237	Substance IC

Establishing Annex XIV

Substances Subject to Authorization



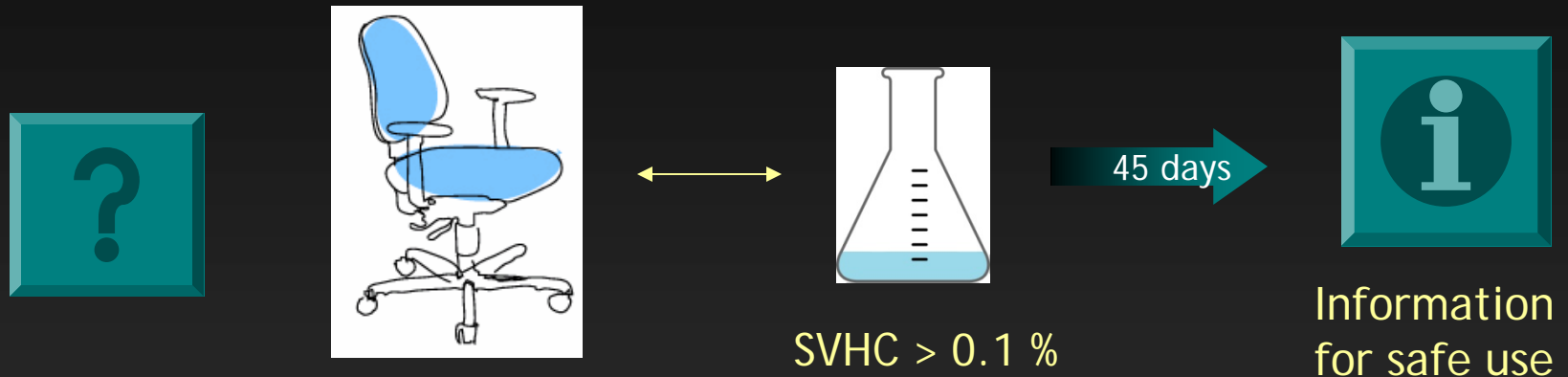
Power of the Candidate List

Triggers immediate information-provision obligation, providing basis for informed decisions throughout supply chain.

A comprehensive Candidate list could:

- Consolidate multiple lists into one REACH-specific list
- Fill data gaps (info on use and exposure):
 - Increase transparency, permit the required grouping
 - Inform and streamline the regulatory process
- Separate identification and prioritization processes
- Provide manufacturers sufficient lead time to:
 - Seek or develop alternative substances
 - Alter processes to reduce use of SVHCs
 - Avoid substitution of one SVHC for another
 - Decrease uncertainty and the costs associated with substitution and multiple authorizations

Obligations Linked to Candidate List: Communicate with Users



From date of substance inclusion on Candidate list:

- Automatically to downstream user, or on request from consumer, suppliers must provide "sufficient information to ensure safe use" of article
- For articles containing a Candidate SVHC above 0.1% (by weight)
- Minimum information is substance name

Obligations Linked to Candidate List: Notify ECHA



SVHC
> 0.1%
> 1 tpa



Notify
Agency

Beginning 2011:

- Any producer or importer of articles
- Containing a Candidate SVHC above 0.1% (by weight)
- In quantities over 1 tpa
- Must notify the Agency

Review

- Outline REACH

non-linear, iterative process

- What are Substances of Very High Concern (SVHC), and how did they come to be that way?

SVHC = CMRs, PBTs, vPvBs and equivalent concern

- Relationship between SIN List 1.0 and REACH Candidate List
- What happens to SVHCs under REACH (ie what can we expect for SIN List chemicals)?

Identification of SVHC → Prepare Dossier → Selection for Candidate List → Decision to include in Annex XIV = Subject to Authorization

Resources

ECHA: Regulation and Guidance documents

http://echa.europa.eu/reach_en.asp

ECHA: Chemical lists (pre-registered, candidate)

http://echa.europa.eu/chem_data_en.asp

WWF Navigating REACH

http://www.panda.org/about_wwf/what_we_do/policy/toxics/publications/?uNewsID=115541

Slides posted @

UC Berkeley Center for Occupational and Environmental Health

<http://coeh.berkeley.edu/greenchemistry>