BIOCIDES FOCUS

On **October 29, 2019**, the seventh Biocide Day was held by ECHA in Helsinky.

In this one-day workshop the latest developments on review program, endocrine disruptors, active substance approval and biocide product families were discussed.

In particular:

1. What Member States, ECHA and Commission are doing to revitalize the Review Programme 3
2. How to assess endocrine disrupting properties
3. How to apply the new framework for a biocidal product family

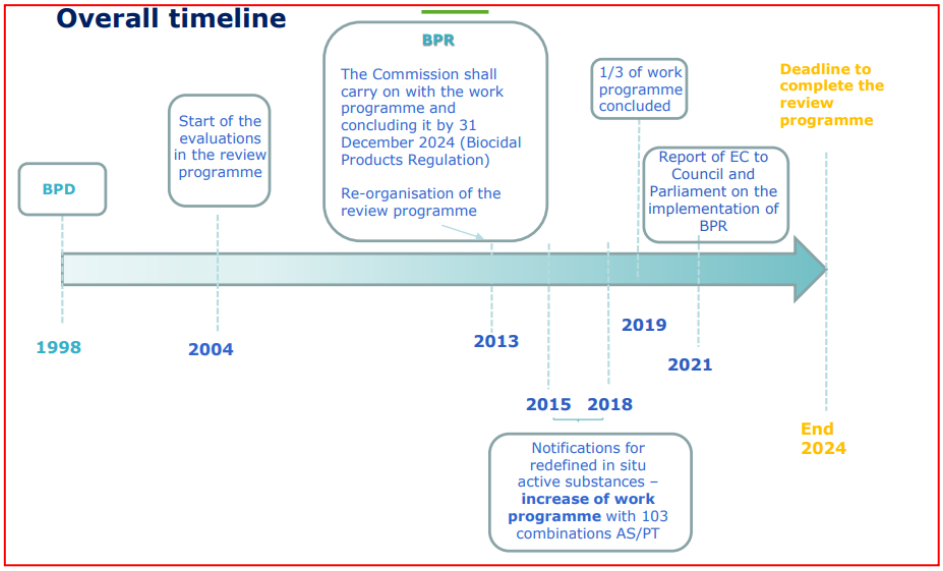
In short (key slides from different presentation are here reported):

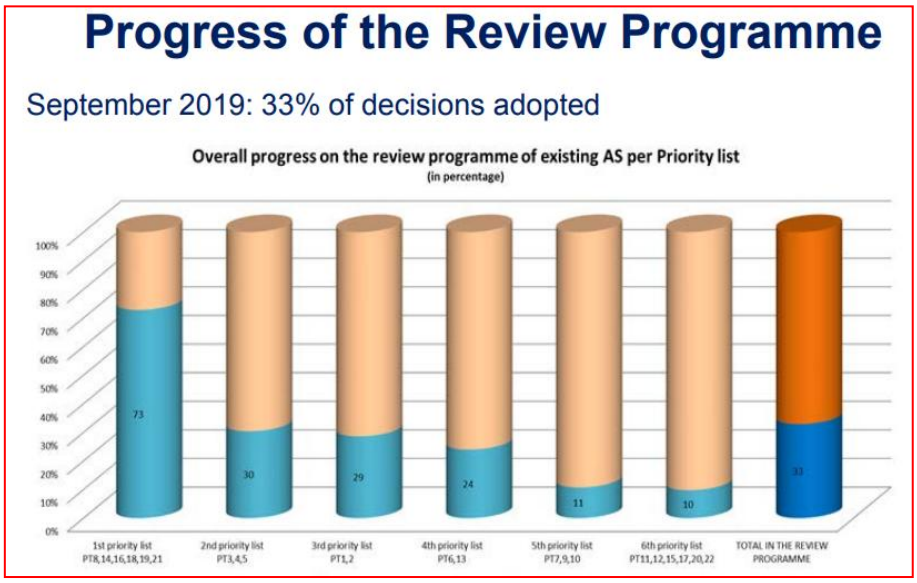
1. Review program

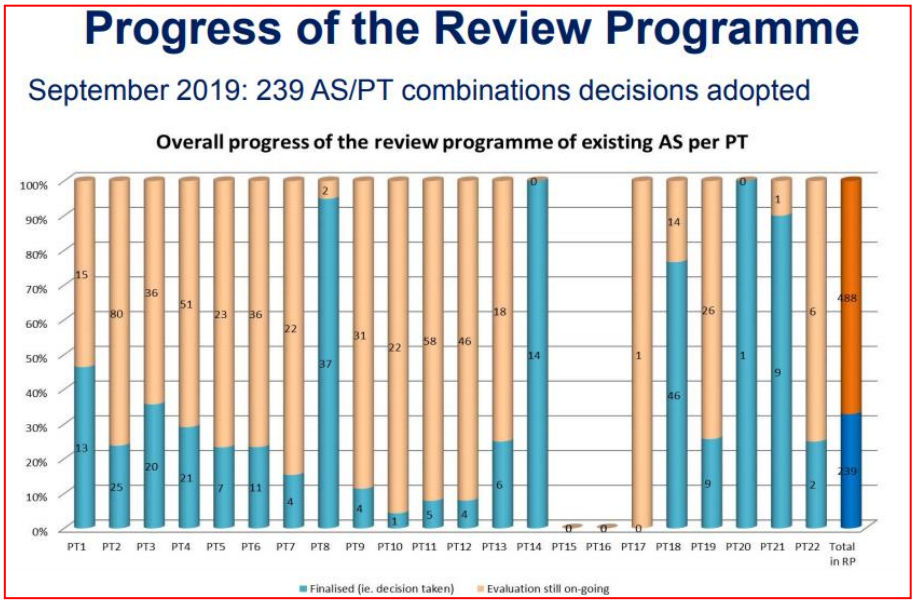
Acquired and well known delays limited the authorities from achieving the expected high level of safety for human health and the environment as many active substances and products remain on the market without proper assessment.

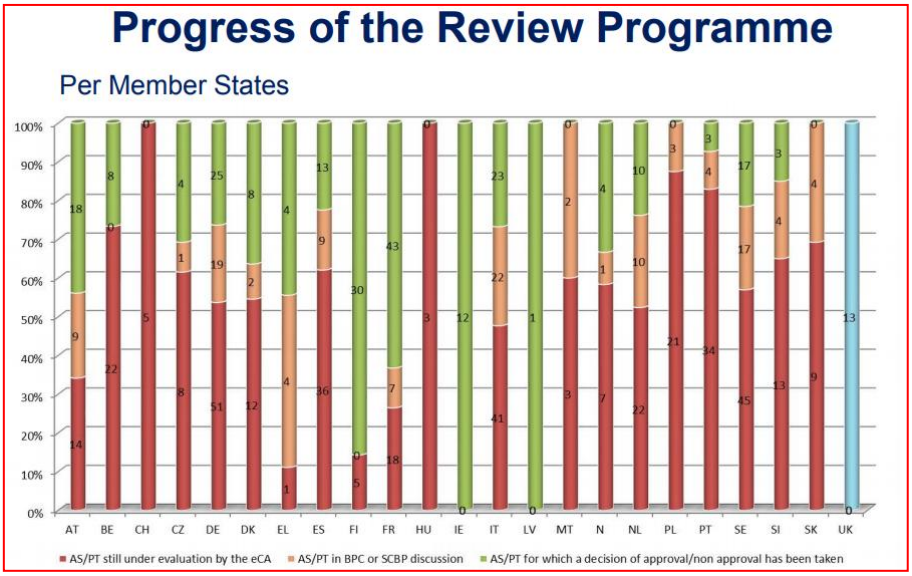
Level playing field not yet achieved, as companies' situations vary depending on the status of their active substance in the Review Programme

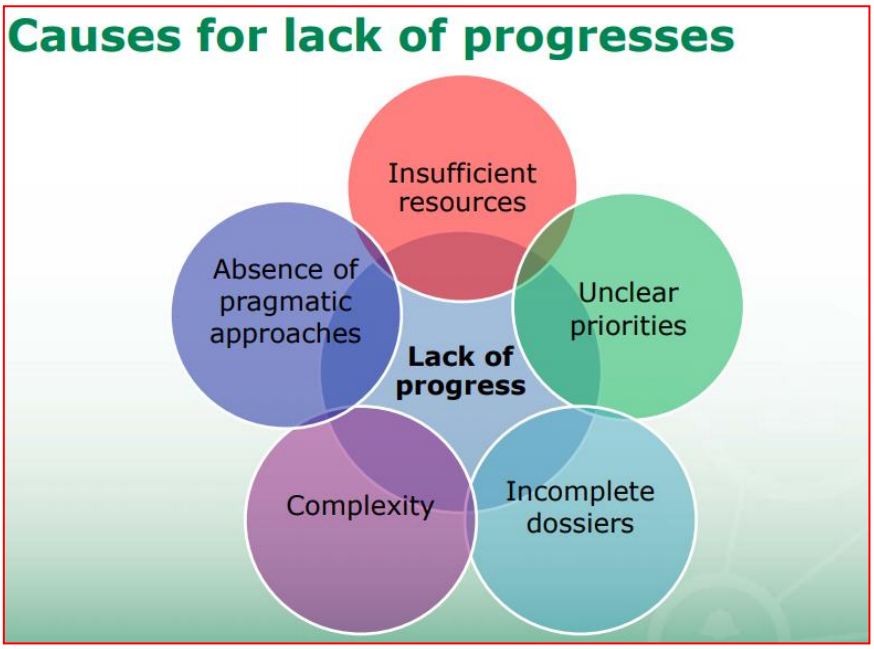
Working on an action plan together with Member States and the Commission




Progress of the Review Programme
September 2019: 33% of decisions adopted
Overall progress on the review programme of existing AS per Priority list
(in percentage)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
73
30
29
24
11
10
33
1st priority list PT8,14,16,18,19,21
2nd priority list PT3,4,5
3rd priority list PT1,2
4th priority list PT6,13
5th priority list PT7,9,10
6th priority list PT11,12,15,17,20,22
TOTAL IN THE REVIEW PROGRAMME

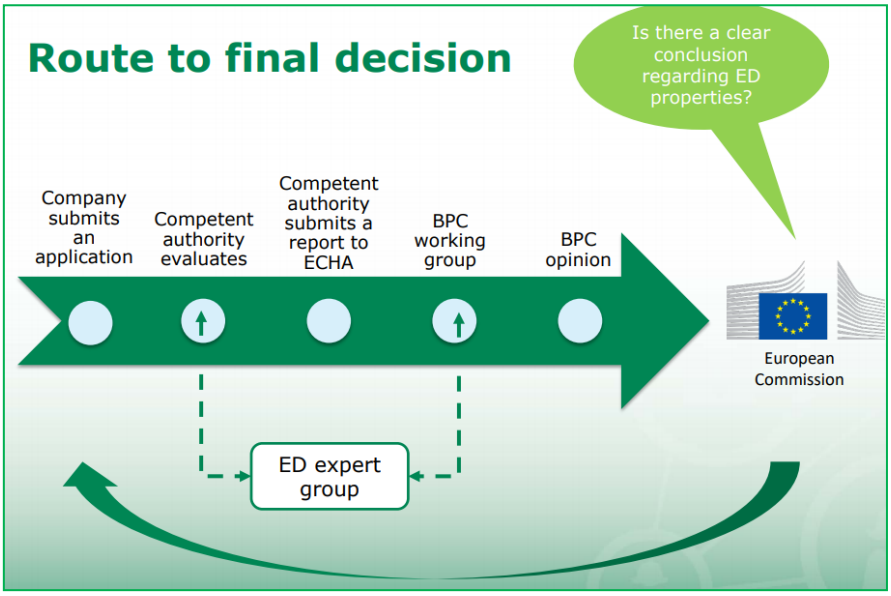

Progress of the Review Programme
September 2019: 239 AS/PT combinations decisions adopted
Overall progress of the review programme of existing AS per PT
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
PT1 PT2 PT3 PT4 PT5 PT6 PT7 PT8 PT9 PT10 PT11 PT12 PT13 PT14 PT15 PT16 PT17 PT18 PT19 PT20 PT21 PT22 Total in RP
Finalised (ie. decision taken)
Evaluation still on-going

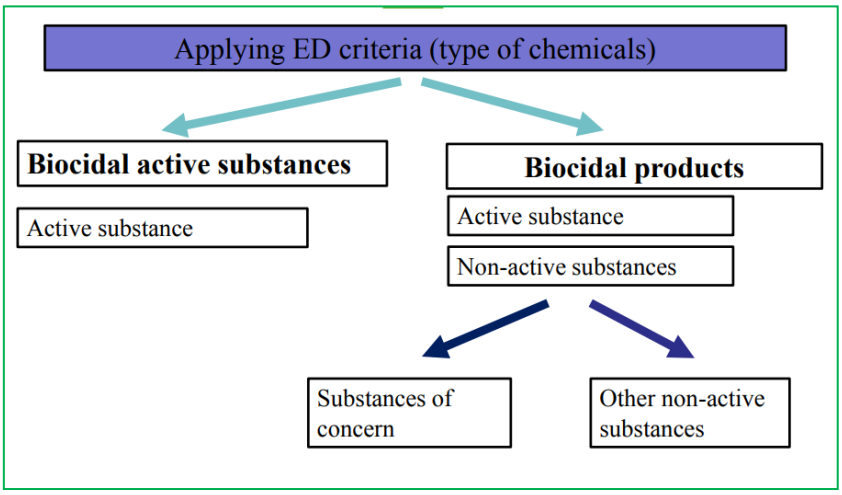

Progress of the Review Programme
Per Member States
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
AT BE CH CZ DE DK EL ES FI FR HU IE IT LV MT N NL PL PT SE SI SK UK
AS/PT still under evaluation by the eCA
AS/PT in BPC or SCBP discussion
AS/PT for which a decision of approval/non approval has been taken

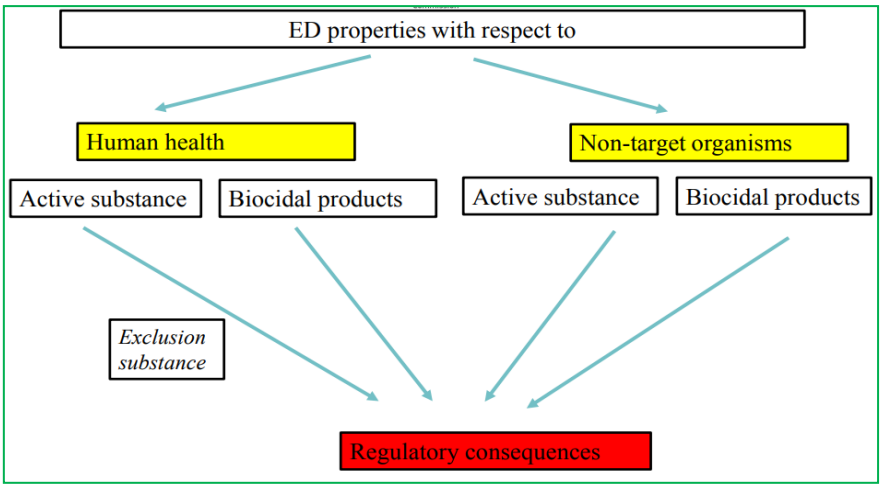


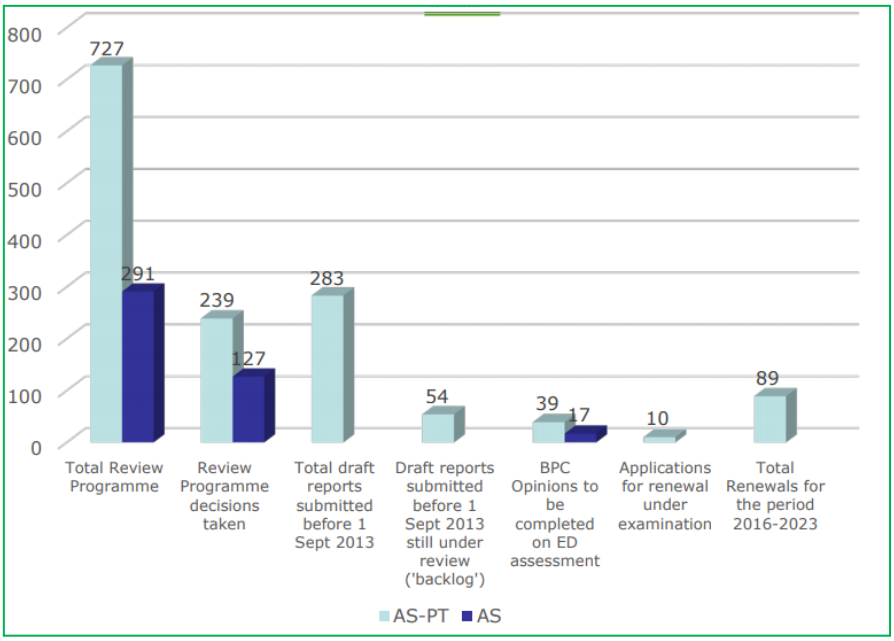
2. Endocrine Disrupting properties

Assessing ED properties requires time and resources
Outcome of the assessment has important consequences
- Can restrict or prevent marketing of products
- Can require reformulation when this relates to co-formulants




Applying ED criteria (type of chemicals)
Biocidal active substances
Active substance
Biocidal products
Active substance
Non-active substances
Substances of concern
Other non-active substances


ED properties with respect to
Human health
Non-target organisms
Active substance
Biocidal products
Active substance
Biocidal products
Exclusion substance
Regulatory consequences


800
700
600
500
400
300
200
100
0
727
291
239
127
283
54
39
17
10
89
Total Review Programme
Review Programme decisions taken
Total draft reports submitted before 1 Sept 2013
Draft reports submitted before 1 Sept 2013 still under review ('backlog')
BPC Opinions to be completed on ED assessment
Applications for renewal under examination
Total Renewals for the period 2016-2023
AS-PT
AS

Regulatory consequences of ED identification: active substance

Human health

- Fulfils exclusion criteria and shall **not** be approved (BPR art. 5(1))
- Can be approved if one of the derogation conditions is met (BPR art. 5(2))
  - **Risk** from exposure is **negligible**
  - **Essential** to prevent or control a serious danger to human/animal health or the environment
  - Non-approval would have a **disproportionate negative impact** on society when compared with the risk

Environment

- Meets the substitution criteria but can be approved (BPR art. 10)
- For substances with intended **biocidal mode of action** consisting of **controlling target organisms** via their **endocrine system(s):**
  - ED assessment should not consider same taxonomic phylum to assess effects on non-target organisms
  - Can only be approved if their use does not lead to unacceptable effects on non-target organisms

Regulatory consequences of ED identification: biocidal products

Product

- If the product contains a substance that is an ED, the product is regarded as an ED
- Products that are considered ED
  - Will not be authorized for use by the **general public**
  - A **comparative assessment** needs to be carried out (Art 23)

Product family

- If the **active substance** is ED, the product family is regarded as ED
- For individual products of a family containing **non-active substances** with ED properties, the decision not to authorise use for general public is limited to these products only

3. Biocidal product family approach

Revised framework for biocide product families has been agreed this year to facilitate the establishment and the assessment of product families

- Will guide companies in organizing the product portfolio
- May impact costs

Practical implementation

GUIDE

Note for Guidance 'Implementing the new concept of biocidal product families'

- Definition of 'similar composition', 'similar uses' and 'similar levels of risk and efficacy'
- Three levels of information
  1. Overall product family
  2. Meta-SPCs
  3. Individual biocidal products
- Authorisation decision including only a 'BPF SPC'
- Post-authorisation notification of new products

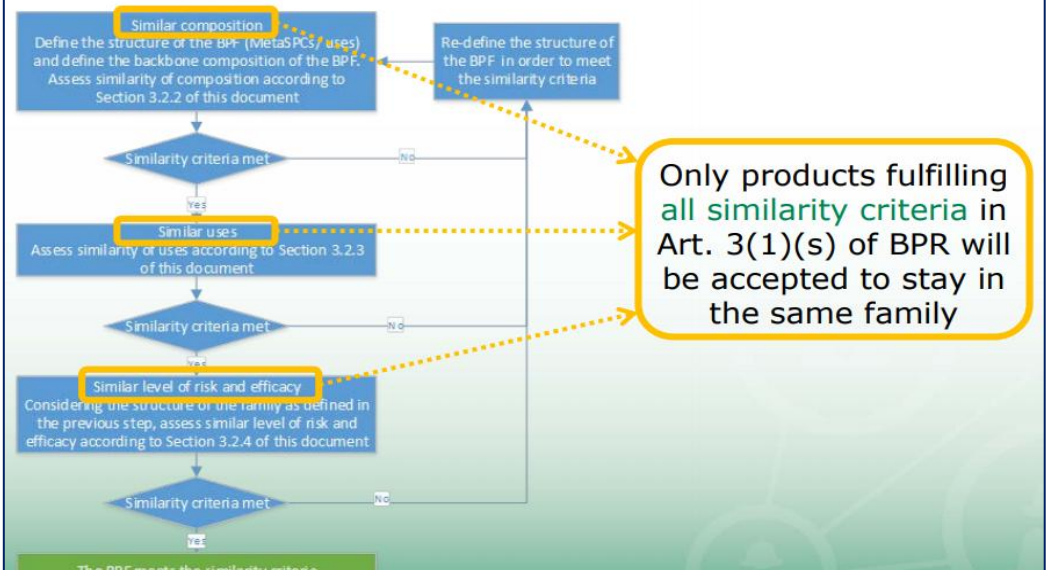
Updated Note for Guidance available

- Agreed at the CA meeting in July 2019
- For new applications, valid as of 1 October 2019
- Repeals the previous Note for Guidance
- Available on our website: Product family page

- Reduced flexibility
- Sometimes case-by-case assessment necessary
- Consequences of splitting ongoing applications

- Increased predictability
- Criteria for more consistent interpretation of BPF
- Pragmatic way forward when Art.3(1)(s) is not met

Follow the decision tree



REACH

New substance evaluation conclusions published

New substance evaluation conclusion documents are now available on ECHA's website for:
Triphenyl phosphite (**EC 202-908-4**, CAS 101-02-0), added to the CoRAP list in 2013 and evaluated by United Kingdom;

A mixture of: N,N'-ethane-1,2-diylbis(decanamide);12-hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide;N,N'-ethane-1,2-diylbis(12-hydroxyoctadecanamide) (**EC 430-050-2**, CAS -), added to the CoRAP list in 2017 and evaluated by Spain;

Reaction mass of 4,4'-methylenediphenyl diisocyanate and o-(p-isocyanatobenzyl)phenyl isocyanate / methylene diphenyl diisocyanate (**EC 905-806-4**, CAS -), added to the CoRAP list in 2015 and evaluated by Estonia.

Four proposals to identify substances of very high concern (SVHCs)

The substances and examples of their uses are:
Perfluorobutane sulfonic acid (PFBS) and its salts (**EC -,** CAS -). The substances are used in polymer production;
Diisohexyl phthalate (**EC 276-090-2**, CAS 71850-09-4). The substance is not registered under REACH;
2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (EC 404-360-3; CAS 119313-12-1). The substance is used in polymer production; and
2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one (**EC 400-600-6**; CAS 71868-10-5). The substance is used in polymer production.

Authorisation process

18 substances of very high concern (SVHCs) are recommended to be added to the REACH Authorisation List.

ECHA's ninth recommendation to the European Commission to prioritize substances of very high concern for authorization includes 18 substances. Thirteen of these substances are toxic for reproduction, of which one has also endocrine disrupting properties. The other substances are an endocrine disruptor, a carcinogen, a very persistent and very bioaccumulative (vPvB) substance and two respiratory sensitizers.

The substances have been prioritized from the Candidate List because of their intrinsic properties in combination with high volume and widespread uses, which may pose a threat to human health or the environment. Some of these substances are currently not used in the EU but could replace other substances recommended for the Authorization List (Annex XIV). Their inclusion should avoid regrettable substitution.

ECHA took into account the comments and registration updates as well as the MSC's opinion when deciding on the substances now recommended to be added to the REACH Authorization List and for proposing the related latest application and sunset dates. All substances that underwent public consultation are included in the final recommendation.

The final decision on the inclusion of the substances in the Authorization List and on the dates by which companies will need to apply for authorization to ECHA will be taken by the European Commission in collaboration with the Member States and the European Parliament.

See copy here of the nine recommendation

ECHA
EUROPEAN CHEMICALS AGENCY

Annex to ECHA News 1 (2)

1 October 2019

Annex to press release ECHA/PR/19/14

ECHA proposes 18 substances for authorisation

Helsinki, 1 October 2019

List of substances included in the ninth recommendation, including examples of their uses in the scope of authorisation

#	Substance name	SVHC-relevant intrinsic property	Examples of uses in the scope of authorisation
1	4,4'-isopropylidenediphenol **(Bisphenol A; BPA)**	Toxic for reproduction, Endocrine disrupting properties - human health and environment	Epoxy resin hardeners
2	1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene **("Dechlorane Plus"™)**	vPvB	Flame retardant in adhesives and polymers
3	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear **(RP-HP)** with ≥0.1% w/w 4-heptylphenol, branched and linear (4-Hbl)	Endocrine disrupting properties - environment	Lubricants and greases
4	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate **(DOTE)**	Toxic for reproduction	Stabiliser in polymers
5	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate **(reaction mass of DOTE and MOTE)**	Toxic for reproduction	Stabiliser in polymers
6	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)	Carcinogenic	Printing inks
7	Dioxobis(stearato)trilead	Toxic for reproduction	Stabiliser in PVC
8	Fatty acids, C16-18, lead salts	Toxic for reproduction	Stabiliser in PVC
9	Trilead dioxide phosphonate	Toxic for reproduction	Stabiliser in PVC; rubber production; mirror backing
10	Sulfurous acid, lead salt, dibasic	Toxic for reproduction	[1]

Annex to news 2 (2)

11	[Phthalato(2-)]dioxotrilead	Toxic for reproduction	[1]
12	Trilead bis(carbonate) dihydroxide	Toxic for reproduction	Artists' paints
13	Lead oxide sulfate	Toxic for reproduction	Mirror backing
14	Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] **(HHPA)**	Respiratory sensitising properties	Epoxy resin hardeners
15	Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] **(MHHPA)**	Respiratory sensitising properties	Epoxy resin hardeners
16	Tetraethyllead	Toxic for reproduction	Additive in aviation fuel
17	2-methoxyethanol	Toxic for reproduction	Solvent
18	2-ethoxyethanol	Toxic for reproduction	Solvent

[1] The substance has no registered uses but is recommended based on grouping considerations as it could potentially replace other lead stabilisers in some of their uses. This is to avoid regrettable substitution.

REACH Pre-registration definitively ends. Rules for registration of phase-in substances clarified

The transitional regime for registering phase-in chemicals under REACH ended on 31 May 2018. The Commission has now clarified that certain provisions for phase-in substances will still apply until 31 December 2019.

The Commission has set 31 December 2019 as the cut-off date after which some conditions stipulated in REACH for phase-in substances will no longer apply.

Companies need to pay attention to the clarifications made in the Implementing Regulation already published. After the cut-off date, companies will need to calculate their manufactured or imported volume per calendar year for each of their substances. To enable registrants to continue with their data-sharing obligations, including for newcomers and updates of the registration dossier, the Implementing Regulation recommends that registrants should use similar informal communication platforms to those used for registering phase-in substances.

From the cut-off date, companies that plan to register a substance will need to submit an inquiry to ECHA to get information on other registrants in order to begin data-sharing negotiations, and they can no longer rely on their pre-registrations.

If data-sharing negotiations started within a substance information exchange forum (SIEF), respective data-sharing disputes can be submitted according to Article 30(3) of REACH until the cut-off date. After this date, all data-sharing disputes will be handled according to Article 27.

Certain phase-in substances will continue to benefit from less stringent information requirements if they are registered at the lowest tonnage band, between 1 and 10 tonnes per year and they do not meet the criteria listed in Annex III to REACH.

L 259/12 EN Official Journal of the European Union 10.10.2019

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1692

of 9 October 2019

on the application of certain registration and data-sharing provisions of Regulation (EC) No 1907/2006 of the European Parliament and of the Council after the expiry of the final registration deadline for phase-in substances

(Text with EEA relevance)

2. After 31 December 2019, pre-registrations made in accordance with Article 28 of Regulation (EC) No 1907/2006 shall no longer be valid and Articles 26 and 27 shall apply to all phase-in substances.

CLP

Public consultation on harmonized classification and labeling.

ECHA is looking for comments on the harmonized classification and labeling proposals for:

N-(2-nitrophenyl)phosphoric triamide (**EC 477-690-9**, CAS 874819-71-3).
Melamine (**EC 203-615-4**, CAS 108-78-1)

A public consultation was launched for four isocyanates which belong to the same group of substances:
1,3-bis(1-isocyanato-1-methylethyl)benzene (**EC 220-474-4**, CAS 2778-42-9);
1,3-bis(isocyanatomethyl)benzene (**EC 222-852-4**, CAS 3634-83-1);
2,4,6-triisopropyl-m-phenylene diisocyanate (**EC 218-485-4**, CAS 2162-73-4); and
1,5-naphthylene diisocyanate (**EC 221-641-4**, CAS 3173-72-6).
The deadline for comments expired on **25 October 2019**.

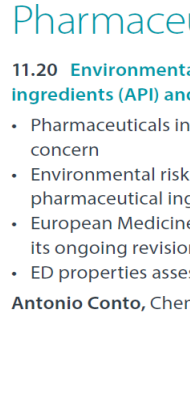
New intentions to harmonise classification and labelling

Three intentions have been received to harmonise the classification and labelling of:
Malathion (**EC 204-497-7**, CAS 121-75-5);
9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylium chloride (**EC 213-584-9**, CAS 989-38-8); and
4-phenoxyphenyl (RS)-2-(2-pyridyloxy) propyl ether (**EC 619-166-6**, CAS 95737-68-1).

CHEMSAFE attendance late 2019-2020

Dublin (Ireland) organized by CIRS
Partner/attendance, Oral presentation by A. Conto "Microplastics: a new challenge for environmental protection"

Frankfurt Am Main (Germany)
Oral presentation by A. Conto, "Environmental impact of active pharmaceutical ingredients (API) and their ED properties



Pharmaceuticals

11.20 Environmental impact of active pharmaceutical ingredients (API) and their ED properties

- Pharmaceuticals in the environment (PIE): a matter of concern
- Environmental risk assessment (ERA) of active pharmaceutical ingredients: the scientific approach
- European Medicines Agency (EMA) guidance 2006 and its ongoing revision
- ED properties assessment for drug actives

Antonio Conto, Chemsafe, Italy

Sao Paulo (Brazil), exhibition booth with three persons

End of the newsletter