Changes of market volumes of chemicals subject to authorisation in 2010-21

October 2022

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Version	Changes	

Changes in market volumes of chemicals subject to authorisation in 2010-21
Reference: ECHA-22-R-06-EN
ISBN: 978-92-9468-136-2
Cat. Number: ED-04-22-104-EN-N
DOI: 10.2823/844275
Publ.date: October 2022
Language: EN

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Executive summary

This specific report[1] presents estimates for changes in market[2] volumes of chemicals (i.e. substances) that have been placed on the EU market that are subject to REACH authorisation from 2010 to 2021. The estimates are based on information from registration dossiers, from applications for authorisation and other sources. The purpose is to get indications of whether authorisation requirements have had an effect on the use of these specific substances of very high concern (SVHCs) in the EU and the European Economic Area.

The main results can be summarised as follows.

- Of 59 substances currently subject to authorisation, no applications were made for 25. Of these 25, five substances had been registered in 2010[3].
- Of the remaining 34 substances, the overall reduction of volumes placed on the market was estimated to be about 600 kilotonnes or 45 % from 2010 and by about 170 kilotonnes or 20 % calculated from the sunset dates.
    - i) The estimated reduction of the volumes of five phthalates (mainly DEHP) was about 90 % from 2010 to 2021.
    - ii) The estimated reduction of anthracene oil and coal tar pitch high temperature was about 25 % from 2010 to 2021.
    - iii) The estimated reduction of other substances subject to authorisation was about 80 %, from 2010 to 2021 of which:
        - Trichloroethylene volumes were estimated to reduce by about 95 %.
        - Chromium trioxide by about 40 %.
        - The placing on the market of some chemicals (such as HBCDD and lead chromate pigments and 1-bromopropate) stopped altogether.
        - The estimated volume of diglyme increased by about 10 % (the only substance that did so).
- The overall annual reduction of the volumes placed on the EU market were estimated at 4 % from 2010 and 14 % from the sunset dates, indicating that in many instances the substitution or cease of use accelerated after the sunset date.
- When available, quantities reported in registration dossiers were used as a starting point. These were complemented with data from applications for authorisation and other sources. Intermediate and other exempted uses were separated out. Data gaps were filled with inter- and extrapolation to prepare the estimates of volume developments for this report.

[1] ECHA's specific reports can be found at https://echa.europa.eu/technical-scientific-reports
[2] Placing on the EU market includes manufacturered substances in the EU as well as imports. Exports are excluded.
[3] Year 2010 was selected as the base year because most of the registrations and many applications for authorisation had the first complete data sets for this year.

- The results of this report are similar to those of a previous specific report with a more limited scope (ECHA 2021b[4]) which concluded that five years after entry to the Authorisation List (Annex XIV), Swedish firms had reduced their annual use of SVHCs requiring authorisation by about 40 % compared to those SVHCs not requiring authorisation.

This report attempts to see whether a relationship can be found between regulatory action under the REACH Authorisation title and the use of SVHCs at EU level. Unlike in ECHA 2021b, it was not possible to demonstrate a causal effect between authorisation and the reduction of uses of substances in this report. For this, it would be important to include in the analysis data from substances not added to Annex XIV.

1. Introduction

The REACH Authorisation process aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less hazardous substances or technologies, where these are technically feasible and economically viable. Apart from ECHA (2021b)[4], conclusions on whether the system achieves this goal have been based mostly on observational studies. However, several data limitations have not been addressed in these studies.

In this specific report, an augmented observational approach is taken to document the development of volumes of the 59 SVHCs that have been placed on the Authorisation List (Annex XIV) of the REACH Regulation over the period 2010-21. These substances can only be used if the Commission grants an authorisation for this or if the use is exempted.

As part of the preparation of this report, ECHA approached some registrants of Annex XIV substances to get additional information, in particular on cease of manufacture or imports. Moreover, the use descriptions were checked to disentangle intermediate uses of SVHCs as defined by Article 3(15) of REACH from those where exposure or emissions can actually be expected.

ECHA prepared this specific report to gain an understanding of the market developments of the SVHCs that are subject to authorisation to see how effective the authorisation system has been to meet one of its goals, i.e. substitution. The understanding is shared in this specific report transparently without publishing information that would reveal directly or indirectly the specific volumes of individual companies.

This specific report is one contribution to the discussion of the impacts that the authorisation system has had on the use of SVHCs and is partly based on the volumes that registrants have reported to ECHA. As it cannot be known what the volumes would have been if these substances had not been subject to authorisation, care should be taken in interpreting the observed changes.

This specific report emphasises the need to get regular reporting of volume data for Candidate List substances. It is hoped that the publication of this specific report illustrates how such data – rather than estimates that are used in this report – could be used during

[4] The study presents a causal analysis of the effect of adding substances to Annex XIV to REACH on substance volumes consumed in Sweden.

the preparation of regulatory action and for monitoring their impacts.

While not in the scope of this study, for some substances, an attempt has been made to see if data would indicate changes of volumes of alternatives to the SVHCs subject to authorisation. After all, the economic activity (e.g. the use of a plasticiser or plating of surfaces) is likely to continue and there is an interest to know what and how much alternative substances are used.

The report starts by summarising the REACH authorisation system and its interlinkage with the REACH registration requirements. Next, the methodology and data used are described and the premises of the report are stated before the volume developments of 22 substances are documented in detail. Where possible and meaningful, the results are triangulated with other public data. The concluding section of the report discusses general trends and possible steps to improve data availability in the future.

2. Background

2.1. Candidate listing

The REACH authorisation process is initiated through a proposal by ECHA (at the request of the European Commission) or an EU Member State to identify a substance (group) of SVHCs. Substances with the following hazard properties may be identified as SVHCs:

- meeting the criteria for classification as carcinogenic, mutagenic, or toxic for reproduction (CMR) category 1A or 1B in accordance with the CLP Regulation;
- being persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII;
- causing an equivalent level of concern as CMR or PBT/vPvB substances.

The SVHC identification process foresees a 45-day consultation during which interested parties may provide information on substance properties, uses and alternatives. Identified substances are included in the Candidate List maintained by ECHA[5]. The inclusion of a substance in this list brings to pass immediate obligations for its suppliers (including the notification of articles containing the substance, provision of safety data sheets to customers, and minimisation of exposures and releases).

2.2. Authorisation listing

As a permanent task, ECHA assesses substances on the Candidate List to determine which ones the Commission should promote to the Authorisation List. This prioritisation is based on information on uses and volumes in registration dossiers of the substance but may also consider other information received during the SVHC consultation or other relevant sources. Priority is given to those substances which have dispersive uses, high volumes, or persistent, bioaccumulative and toxic (PBT/vPvB) properties.

[5] As of August 2022, the Candidate List comprised 224 (groups of) substances. Since the last REACH Review report in 2017, 50 (groups of) substances were newly identified as SVHCs.

Based on the prioritisation, ECHA makes recommendations which establish:

i. a sunset date from which the placing on the market and use of a substance requires an authorisation (unless its use is exempt from the authorisation requirement);

ii. a latest application date by which an application for continued use of the substance must have been received by ECHA to benefit from transitional arrangements until a decision is made by the European Commission;

iii. review periods for specific uses, if any; and

iv. a list of uses that are exempt from the authorisation requirement, if any.[6]

Draft recommendations are subject to another consultation and the Member State Committee (MSC) reviews the comments submitted during that consultation when preparing its opinion on the draft recommendations. ECHA considers the MSC opinion before submitting a final recommendation to the European Commission for a decision on the priority substances to be included in the Authorisation List. These recommendations are made every two years.

2.3. Applications for authorisation

Firms that intend to continue using a substance included in the Authorisation List after the sunset date need to prepare an application for authorisation (unless their use is exempt). An application for authorisation can be submitted for one or several uses of one or a group of similar substances. Applicants may apply for authorisation of their own use or of uses for which they intend to place the substance on the market.

ECHA (2021a) summarised the socio-economic impacts of REACH authorisations until now. The report concluded that applying for an authorisation was a costly enterprise — according to an applicant survey, the average cost per use applied for is close to €200 000 — which firms would do if switching to alternative substances or technologies was technically or economically not feasible.

This suggests that the authorisation requirement creates an incentive to cease and, where viable, substitute uses of SVHCs in the EU. Indeed, ECHA has not received applications for almost half of the substances currently on the Authorisation List. Moreover, an ECHA (2020) study on the impacts of REACH restriction and authorisation on substitution found that firms seek to substitute SVHCs before their use becomes subject to authorisation. Based on these reasons, ECHA suspects that the REACH Authorisation title has contributed to reducing the use of SVHCs in the EU.

2.4. Reporting requirements for REACH registrants

The Registration title of REACH requires firms to report information on all substances manufactured in or imported into the EU in quantities above one tonne per year. Registration is done in tonnage bands (1-10, 10-100, 100-1 000, or above 1 000 tonnes per year) which determine the maximum amount at which the registrant can operate the

[6] As of August 2022, there are 59 (groups of) substances are on the Authorisation List. Since the last REACH Review report in 2017, 27 (groups of) substances were newly added.

substance, and set information requirements for the registration.

As part of the standard information requirements, REACH registrants are obliged to indicate the estimated quantity in the calendar year of the registration. Once registered, there is no legal requirement to report on the precise quantity for subsequent years.

Registrants need to update their registrations if they (i) increase their manufacture or import of the substance into a higher tonnage band, or (ii) cease manufacturing or importing the substance entirely. In 2020, the Commission clarified the deadlines for updating registrations for the different update reasons.

3. Methodology

3.1. Raw data

REACH registrations of Authorisation List (Annex XIV) substances have been one source for this study. To track changes in substance volumes, annual quantities reported in registration dossiers were complemented by inter- and extrapolations and other data as the registrations did not contain year-by-year annual volumes for many substances (as this is not a requirement).

The annual quantities related to intermediate uses were removed from the data. This took time because the use descriptions included both intermediate and possible non-intermediate uses. This was, in particular, the case for EDC, where over 99 % of the use is not subject to authorisation as EDC is mainly used to produce PVC.

For chromium trioxide Eurostat has a specific code and thus, it was possible to extract the data from Eurostat's reference database Comext and – after verification of these data with the uses applied for in applications for authorisation – use these data in this report.

Updating campaign. ECHA launched a dossier update campaign focusing on registrations of substances listed on Annex XIV to REACH, for which the sunset date has expired. According to Article 56(1) of REACH, it is expected that after the sunset date, the only supported uses in such registrations are those exempted from authorisation or uses that have been authorised.

For this campaign, companies were notified about their obligation under REACH Article 22 to keep their registrations up to date with certain relevant new information and to submit them to ECHA. Following ECHA's assessment of the identified uses against the authorisations received (or granted) for the substances, companies were contacted for further information where it could not be determined if the reported uses were covered by an authorisation. This campaign resulted in updates clarifying the current situation of companies that had registered Annex XIV substances. These data were also used in this report.

3.2. Data cleaning and processing

This section describes how the raw data was cleaned and processed mainly in two ways: i) checking and removing intermediate uses and ii) interpolation of data between two data points and extrapolating data after the last observation.

Checking and removing intermediate uses. One of the most common exemptions for authorisation is the use of the substance as an intermediate. REACH defines an intermediate as "a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance" (Article 3(15)). To determine if a substance is used as an intermediate, an overview of the registration dossiers for these substances was done, paying special attention to Section 3.5 where this information can usually be found.

In Section 3.5 of the registration dossier, the company must state the different uses they foresee for the substance they are registering, be it manufacture, formulation, re-packing, its uses at industrial sites, by professional workers or by consumers. They must also indicate the product category used, the sector of end use and the technical function of the substance during use. Furthermore, the chemical safety report can also provide this information in more detail, also taking into account possible exposure scenarios for the different uses covered by the dossier.

Another way to determine if a substance is being used as an intermediate is by checking on their dossier type. For transported isolated intermediate uses (TII) and on-site isolated intermediate uses (OSII), the registrant can declare if their substance falls into either of those two cases, stating the tonnage band for which they are applying to during the creation of its dossier. If a registration dossier is declared as a TII or an OSII, it is considered as an intermediate use and, therefore, exempted from authorisation.

Interpolations and extrapolations. One challenge with using REACH registration data as a proxy to track yearly market volumes of substances is that such data is not required to be systematically provided, and hence many registrations have reporting gaps, i.e. volumes are only provided for certain years. These data gaps may be filled by using an adequate filling algorithm. For this report, all gaps were filled using linear interpolation between two consecutive records of a registration. If there were gaps at the end of the reporting period, they were extrapolated using the last available record ("forward propagation of the last record") assuming that that no change has taken place.

The information of cease of manufacture or imports has been very important. Under REACH, the cease of manufacture is recorded when the registrant provides the information to ECHA. However, it was evident that the cessation has often taken place earlier (as the sunset date of the use of the substance has been earlier). In such cases, **no** additional processing was made (e.g. moving the cease of manufacture to the year of the sunset date). Due to this, extrapolated data are likely to be somewhat higher than in reality, implying that the changes are to some extent underestimated. It was not possible to estimate the importance of this underestimation, but it is likely to be small and not change the main results of this report.

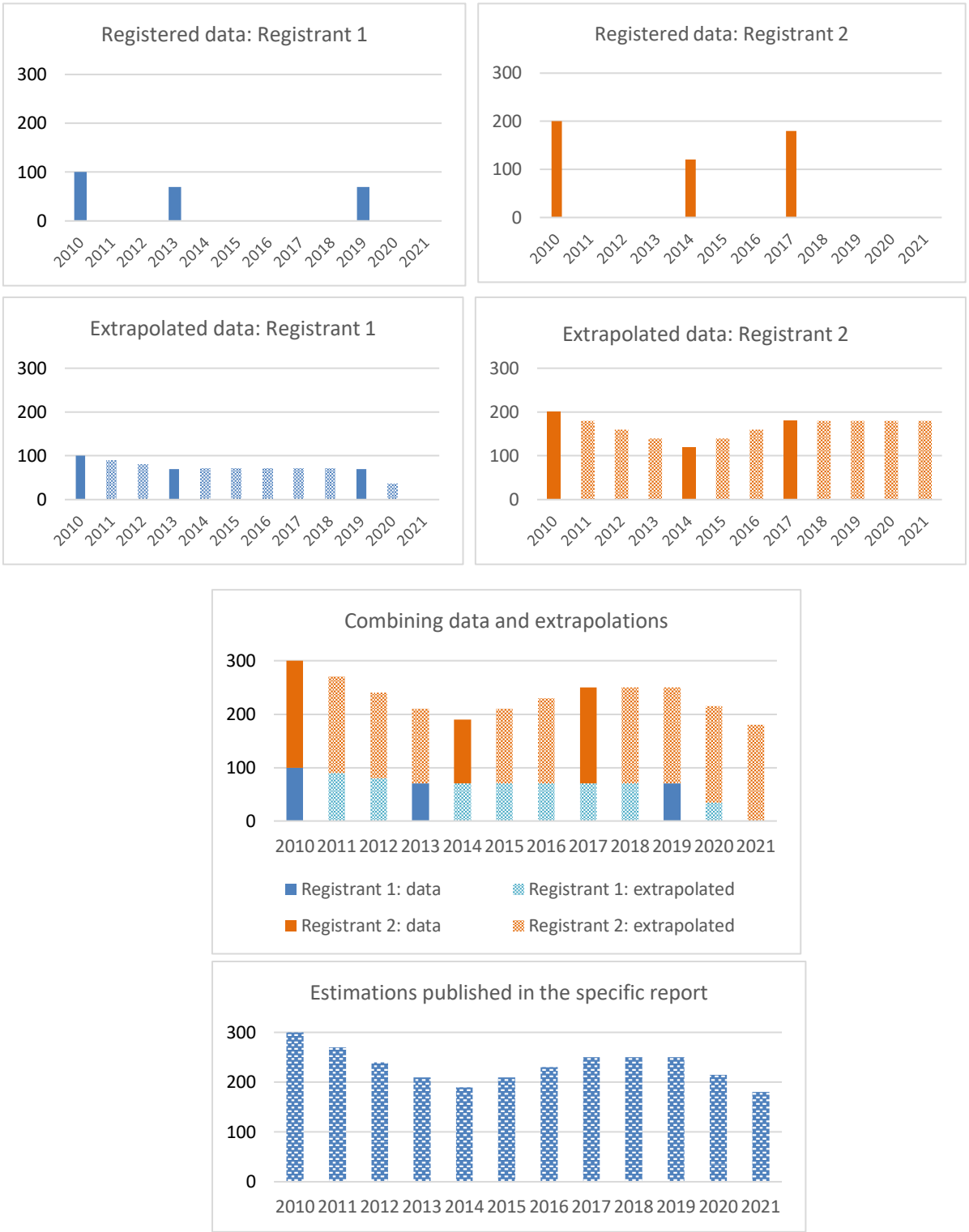

Figure 1 Graphical representation of the filling algorithm

Figure 1 gives an illustration of the filling algorithm. In this illustration, Registrant 1 provided annual volume data for 2010, 2013 and 2019, and reported cease of manufacture in 2021 (i.e. 0 tonnes). Registrant 2 provided annual volume data for 2010, 2014 and 2017. As there was no additional information, it is assumed that tonnage remained the

same (180 tonnes) after that year. If there were less than three registrants, the changes were provided only in relative terms.

The combined graph illustrates how the data have been aggregated showing both actual data and the interpolations and extrapolations (for at least three registrants). The graph "Estimations published in the specific report" illustrates how the inter- and extrapolated data are presented in this report.

4. Main results

Overall, between 2010 and 2021 the volumes of substances that were subject to authorisation in 2022 were estimated to have reduced by 45 % in the EU. The estimates of the changes of different groups of substances are also shown (see Figure 2) as Coal tar pitch high temperature (CTPHT) is in its own category as the volumes placed on the market in 2021 were estimated to correspond to almost 90 % of all SVHCs subject to authorisation. Together with anthracene oil, the market volume of CTPHT subject to authorisation was estimated to have reduced by a quarter from 2010. The changes of other SVHCs subject to authorisation were estimated to be more profound with a reduction of over 80 % from 2010 till 2021.

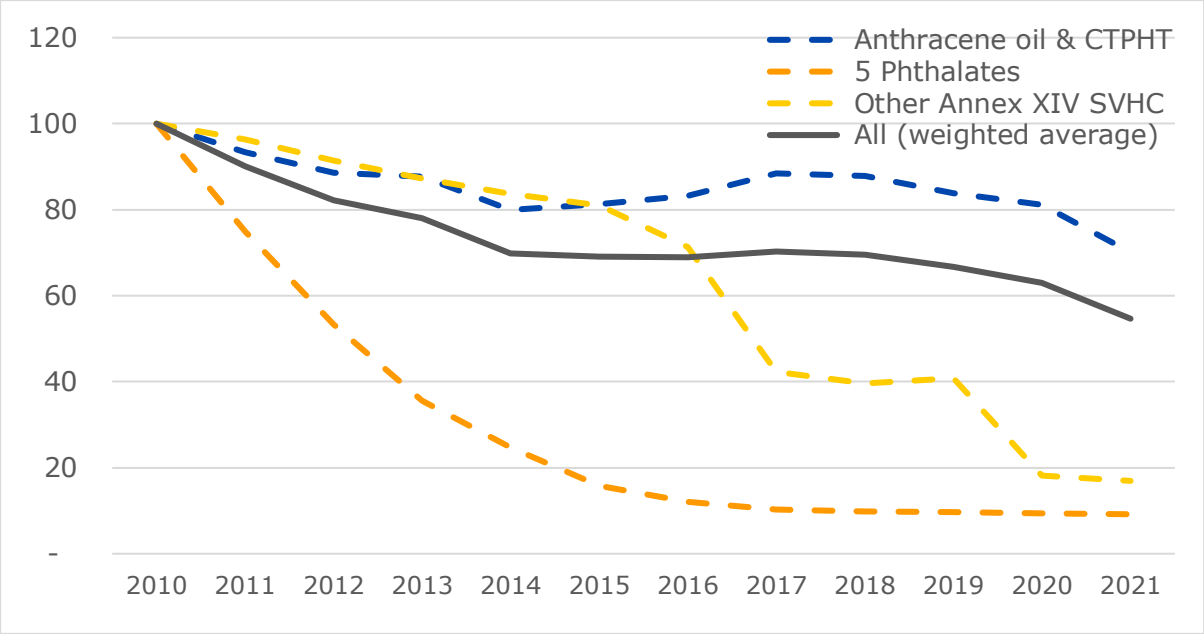

Figure 2 Estimates of relative changes in the volumes of chemicals subject to authorisation placed on the EU market, 2010-21 (index 2010 = 100)

Figure 3 gives the same estimates as Figure 2 but in tonnes. The dominance of CTPHT in the results is illustrated well. The overall volume of SVHCs subject to authorisation is estimated to have changed from 1.3 million tonnes to about 0.7 million tonnes from 2010 to 2021.

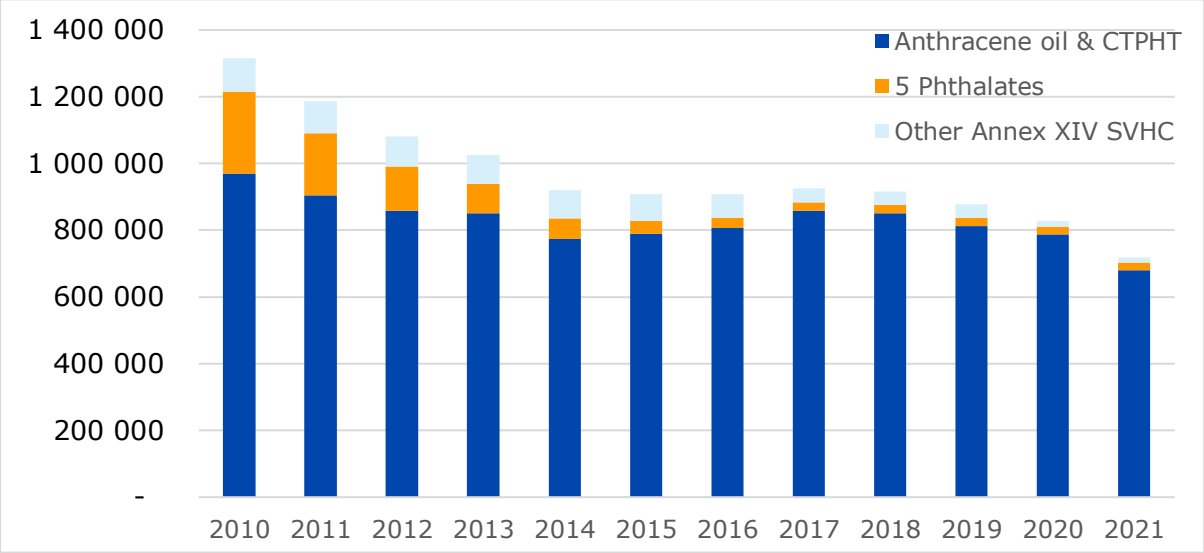

Figure 3 Estimates of volumes of chemicals subject to authorisation placed on the EU market, 2010-21, tonnes

The estimated change from 2010 onwards does not take into account when the substance was added to the Authorisation List. In Table 1, it can be seen that – apart from phthalates – there was a marked additional reduction of the volumes of substances subject to authorisation after the sunset date. For anthracene oil and CTPHT, there is only one datapoint after the sunset date (2020) so the change is not representative of a trend. However, for the other substances subject to authorisation the change is more representative. In sum, it seems that after the sunset date there was an additional reduction of the use of substances subject to authorisation.

Table 1 Changes in estimated volumes of chemicals subject to authorisation placed on the EU market from 2010 and sunset dates (tonnes and annual %)

	Volumes			Annual change	
	in 2010	At sunset date	in 2021	from 2010	From sunset date
Anthracene oil & CTPHT	969 642	787 117	679 688	-2%	-14%
5 Phthalates	246 531	38 918	22 624	-8%	-7%
Other Annex XIV SVHC	99 821	66 412	16 906	-7%	-14%
All **(weighted average)**	**1 315 994**	**892 447**	**719 218**	**-4%**	**-13%**

Notes: *only for 1 year; **Weighted change (volumes in sunset date were used as weights)

The information in Table 1 is broken down per substance in Table 2. In some cases, there seemed to be an anticipatory reduction before the sunset date (e.g. DEHP), and in others, no major change seems to have taken place after the sunset date (e.g. DIDP and chromium trioxide). In other cases (e.g. arsenic acid, HBCDD, lead chromate pigments and trichloroethylene), the reduction of use is much higher after sunset date than during the period preceding it.

Table 2 Estimated relative changes in volumes of chemicals subject to authorisation in the EU from 2010 and sunset dates (annual changes %)

	Change from 2010 to sunset date per year	Change from sunset date to 2021 per year	Change from 2010 to 2021 per year
1,2-dichloroethane (EDC)	-5 %	-7 %	-5 %
1-bromopropane (n-propyl bromide)	-9 %	-100 %	-8 %
Anthracene oil	-3 %	0 %	-3 %
Arsenic acid	-8 %	-23 %	-8 %
Benzyl butyl phthalate (BBP)	-10 %	-17 %	-8 %
Bis(2-ethylhexyl) phthalate (DEHP)	-14 %	-7 %	-8 %
Bis(2-methoxyethyl) ether (Diglyme)	7 %	-5 %	0 %
Chromium trioxide	-4 %	-4 %	-3 %
Diarsenic trioxide	n/a	-3 %	n/a
Dibutyl phthalate (DBP)	4 %	0 %	2 %
Diisobutyl phthalate (DIBP)	-17 %	-17 %	-8 %
Diisopentyl phthalate	-8 %	-100 %	-8 %
DOTE*	n/a	n/a	-2 %
Hexabromocyclododecane (HBCDD)	-10 %	-17 %	-8 %
Lead chromate molybdate sulfate red	-5 %	-12 %	-7 %
Lead sulfochromate yellow	-1 %	-11 %	-7 %
Coal tar pitch, high temp.	-2 %	-15 %	-2 %
Tetraethyllead*	n/a	n/a	-8 %
Trichloroethylene	-1 %	-19 %	-8 %
Tris(2-chloroethyl) phosphate	-8 %	0 %	-8 %
Total	**-4 %**	**-14 %**	**-3 %**

Notes: *Sunset date is after August 2022; n/a = not applicable (sunset date is later)

5. Results per substance

5.1. Substances for which no applications were received

Table 3 indicates for which substances ECHA has not received any applications. For these 25 substances, the registrations indicated uses before the sunset dates. These have been marked with an asterisk.

Table 3 Substances for which no applications were submitted by August 2022 (N=25)

Substance name	EC No.	CAS No.	Re-gist-ered?	Latest Application date	Sunset date
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	201-329-4	81-15-2	No	21-Feb-2013	21-Aug-2014
4,4'- Diaminodiphenylmethane (MDA)	202-974-4	101-77-9	Yes	21-Feb-2013	21-Aug-2014
Benzyl butyl phthalate (BBP)*	201-622-7	85-68-7	Yes	21-Aug-2013	21-Feb-2015
Diisobutyl phthalate (DIBP)*	201-553-2	84-69-5	Yes	21-Aug-2013	21-Feb-2015
Diarsenic pentaoxide	215-116-9	1303-28-2	No	21-Nov-2013	21-May-2015
Tris(2-chloroethyl) phosphate*	204-118-5	115-96-8	Yes	21-Feb-2014	21-Aug-2015
2,4-dinitrotoluene (2,4-DNT)	204-450-0	121-14-2	No	21-Feb-2014	21-Aug-2015
Diisopentyl phthalate*	210-088-4	605-50-5	Yes	04-Jan-2019	04-Jul-2020
1-bromopropane (n-propyl bromide)*	203-445-0	106-94-5	Yes	04-Jan-2019	04-Jul-2020
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	276-158-1	71888-89-6	No	04-Jan-2019	04-Jul-2020
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	68515-42-4	No	04-Jan-2019	04-Jul-2020
1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear	284-032-2	84777-06-0	No	04-Jan-2019	04-Jul-2020
Bis(2-methoxyethyl) phthalate	204-212-6	117-82-8	No	04-Jan-2019	04-Jul-2020
Dipentyl phthalate	205-017-9	131-18-0	No	04-Jan-2019	04-Jul-2020
n-pentyl-isopentyl phthalate	933-378-9	776297-69-9	No	04-Jan-2019	04-Jul-2020
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	No	27-Aug-2021	27-Feb-2023
Dihexyl phthalate	201-559-5	84-75-3	No	27-Aug-2021	27-Feb-2023
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters	-	-	No	27-Aug-2021	27-Feb-2023
Sodium perborate, perboric acid, sodium salt	-	-	Yes	27-Nov-2021	27-May-2023
Sodium peroxometaborate	231-556-4	7632-04-4	No	27-Nov-2021	27-May-2023
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2]	-	-	Yes	27-Feb-2022	27-Aug-2023
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	25973-55-1	Yes	27-May-2022	27-Nov-2023
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	223-383-8	3864-99-1	No	27-May-2022	27-Nov-2023
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	253-037-1	36437-37-3	No	27-May-2022	27-Nov-2023
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7	No	27-May-2022	27-Nov-2023

Note: * Indicates that use took place before the sunset date, i.e. no applications for authorisation were made.

5.2. Details of the uses

In this section, details of the estimated volumes of substances for which ECHA has received applications for authorisation by August 2022 are covered. In addition, two developments are given for substances for which ECHA expects to receive applications. These are covered in sections 4.2.12-13.

Volume data are not disclosed if there are less than three registrants. In such cases, relative changes are given setting year 2010 as 100.

5.2.1. HBCDD

Several companies applied for the use of HBCDD as a flame retardant while they were taking the alternative into use. The authorisation expired in 2016, after which HBCDD was no longer used. However, the cease of manufacture notification was made by some registrants only in 2021 and, therefore, the extrapolation from 2016 indicates that HBCDD would have been used, although it was not in reality (see Figure 4). In sum, the use of HBCDD ceased in the EU by 2016 as the result of the authorisation requirement.

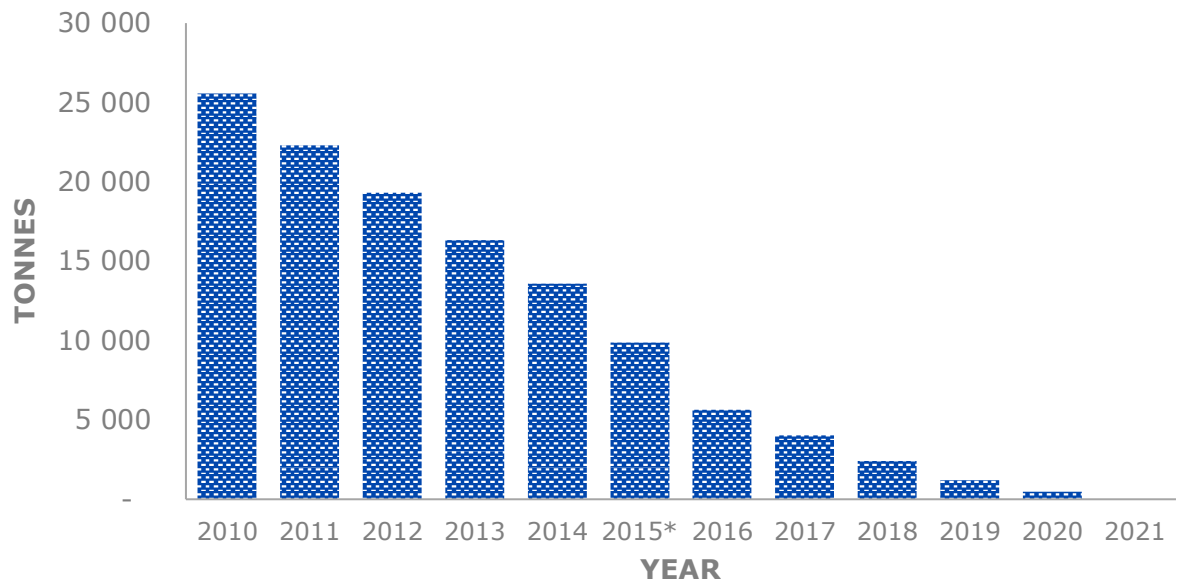

Figure 4 Estimates of volumes of HBCDD placed on the EU market, 2010-21, tonnes
Note: * Sunset date

Benzene, ethenyl-, polymer with 1,3-butadiene, brominated (CAS 1195978-93-8) was selected by industry as the replacement for HBCDD in expanded polystyrene (EPS) and extruded polystyrene (XPS) (Ineos, 2014). Benzene, ethenyl-, polymer with 1,3-butadiene, brominated (CAS 1195978-93-8) is not registered, as it is a polymers. Thus, ECHA has no knowledge of the changes in volumes of that substance.

5.2.2. Phthalates

Figure 5 indicates the estimated volume changes for five phthalates – BBP, DBP, DIBP, DEHP and diisopentyl phthalates – that have been included in Annex XIV. Overall, the estimated reduction has been 91 % since 2010. The driver for this development has been DEHP, which was estimated to have been placed on the EU market of almost 240

kilotonnes (being 96 % of these five phthalates) in 2010.

After 2017, the registrants of DEHP have not reported their annual market volumes in the registration dossiers (the manufacturing of the other four pthalates ceased earlier). In a recent substitution plan, the only manufacturer of DEHP in the EU reported the amount placed on the EU market subject to authorisation was "under 10 % of what it was a decade ago" (DEZA 2020). DEHP is used to manufacture blood bags, which became subject to authorisation when the Commission amended Annex XIV and included endocrine disrupting properties as an endpoint subject to authorisation. Thus, the amounts of DEHP registered in 2021 also include this volume.

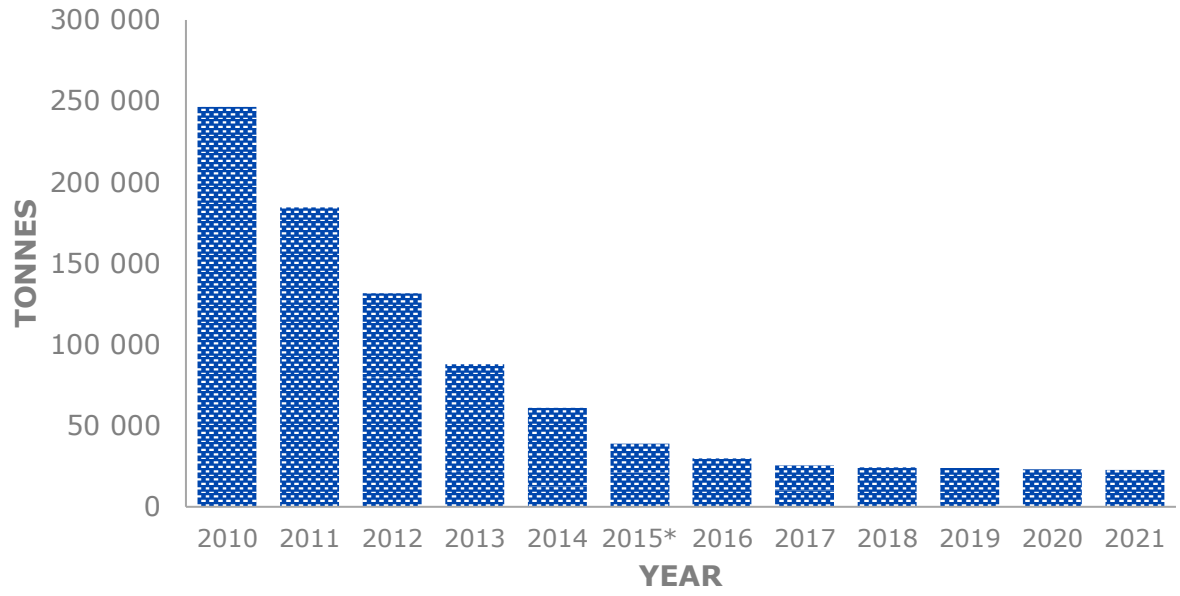

Figure 5 Estimates of volumes of DEHP, DBP, PBP, DIBP and diisopentyl phthalates placed on the EU market, 2010-21, tonnes
Note: * Sunset date

The restriction of the use of DEHP, DBP, BBP and DIBP entered into effect in July 2020 while the Commission has not decided on the application for authorisation made in 2013. The regulatory action of the EU seems to have had a significant impact on the use of these phthalates in the EU. After the sunset date on 21 February 2015, the use of DEHP and other four phthalates have been estimated to have dropped by about 40 %.

An attempt was made to see to what extent the alternatives to DEHP, namely DINCH, DINP and DIDP would have picked up the market share. Based on the volumes reported in the registration dossiers it was estimated that the volumes of these three substances had increased by about 70 kilotonnes while the volume of DEHP (and the other four phthalates) would have shrunk by over 200 kilotonnes. Part of the apparent discrepancy is possibly due to the use of DINCH increasing, as its main producer increased its production capacity from 100 to 200 kilotonnes in 2014 (Business Standard, 2014). However, as not all registration dossiers of DINCH contain annual volume information after 2014, this explanation cannot be verified.

DINP and DIDP were included in ECHA (2021c) with a conclusion that there would be a need for EU-wide restriction combined with authorisation.

5.2.3. Lead chromate pigments

Lead sulfochromate yellow and lead chromate molybdate sulfate red pigments were used to give colour to paints and plastics. One importer of these pigments applied for authorisation in the EU and the Commission granted the authorisation for certain uses for some time.

In 2022, the Commission decided to refuse the authorisation for the last uses. This was close to the end of the authorisation in 2022 and the use of these two pigments ceased in that year in the EU.

As the information is only from one company, it is not possible to present the actual tonnages placed on the market. Therefore, in Figure 6 the evolution of the volumes of these pigments in the EU is given relative to 2010 (=100).

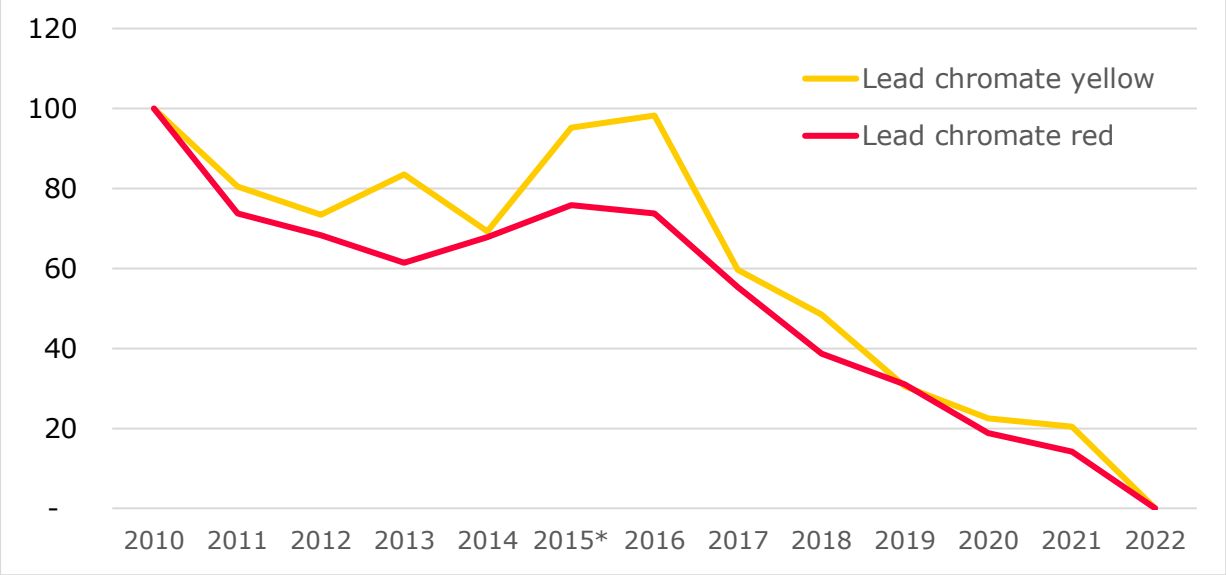

Figure 6 Estimates of changes in the volumes of lead chromate yellow and red placed on the EU market, 2010-22 (index 2010 = 100)
Note: * Sunset date

The placing on the market of lead chromate pigments (in particular red) was estimated to have reduced to some extent by the sunset date of 2015. Since the sunset date, the reduction was more pronounced and related to the end of authorisation of some uses (e.g. painting of road markings) by 2019 and the rest by 2022.

5.2.4. Arsenic acid

The Commission has granted one authorisation for the use of arsenic acid for the treatment of copper foil used in the manufacture of printed circuit board until 2024. The amount applied for was 3.25 tonnes per year (ECHA 2017). Overall, the reported annual quantity of arsenic in registration dossiers was low in 2010. Two registrants notified ECHA in 2022 that the manufacture had ceased. It is likely that the actual cessation took place at the latest by the sunset date (2016) or even well before this.

5.2.5. 1-Bromopropane

The registrants notified ECHA in 2021 about the cease of manufacture. It is likely that the actual use ceased earlier, probably before the sunset date of 21 October 2014. No annual volume information was reported since 2013. In sum, the use of 1-Bromopropanes has ceased in the EU most likely by 2014.

5.2.6. Trichloroethylene

Applications were made to use trichloroethylene (TCE) for various uses and the Commission granted the authorisations. ECHA (2022b) reports the experience of the authorisation requirement in detail. The main development in the EU was that the authorisation of the main applicant expired on 21 October 2021, but it submitted a review report for a relatively small amount of TCE compared to the use in 2010. The remaining uses submitted were estimated to amount in total to 1 200 tonnes, which was used for in this report.

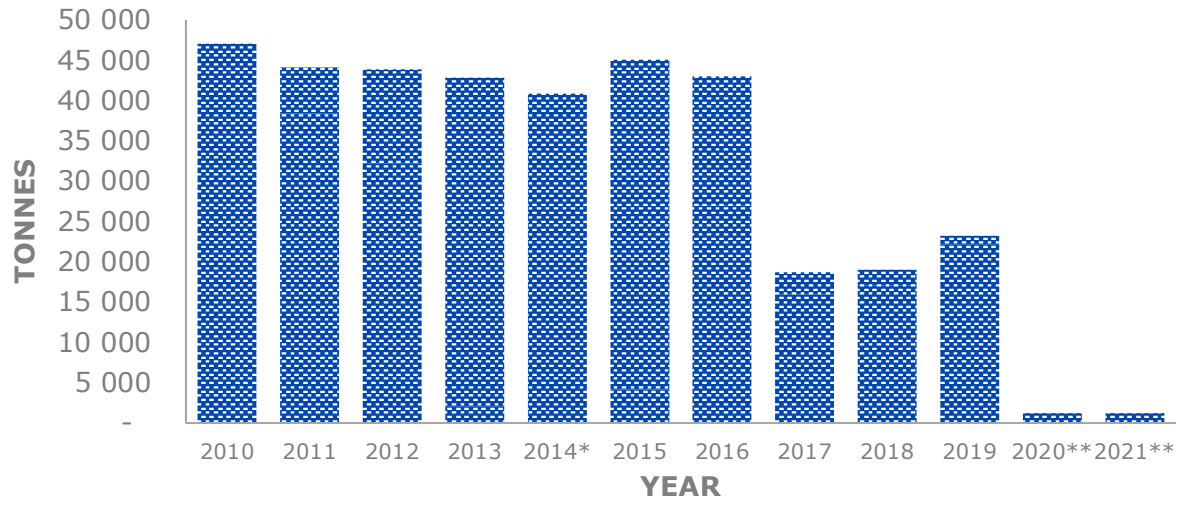

Figure 7 Estimates of volumes of trichloroethylene placed on the EU market, 2010-21, tonnes
Notes: * Sunset date, ** volume based on applications

Overall, the volumes of TCE placed on the EU market are estimated to have reduced by about 95 % from 2010 or the sunset date (see Figure 7). The main alternative to TCE, perchloroethylene has not been subject to regulation in the EU. The registration data only contains partial information on annual volumes after 2014 and thus it has not been possible to see if there has been a change in the volumes of perchloroethylene as a result of the reduction in the use of TCE in the EU.

5.2.7. Chromium and diarsenic trioxides

Only limited data was reported about the annual volumes related to the use of chromium trioxide since 2013. However, all chromium trioxide used in the EU is imported and Eurostat's database (Comext) has a specific code for chromium trioxide, making it possible to extract the data from Comext. The data was triangulated with data from applications

and corresponded well to the overall magnitudes. Figure 8 gives the results.

The placing of chromium trioxide was about 14 000 tonnes in the EU in 2010. It reduced by about 40 % from 2010 to 2021 and by about 20 % from the sunset date of 2017 to 2021. There was a dip in 2020 which is probably related to the reduced economic activity related to the Covid pandemic resulting in less surface treatment.

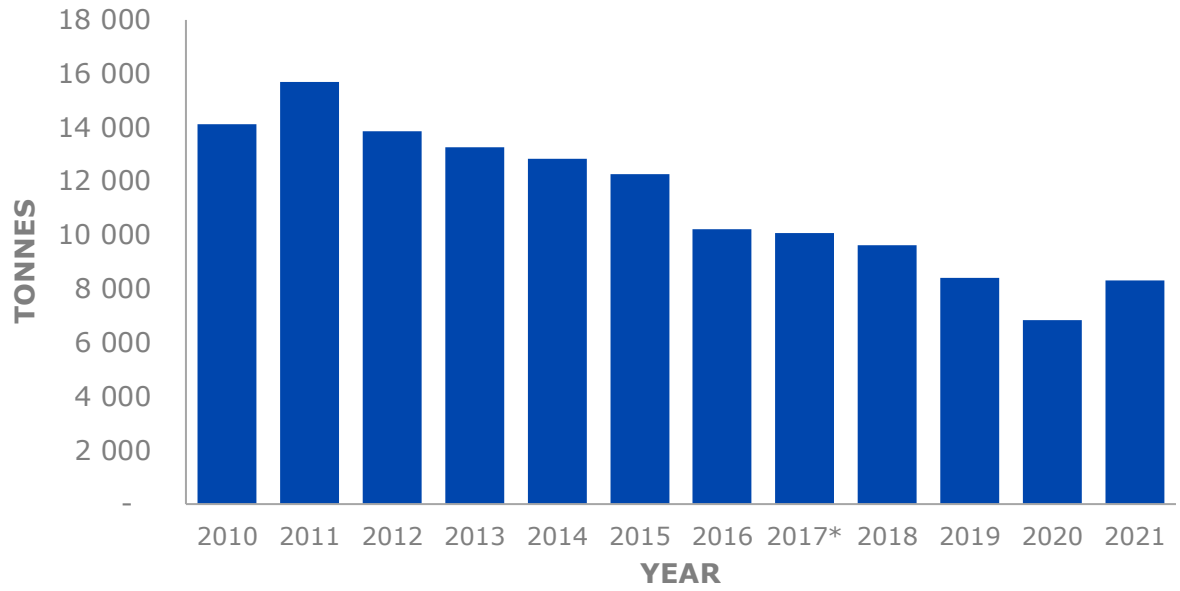

Figure 8 Chromium trioxide placed on the EU market, 2010-21, tonnes
Source: COMEXT
Note: * Sunset date

No annual volume data on diarsenic trioxide was reported in 2010-12 and the quantities reported in the registration dossiers are rather low, less than 1 000 tonnes. After the sunset date in 2015, the volume of diarsenic trioxide placed on the market was estimated to be about 20 % lower than in 2021 (see Figure 9). A similar dip in the use of diarsenic trioxide was evident in 2020 as for chromium trioxide.

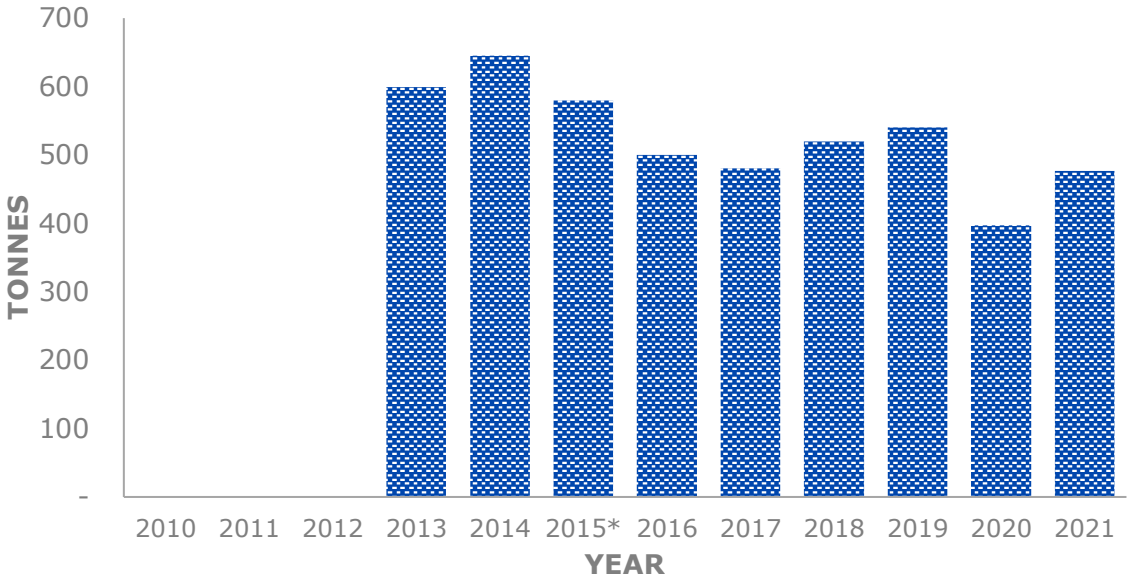

Figure 9 Estimates of volumes of diarsenic trioxide placed on the EU market, 2010-21, tonnes

5.2.8. Coal Tar Pitch High Temperature and Anthracene oil

Of the substances subject to authorisation, Coal Tar Pitch High Temperature (CTPHT) is completely in its own category when it comes to volumes: it represents about 70 % of all use in 2010 and almost 90 % in 2021. Thus, any development with CTPHT would mask the developments in other SVHCs subject to authorisation. Furthermore, CTPHT also has intermediate uses and thus, care should be taken when interpreting the data in this report.

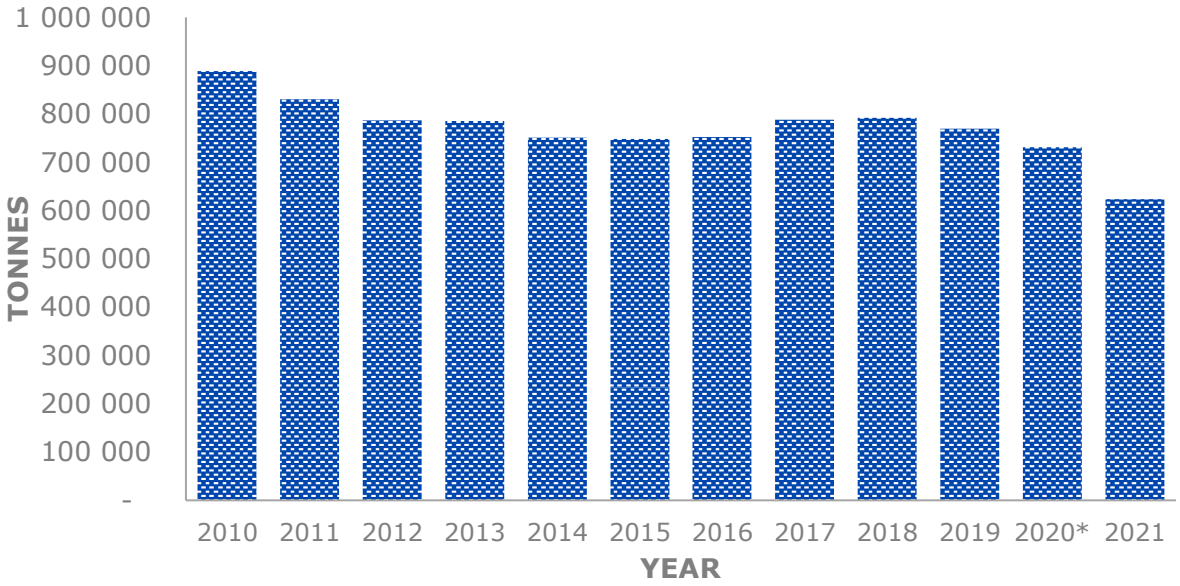

Figure 10 Estimates of volumes of Coal tar pitch, high temperature placed on the EU market, 2010-21, tonnes
Note: * Sunset date

The volumes of CTPHT are estimated have reduced by a third from 2010 and by 15 % from the sunset date in 2021 (Figure 10).

Anthracene oil had the same sunset date and similar developments as CTPHT from 2010: an estimated reduction by a third from 2010, however, no change in 2021 compared to 2020, but this is rather 2 a consequence of that no new volume information was recieved from registrants (Figure 11).

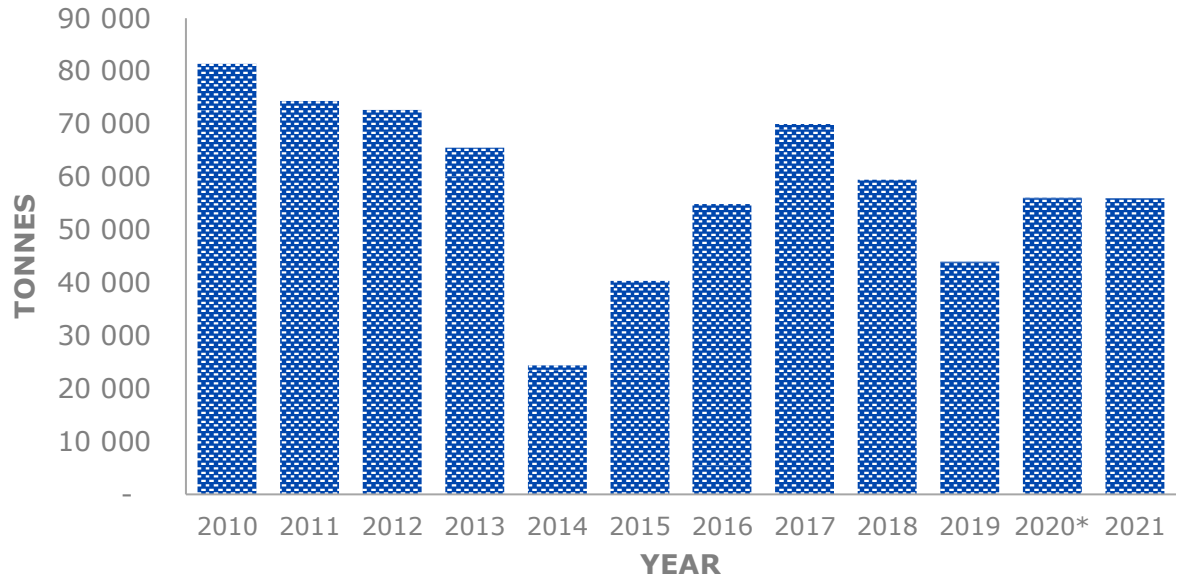

Figure 11 Estimates of volumes of Anthracene oil placed on the EU market, 2010-21, tonnes
*Note: * Sunset date*

The volumes reported in the registrations were triangulated with the amounts applied for in the applications for authorisation. In the applications, CTPHT authorisation was applied for 434 kilotonnes which is the lower that the 624 kilotonnes found in the registrations.

For anthracene oil the applied amount was 136 kilotonnes which was higher than the amounts reported in the registrations of 56 kilotonnes[7]. It should be noted that it is possible to have a higher amount applied for than what is in the amounts reported in the registrations and *vice versa*. The volumes applied for are in similar orders of magnitude to the amounts reported in the registrations indicating that the trends available from the registration dossiers are likely to be representative of the developments of the uses. However, the absolute values, including changes are uncertain.

5.2.9. Diglyme

The registrants did not report tonnages of Bis(2-methoxyethyl) ether (i.e. diglyme) in 2011-16, but since then the registration dossiers contained annual volume information, including a cease of manufacture in 2021. Overall, the amount placed on the EU market was estimated to be below 1 000 tonnes per year. No reduction has been observed of the use, rather there was an increase of about 10 % between the sunset date in 2017 and 2021 (see Figure 12). Of all substances subject to authorisation, diglyme was estimated

[7] Anthracene oil is manufactured in or imported to the EU 100-1000 kilotonnes per annum. (Substance Infocard available at https://echa.europa.eu/substance-information/-/substanceinfo/100.084.153)

to be the only one where such an increase has been observed.

The uses applied for diglyme were 374 tonnes indicating that the data in the registration dossier corresponds well to the applications.

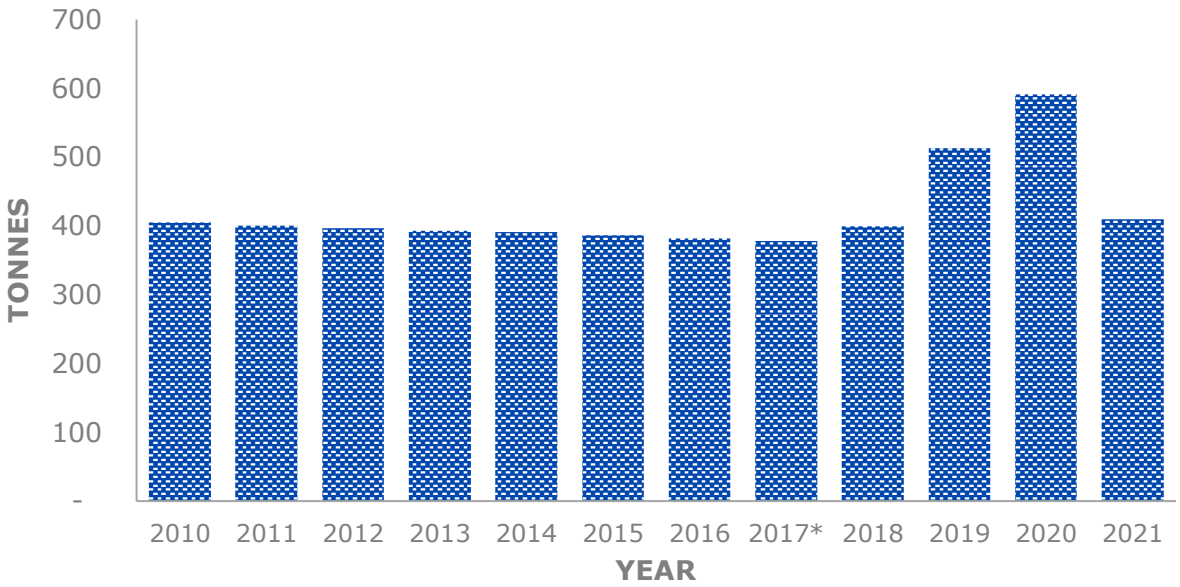

Figure 12 Estimates of volumes of diglyme placed on the EU market, 2010-21, tonnes
Note: * Sunset date

5.2.10. Octyl- and nonylphenols, ethoxylated

ECHA received applications for authorisation for over 100 uses of octyl- and nonylphenols, ethoxylated (OPE and NPE). The amounts applied for were 385 tonnes and 4 tonnes, respectively. However, OPE has not been registered and thus ECHA's registration database cannot be used to observe changes in volumes. NPE consisted of many substances and some were expected to fulfil the REACH definition of polymers and therefore exempt from registration (ECHA, 2015). For these reasons, it was practically impossible to use the volumes for tracking changes in volumes in the past. Thus, the dataset in this report excludes OPE and NPE. Overall, the impact is small given that volumes applied for are below 400 tonnes, i.e. under 0.03% of the total volume of substances subject to authorisation in the EU.

In ECHA (2021a) (Figure 8, reproduced here) it was shown that the future emissions of OPE and NPE subject to authorisation would reduce from about 10 tonnes in 2020 by over 90 % in 2032. With information from the applicants, 50 % of the reduction has already taken place, as projected, in 2022.

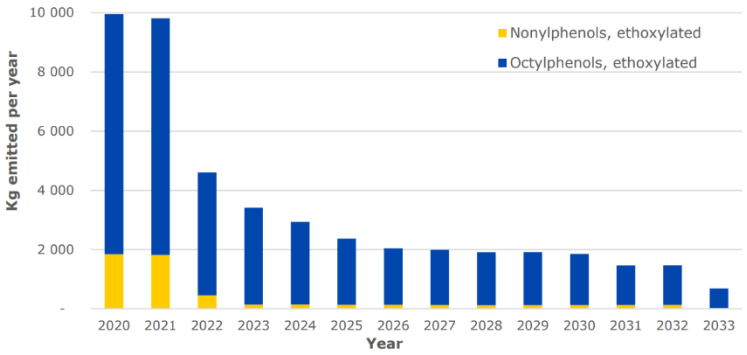

Figure 8: Forecasted annual emissions of nonyl- and octylphenols, ethoxylated, for applications evaluated by December 2020.

5.2.11. 1,2-dichloroethane

1,2-dichloroethane (EDC) is used mainly to produce PVC. This use is considered an intermediate use and thus does not require authorisation as is the case for some other minor intermediate uses of EDC. The total reported quantities in registrations of EDC has been in the range of 5 million tonnes in 2010-2021 while the use applied for was only 1.6 kilotonnes.

ECHA analysed the reported tonnes of EDC carefully to ensure that no PVC or other intermediate related registrations were included in this report. While the data were analysed and corrected as described in footnote[8], the resulting data are not likely to be reliable. They present only 0.02 % of the total reported annual quantities of. It is possible that the amount in the uses applied for are higher than the total amount that was bought from the manufacturers of EDC. While the data are not reliable, the overall volume is corroborated with the uses applied for.

The use of EDC subject to authorisation has been estimated to reduce by roughly 50% from 2010 and from the sunset date (22 November 2017) the use subject to authorisation has been estimated to be reduced by 26 %. (See Figure 13).

[8] Some registrants were contacted when the reported volumes included both intermediate/PVC and non-intermediate use descriptions to clarify the intermediate status. In one case, the reported annual quantity of one registrant in 2010 was about 100 kilotonnes without any information of intermediates, while for the following years the intermediate uses and exports represented 99.8 % of the use. This ratio was also used in 2010 for this data point. In the case of two other registrants, the companies had reported "cease of manufacture" in 2012 and 2013. Both produced PVC and reported the use of EDC in this regard, but also for possible other uses. As the companies ceased manufacturing it was not possible to contact them. The data of these registrants were removed from the dataset as it was very likely that all registered use was not subject to authorisation but related to the production of PVC. The reason for imputing the data point of one registrant and the deletion of two registrants from the dataset used in this report was to avoid falsely giving an impression that the use of EDC subject to authorisation had dropped by 99 % in early 2010-13. Further, the sunset date of EDC was 22 November 2017. It is very unlikely that the cease of manufacture of the two registrants had anything to do with the authorisation requirement for EDC for other uses than the manufacture of PVC.

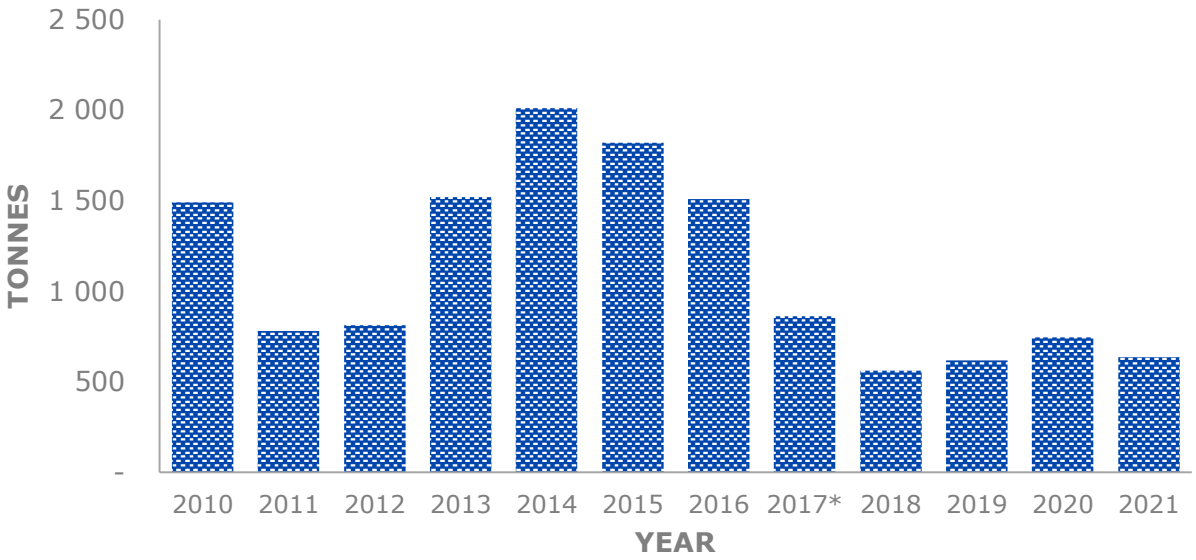

Figure 13 Estimates of volumes of 1,2-dichloroethane (EDC) subject to authorisation placed on the EU market, 2010-2021, tonnes
Note: * Sunset date

5.2.12. DOTE

DOTE and the reaction mass DOTE:MOTE are used in the production of PVC as heat stabilisers. It was added to the Candidate List in 2014. The sunset date for the use of DOTE is 1 May 2025 (and the latest application date is 1 November 2023). Thus, any change in volumes up to 2023 would be anticipatory. The overall volume of DOTE was estimated at 6 000 tonnes in 2010 and its use is estimated to be about a third lower in 2021 (see Figure 14).

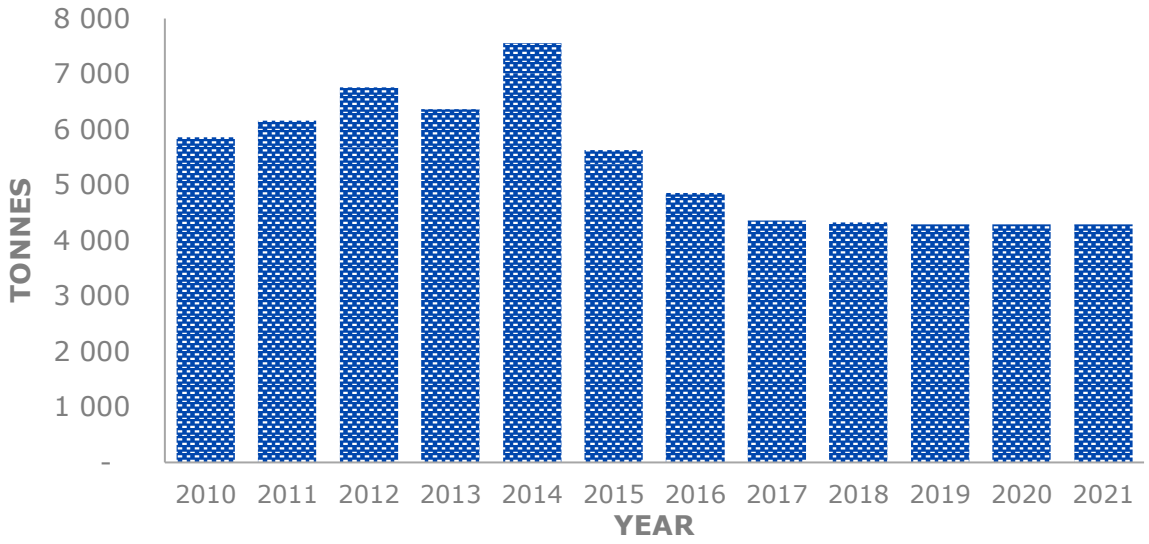

Figure 14 Estimates of the volumes of DOTE placed on the EU market, 2010-21, tonnes

The last fully reported data was from 2016 (being 20 % lower than in 2010). It can be concluded that it is likely that there has been a reduction in the use of DOTE from 2010 to

2021 but it is not possible to say by how much. Once the applications for the use of DOTE have submitted to ECHA, it will be possible to shed more light on the quantities.

5.2.13. Tetraethyl lead

Tetraethyl lead (TEL) is used as an anti-knock agent in aviation gasoline, as was the case in car engines up to the 1980s. It was added to the Candidate List in 2012, the sunset date is 1 May 2025 and the latest application date is 1 November 2023. With the development of engine technology, the number of small planes that need TEL has reduced and thus, the use of TEL has been estimated to have reduced by 92 % in the EU from 2010 (See Figure 15). The alternatives to TEL are described in detail in ECHA (2022b). Once the applications for the use of TEL have been submitted to ECHA, it will be possible to shed even more light on the quantities. But given the technological development, it is likely that the downward trend in the use of TEL in the EU will continue.

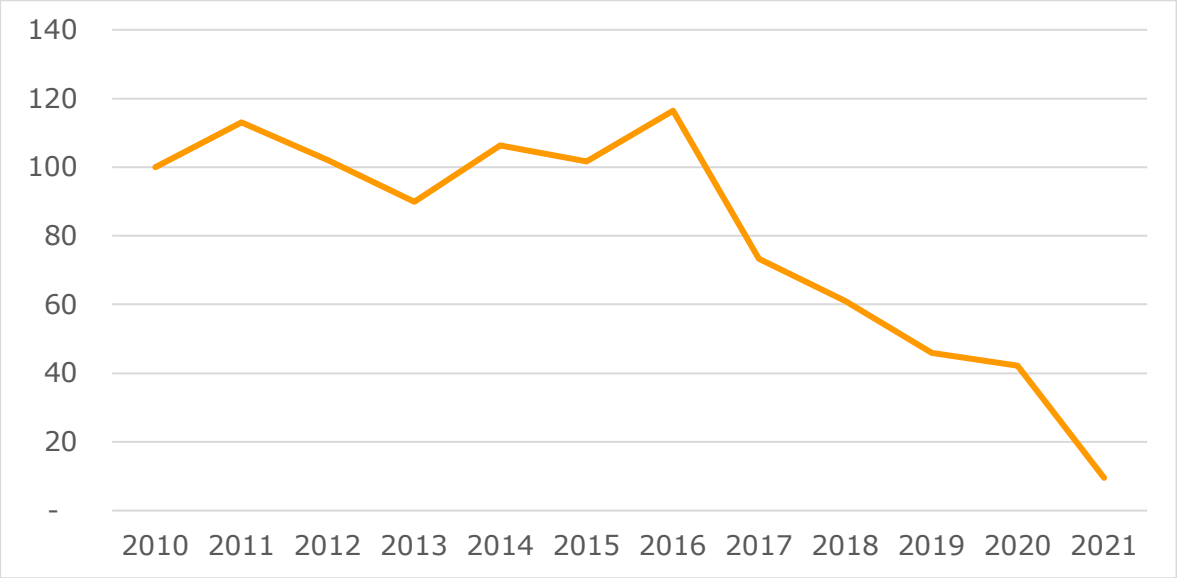

Figure 15 Estimates of changes in the volumes of Tetraethyl lead placed on the EU market, 2010-21 (index 2010 = 100)

6. Discussion

Given the novel approach taken in the collection from different sources, the inter- and extrapolation and data treatment, in this section the estimates are discussed:

- A substantial decline in volumes of substances subject to authorisation placed on the EU market has been observed. Therefore, the use of these substances should logically have declined similar fashion.

- The decline cannot be claimed – based on the estimates used in this report – to have taken place due to the authorisation requirement. However, the estimated decline of 45 % in the use of the Annex XIV substances from 2010 to 2021 is significantly more substantial than the reduction of the overall use of chemicals in the EU of 2 % in the same period (Eurostat 2022). Against this background it is

plausible that the authorisation requirement of these substances has lowered their consumption in the EU.

- There are four possible explanations for the reduction of the consumption of substances subject to authorisation:
    - Overreporting in 2010: registration volumes were higher than what was actually placed on the EU market;
    - Efficiency: companies found ways to reduce the quantities of SVHCs used;
    - Withdrawal or relocation: companies ceased the use of the SVHCs in the EU;
    - Substitution: companies found ways to substitute the SVHCs;
- It is possible that the initial reporting of the registered substances was higher than what was actually placed on the EU market. If there was overreporting in 2010 and more accurate reporting in later years, the reduction percentages reported in this study would be higher than in reality.
- It is plausible that some companies have identified – as part of the review of their production processes in preparing the chemical safety report – ways to improve the efficiency of their production methods and thus to reduce exposure. Therefore, it is possible that some reduction in the consumption of the substances subject to authorisation did occur.
- Some companies may have just stopped the production of the substance. For instance, in 2013 Arkema closed down its plant in Chauny, France which produced DEHP (L'usine nouvelle, 2013).
- There are clear indications (e.g. ECHA 2021a) that companies have substituted the uses of chemicals to other substances, such as perchloroethylene instead of trichloroethylene, other plasticisers instead of the regulated phthalates, or brominated polymer flame retardants instead of HBCDD.

It is likely that all four explanations are valid when trying to identify the causes for the reduction of substances subject to authorisation in the EU.

7. Conclusions

How well the REACH authorisation process is achieving the goal of substituting SVHCs has been debated for a decade, while there has been little empirical evidence to support one view or another.

This specific report, in addition to ECHA (2021b), sheds some light on the question in an evidence-based manner. ECHA 2021b concludes that five years after a substance entered Annex XIV, the average annual SVHC use of Swedish firms dropped by about 40 % compared to SVHCs that were not subject to authorisation. This is a strong finding which suggests that the inclusion of a substance in the Authorisation List has a sizeable substitution effect in Sweden. However, it is unclear how far this finding is representative for other EU Member States.

This report cannot make a causal conjecture of the relationship but was able to establish that the reduction of substances subject to authorisation changed from 2010 onwards in the EU. The overall use reduction of substances subject to authorisation was estimated to have decreased by about 600 kilotonnes or 45 % from 2010 and by about 170 kilotonnes or 20 % calculated from the sunset date. The reduction of five phthalates (mainly DEHP) was estimated to be 90 % from 2010 to 2021 and 25 % for anthracene oil and coal tar pitch high temperature. The reduction of other substances subject to authorisation was estimated to be 80 %. The overall annual reduction was estimated to be 4 % from 2010 and 14 % from the sunset date indicating that, in many instances, the sunset date was an important milestone to reduce the use of substances subject to authorisation.

For 25 substances (out of 59) subject to authorisation, no applications were made. This means that either substitutes were found or the substances were not used in the EU when they were entered into the Authorisation List (Annex XIV).

ECHA 2021b and this report highlight the importance of accurate, complete, and regularly reported volume data for any meaningful analysis of the effects of chemicals regulation. Annual market volume data of substances on the Candidate List would be needed to see whether the substitution effect found in this specific report is a general response to the authorisation listing. Such data would also be helpful to monitor the impacts of other regulatory risk management on chemicals in the EU.

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