Ministry of Environment and Food of Denmark
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Effect of some legal interventions under REACH and CLP

Exemplified with notification volumes in the Nordic Product Registers

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Background and objective
Previous studies have investigated and assessed the extent to which the REACH authorisation process for Substances of Very High Concern (SVHC) drives substitution of these substances. Based largely on stakeholder interviews, it is qualitatively assessed that inclusion of substances in the Candidate List and possible later inclusion in the Authorisation List (REACH Annex XIV) contribute to driving substitution and reducing exposure along with other legislation and other market factors.

Quantitative evidence has been lacking as the studies that looked into EUROSTAT/PRODCOM data deemed such evidence to be too unspecific and REACH registrations data were deemed not sensitive enough because registration volumes were updated too infrequently.

The current study therefore focuses on volumes notified in the Product Registers in Denmark, Norway, Sweden and Finland as available in the SPIN database, with non-confidential registration information from the four Nordic registers. Although they have varying scopes, which also deviate from the scope of REACH and a number of other inherent uncertainties, an advantage of these registers is a requirement for frequent updates of volumes.

The REACH authorisation process is costly and labour intensive for industry (applicants) and authorities. In order to shed light on the effectiveness of this effort, the current project analyses trends in SPIN volume data to see if conclusions can be drawn as to the relative importance of various legal interventions.

Scope and methodology
The study focuses on the 43 entries (substances listed alone or as part of a group entry) in the current (November 2018) Authorisation List (REACH Annex XIV).

The developments in notified amounts in the four Nordic countries over the years (and as available in SPIN) were plotted against three regulatory dates:
- The trigger date; i.e. when a substance was first assigned the SVHC property (for CMRs, this was defined as the original harmonised classification equivalent with REACH CMR properties, i.e. sometimes it was an 'old' classification under Directive 67/548/EEC),
- The candidate listing date, and
- The Authorisation List inclusion date.

SPIN provides information for 2000-2016 at the time of writing this report. As some substances were originally classified prior to 2000, retrieving older (pre-2000) data directly from the Nordic Product Registers was attempted. Within the time frame of the project it was only possible to obtain reliable data from Sweden for the period 1992-1999 in a form compatible with data in SPIN.

Conclusions
SPIN data are associated with a range of uncertainties and are therefore difficult to interpret in some situations. Therefore, care should be taken in drawing overly firm conclusions based on these data.

The current study clearly indicates that regulatory action (including harmonised classification/assigning the SVHC designation) over the past decades on substances currently on the

REACH Authorisation List has resulted in considerably reduced tonnages in the Nordic countries Denmark, Norway, Sweden and Finland. This is illustrated in reduced notified volumes to the countries' product registers. As pointed out by others, this might be more pronounced in the Nordic countries with their strong historical focus on substitution of hazardous substances than in the EU on average.

It appears that candidate listing and Authorisation List inclusion generally keep or drive tonnages to low levels and thus may function as drivers for eventual substitution in situations where it would be difficult to identify substitutes in the short term.

The findings of the project cannot support that one type of legal intervention (e.g. harmonised classification) is more or less important than another (e.g. candidate listing or Annex XIV inclusion).

The relative effects of these interventions appear to differ from substance to substance, from country to country, and from application to application and often data indicate that various legal interventions act together to reduce volumes. This finding is in line with findings in previous studies on this issue.

Further detailed analysis of the data in the current study combined with further research related to specific substances, substance groups and applications may provide further insight into when and why one legal intervention is more powerful than another.

Sammenfatning

Baggrund og formål
Tidligere studier har undersøgt og vurderet, i hvilket omfang REACH-godkendelsesprocessen for særligt problematiske stoffer (SVHC: Substances of Very High Concern) leder til substitution af disse stoffer. Disse studier er i stor udstrækning baseret på kvalitative interviews med aktører og vurderer på den baggrund, at optagelse af stoffer på kandidatlisten og eventuel senere optagelse på godkendelseslisten (REACH bilag XIV) medvirker til substitution og reduktion af eksponeringen i samspil med anden lovgivning og andre markedsmæssige faktorer.

Der er mindre kvantitativ evidens til at underbygge disse konklusioner. De tidligere undersøgelser har set på Eurostat / PRODCOM data, som blev vurderet til at være for uspecifikke, samt på REACH registrerings data, som er blevet fundet ikke at være følsomme nok, da de ikke opdateres løbende.

Nærværende undersøgelse fokuserer derfor på de mængder, der er anmeldt i produktregistrene i Danmark, Norge, Sverige og Finland. Mere specifikt har projektet anvendt SPIN-databasen, som indeholder ikke-fortrolige registreringsoplysninger fra de fire nordiske registre. Fordelen ved at anvende informationer fra disse registre er, at der er krav om regelmæssig opdatering af registrerede mængder. Disse fordele vurderes at opveje at informationerne er forbundet med en række iboende usikkerheder, samt at registrene varierer indbyrdes og i forhold til REACH, med hensyn til hvilke stoffer og anvendelser som er omfattet.

REACH-godkendelsesprocessen er dyr og arbejdskrævende for industrien (ansøgerne) og for myndighederne. For at bidrage til at belyse effektiviteten af denne indsats, analyserer nærværende projekt udviklingstendenser i de anmeldte mængder i SPIN, for at se om der kan drages konklusioner om den relative betydning af forskellige lovgivningsmæssige tiltag over for særligt problematiske stoffer.

Omfang og metode
Undersøgelsen fokuserer på de 43 stoffer eller stofgrupper, som er listet på den nuværende (november 2018) godkendelsesliste (REACH bilag XIV).

Udviklingen i anmeldte mængder i de fire nordiske lande over årene (som de er tilgængelige i SPIN) blev vist grafisk med indikation af tre datoer for regulatoriske indgreb:
• En 'trigger' dato; som er det tidspunkt et stof blev vurderet til at have en særligt problematisk egenskab (for CMR-stoffer, blev dette defineret som den oprindelige harmoniserede klassificering svarende til REACH CMR-egenskaber, dvs. nogle gange var det en 'gammel' klassificering i henhold til direktiv 67/548/EØF)
• Datoen for optagelse på kandidatlisten
• Datoen for optagelse på REACH godkendelseslisten.

For nuværende (slut 2018) indeholder SPIN-databasen oplysninger for årene 2000-2016. Da nogle stoffer oprindeligt blev klassificeret før 2000, blev det forsøgt at indhente ældre (præ 2000) data direkte fra de nordiske produktregistre. Inden for projektets tidsramme var det muligt at opnå pålidelige data fra Sverige for perioden 1992-1999 i en form, der var sammenlignelig med data i SPIN.

Konklusioner
Undersøgelsen har vist, at informationerne i SPIN-databasen er forbundet med en række usikkerheder. Man bør derfor være varsom med at drage meget håndfaste konklusioner baseret på de tilgængelige data.

Nærværende undersøgelse indikerer klart, at lovgivningsmæssige tiltag (herunder harmoniseret klassificering og optagelse på kandidat-/og godkendelseslisten) i løbet af de seneste årtier har ledt til en betydelig reduktion i anvendte mængder af særligt problematiske stoffer i Danmark, Norge, Sverige og Finland. Dette er illustreret i reducerede anmeldte mængder til landenes produktregistre. Som det påpeges i andre studier, kan dette være mere udtalt i de nordiske lande med et stærkt historisk fokus på substitution af farlige stoffer end i EU som gennemsnit.

Det ser ud til at optagelse på kandidatlisten og godkendelseslisten generelt fastholder eller leder til lave anvendte mængder - og således bidrager til substitution - i situationer, hvor det kan være vanskeligt at substituere på kort sigt.

Resultaterne af projektet kan ikke understøtte at én type regulatorisk indgreb (fx harmoniseret klassificering) er mere eller mindre vigtig end en anden type (fx optagelse på kandidatlisten eller godkendelseslisten).

Den relative vigtighed af disse regulatoriske indgreb synes at variere fra stof til stof, fra land til land og fra anvendelse til anvendelse, og ofte viser data, at forskellige reguleringsmæssige indgreb alle bidrager til reduktion af anvendte mængder. Denne konklusion er i tråd med konklusioner fra tidligere undersøgelser af dette emne.

Yderligere detaljerede undersøgelser kombineret med yderligere informationsindsamling relateret til specifikke stoffer, stofgrupper og anvendelser kan muligvis give yderligere indsigt i, hvornår og hvorfor ét lovgivningsmæssigt indgreb er mere effektivt end et andet.

Acronyms and Abbreviations

ATP	Adaptation to Technical Progress
BBP	Benzyl butyl phthalate
CAS no	Chemical Abstracts Service Number
CMD	Carcinogens and Mutagens Directive
CMR	Carcinogenic, Mutagenic, Toxic for reproduction
DBP	Dibutyl phthalate
DEHP	Bis(2-ethylhexyl) phthalate
DHNUP	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters
DIBP	Diisobutyl phthalate
DIHP	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich
DIPP	Diisopentylphthalate
DK	Denmark
DMEP	Bis(2-methoxyethyl) phthalate
DPP	Dipentyl phthalate
EC	European Commission
EPA	Environmental Protection Agency
FI	Finland
IC-NACE	International system for Industrial Category grouping
HBCDD	Hexabromocyclododecane
MDA	3,4-Methylenedioxyamphetamine
MOCA	2,2'-dichloro-4,4'-methylenedianiline
NO	Norway
NPE	4-Nonylphenol, branched and linear, ethoxylated
OSH	Occupational safety and health
PBT	Persistent, bioaccumulative and toxic
PRODCOM	Community Production, PRODCOM provides statistics on the production of manufactured goods.
RAC	ECHA’s Risk Assessment Committee
RiME	ECHA’s informal Risk management and evaluation platform for coordination between Member States and ECHA
RoI	Registry of Intention
RMOA	Risk Management Option Analysis
R&D	Research and Development
SE	Sweden
SEAC	ECHA’s Socio-economic Analysis committee
SPIN	Substances in Preparations in Nordic Countries
SUBSPORT	Substitution Support Portal
SVHC	Substances of Very High Concern
TCE	Trichloroethylene
TCEP	Tris(2-chloroethyl)phosphate
UC62	International system for Use Category grouping
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
vPvB	Very Persistent and very Bioaccumulative

1. Introduction

1.1 Background

Within the scope of CLP[1] and REACH[2], different types of legal interventions can be introduced for chemical substances, including Harmonised Classification & Labelling (CLH) (CLP Annex VI), identification as Substances of Very High Concern (SVHC) and thereby inclusion in the Candidate List and possible later inclusion in the Authorisation List (REACH Annex XIV), as well as Restrictions (REACH Annex XVII).

Substances with SVHC properties can in principle be subject to any of these types of legal interventions.

In the recent REACH review (EC, 2018), the European Commission concluded that the REACH authorisation procedure fulfils its purpose, the Candidate List being one of the main drivers for substitution, which begins as soon as the substance is identified as a SVHC and included in the Candidate List.

One challenge with the REACH authorisation procedure is that it is highly labour intensive for applicants (industry), as well as for authorities, including Member States, ECHA (European Chemicals Agency) Committees (RAC and SEAC), the ECHA secretariat, and the European Commission. Various parties have therefore attempted to investigate the effectiveness of the REACH authorisation process.

1.2 Objectives

The objective of the project is to analyse how tonnage data in the Nordic SPIN database[3] change *vis-a-vis* the timing of various legislative interventions under CLP and REACH with the aim of identifying the possible relative importance of such interventions on the tonnages used.

The results will be discussed and compared with the results of other studies that have analysed effects of CMR classification (or other SVHC identification), Candidate List inclusion and Annex XIV inclusion.

The results will feed into the authorities' discussions about cost-effectiveness of various types of legal interventions.

1.3 Scope and information sources

1.3.1 Substances

The project focuses on the 43 substances/substance groups included in the Authorisation List (REACH Annex XIV) as of November 2018.

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[1] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[3] Se reference: Substances in Preparations in Nordic Countries, norden, n.d.

1.3.2 Amounts/tonnage

As will be presented in Section 1.4, other studies have investigated various tonnage data to measure the effects of the REACH authorisation process. Those studies indicate that EUROSTAT/PRODCOM data are not specific enough and that REACH registration data are not sensitive enough for monitoring the effects of legal interventions due to infrequent registration updates. One study investigating SPIN data for three substances indicated that SPIN data might reveal more information.

The current project therefore investigates changes in amounts/tonnage as notified in the Nordic product registers and as available in the SPIN database for a larger number of substances.

The SPIN database contains non-confidential information from the Danish, Norwegian, Swedish, and Finnish product registers. A brief description of the scope of these registers can be found in Section 1.3.4.

1.3.3 Time aspects

At the time of the data analysis (November-December 2018), SPIN provided information from the time period 2000 to 2016.

Some of the substances on the REACH Authorisation List were classified prior to 2000. For these, the harmonised CLP classification triggering their CMR status under REACH is a 'translation' of their original cat. 1 or cat. 2 Carc., Mut. and/or Repr. classification under the previous classification system (according to Directive 67/548/EEC).

To analyse this further, the four Nordic product registers have been contacted in order to obtain pre-SPIN data; i.e. data from earlier than 2000. Within the time frame of the project, the Danish and the Swedish Product Registers have been able to provide data. However, as will be discussed in later chapters, only the Swedish data can be considered reliable for investigating possible changes caused by pre-2000 classifications.

1.3.4 Introduction to the Nordic Product Registers

This section provides a general description of the Danish, Swedish, Norwegian and Finnish product registers. The purpose is to give a general idea about the scope of the product registers, which differ slightly in scope across countries.

The Danish Product Register

The Danish Product Register was established in 1979.

The legal basis for the product register is a statutory order[4].

The register provides for notification/registration of certain chemicals imported to or manufactured in Denmark for industrial and professional purposes (i.e. used in 'occupational settings').

Hazardous chemical substances and mixtures need to be registered. For such products, information on non-classified ingredients must also be provided as part of the notification. Articles are outside the scope.

Several products regulated under other legislations are exempted: Food, pharmaceuticals, feed, cosmetics, waste, radioactive materials, and medical equipment.

[4] Statutory Order 1794 (2015) Bekendtgørelse om særlige pligter for fremstillere, leverandører og importører m.v. af stoffer og materialer efter lov om arbejdsmiljø

The tonnage trigger for registration of hazardous[5] mixtures is 100 kg per year per product. For notification of hazardous substances "as such" (i.e. alone and not as part of a preparation), the trigger was capped at 1000 kg/year in 2016 (i.e. notifications have to be made for amounts between 100 kg and 1000 kg/year). One thousand kg/year is equivalent to the lower REACH registration tonnage trigger. As this limit was introduced in January 2016, SPIN data from earlier years also cover notifications for substances in higher volumes.

The following types of information need to be provided to the register: Detailed information about composition, where the registered product is used (by identifying function and industry categories), classification and labelling information on mixture and components, and quantity of product.

Registrations are made online via a new web-based user interface, which was introduced on 1 April 2017.

Further information about the registry and how to register, including a guidance document, can be found here: http://engelsk.arbejdstilsynet.dk/en/produktregistret.

The Swedish Product Register

The Swedish Product Register was established in 1978. The legal basis for the register is the Swedish Environmental Code, chapter 14, 10-12 §§. These rules warrant that the government can enact rules on a product register. Such rules have been adopted in the Chemical Products and Biotechnical Ordinance[6]. This Ordinance in turn gives the Swedish Chemicals Agency authority to adopt implementing rules (§§25-26).

Chemical products (substances and mixtures) whose customs tariff numbers are on the list of customs numbers in Annex 1 to the Chemical Products and Biotechnical Organisms Ordinance must be notified/registered. This requirement basically covers all chemicals, as opposed to the Danish and Norwegian registers, where 'only' hazardous chemicals are within scope.

The company importing, manufacturing or transferring the chemical product is responsible for the notification/registration.

Products for occupational as well as for consumer use are within scope of registration. Articles are outside the scope of registration.

A few products regulated under other legislation are exempted: Waste, food, animal feed, medicinal products, cosmetics, and tattoo inks.

The tonnage trigger for registration is 100 kg per year per product, i.e. substances and mixtures.

Further information about the registry can be found here: https://www.kemi.se/produktregistret.

The Norwegian Product Register

The Norwegian Product Register was established in 1981 with the overall objective of monitoring chemicals on the market, performing risk analyses related to chemical substances, and dealing with acute situations using the data collected by the register.

[5] Including mixtures classified according to CLP, mixtures containing substances with a Danish Occupational Exposure Limit (OEL), and/or mixtures for which a Safety Data Sheet has to be provided.

[6] http://www.notisum.se/rnp/sls/lag/20080245.htm

The legal basis for the register is a regulation for the registration of chemicals with the product register[7].

Manufacturers or importers of chemicals (substances or mixtures) classified as hazardous must notify/register the chemical product (substance or mixture) with the Norwegian Product Register.

Occupationally applied and consumer products are within scope. The registration threshold is 100 kg per product per year.

A few products regulated under other legislation are exempted: Alcoholic beverages, waste, food, cosmetics, pharmaceuticals, medical devices, radioactive chemicals, and tobacco.

Further information on the product register can be found here: http://miljodirektoratet.no/en/Areas-of-activity1/Chemicals/The-Product-Register/Use-of-the-Data-in-the-Product-Register/.

The Finnish Chemical Products Register

The Finnish Chemical Products Register was established in 1979.

The legal basis for the product register is the Finnish Chemicals Act 599/2013. Further provisions on submitting information are given by a decree of the Ministry of Social Affairs and Health: Ministry of Social Affairs and Health Decree on submission of information on chemicals 553/2008, and Ministry of Social Affairs and Health Decree on submission of quantity information 1155/2011.

The register provides for notification/registration of chemicals imported to or manufactured in Finland for industrial and professional use and/or consumer uses. A chemical notification must be submitted about chemicals (substances and mixtures) that are classified as dangerous to health or the environment or as comprising a fire or explosion hazard. A notification must also be submitted about unclassified mixtures if they contain one or more substances that poses a risk to health or the environment, or a substance which has a European Community workplace exposure limit (in practice in all cases where SDS must be provided; obligatory or requested according to REACH Art 31).

Various products are exempted: chemicals used on an experimental basis in scientific research or product development, chemicals that do not pose a risk, articles, cosmetics, alcoholic beverages, waste, food, human and animal pharmaceuticals, and radioactive chemicals.

In provisions on submitting information given by a decree of the Ministry of Social Affairs and Health 553/2008, there are no amounts specified for which a chemical notification must be delivered. In the regulation 553/2008 it is stated: *"An exception to the notification duty are chemicals […] supplied in such small quantities that they do not pose a risk."* The tonnage trigger for providing amount information, according to the Ministry of Social Affairs and Health Decree on submission of quantity information 1155/2011, is 100 kg.

A chemical notification must include the data that is stated in the safety data sheet according to REACH Appendix II. In addition, the chemical notification shall provide use and industry categories. Quantity information about the products which have been on the market in Finland is gathered annually by The Finnish Chemicals and Safety Agency (Tukes).

Registrations have been made until the time of writing by e-mail correspondence (Tuoterekisteri@tukes.fi). There will be a new online system called “KemiDigi” in early 2019. Access to KemiDigi is granted through the Suomi.fi e-authorisation service. Further information

[7] https://lovdata.no/dokument/SF/forskrift/2015-05-19-541?q=deklareringsforskriften

about the registry and how to register can be found here: https://tukes.fi/en/chemicals/submitting-information-on-chemicals. More information about KemiDigi is available here: https://tukes.fi/en/article/-/asset_publisher/kemidigi-etenee-ja-kayttoonotto-lahenee.

1.4 Main conclusions from other studies

In this section, the main conclusions from other studies investigating the effects of the REACH authorisation procedure are summarised. These studies were generally commissioned by the EU and some of the results have been used in the REACH review (EC, 2018). The studies often combine data on use volumes with other information such as questionnaires and interviews with stakeholders.

1.4.1 Impacts of REACH Authorisation (EFTEC, 2017)

This study (also referred to in the REACH review) finds that the REACH authorisation process generally leads to substitution where technically feasible. The report sets out several drivers for these substitutions, with numerous case study examples. Below, some of the conclusions central to this study are summarised.

Legislative activities go long back

The report concludes that REACH authorisation is not the only reason for companies to substitute SVHCs, as some of the substances that are now subject to authorisation have also previously been in focus in other REACH and ECHA-related processes, such as classification or other regulation. Therefore, substitution-related activities may have been ongoing for many years for other reasons[8].

The announcement effect

The report describes evidence of the “announcement effect”. Below is a list of key actions that 56 respondents reported as being the most important legislative incentives:

Screening of substance and Risk Management Option Analysis (RMOA)	9 %
Inclusion of substance in Candidate List	43 %
Recommendation for inclusion of substance in Authorisation List (Annex XIV)	27 %
Inclusion of substances in Annex XIV	7%
Applications for authorisation (AfA)	11%
Post-authorisation decisions (e.g. after sunset date)	3 %

EuroStatistics and REACH registration data have limitations

The report found that Eurostat (PRODCOM) data showed that EU sales of SVHCs have generally followed the same market trend as the overall EU chemicals market. It was not possible to assess whether REACH authorisation has led to a reduction in EU sales of SVHCs and an increase in sales of alternative substances in line with the goal of the authorisation system. Important limitations in the usability of the data were that the codes for the substance in Eurostat are not similar to the way the substances are identified in the authorisation system. For those substances where a match could be made, much of the use reported to Eurostat was intermediate use. Moreover, data were only available until 2015.

The report also provides information retrieved from REACH registration data and concluded that these data were not particularly useful for observing trends. It was briefly noted, however, that in November 2016, ECHA had identified 103 registrants that had ceased manufacture or import of an SVHC, of which 69 occurred on the candidate list and 34 on the authorisation list. This note indicates that the authorisation procedure appears to have some effect, but also that even after a substance is placed on the Authorisation List, a significant number of registrations

[8] See also further discussion of this issue in Section 3.1.

remain, which may be due to the continued use of the substances for e.g. intermediate uses which are not subject to authorisation.

Drivers and barriers for substitution

The report assesses the importance of different drivers and barriers for substitution. Based on interviews with 61 respondents, the report concludes that the REACH authorisation process is clearly a main driver, particularly through the demand for assessing suitable alternatives in the application for authorisation. Other less important drivers are new opportunities on the market, financial savings, and legislation other than the authorisation scheme, including other REACH provisions. Barriers to substitution mainly include lack of technically and economically suitable alternatives that would be accepted on the market.

The report also highlights that successful substitution away from an SVHC can be time-consuming; therefore, it is likely still too early to observe changes in the EU market due to REACH authorisation. The report speculates that for those uses where authorisation has been granted for a review period, there could be increased demand/sales from the continued use of the SVHC after the sunset date.

In summary, many factors influence the quantities of SVHCs that are marketed and used, meaning that effects of the REACH authorisation cannot be seen in isolation.

1.4.2 Austrian study (Backes, 2017)

This study was instigated by ECHA's informal Risk Management and Evaluation platform for coordination between EU Member States and ECHA (the RiME group) with the aim of testing a methodology proposed by the Monitoring Task Force of RiME to measure if and how the objectives of the authorisation under REACH have been achieved. The study used SPIN data for several substances in combination with other sources of information, including REACH registration data and Eurostat data from the Commission's PRODCOM database.

It was concluded that the method was not sufficient to answer the questions posed regarding the effect of candidate listing and Annex XIV inclusion. The proposed methodology was largely based on the assumption that relatively simple indicators, mainly derived from REACH registration information, would provide useful quantitative figures. However, the project found that volume information is not regularly updated by REACH registrants, which means that there are systematic errors in the volume information, which would otherwise be a valuable indicator for measuring substitution progress. This lack of updating was concluded to likely be due to the fact that updates of tonnages in registration dossiers are only legally required if the tonnages increase up to the next tonnage band (REACH Article 22 (1c)).

The report provides data and discussion on several substances that shall not be summarised here. In short, selected substances, such as TCE, DEHP and DBP, are highlighted with the conclusion that *"the SPIN database shows, for a number of SVHCs, a significant decrease over the last years. Information on the three selected substances is seen to provide an excellent indicator for substitution progresses. The situation in Scandinavian countries is, however, not representative for the whole of Europe"*. Moreover, the report concludes that the most significant substitution effects in the Nordic region may be observed long before REACH came into force, so in those cases REACH policy has clearly not been the incentive for substitution.

Another remarkable result found in this project was the fact that for the selected SVHCs, the milestone "inclusion of a substance in the Candidate List" had no visible impact on substitution efforts and use volume (the only exceptions being the four lead compounds).

1.4.3 Study monitoring the impacts of REACH on innovation (CSES, 2015)

Based on interviews with industry representatives, CSES (2015) concludes that the relationship between a substance that has been identified as a SVHC and its respective Research and Development (R&D) funding is complex and varies across substances. Cobalt compounds and other high value-adding substances, for instance, might attract increased R&D investments. Others, such as arsenic by-products, may just be withdrawn. Interviewees indicated that companies would be less inclined to carry out additional R&D and just apply for authorisation when there are no substitutes readily available. Some substances have alternatives that run the risk of being added to the Candidate List in future, e.g. lead. For industries that use such substances, it may hinder investment. Placing a substance on the Candidate List may also reduce investors' interest; the study gives industrial gases as an example. Finally, industry representatives stated that finding suitable substitutes for some of the substances on the Candidate List was difficult, for example for those used in coatings and lubricants.

Whether REACH had triggered innovation, or whether it had a hampering effect, the study finds that industry representatives tend to hope for positive long-term results. However, in the short term, the compliance aspect (e.g. substituting with known substances with lower technical performance, but with fewer hazardous characteristics) was predominant. Some representatives further expressed that the existence of REACH provided an incentive for companies to look for options that do not include SVHCs. Consequently, research and innovation in industry towards safer and more environmentally friendly technologies might be facilitated.

1.4.4 REACH review (EC, 2018)

The REACH review mainly examines ways to improve identification processes and simplify procedures, but there are also references to key findings related to the system’s ability to act as a main driver for substitution.

The review states in the main conclusions (Doc 1, section 7) that there is a clear added value of the REACH authorisation’s process in progressively leading to identification and effective control of hazardous substances. In the more detailed discussion on innovation (doc 1, section 6.1.1.3.3), the 'Porter hypothesis' is quoted, which states that stricter environmental legislative requirements may encourage companies to increase spending on research programmes, thus acting as a trigger for innovation towards sustainability, which may provide first movers with competitive advantages. Authorisation affects the innovation activity as a driver for research to find alternative substances or technologies. However, some industry stakeholders highlighted that the authorisation process is slowing down product development and diverting resources from innovation that would improve competitiveness. Other expressed the view that the Candidate List and other instruments are increasing transparency and providing guidance for companies in research and development directions, which in turn may lead to safer and more environmentally friendly chemicals.

The review further concludes that REACH as a whole encourages substitution with safer substances, but it is difficult to attribute substitution effects strictly to REACH as substitution is also encouraged by other legislation (e.g. OSH) and supported by other drivers, such as consumer demands, market circumstances and other initiatives, for example the Substitution Support Portal (SUBSPORT) under the European Union’s Life programme.

The review states that there is not much evidence so far that chemical legislation in general terms is in itself a stimulus to more fundamental development of alternative technologies and substances, new business models and non-chemical solutions, as innovation is predominantly market driven.

When substitution is not possible, there is evidence from several applications that REACH authorisation has led to improved risk management, thereby reducing workers' exposure, which is one of the aims of the authorisation provisions (doc 1, section 5.6, EFTEC, 2017). However, negative effects of the authorisation scheme such as relocation of production to countries outside the EU and a competitive disadvantage compared to other regions have also been reported by companies.

In Annex 5, the review quotes the results of the business survey (CSES, 2015) which suggests that the inclusion of substances into the Candidate List acts an early driver for research to find alternative substances or technologies. From the sample of respondents affected by the inclusion of a substance in the Candidate List, about 9% mentioned initiatives to develop new substances and 30% launched initiatives to find alternative formulations. The response of companies to the inclusion of substances in Annex XIV (Authorisation List) was broadly similar.

The REACH review further quotes another study. Milieu et al. (2017) concludes that that the legislative requirements are seen as the main driver of substitution from a survey of Member State competent authorities, industry stakeholders and external consultants on developing a non-toxic environment strategy. Respondents indicated that placing a substance on the Candidate List for authorisation is the key mechanism that initiates the search for safer alternatives.

2. Methodology

This chapter presents the methodological steps and considerations applied in the project in order to obtain relevant illustrations of trends in amounts *vis-a-vis* the timing of legal interventions, to be analysed and discussed in Chapters 3 and 4.

2.1 Managing group entries

The Authorisation List includes group entries covering several individual substances. For these group entries, a number of individual substances pertaining to the groups (identified by CAS number, i.e. Chemical Abstracts Service number) have been identified based on substance groups cordially provided by ECHA or as listed on the ECHA website. The groups provided by ECHA originate from analyses of Authorisation List substances carried out by ECHA. Specific substances considered within the group entries are displayed in Table 1.

2.2 SPIN screening for relevant information

For the substances covered by individual entries or under group entries in the Authorisation List, a preliminary screening of information in SPIN was undertaken.

SPIN can only reveal non-confidential information. In the case of limited numbers of products in a given product category and/or a limited number of notifiers, the information is considered confidential and not provided by SPIN. Information might also be lacking for other reasons, such as erroneous notifications or if a given substance has been registered under a different CAS number. The latter is likely e.g. for UVCB substances[9] or for groups of similar substances.

The substances for which SPIN does not provide information on amounts applied were excluded during this screening step. See Table 3 for the list of deselected substances and the associated explanations for deselection.

2.3 Specification and Identification of Regulatory dates

For the substances analysed, the following 'regulatory dates' have been identified and applied:

- The date where the properties triggering that a given substance is a SVHC was regulatory assigned to the substance ("Trigger date")
- The date of inclusion in the Candidate List
- The date of inclusion in the Authorisation List.

The two latter dates are unambiguous, and they are relatively easily found on the ECHA website. These dates were, however, cordially provided by ECHA and taken from a previous similar ECHA activity.

The 'trigger date' is in the current study identified as follows:

- For CMR properties: The date where a harmonised classification equivalent with 'REACH CMR' properties was published in the Official Journal (Trigger date “C”, Trigger date “M”, Trigger date “R”, Trigger date “CM”, etc.). This corresponds to Carc., Mut. and/or Repr. cat. 1 or cat. 2, according to Directive 67/548/EEC or to cat. 1A or 1B if the substance obtained

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[9] Substance of Unknown or Variable composition, Complex reaction products or Biological materials

its harmonised classification for the given CMR property under CLP. For substances classified according to criteria in Directive 67/548/EEC, the dates have been identified via searches under 'Legal acts' in EUR-Lex[10] to identify the relevant ATP (Adaptation to Technical Progress). The harmonised classification for some substances has been adapted or altered several times in different ATPs. In these situations, the ATP first assigning a classification equivalent to 'REACH CMR' was identified.

- For PBT[11], vPvB[12] and similar concern (including endocrine disruption) properties: The 'RoI[13] date', i.e. the date when a Member State or ECHA registered its intention to propose a substance to be identified as an SVHC, was applied. It could be argued that an earlier date should be applied as there has been previous regulatory work and 'semi-authoritative' lists of PBTs and endocrine disrupters. However, such an approach would not yield unambiguous dates and it would be difficult to establish a consistent approach.

For substances with more than one property of high concern identified at different points in time, several trigger dates may apply. The dates in Table 1 (including application and sunset dates), and more specifically in Table 2, provide an overview of Trigger dates for CMRs and the associated identified legal act for the substances analysed in this project.

2.4 Comparison of dates and amounts

The 2000-2016 development of amounts per substance notified to the Nordic product registers are presented graphically with the regulatory dates being inserted. For some of the substances, relevant Swedish pre-SPIN data for the period 1992 to 1999 are included as well.

As amounts in the product registers are given per year and therefore cannot be used to distinguish between months within a year, regulatory dates are plotted for the year in which the regulatory date occurs. For example, for the same year, a regulatory date in February will be plotted in the same way as a date in November.

If there is more than one trigger date (i.e. for substances with multiple SVHC properties), multiple trigger dates are indicated.

For each graph, the effect of the regulatory interventions on the amounts notified to the product registers are initially analysed and discussed. Based on this initial analysis, the substances are grouped into categories indicating whether any trends are identified, and if so, the different types of trends.

To understand in more detail which uses/applications have been affected by legal interventions, underlying Industry Category (IC-NACE) and Use Category (UC62) data (as available in SPIN) are analysed for selected substances. For some of these, information on uses and applications in RMOAs[14], where provided by the Danish EPA, has been reviewed.

The substances analysed in more detail have been selected among those where the initial analysis indicated trends and where the Danish EPA has been able to make RMOAs available

[10] https://eur-lex.europa.eu/homepage.html?locale=en

[11] PBT: Persistent, Bioaccumulative and Toxic

[12] vPvB: very Persistent and very Bioaccumulative

[13] Registry of Intention

[14] Risk Management Option Analysis carried out by authorities prior to legal interventions.

within the time period of the project. The following substances are analysed in terms of IC-NACE[15] and UC62[16]:

- Bis(2-ethylhexyl) phthalate (DEHP), CAS no 117-81-7
- Benzyl butyl phthalate (BBP), CAS no 85-68-7
- Dibutyl phthalate (DBP), CAS no 84-74-2
- Diisobutyl phthalate (DIBP), CAS no 84-69-5
- Lead sulfochromate yellow (C.I. Pigment Yellow 34), CAS no 1344-37-2
- Lead chromate molybdate sulfate red (C.I. Pigment Red 104), CAS no 12656-85-8
- Tris(2-chloroethyl)phosphate (TCEP), CAS no 115-96-8
- 2,4-Dinitrotoluene, CAS no 121-14-2
- Trichloroethylene (TCE), CAS no 79-01-6
- Chromium trioxide, CAS no 1333-82-0
- Potassium dichromate, CAS no 7778-50-9.

The findings from this additional analysis are included in the substance-specific presentations and discussion in Section 3.2. The plots with UC (UC62 codes) and IC (NACE codes) can be found in Appendix 1. Not all UCs and ICs are included, but up to five codes representing the highest tonnage available in SPIN are included. In practice this method only leaves out minor uses.

[15] International system for Industrial Category grouping

[16] International system for Use Category grouping

Table 1. List of substances that are included in the Authorisation List. The table contains information on regulatory dates and other milestone dates. (RoI inclusion and trigger date: See explanation in Section 2.3; LAD: Latest Application Date; SD: Sunset date). * Denotes that the trigger date has not been identified as substance has been deselected due to lack of relevant SPIN data, see Section 2.2 and Table 3.

Entry No.	CAS no	Name	RoI inclusion	Trigger date (Property)	Candidate List	Authorisation List		
						Inclusion	LAD	SD
1	81-15-2	5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	13-05-2008	13-05-2008 (=RoI) (vPvB)	28-10-2008	17-02-2011	21-02-2013	21-08-2014
2	101-77-9	4,4'- Diaminodiphenylmethane	15-04-2008	19-12-1994 (C)	28-10-2008	17-02-2011	21-02-2013	21-08-2014
3	25637-99-4; 134237-52-8; 3194-55-6; 134237-50-6; 134237-51-7	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane.	08-05-2008	*	28-10-2008	17-02-2011	21-02-2014	21-08-2015
4	117-81-7	Bis(2-ethylhexyl) phthalate (DEHP)	08-05-2008	06-08-2001 (R)	28-10-2008	17-02-2011	21-08-2013	21-02-2015
5	85-68-7	Benzyl butyl phthalate (BBP)	30-04-2008	29-04-2004 (R)	28-10-2008	17-02-2011	21-08-2013	21-05-2015
6	84-74-2	Dibutyl phthalate (DBP)	30-04-2008	06-08-2001 (R)	28-10-2008	17-02-2011	21-08-2013	21-02-2015
7	84-69-5	Diisobutyl phthalate (DIBP)	09-02-2009	15-01-2009 (R)	13-01-2010	14-02-2012	21-08-2013	21-02-2015
8	1327-53-3	Diarsenic trioxide	29-04-2008	15-12-1998 (C)	28-10-2008	14-02-2012	21-11-2013	21-05-2015
9	1303-28-2	Diarsenic pentaoxide	29-04-2008	*	28-10-2008	14-02-2012	21-11-2013	21-05-2015
10	7758-97-6	Lead chromate	02-07-2009	19-12-1994 (R) 21-08-2008 (CR)	13-01-2010	14-02-2012	21-11-2013	21-05-2015
11	1344-37-2	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	02-07-2009	19-12-1994 (R) 21-08-2008 (CR)	13-01-2010	14-02-2012	21-11-2013	21-05-2015
12	12656-85-8	Lead chromate molybdate sulfate red (C.I. Pigment Red 104)	02-07-2009	19-12-1994 (R) 21-08-2008 (CR)	13-01-2010	14-02-2012	21-11-2013	21-05-2015
13	115-96-8	Tris(2-chloroethyl)phosphate (TCEP)	30-04-2008	15-01-2009 (R)	13-01-2010	14-02-2012	21-02-2014	21-08-2015
14	121-14-2	2,4-Dinitrotoluene	12-01-2009	29-04-2004 (C) 15-01-2009 (CM)	13-01-2010	14-02-2012	21-02-2014	21-08-2015
15	79-01-6	Trichloroethylene (TCE)	02-07-2009	06-08-2001 (C)	18-06-2010	17-04-2013	21-10-2014	21-04-2016
16	1333-82-0	Chromium trioxide	18-12-2009	30-07-1996 (C) 29-04-2004 (CM)	15-12-2010	17-04-2013	21-03-2016	21-09-2017
17	7738-94-5; 13530-68-2	Acids generated from chromium trioxide and their oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid.	27-08-2010	*	15-12-2010	17-04-2013	21-03-2016	21-09-2017
18		Sodium dichromate	29-04-2008	30-07-1996 (CM)	28-10-2008	17-04-2013	21-03-2016	21-09-2017

Entry No.	CAS no	Name	RoI inclu-sion	Trigger date (Property)	Candidate List	Authorisation List		
						Inclusion	LAD	SD
	7789-12-0; 10588-01-9			29-04-2004 (CMR)				
19	7778-50-9	Potassium dichromate	14-01-2010	30-07-1996 (CM) 29-04-2004 (CMR)	18-06-2010	17-04-2013	21-03-2016	21-09-2017
20	7789-09-5	Ammonium dichromate	14-01-2010	*	18-06-2010	17-04-2013	21-03-2016	21-09-2017
21	7789-00-6	Potassium chromate	14-01-2010	*	18-06-2010	17-04-2013	21-03-2016	21-09-2017
22	7775-11-3	Sodium chromate	14-01-2010	*	18-06-2010	17-04-2013	21-03-2016	21-09-2017
23	25214-70-4	Formaldehyde, oligomeric reaction products with aniline (technical MDA)	06-04-2011	19-12-1994 (C) (structurally re-lated to no 2)	19-12-2011	14-08-2014	22-02-2016	22-08-2017
24	7778-39-4	Arsenic acid	12-11-2010	*	19-12-2011	14-08-2014	22-02-2016	22-08-2017
25	111-96-6	Bis(2-methoxyethyl) ether	02-12-2010	*	19-12-2011	14-08-2014	22-02-2016	22-08-2017
26	107-06-2	1,2-Dichloroethane; ethylene dichloride	04-05-2011	01-09-1993 (C)	19-12-2011	14-08-2014	22-05-2016	21-11-2017
27	101-14-4	2,2'-dichloro-4,4'-methylenedianiline	20-07-2011	19-12-1994 (C)	19-12-2011	14-08-2014	22-05-2016	22-11-2017
28	24613-89-6	Dichromium tris(chromate)	20-04-2011	*	19-12-2011	14-08-2014	22-07-2017	22-01-2019
29	7789-06-2	Strontium chromate	23-11-2010	30-07-1996 (C)	20-06-2011	14-08-2014	22-07-2017	22-01-2019
30	11103-86-9	Potassium hydroxyoctaoxodizincatedichromate	20-04-2011	30-07-1996 (C)	19-12-2011	14-08-2014	22-07-2017	22-01-2019
31	49663-84-5	Pentazinc chromate octahydroxide	20-04-2011	30-07-1996 (C)	19-12-2011	14-08-2014	22-07-2017	22-01-2019
32	106-94-5	1-bromopropane; n-propyl bromide	10-08-2012	*	19-12-2012	13-06-2017	04-01-2019	04-07-2020
33	605-50-5	Diisopentylphthalate (DIPP)	19-04-2011	*	19-12-2012	13-06-2017	04-01-2019	04-07-2020
34	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	25-10-2010	21-08-2008 (R)	20-06-2011	13-06-2017	04-01-2019	04-07-2020
35	68515-42-4	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	04-10-2010	29-04-2004 (R)	20-06-2011	13-06-2017	04-01-2019	04-07-2020
36	84777-06-0	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	27-02-2012	*	19-12-2012	13-06-2017	04-01-2019	04-07-2020
37	117-82-8	Bis(2-methoxyethyl) phthalate (DMEP)	08-02-2011	30-07-1996 (R)	19-12-2011	13-06-2017	04-01-2019	04-07-2020
38	131-18-0	Dipentyl phthalate (DPP)	09-11-2011	29-04-2004	20-06-2013	13-06-2017	04-01-2019	04-07-2020
39	776297-69-9	N-pentyl-isopentylphthalate	06-08-2012	*	19-12-2012	13-06-2017	04-01-2019	04-07-2020
40	90640-80-5	Anthracene oil	09-02-2009	*	13-01-2010	13-06-2017	04-04-2019	04-10-2020

Entry No.	CAS no	Name	RoI inclusion	Trigger date (Property)	Candidate List	Authorisation List		
						Inclusion	LAD	SD
41	65996-93-2	Pitch, coal tar, high temp.	27-06-2008	19-12-1994 (C) 27-06-2008 (=RoI) (PBT vPvB)	13-01-2010	13-06-2017	04-04-2019	04-10-2020
42	2315-67-5; 2315-61-9; 9002-93-1; 2497-59-8	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (4-tert-Octylphenol ethoxylates)	14-06-2012	14-06-2012 (=RoI) (ED)	19-12-2012	13-06-2017	04-06-2019	04-01-2021
43	104-35-8; 7311-27-5; 14409-72-4; 20427-84-3; 26027-38-3; 27942-27-4; 34166-38-6; 37205-87-1; 127087-87-0; 156609-10-8	4-Nonylphenol, branched and linear, ethoxylated (NPE)	04-01-2013	04-01-2013 (=RoI) (ED)	20-06-2013	13-06-2017	04-07-2019	04-01-2021

Table 2. List of substances from the Authorisation List where there are SPIN data available and information on their SVHC property and the ATP where these were adopted (ATP: Adaptation to Technical Progress).

Entry No.	CAS no	Name	SVHC property	Harmonised Classification	Classification	Translated[17]	ATP for CMR ('RoI' for PBT, vPvB and similar concern)
1	81-15-2	5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	vPvB	29-04-2004	Carc. Cat. 3; R40	Car. 2	Commission Directive 2004/73/EC
				08-10-2008	vP and vB		RoI
2	101-77-9	4,4'- Diaminodiphenylmethane	Carcinogenic	19-12-1994	Carc. Cat. 2; R45	Carc. 1B	Commission Directive 94/69/EC
				19-05-2000	Carc. Cat. 2; R45& Muta. Cat. 3; R40	Carc. 1B& n/a	Commission Directive 2000/32/EC
				29-04-2004	Carc. Cat. 2; R45& Muta. Cat. 3; R68	Carc. 1B& Muta. 2	Commission Directive 2004/73/EC
4	117-81-7	Bis(2-ethylhexyl) phthalate (DEHP)	Toxic for reproduction	06-08-2001	Repr. Cat. 2; R60-61	Repr. 1B	Commission Directive 2001/59/EC
5	85-68-7	Benzyl butyl phthalate (BBP)	Toxic for reproduction	29-04-2004	Repr.Cat.2; R61& Repr.Cat.3; R62	Repr. 1B	Commission Directive 2004/73/EC
6	84-74-2	Dibutyl phthalate (DBP)	Toxic for reproduction	06-08-2001	Repr. Cat. 2; R61& Repr. Cat. 3; R62	Repr. 1B	Commission Directive 2001/59/EC
7	84-69-5	Diisobutyl phthalate (DIBP)	Toxic for reproduction	15-01-2009	Repr. Cat. 2; R61& Repr. Cat. 3; R62	Repr. 1B	Commission Directive 2009/2/EC
8	1327-53-3	Diarsenic trioxide	Carcinogenic	15-12-1998	Carc. Cat. 1; R 45	Carc. 1A	Commission Directive 98/98/EC
10	7758-97-6	Lead chromate	Carcinogenic Toxic for reproduction	19-12-1994 30-07-1996 15-12-1998	Carc. Cat. 3; R40& Repr. Cat. 1; R61& Repr. Cat. 3; R62	Carc. 2& Repr. 1A	Commission Directive 94/69/EC Commission Directive 96/54/EC Commission Directive 98/98/EC
				21-08-2008	Carc. Cat. 2; R45& Repr. Cat. 1; R61& Repr. Cat. 3; R62	Carc. 1B& Repr. 1A	Commission Directive 2008/58/EC
11	1344-37-2	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	Carcinogenic Toxic for reproduction	19-12-1994 15-12-1998 19-05-2000	Carc. Cat. 3; R 40& Repr. Cat. 1; R 61& Repr. Cat. 3; R 62	Carc. 2& Repr. 1B	Commission Directive 94/69/EC Commission Directive 98/98/EC Commission Directive 2000/32/EC
				21-08-2008	Carc. Cat. 2; R45& Repr. Cat. 1; R61& Repr. Cat. 3; R62	Carc. 1B& Repr. 1A	Commission Directive 2008/58/EC
12	12656-85-8	Lead chromate molybdate sulfate red (C.I. Pigment Red 104)	Carcinogenic Toxic for reproduction	19-12-1994 15-12-1998 19-05-2000	Carc. Cat. 3; R 40& Repr. Cat. 1; R 61& Repr. Cat. 3; R 62	Carc. 2& Repr. 1A	Commission Directive 94/69/EC Commission Directive 98/98/EC Commission Directive 2000/32/EC

[17] see translation list https://echa.europa.eu/regulations/clp/legislation

Entry No.	CAS no	Name	SVHC property	Harmonised Classification	Classification	Translated[17]	ATP for CMR ('RoI' for PBT, vPvB and similar concern)
				21-08-2008	Carc. Cat. 2; R45& Repr. Cat. 1; R61& Repr. Cat. 3; R62	Carc. 1B& Repr. 1A	Commission Directive 2008/58/EC
13	115-96-8	Tris(2-chloroethyl)phosphate (TCEP)	Toxic for reproduction	15-12-1998	Carc. Cat. 3; R40	Carc. 2	Commission Directive 98/98/EC
				15-01-2009	Carc. Cat. 3; R40& Repr. Cat. 2; R60	Carc. 2& Repr. 1B	Commission Directive 2009/2/EC
14	121-14-2	2,4-Dinitrotoluene	Carcinogenic	29-04-2004	Carc. Cat. 2; R45& Muta. Cat. 3; R68& Repr. Cat. 3; R62	Carc. 1B& Muta. 2& Repr. 2	Commission Directive 2004/73/EC
				15-01-2009	Carc. Cat. 2; R45& Muta. Cat. 3; R68& Repr. Cat. 3; R62	Carc. 1B& Muta. 1B& Repr. 2	Commission Directive 2009/2/EC
15	79-01-6	Trichloroethylene (TCE)	Carcinogenic	30-07-1996	Carc. Cat. 3; R 40	Carc. 2	Commission Directive 96/54/EC
				06-08-2001	Carc. Cat. 2; R45& Muta. Cat. 3; R68	Carc. 1B& Muta. 2	Commission Directive 2001/59/EC
16	1333-82-0	Chromium trioxide	Carcinogenic Mutagenic	30-07-1996	Carc. Cat. 1; R 49	Carc. 1A	Commission Directive 96/54/EC
				29-04-2004	Carc. Cat. 1; R45& Muta. Cat. 2; R46& Repr. Cat. 3; R62	Carc. 1A& Muta. 1B& Repr. 2	Commission Directive 2004/73/EC
18a&b	7789-12-0 10588-01-9	Sodium dichromate	Carcinogenic Mutagenic Toxic for reproduction	30-07-1996	Carc. Cat. 2; R 49& Muta. Cat. 2; R 46	Carc. 1B& Muta. 1B	Commission Directive 96/54/EC
				29-04-2004	Carc. Cat. 2; R45& Muta. Cat. 2; R46& Repr. Cat. 2; R60-61	Carc. 1B Muta. 1B& Repr. 1B	Commission Directive 2004/73/EC
				15-01-2009 (only 32b)			Commission Directive 2009/2/EC
19	7778-50-9	Potassium dichromate	Carcinogenic Mutagenic Toxic for reproduction	30-07-1996	Carc. Cat. 2; R 49& Muta. Cat. 2; R 46	Carc. 1B& Muta. 1B	Commission Directive 96/54/EC
				29-04-2004	Carc. Cat. 2; R45& Muta. Cat. 2; R46& Repr. Cat. 2; R60-61	Carc. 1B& Muta. 1B& Repr. 1B	Commission Directive 2004/73/EC
23	25214-70-4	Formaldehyde, oligomeric reaction products with aniline (technical MDA)	Carcinogenic	19-12-1994	Carc. Cat. 2; R45	Carc. 1B	Commission Directive 94/69/EC
26	107-06-2	1,2-Dichloroethane; ethylene dichloride	Carcinogenic	01-09-1993		Carc. 1B	Commission Directive 93/72/EEC
27	101-14-4	2,2'-dichloro-4,4'-methylenedianiline	Carcinogenic	19-12-1994	Carc. Cat. 2; R45	Carc. 1B	Commission Directive 94/69/EC
29	7789-06-2	Strontium chromate	Carcinogenic	30-07-1996	Carc. Cat. 2; R 45	Carc. 1B	Commission Directive 96/54/EC
30	11103-86-9	Potassium hydroxyoctaoxodizincatedichromate	Carcinogenic	30-07-1996	Carc. Cat. 1; R 45	Carc 1A	Commission Directive 96/54/EC

Entry No.	CAS no	Name	SVHC property	Harmonised Classification	Classification	Translated[17]	ATP for CMR ('RoI' for PBT, vPvB and similar concern)
31	49663-84-5	Pentazinc chromate octahydroxide	Carcinogenic	30-07-1996	Carc. Cat. 1 R 45	Carc. 1A	Commission Directive 96/54/EC
34	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	Toxic for reproduction	21-08-2008	Repr. Cat. 2; R61	Repr. 1B	Commission Directive 2008/58/EC
35	68515-42-4	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	Toxic for reproduction	29-04-2004	Repr. Cat. 2; R61& Repr. Cat. 3; R62	Repr. 1B	Commission Directive 2004/73/EC
37	117-82-8	Bis(2-methoxyethyl) phthalate (DMEP)	Toxic for reproduction	30-07-1996	Repr. Cat. 2; R61& Repr. Cat. 3; R62	Repr. 1B	Commission Directive 96/54/EC
41	65996-93-2	Pitch, coal tar, high temp.	Carcinogenic PBT vPvB	19-12-1994	Carc. Cat. 2; R 45	Carc. 1B	Commission Directive 94/69/EC
				16-12-2008			RoI
42	9002-93-1	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (4-tert-Octylphenol ethoxylates)	Endocrine disrupting properties	14-06-2012			RoI
43a	26027-38-3	4-Nonylphenol, branched and linear, ethoxylated (NPE)	Equivalent level of concern having probable serious effects to environment	04-01-2013			RoI
43b	37205-87-1						
43c	127087-87-0						

Table 3. List of substances from the Authorisation List that were excluded from this analysis because of limited data availability in the SPIN database.

#	CAS no	Name	Reason for exclusion
3	25637-99-4; 134237-52-8; 3194-55-6; 134237-50-6; 134237-51-7	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane.	No data available or data are confidential
9	1303-28-2	Diarsenic pentaoxide	Most data are confidential
17	7738-94-5; 13530-68-2	Acids generated from chromium trioxide and their oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid.	
20	7789-09-5	Ammonium dichromate	Data are confidential
21	7789-00-6	Potassium chromate	Most data are confidential
22	7775-11-3	Sodium chromate	
24	7778-39-4	Arsenic acid	Data are confidential
25	111-96-6	Bis(2-methoxyethyl) ether	Most data are confidential
28	24613-89-6	Dichromium tris(chromate)	
32	106-94-5	1-bromopropane; n-propyl bromide	
33	605-50-5	Diisopentylphthalate (DIPP)	Data are confidential
36	84777-06-0	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	
38	131-18-0	Dipentyl phthalate (DPP)	Most data are confidential
39	776297-69-9	N-pentyl-isopentylphthalate	No data available
40	90640-80-5	Anthracene oil	Most data are confidential

3. Results and discussion

For the substances for which SPIN provides relevant information on notified amounts, the current chapter presents and discusses the corresponding plots including amount per year and the regulatory dates. In addition, plots showing development in terms of number of preparations in which the substance occurs will be provided. Please note that in this chapter, the SPIN terminology "preparation" is used for what under CLP and REACH terminology would be termed “mixtures”.

As uncertainties are associated with the chosen data sources, these uncertainties will first be described as it is important to have these in mind as a background when analysing the data.

3.1 Uncertainties related to the type and choice of data sources

3.1.1 Notified tonnages as an indicator

The project analyses tonnage (and number of preparations) notified. Tonnage is a crude proxy for exposure and for risk. A decrease in the tonnage is therefore only an indirect indication of decrease in exposure and risk.

When analysing the tonnage data, it shall be taken into account that many of the substances on the Authorisation List have been in regulatory focus for several years and that legislation other than REACH authorisation and CLP affects trends in use volumes. For example, when a substance is classified as having CMR (cat 1A and 1B) properties, it will be banned in mixtures sold to the general public, according to REACH Annex XVII entry 28-30. This provision has also been in place in previous legislation since 1994. Hazard classification also triggers consequences on substances’ use in the working environment, such as the provisions of the Carcinogens and Mutagens Directive[18] (CMD), and in downstream legislation such as the Toys Directive[19] and the Cosmetics Regulation[20], both restricting the use of CMR-substances.

Furthermore, variations in tonnage might not only be triggered by legal interventions, but also by other factors and events such as the financial crisis of 2008. Furthermore, innovation, market pressure (from downstream users and consumers), and voluntary agreements between authorities and specific industries may lead to substitution. The latter factors and events may constitute an indirect result of CLP or REACH but might also be triggered by other factors. See also considerations in other studies on these issues in Section 1.4.

It should be noted that these uncertainties would be the same if tonnages registered under REACH were analysed. It should also be noted that this and other studies discussed in Section 1.4 have mainly focused on substances and preparations and not on the presence of SVHC in articles affected by REACH Article 33.

[18] Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

[19] Directive 2009/48/EC on the safety of toys

[20] Regulation (EC) No 1223/2009 on cosmetic products

3.1.2 Nordic product register data

The Nordic countries providing data for the SPIN database may not be representative for the EU average. It may, however, still be possible to see trends in data from SPIN; the approach applied in this project is therefore considered relevant, although generalisations as regards the EU level should be made with care.

As can be seen in the Section 1.3.4, the four Nordic product registers have scopes differing from REACH, e.g. in terms of tonnage triggers and which substances are included and which are exempted. Moreover, these scopes differ between the Nordic Product Registers, e.g. in terms of whether substances and mixtures used for consumer products are included or not. Tonnages notified might therefore, to some extent, miss substances within the scope of REACH and/or include substance outside the scope of REACH.

Furthermore, Nordic product register tonnage data from Denmark, Norway and Sweden represent use (i.e. import plus manufacturing minus export) for each individual country. The export tonnages extracted may represent export to other EU countries or to countries outside the EU. One consequence of this situation would be that large amounts are imported as substances to one of the Nordic countries, incorporated into a mixture, and eventually exported to another EU country. This flow would still be REACH-relevant, but the volume would not appear in the statistics as it is first added as an imported tonnage and then subtracted as an exported tonnage. This approach may also lead to negative values for certain years, where there may be greater export than import/manufacture for that year because of stock of the substance. It should be noted that export is not subtracted in the Finnish product register data; therefore, tonnages for Finland represent manufacture plus import.

It should also be considered that amounts of substances in preparations in some situations can be notified as a range. The possible size of this range varies among countries, and may vary depending on type of substance, type of mixture, and classification. Overall, however, all four Nordic product registers have confirmed that data on amounts of a given substance are calculated based on the upper end of the notification interval. Thus, total amounts in SPIN are overestimated, but as the same approach has been taken over the years, it is assumed that it would generally not affect possible trends in amounts.

The four product registers currently require that notifiers update their notifications yearly or, for the Danish Product Register, every second year. Still, however, it cannot be ruled out that there may be delays as to when the notifiers update their notifications with the correct tonnages. It may also be the case that the contents of products (formulations) are not always regularly updated.

The Danish Product Register has stated that the mandatory requirement for updates was introduced with effect from the 2004/2005 notifications. Thus, prior to this date, tonnages were not regularly updated, meaning that products on the market could be used in greater or lesser amounts than what was in the system, including products no longer on the market that were still listed in the product register. Therefore, Danish SPIN data before 2004/2005 are associated with high uncertainty, and following dialogue with the Product Register, it was recommended not to include the requested pre-SPIN data in the current project.

The Norwegian Product Register has stated that due to transfer to a new database system in 2015, some challenges with units occurred (kg vs. tons) meaning that some SPIN data entries from the year just before and after (2014 to 2016) may be incorrect.

The Swedish product register has provided data beyond SPIN, back to 1992. The register notes that data from 1992-1994 may be associated with uncertainty as the tonnage registration system was built during those years.

The Finnish Chemical Product Register has stated that 2001 data are associated with high uncertainty and that those data are normally disregarded when Finnish authorities analyse Finnish product register data. This issue has been taken into account when analysing the data in the current report.

Finally, as will be seen in the graphs below, SPIN data for some countries for certain years appear very different from the year before and the year after. There is no unambiguous explanation available for the reason for such significant deviations (possible outliers) but possible causes include typing mistakes in the national notifications, mistakes occurring during the transfer of data from the national registers to SPIN, or companies increasing or using their stocks.

3.1.3 Other uncertainties

As noted previously, we have only been able to obtain relevant product register data from the 'pre-SPIN' period (before 2000) from Sweden within the time frame of the project. Conclusions referring to pre-2000 are therefore only based on Swedish data.

It is important to keep in mind when interpreting the following results that after REACH took form and entered into force in the mid-2000s, companies have been aware that a CMR classification would likely lead to inclusion in the Candidate List and possibly in REACH Annex XIV. Given this integrated association between the regulatory dates, it can be difficult to separate the effect of a CMR classification from the effect of candidate listing and Annex XIV inclusion for the period after about 2005.

All in all, there are many uncertainties related to the use of SPIN data and to the methodological approach. However, it cannot be concluded that data from the SPIN database cannot be used for observing trends. However, the uncertainties listed are reflected in the cautious analysis of the data in the following sections and in the discussion and conclusions in Chapters 4 and 5.

3.2 Presentation and discussion of SPIN data vs regulatory dates for each substance

Comments on the individual plots

For substances retained in the assessment, the following paragraphs present plots with the trends in reported SPIN data for the period 2000-2016 for Denmark, Sweden (also, where available, data from 1992-1999), Norway, and Finland. However, data are not always available for all countries. The plots also indicate the year for each of the regulatory dates: Trigger date, candidate listing and inclusion into REACH Annex XIV. For each substance, an initial analysis and assessment of data are given, including whether one or more of the regulatory dates appear to have led to reduction in use.

The assessments and interpretations of the plots constitute simple basic visual examination addressing how the use pattern develops before and after each regulatory date in each country. In addition to the plots, the report authors have also inspected the corresponding tables with actual notified data for each year for each substance by country (available in SPIN). For some substances, this has enabled more detailed judgement, particularly as regards the low tonnages, than if only the plots were investigated. Overall, the interpretations and discussions are based on expert judgement, including discussion with Danish EPA desk officers. This approach has also been applied to identify possible outliers.

A more sophisticated approach employing statistical methods was considered but discarded for a number of reasons. The data were considered unsuitable for statistical analysis as this would require indexing of both the volumes and the time between the regulatory dates, which are both sometimes zero. Furthermore, in discussing the nature and uncertainties of the data (Section 3.1) and the corresponding plots with statisticians, no consistent approach for such an analysis was identified.

In addition to plots with amounts (in tonnes/year), the development in the number of preparations containing the substance (also provided in SPIN) is also presented. However, the data for preparations are only used as supporting indications in the description of the trends for a few substances, as the total volume on the market is considered more interesting from an environmental and health perspective.

As described under the methodology section, additional analysis of use and industry category data and RMOA information has been carried out for a selected number of substances. The relevant discussion is included under the substances selected for such additional analysis.

The numbers in the headline (and therefore the order in which substances are discussed) relate to the entry number in Annex XIV as shown on ECHA's website (https://echa.europa.eu/da/authorisation-list).

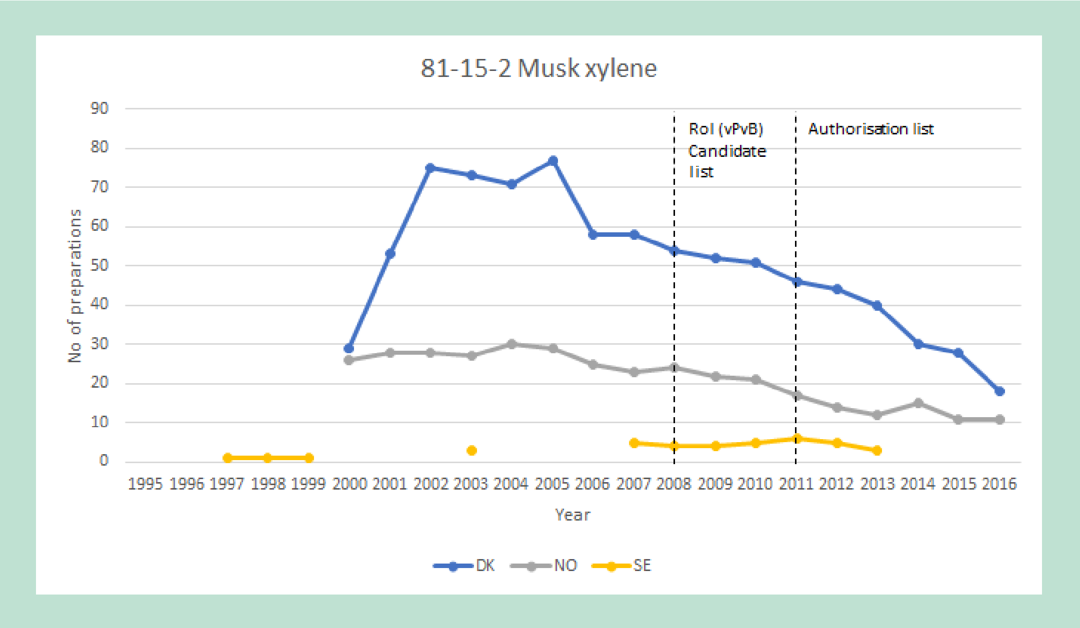

FIGURE 1. CAS no 81-15-2, 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)

The volume of use of this substance is reported as zero in Denmark, Sweden and Norway throughout the period and data are missing for Finland. Therefore, musk xylene is not suitable for the analysis of the impact of the various legal interventions.

However, the use of preparations containing this substance is reported for Denmark, Norway and Sweden. The general trend is decreasing numbers of preparations during the period. As no applications for REACH authorisation have been submitted for musk xylene, musk xylene might be used in applications for which no authorisation is required. The very low volumes indicate that musk xylene is used in very low percentages in products or that data on tonnage are confidential.

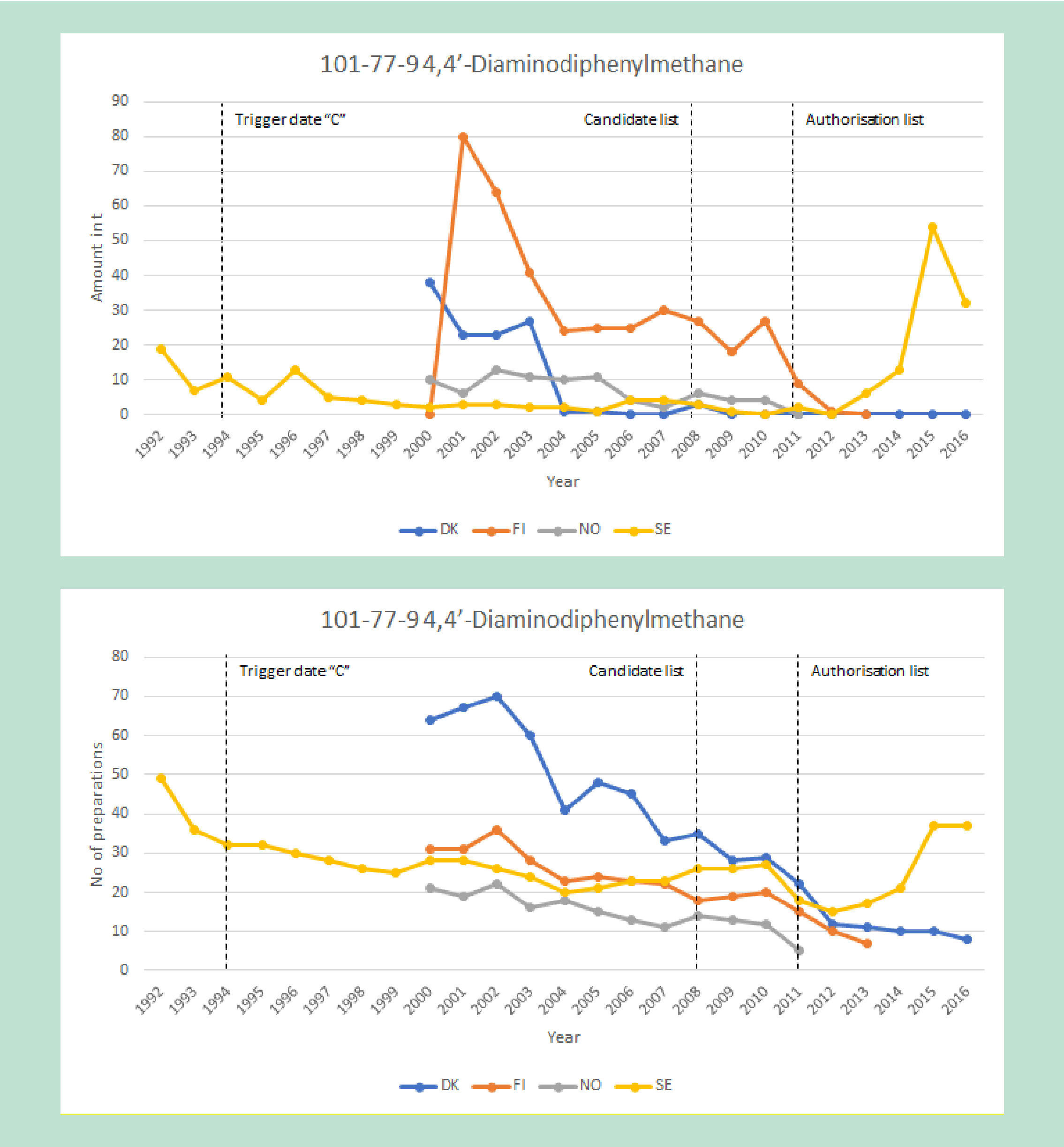

FIGURE 2. CAS no 101-77-9, 4,4'- Diaminodiphenylmethane

In Denmark, the volume of use of this substance decreased from 38 (year 2000) to zero t/yr in 2006; in Norway amounts approached zero t/yr in 2011, and in Sweden, use reached zero t/yr in 2012, but increased in subsequent years. In Finland, a decrease from 2001 is seen; therefore, the amount of zero t/yr in 2000 is assumed to be an error.

The pre-2000/pre-SPIN data from Sweden indicates that the first trigger date in 1994 for the substance had an effect, although according to the Swedish Product Register, data from 1992-1994 should be interpreted with care. Moreover, the continued regulatory focus seems to have led to further reduction in use as the amount reached zero t/yr in Denmark, Finland, and Norway. However, for Sweden – after reaching zero - new use of up to 54 t/yr has been reported to SPIN after 2012. The increase in amounts from 2000 to 2001 in Finland seems unlikely; the 2000 figure could indicate a notification or an error when transferring data to SPIN. The sudden increase in Sweden after 2012 could also signify a mistake; however, the figures are supported by an increase in the number of preparations, so the likelihood is that a new use has begun in recent years. This observation does not necessarily rule out that continued regulatory attention has had an effect on use, as a decreasing trend in tonnage can be seen in the other countries.

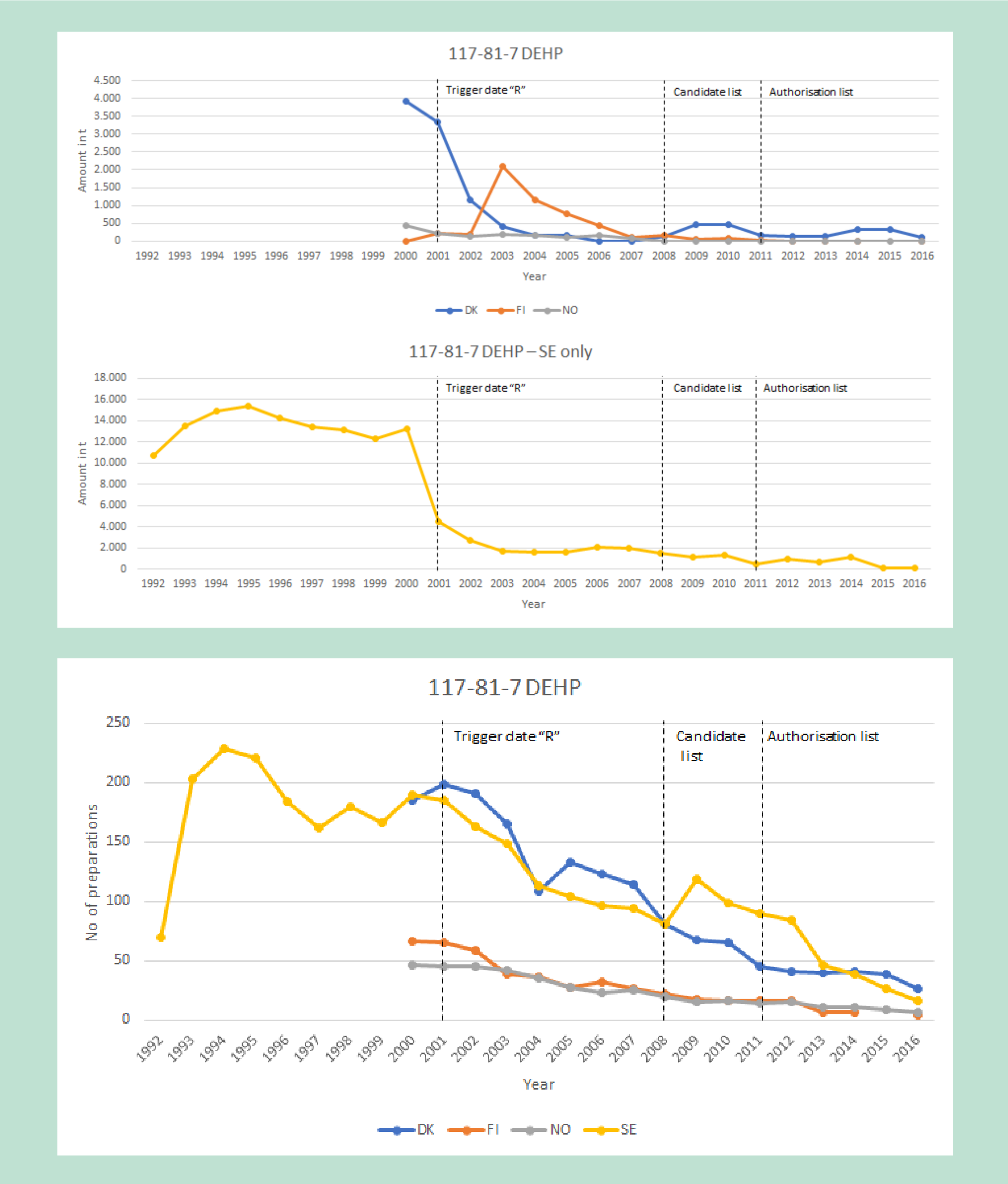

FIGURE 3. CAS no 117-81-7, Bis(2-ethylhexyl) phthalate (DEHP)

There is a clear decrease in the use of DEHP in Denmark, Sweden and Norway in the given period, as well as a significant decrease for amounts used in Sweden prior to the SPIN reporting period. There is also a clear decrease in all countries in the beginning of the reporting period, although in Finland this decrease occurs only from 2003. In the pre-SPIN Swedish data, a sharp decline before the trigger date is seen. Therefore, DEHP appears to be an example of a substance where the first trigger (i.e. harmonised classification for reprotoxicity) – together with much political focus and market pressure to substitute DEHP as a softener in PVC - exerted significant influence on use. The continued focus may have caused sustained reduction in use, as indicated by the decline in number of preparations.

Six applications for REACH authorisation had been submitted by December 2016 (Backes, 2017).

From the IC-UC plots shown in Appendix 1, it can be clearly seen that the significant drop in amounts used in the early 2000s is associated with "Manufacture of rubber and plastic products" when analysing the IC-NACE codes and as "Softeners" when analysing the UC62 codes. This drop appears to have occurred because of substitution of DEHP as softener in flexible PVC.

Other uses, although at much lower volumes than those applied for softening PVC and which have also declined to low levels at present, are mainly covered by the generic IC-NACE code "Manufacture of chemicals and chemical products" and UC62 codes "Fillers" (for Denmark) and "Paint, lacquers and varnishes" (for Norway).

These findings are in line with information in the RMOA for 'the four phthalates'[21] which lists numerous applications of phthalates for (flexible) PVC and use in lacquers for wooden floors and furniture.

[21] DEHP, BBP, DBP and DIBP.

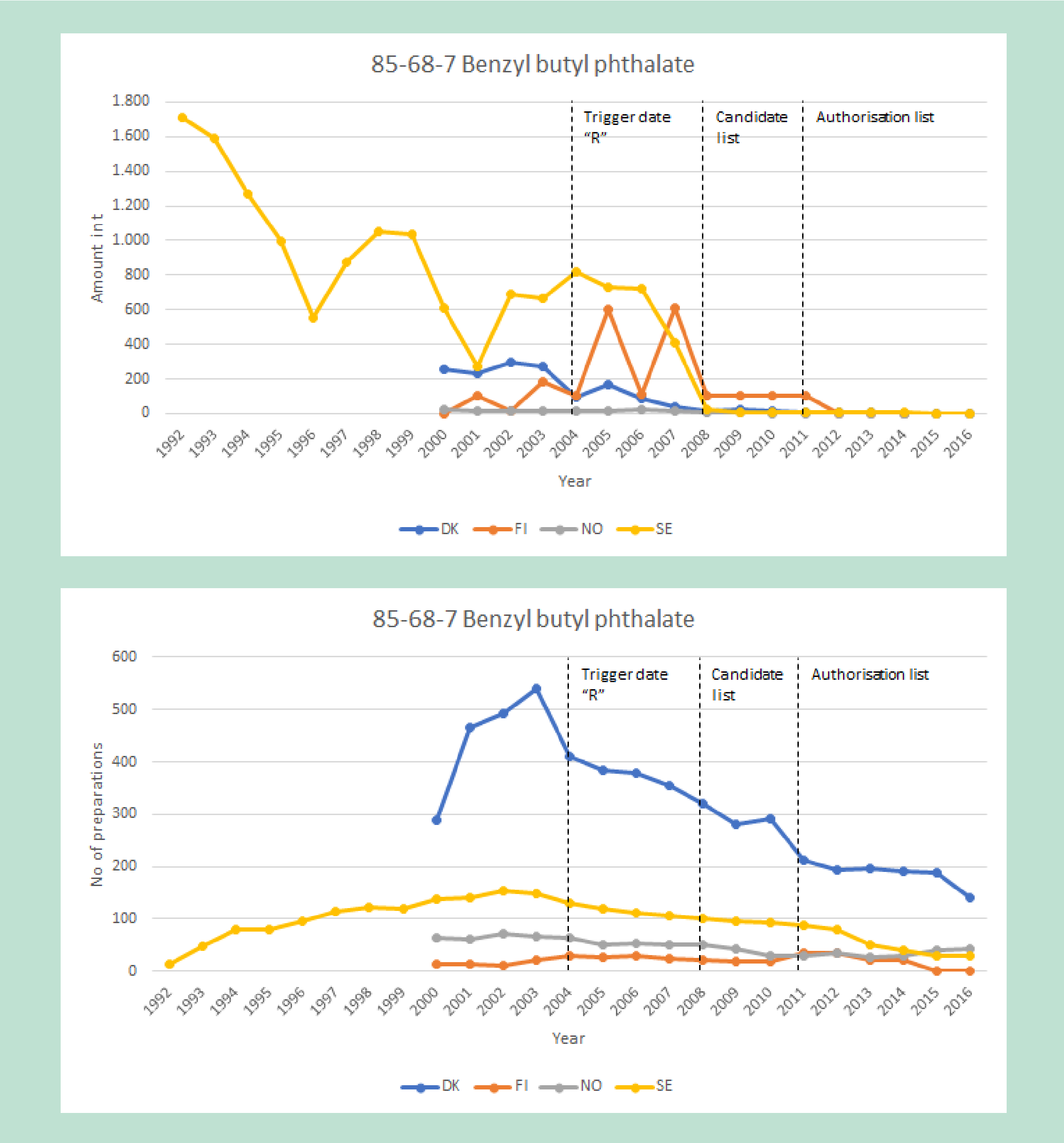

FIGURE 4. CAS no 85-68-7, Benzyl butyl phthalate (BBP)

In Sweden and Denmark, the volume of use of this substance was decreasing before and after the trigger date. In Norway the volume was close to zero t/yr for the whole period, and in Finland the volume reached zero t/yr after inclusion in Annex XIV.

BBP is an example of a substance where candidate listing and inclusion in Annex XIV seems to have affected use patterns in all countries**.** The volume is reported as zero t/yr in all countries after inclusion in Annex XIV**.**

No application for REACH authorisation was made for this substance by the deadline (Latest Application Date, LAD) in 2013 and therefore it was not permitted in non-authorised uses after 2015. There are still some preparations reported, which could be attributable to lack of updates or uses that do not require authorisation, such as in R&D.

The IC-UC plots in Appendix 1 provide no clear picture. Uses seem to fluctuate in most countries, although there is a declining trend after 2010. IC-NACE codes indicate the following main uses: "Construction" (Denmark and Norway), "Manufacture of rubber and plastic products"

(Denmark), "Manufacture of chemicals and chemical products" (Denmark and Sweden), "Manufacture of furniture, manufacturing n.e.c." (Finland), and "Sale, maintenance and repair of motor vehicles and motorcycles…" (Norway). UC62 codes indicate the following main applications: "Softeners" (Sweden), "Fillers" (Denmark and Norway), "Paints, lacquers and vanishes" (Denmark and Norway) and "Others" (Denmark, Finland and Sweden).

These UC and IC categories are, to some extent, in line with uses/applications listed in the RMOA (similar to DEHP, i.e. uses for flexible PVC and for lacquers), but could also indicate a wider application area that cannot be specified further than the relatively generic codes such as "Others".

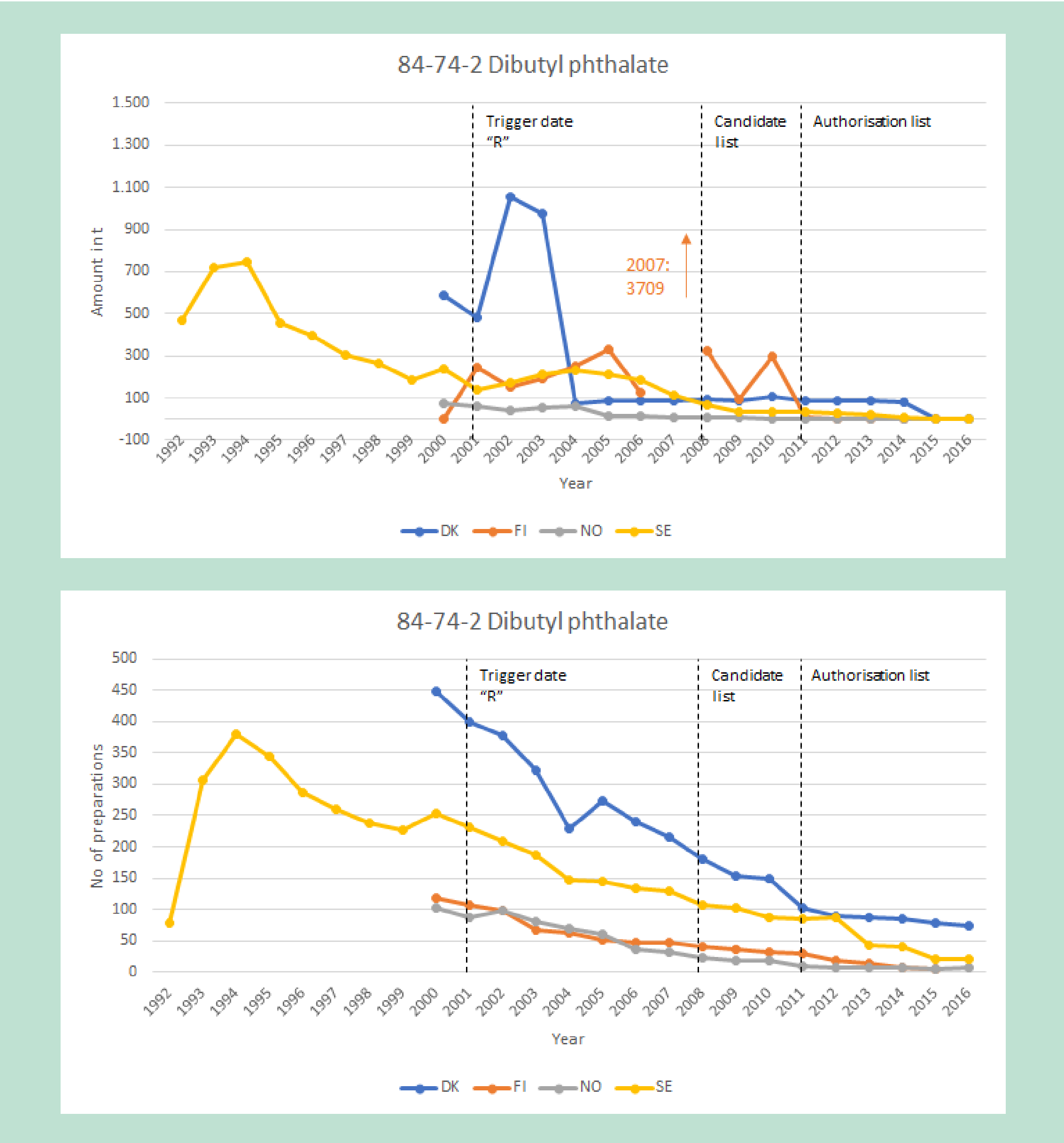

FIGURE 5. CAS no 84-74-2, Dibutyl phthalate (DBP)

Overall, data do not appear to indicate a drop in use of this substance following the classification trigger data. Volumes, however, seem to decline when approaching the candidate listing date, except for Finland. Finland apparently had high use in 2007, but this may indicate an outlier (possibly an erroneous notification) as 2006 and 2008 volumes are much lower. In subsequent years, the use in Finland drops to close to zero.

Classification in 2001 may have had a delayed effect on the use pattern, but the continued focus may have led to further reduction to very low volumes. The use pattern for numbers of preparations support this assumption.

Five applications for dibutyl phthalate for seven uses have been submitted only for industrial uses, which may explain the number of preparations still on the market.

The IC-UC plots in Appendix 1 inhibit clear conclusions. IC-NACE codes indicate the following main uses: "Manufacture of chemicals and chemical products" (Denmark, Norway and Sweden), "Manufacture of rubber and plastic products" (Finland and to some extent Denmark and Norway), "Construction" (Denmark and to some extent Norway and Sweden) and "Manufacture of pulp, paper and paper products" (Sweden). UC62 codes indicate the following main applications: "Softeners" (Sweden), "Paints, lacquers and vanishes" (Denmark and to some extent Finland and Norway), "Adhesive, binding agents" (all countries), Construction material" (Denmark) and "Fillers" (Denmark), and in the early 2000s a use as "Rheopgraphic agents" in Norway.

As for benzyl butyl phthalate (BBP), these UC and IC categories are to some extent in line with uses/applications listed in the RMOA (similar to DEHP, i.e. uses for flexible PVC and for lacquers), but could also indicate a wider applications area that cannot be specified further from the relatively generic IC and UC codes.

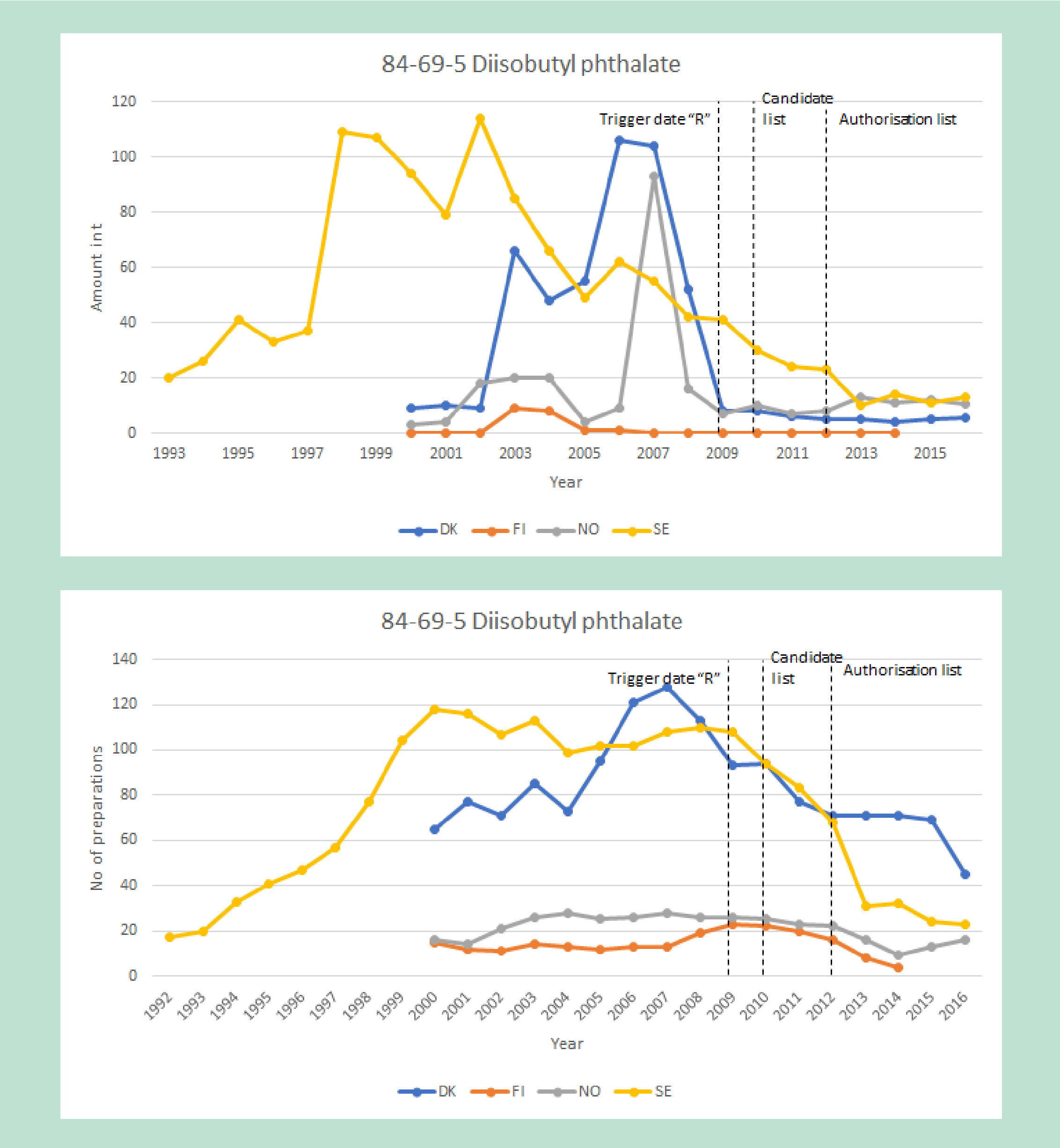

FIGURE 6. CAS no 84-69-5, Diisobutyl phthalate (DIBP

The reported amount fluctuates a great deal for this substance, particularly in the beginning of the period, possibly indicating erroneous reporting. Moreover, the regulatory dates follow very closely for this substance, which makes it difficult to assess the significance of each regulatory intervention. In Sweden, there is a continued decrease in the period before the trigger date. In Denmark and Norway, there is an increase in the use before the 2009 trigger date; however, for Norway, this may be an error. The amounts decrease again after the trigger date and the amounts do not alter much after this.

It appears that regulatory focus has had an effect, but as noted, the regulatory dates are too close to differentiate which one might be the more important.

No applications for REACH authorisation were submitted for this substance, indicating that the current relatively limited use of around 10 t/yr is outside the scope of the authorisation scheme. Another possible explanation is that the product register notifications may have not been updated.

According to the IC-UC plots in Appendix 1, the main IC-NACE code for Denmark and Finland is "Manufacture of rubber and plastic products". In Norway, the main code is "Construction" until 2007 and "Specialised construction activity" from 2008, probably covering the same uses but with a change in grouping from 2007-2008. In Sweden, the situation is less clear with the following main applications: "Manufacture of pulp, paper and paper products", "Manufacture of rubber and plastic products" and "Manufacture of chemicals and chemical products". UC62 codes indicate "Process regulator" as the main code for Denmark, Finland and Norway, whereas "Adhesives, binding agents" has been the main code assigned in Sweden.

These UC and IC categories are to some extent in line with uses/applications listed in the RMOA (similar to DEHP, i.e. uses for flexible PVC and for lacquers), but could also indicate a wider application area that cannot be specified further from the relatively generic IC and UC codes.

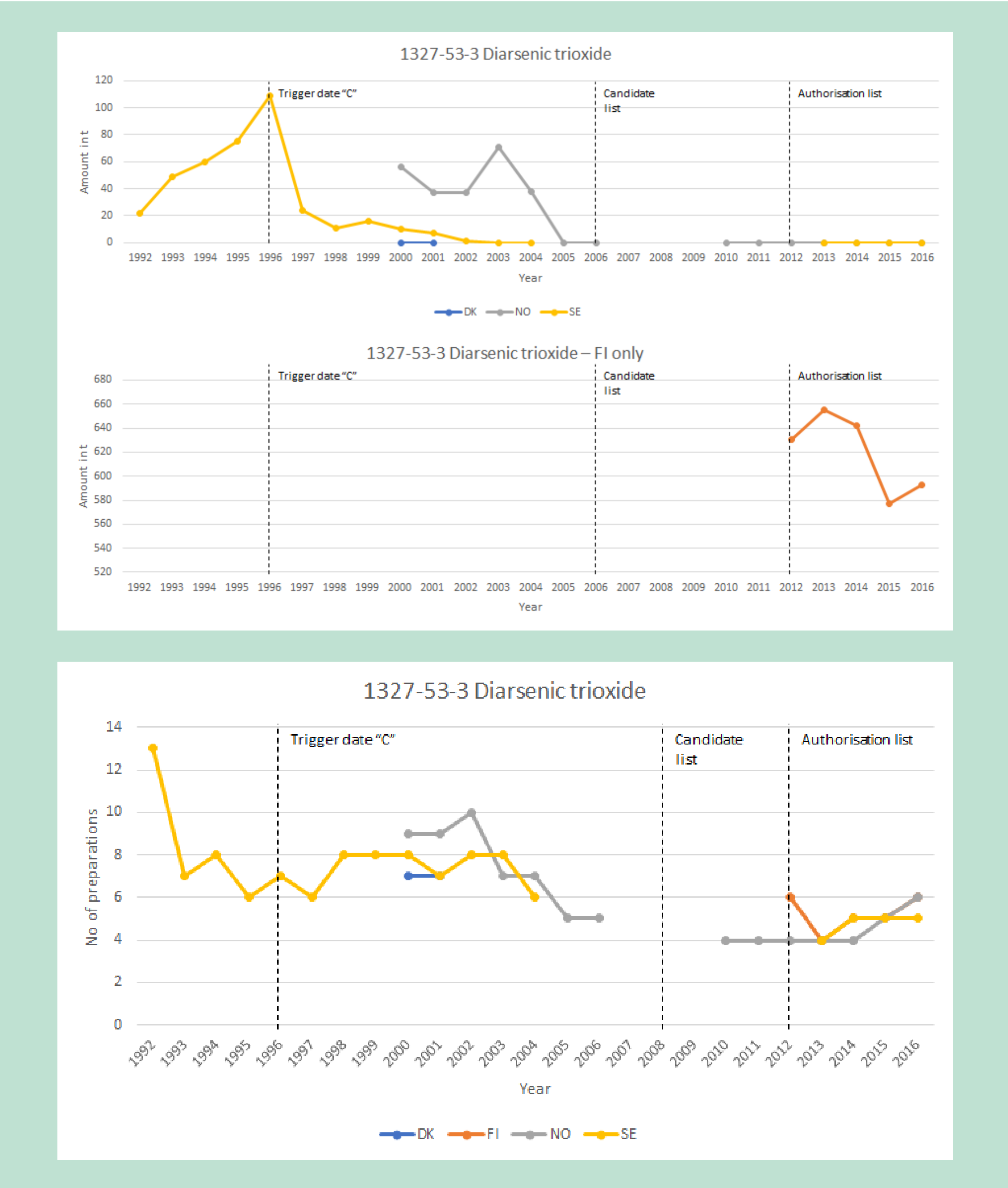

FIGURE 7. CAS no 1327-53-3, Diarsenic trioxide

Use in Denmark and Sweden was zero t/yr for this substance for some years before candidate listing. In Norway there appears to be a drop just before candidate listing. Based on the pre-SPIN data from Sweden, there appears to be a clear increase leading up to the classification and then a quick drop associated with the classification. For Finland, there are no data before the candidate listing, but from the year of inclusion (2012) a significant amount is notified, a level that was stable up until 2016. The reason for this remains unclear.

Overall, if there was an effect of legislation, it appears to be mainly associated with the classification trigger, but continued focus may also have kept the volumes low or close to zero t/yr.

By 2016, four applications for REACH authorisation had been received for this substance (Backes, 2017).

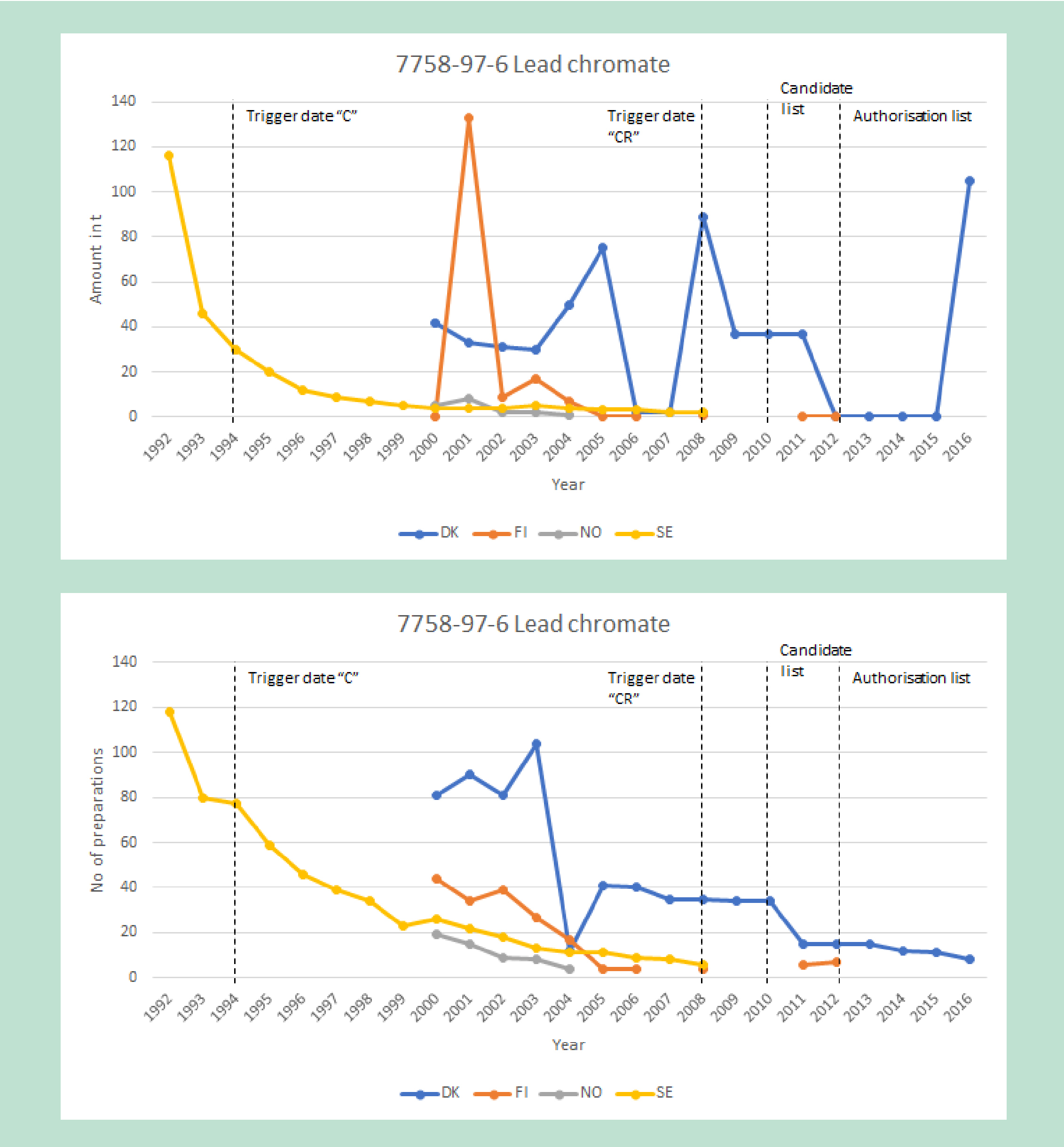

FIGURE 8. CAS no 7758-97-6, Lead chromate

The second trigger date and the two later regulatory dates occur closely together for this substance. In Denmark, usage fluctuated with a drop to zero from 2012, increasing abruptly again in 2016, which is more likely to be an error than a significant new use (tonnage is above what has earlier been seen in Denmark), as use of lead compounds has generally been banned in Denmark since 2001. In Norway, volumes are low and remain zero as of 2005 and in Sweden, there is a clear decrease in the early period before and after the first trigger date (although the Swedish data from 1992-1994 must be interpreted with care) and zero use from 2009, indicating that the first trigger had an effect. Overall, trends may indicate that there has been an effect of continued focus and that candidate listing and inclusion in Annex XIV, may have eventually driven the use to low values in all countries. The use pattern for preparations support this assessment.

Only one application for REACH authorisation was submitted by 2016 (Backes, 2017).

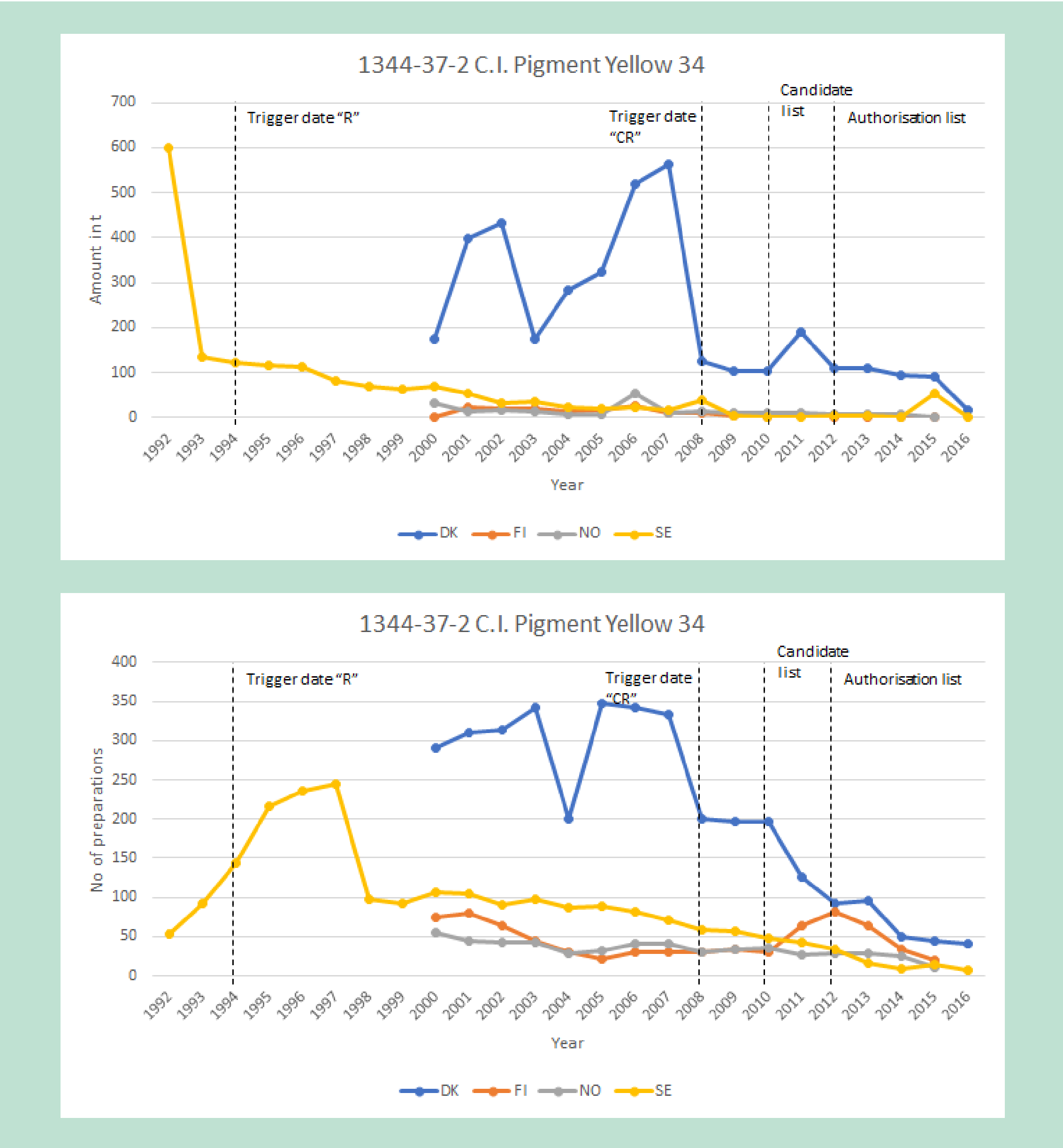

FIGURE 9. CAS no 1344-37-2, Lead sulfochromate yellow (C.I. Pigment Yellow 34)

The second classification trigger date and the two later regulatory dates for this substance occur very closely. Amounts clearly decrease in Sweden before the first trigger in 1994, and in Denmark before the second classification. However, there is significant uncertainty associated with the Swedish data from 1992-1994 as noted by the Swedish Product Register. In all countries there is also a drop in volume at the end of the period, indicating that continued focus, including Annex XIV inclusion, may have also have had some effect.

Only one application for REACH authorisation was submitted for pigment red and yellow together. Two Danish industries are currently using the substances as pigments in polymer blends under the authorisation granted.

From the IC-UC plots in Appendix 1, it becomes evident that the significant drop in uses during the first half of the 2000s was associated with uses such as colouring agent/pigment in rubber and plastic products, as well as in paints, lacquers and vanishes. Various codes covering transport equipment in general, and more specifically vehicles and motorcycles, as well as construction and manufacture of basic metals indicate more specific areas where the substance has been used in coating applications.

This use pattern appears to be well in line with the main uses and areas of use listed in the RMOA:

- Colouring and pigments manufacturing for paints, varnishes, preparations, printing inks and for outdoor paints applications in the sector of car industry, agricultural mechanization, road naval and aeronautic marking;
- Metallurgy and metal working;
- Manufacturing of plastics, and
- Aeronautic and spacecraft building.

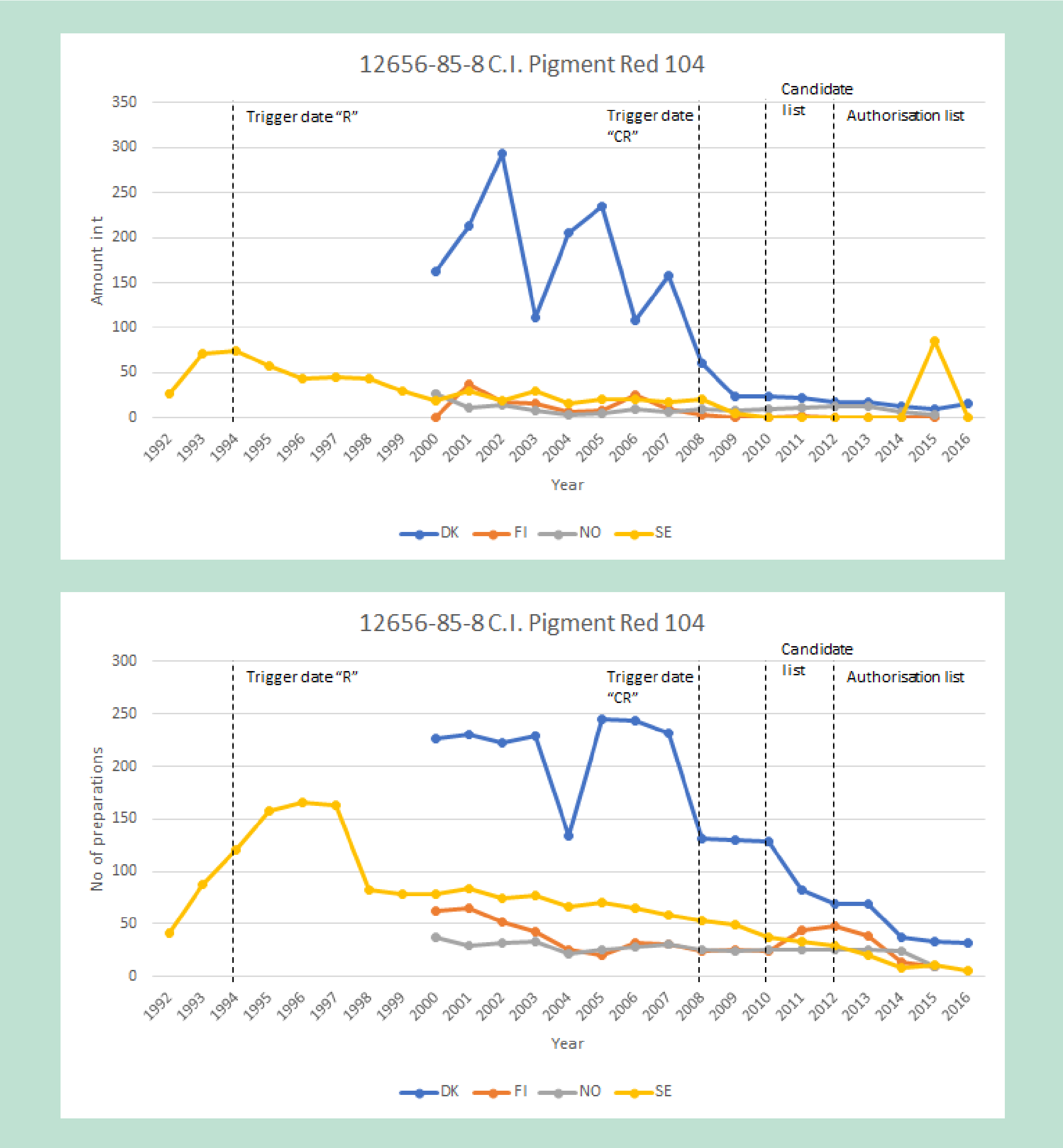

FIGURE 10. CAS no 12656-85-8, Lead chromate molybdate sulfate red (C.I. Pigment Red 104)

The second classification trigger date and the two later regulatory dates for this substance occur closely - within only four years - which makes it difficult to discern their individual effects. The volume was declining before 2008 (second classification). In Denmark a decrease can be observed from 60 – 24 t/yr over a period of one year after 2008. After this a weaker decline is seen.

The pre-SPIN data from Sweden indicate a decline in use following the first classification trigger. The use of this substance also declines a great deal in Denmark and slightly, from lower initial volumes, in the other countries in the period between the first trigger date and the second trigger date in 2008. The continued focus may also have influenced the further reduction seen after candidate listing and inclusion in Annex XIV. This supposition is also supported by the development in number of preparations in Sweden and Denmark towards the end of the period.

From the IC-UC plots in Appendix 1, a similar pattern as for C.I. Pigment Yellow 34 can be seen: that the significant drop in use during the 2000s was associated with uses such as colouring agent/pigment in rubber and plastic products, as well as various paint and other coating products for vehicles and transport equipment, machinery equipment, and other metal working applications.

This use pattern appears to be in line with the main uses and areas of use listed in the RMOA (similar to C.I. Pigment Yellow 34):

- Colouring and pigments manufacturing for paints, varnishes, preparations, printing inks and for outdoor paint applications in the sectors of car industry, agricultural mechanization, road naval and aeronautic marking;
- Metallurgy and metal working;
- Manufacturing of plastics, and
- Aeronautic and spacecraft building.

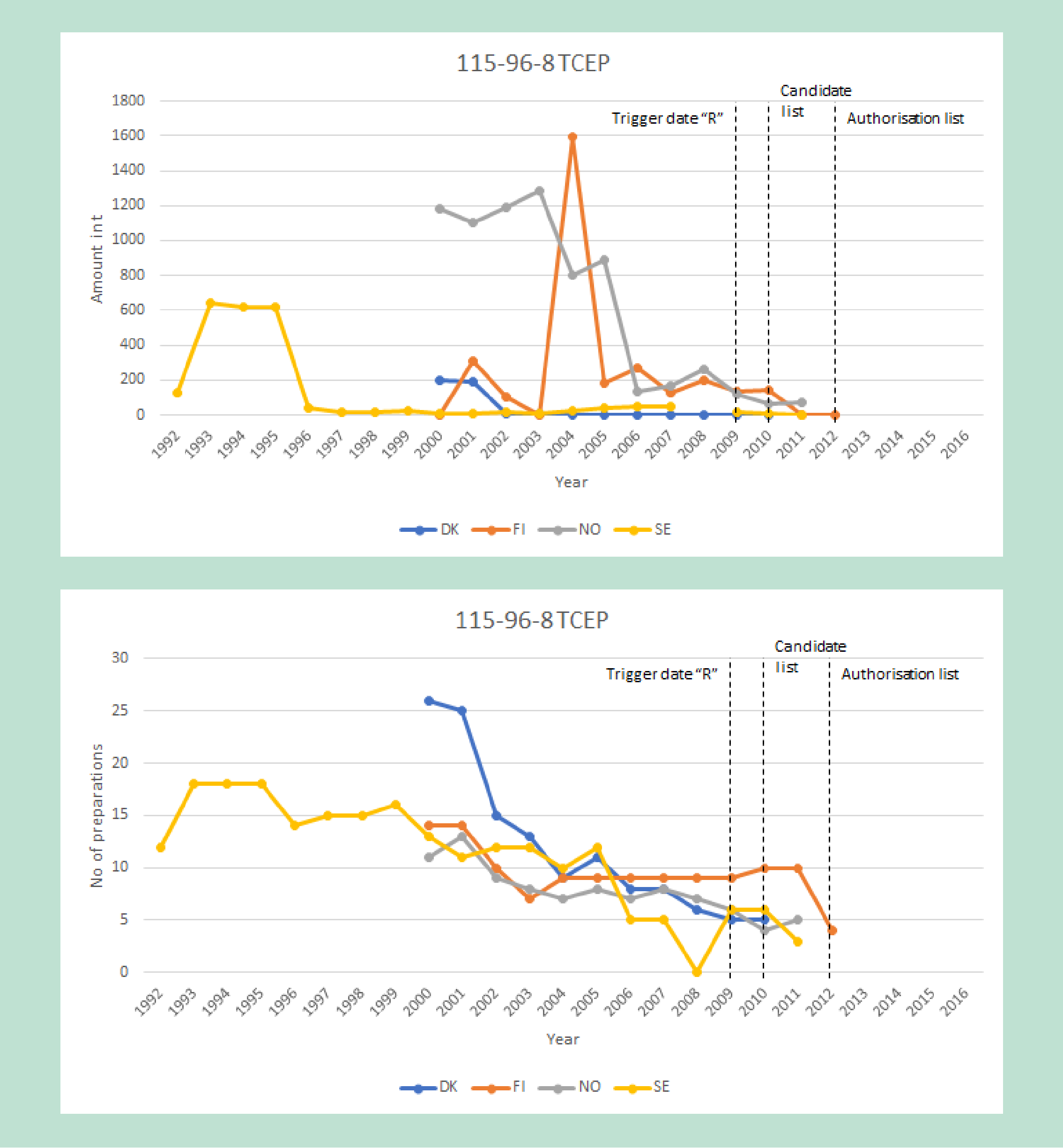

FIGURE 11. CAS no 115-96-8, Tris(2-chloroethyl)phosphate (TCEP)

The use of this substance has been declining since before the trigger date in 2009. In Denmark, the volume has amounted to zero since 2004; in Norway the volume has been zero since 2012, after a declining trend since 2005. In Sweden and Finland, amounts were zero since 2011, i.e. one year after candidate listing. The regulatory dates are close, which makes it difficult to draw conclusions on their separate effects, but as a whole the regulatory focus has clearly had an effect.

No applications for REACH authorisation have been submitted for this substance.

Reading the IC-UC plots in Appendix 1, limited information is available in SPIN, probably because of confidentiality in line with the relatively low number of preparations. It can be seen that the use for rubber and plastic products in Sweden increased from 2003 to 2006 and then by 2010 decreased to the original level. This pattern may be a result of temporary substitution of brominated flame retardants with TCEP, a likely substitution pattern indicated in the RMOA for TCEP. The use in rubber and plastic products also fits well with the main use indicated in the RMOA *"TCEP is mainly used as an additive plasticiser and viscosity regulator with flame-retarding properties for polyurethane, polyesters, polyvinyl chloride and other polymers. It is estimated that the production of unsaturated polyester resins currently accounts for 80% of uses"*.

The RMOA also notes *"Other fields of application are acrylic resins, adhesives and coatings. The main industrial branches to use TCEP as a flame-retardant plasticiser are the furniture, the textile and the building industry (roof insulation); it is also used in the manufacture of cars, railways and aircrafts* [...and] *other utilisation of TCEP is represented by flame resistant paints and varnishes, e.g. for polyvinyl acetate or acetyl cellulose and the use as a secondary plasticiser for polyvinyl chloride to suppress the flammability resulting from plasticisers such as phthalates."*

FIGURE 12. CAS no 121-14-2, 2,4-Dinitrotoluene (DNT)

The regulatory dates for this substance are close, and as data from Denmark and Finland are not available, and use in Norway was zero during this period, no thorough assessment regarding the effects of regulatory instruments in Nordic countries is possible for this substance. In Sweden there is a decline throughout the period with a drop to zero in 2013 after inclusion in Annex XIV. The regulatory dates are close, making it difficult to draw conclusions on their separate effects; therefore, no assessment is made for this substance other than that the regulatory focus appears to have had an effect. The continued increase in number of preparations cannot be explained based on the available data. However, it should be noted that the absolute number of preparations is low.

No applications for REACH authorisation were submitted for this substance.

From the IC-UC plots in Appendix 1, it can be seen, as expected, that the decline in the use of this substance (DNT) is related to the reduced use in explosives (the only UC62 category for which there is data).

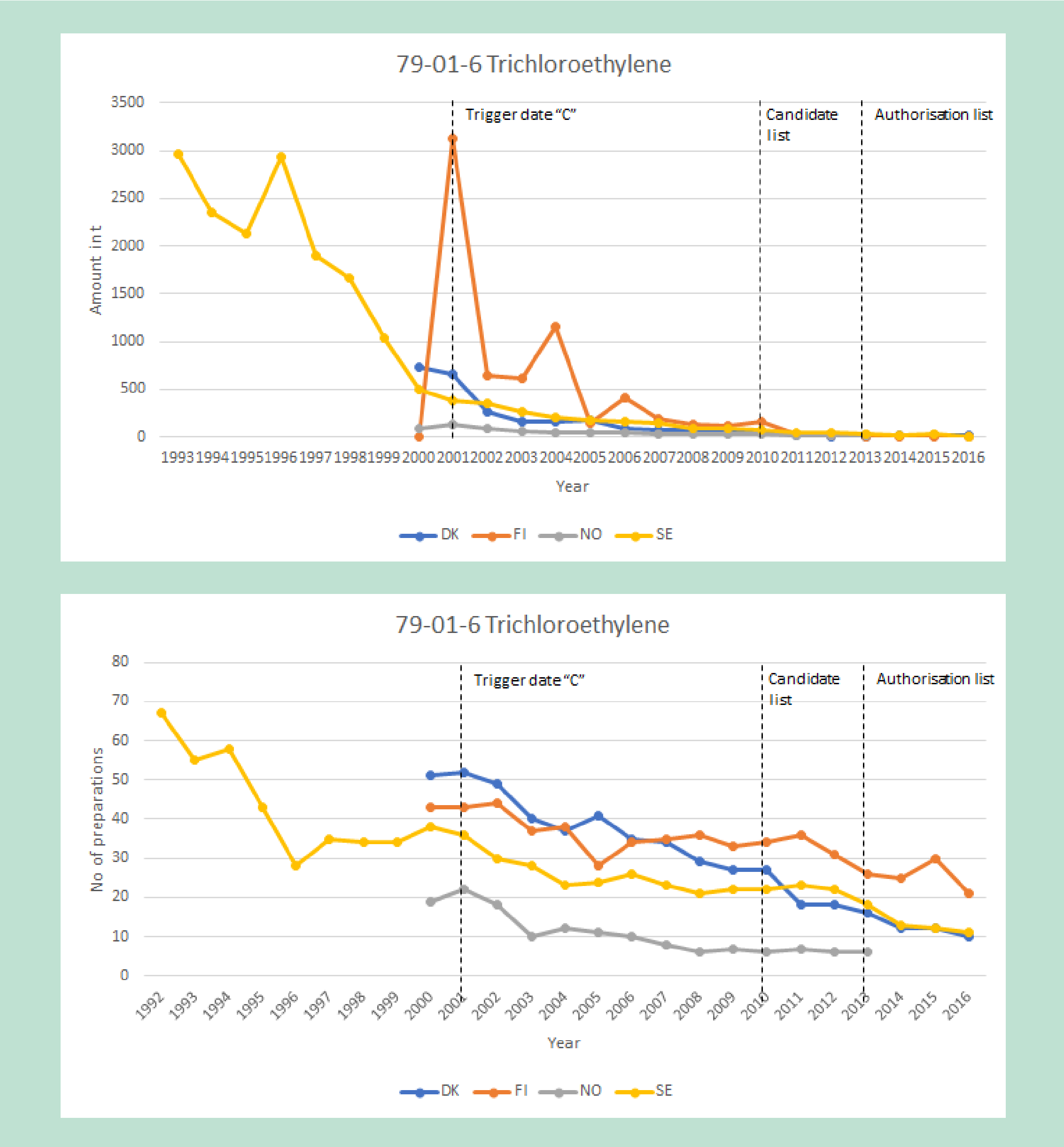

FIGURE 13. CAS no 79-01-6, Trichloroethylene (TCE)

The use of trichloroethylene decreased a great deal during the analysed period: from 139, 504 and 736 t/yr to 0, 7 and 10 t/yr in 2016 in Norway, Sweden and Denmark, respectively. In Finland, there was also an apparent decrease from values of more than 1,000 to 7 t/yr. Amounts for the first two years (2000 and 2001) are discarded as probably erroneous as the Finnish Product Register has emphasised that the data for year 2001 is highly uncertain (see Section 3.1.2). A large decline occurs immediately after the classification trigger in 2001, but the trend continues after 2010, indicating that classification has had an effect on the use pattern but also that the continued focus may have led to further reduction.

There have been 13 applications for REACH authorisation of this substance for 15 uses.

From the IC-UC plots in Appendix 1, it can clearly be seen that the main application substituted was the use of TCE as an organic solvent/cleaning agent on metal surfaces of various types of machinery, equipment and vehicles. Limited uses in "Adhesives, binding agents" associated with "Manufacture of rubber and plastic products" are documented.

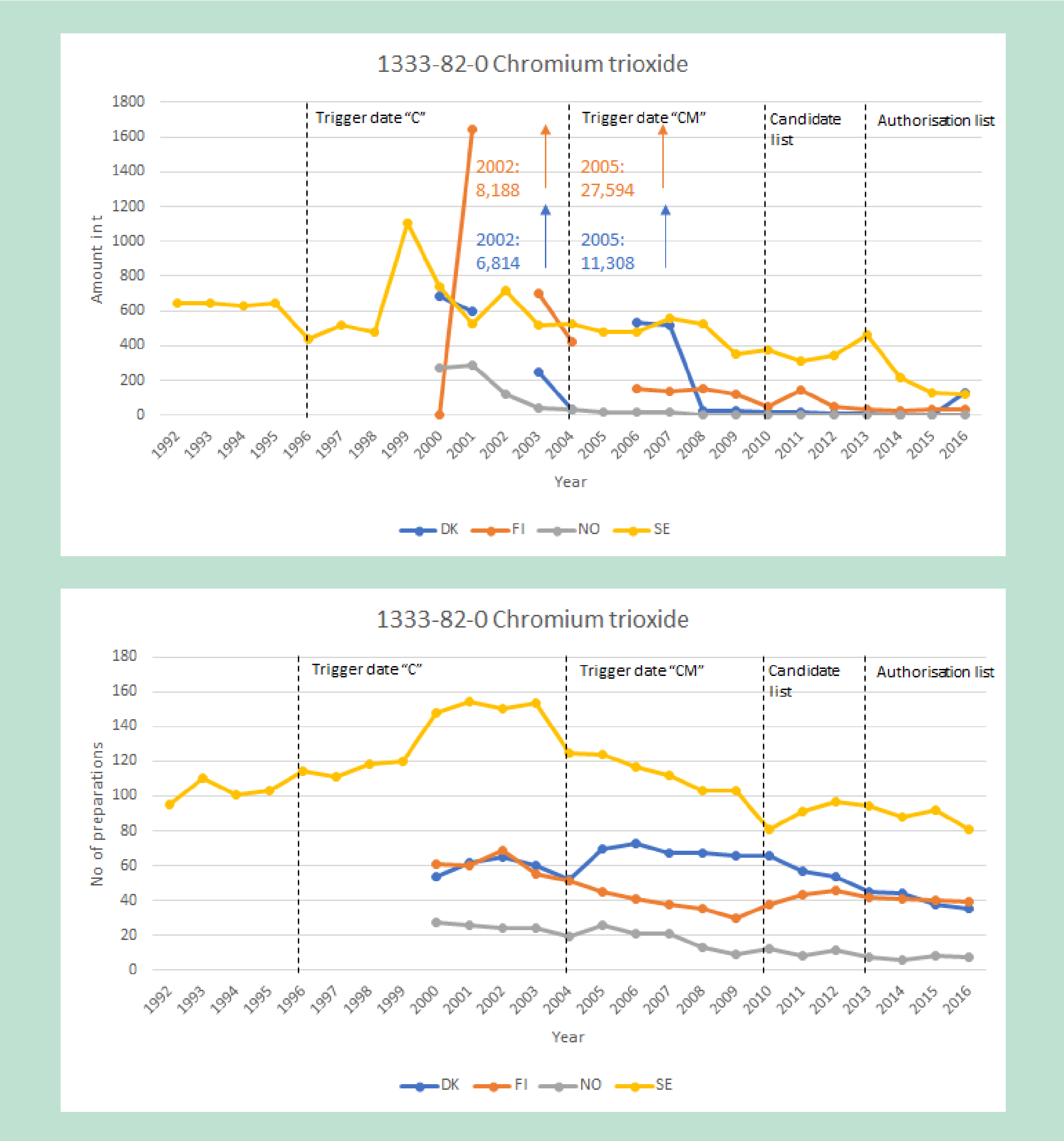

FIGURE 14. CAS no 1333-82-0, Chromium trioxide

The pre-SPIN data from Sweden for this substance does not indicate an effect in use associated with the first classification trigger. However, when removing outliers (very high values in 2002 and 2005 in Denmark and Finland, possibly resulting from erroneous notifications or incorrect data transfer to SPIN) from the plots, there is a decrease in the volume of chromium trioxide in all countries throughout the period. For this substance, much of the decrease in volume occurs at the end of the period, indicating that the consecutive regulative actions by authorities seem to have functioned as a continued incentive towards substitution of this substance, including its eventual inclusion into the REACH authorisation scheme.

Twenty-seven applications had been submitted for this substance by 2016, indicating that although uses are decreasing, there are still many companies at the EU level that wish to continue use.

The respective IC-UC plots in Appendix 1 reveal that the main uses substituted for this substance are largely for surface treatment/as electroplating agent (for chrome plating)/as corrosion inhibitor for machinery, equipment and other metal products. In the early to mid-2000s, data suggest high use levels in Sweden, Norway and Finland under the UC-NACE code "Manufacture of wood and products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials".

This use pattern fits with the first two main uses of chromium trioxide, which are indicated in the RMOA:
- Metal finishing and
- Manufacture of wood preservation products (biocidal agent (excluded from authorisation requirement under REACH); fixing agent in waterborne wood preservatives).

The RMOA also list the following uses of the substance:
- Catalyst manufacture;
- Chromium dioxide manufacture;
- Pigment manufacture, and
- Oxidant in organic chemistry.

The reason why these uses cannot be clearly identified from the SPIN data is possibly due to a combination of the following factors: Too few notifications because of confidentiality issues, manufacture takes place in other EU countries but not in the Nordic countries, and/or the volumes are low compared with metal finishing and applications for manufacture of wood preservation products.

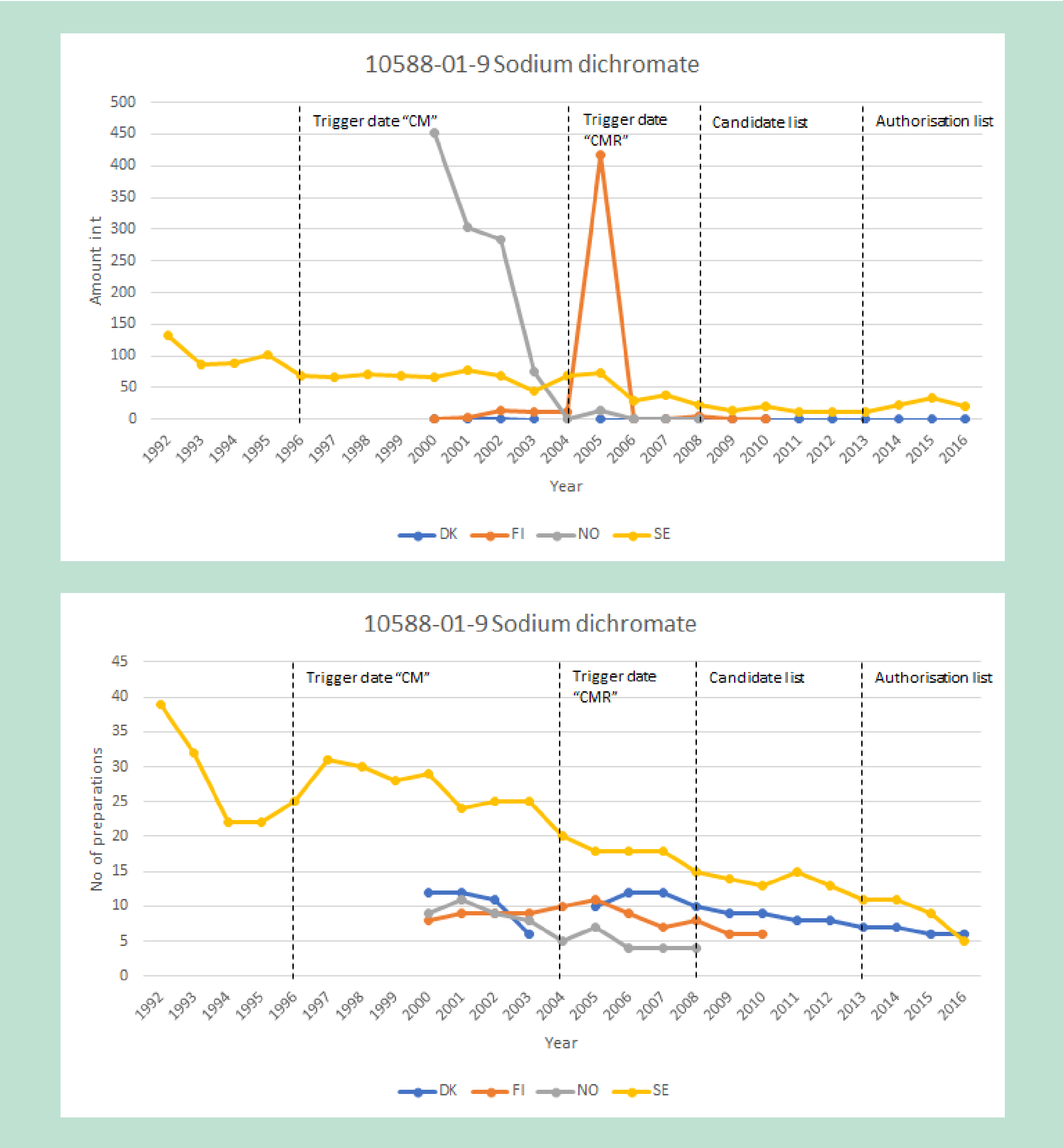

FIGURE 15. CAS no. 10588-01-9, Sodium dichromate

In Denmark, the volume remains close to zero t/yr during the whole period for this substance. In Norway, use continuously decreased from 2000 to 2004 where it reaches zero t/yr in the year of classification. In Sweden, there is a decreasing trend reaching its lowest point in 2012/2013, which is the year of inclusion in Annex XIV. The volume increases slightly after this date. In Finland, there appears to be a significant peak in 2005 (the year after classification), but volumes drop rapidly afterward, indicating that this may be an outlier. Overall, the use pattern may indicate an effect of continued focus, although the Swedish pre-SPIN data shows limited effect associated with the first classification trigger.

By 2016, 18 applications for REACH authorisation had been submitted (Backes, 2017).

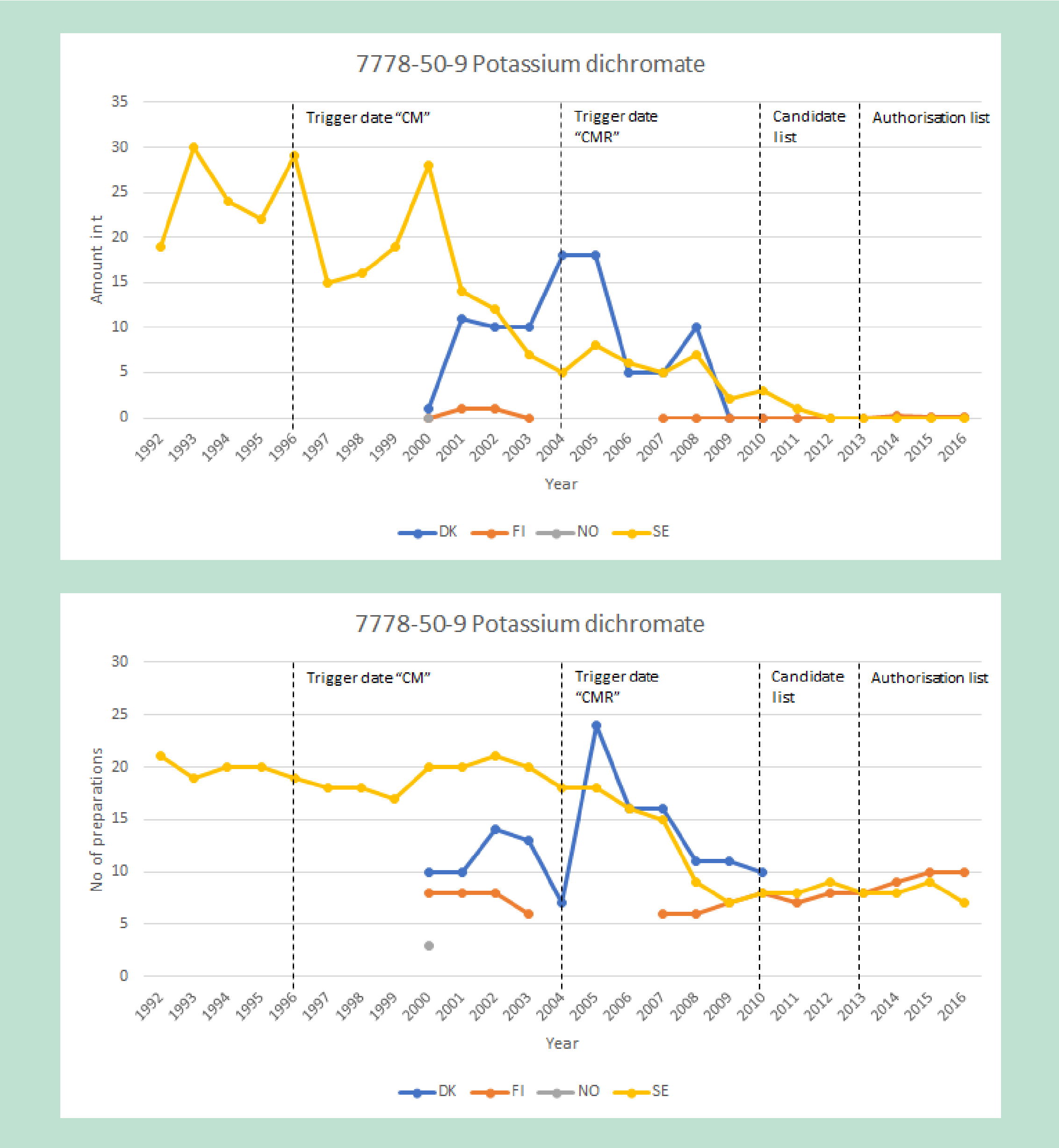

FIGURE 16. CAS no 7778-50-9, Potassium dichromate

For Norway, there is no reported use in the period for this substance. In Denmark the use greatly declines from 2006, eventually decreasing to zero in 2009. In Sweden the use is low as of 2003 and zero as of 2012, indicating that there is an effect resulting from continued focus and that candidate listing and inclusion in Annex XIV have influenced the decline towards zero use in the Nordic countries.

By 2016, five applications had been submitted for REACH authorisation (Backes, 2017).

Limited detailed information on IC and UC is available (see Appendix 1), including a lack of detailed information for Denmark. From the Swedish data, it can be seen that the substance is mainly used for surface treatment/as electroplating agent of metal products, uses which have been substituted, as well as some minor use as laboratory chemical in Finland.

This is in line with the RMOA, which indicates that 80% of the use of this substance is for "Chromium metal manufacture".

The RMOA lists the following additional uses not associated with metal products:

- Wood preservation products;
- Catalyst manufacture;
- Pigments manufacture;
- Mordant in dying, and
- Colouring agent in ceramics.

FIGURE 17. CAS no 25214-70-4, Formaldehyde, oligomeric reaction products with aniline (technical MDA)

The volume of use for this substance varies between zero and 3 t/yr in all countries during the indicated period. There are many gaps in the data and the classification trigger date occurred prior to the reporting period. There are no data in the most recent years leading up to inclusion in Annex XIV. Given the scattered data available, it is not possible to assess effects of different legal interventions other than to make the observation that the use of this substance is generally low.

By 2016, only one application for REACH authorisation had been submitted (Backes, 2017).

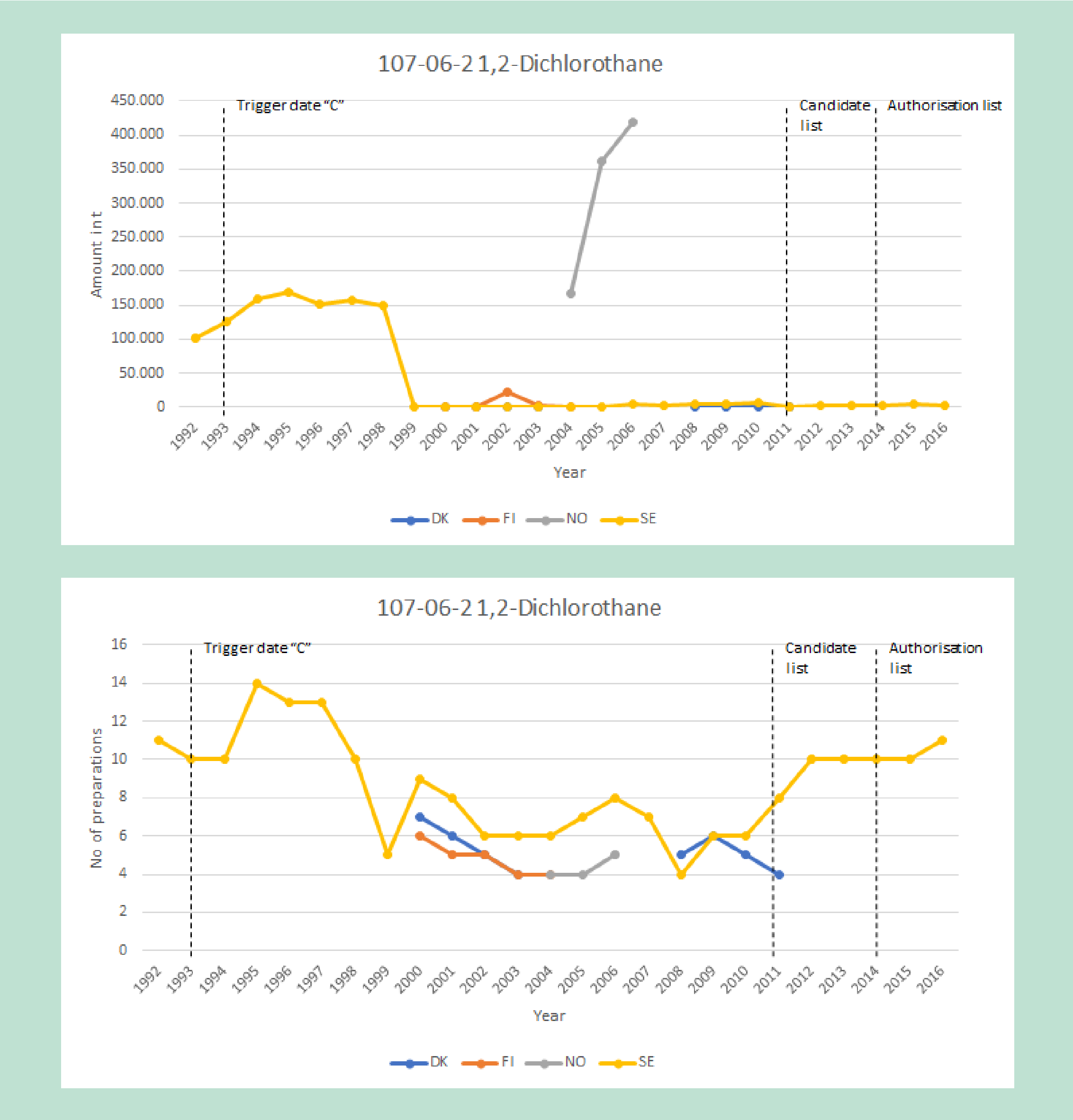

FIGURE 18. CAS no 107-06-2, 1,2-Dichloroethane; Ethylene dichloride (EDC)

The use of this substance in Denmark is zero throughout the period. For Norway and Finland use is also zero, except for short periods with high volumes in Norway. In Sweden there are relatively high volumes in use until 1998-1999.

The data for this substance shows no clear effect of any of the three regulatory incentives. The pattern may indicate specific uses in high volumes. However, the low number of preparations likely indicates that peaks in Finland and Norway may have involved incorrectly notified amounts and/or incorrect transfer of data to SPIN. The pre-SPIN Swedish data does not indicate an immediate effect of classification. Overall, these plots are not seen as useful for further assessment.

By 2016, 15 applications for REACH authorisation were submitted (Backes, 2017).

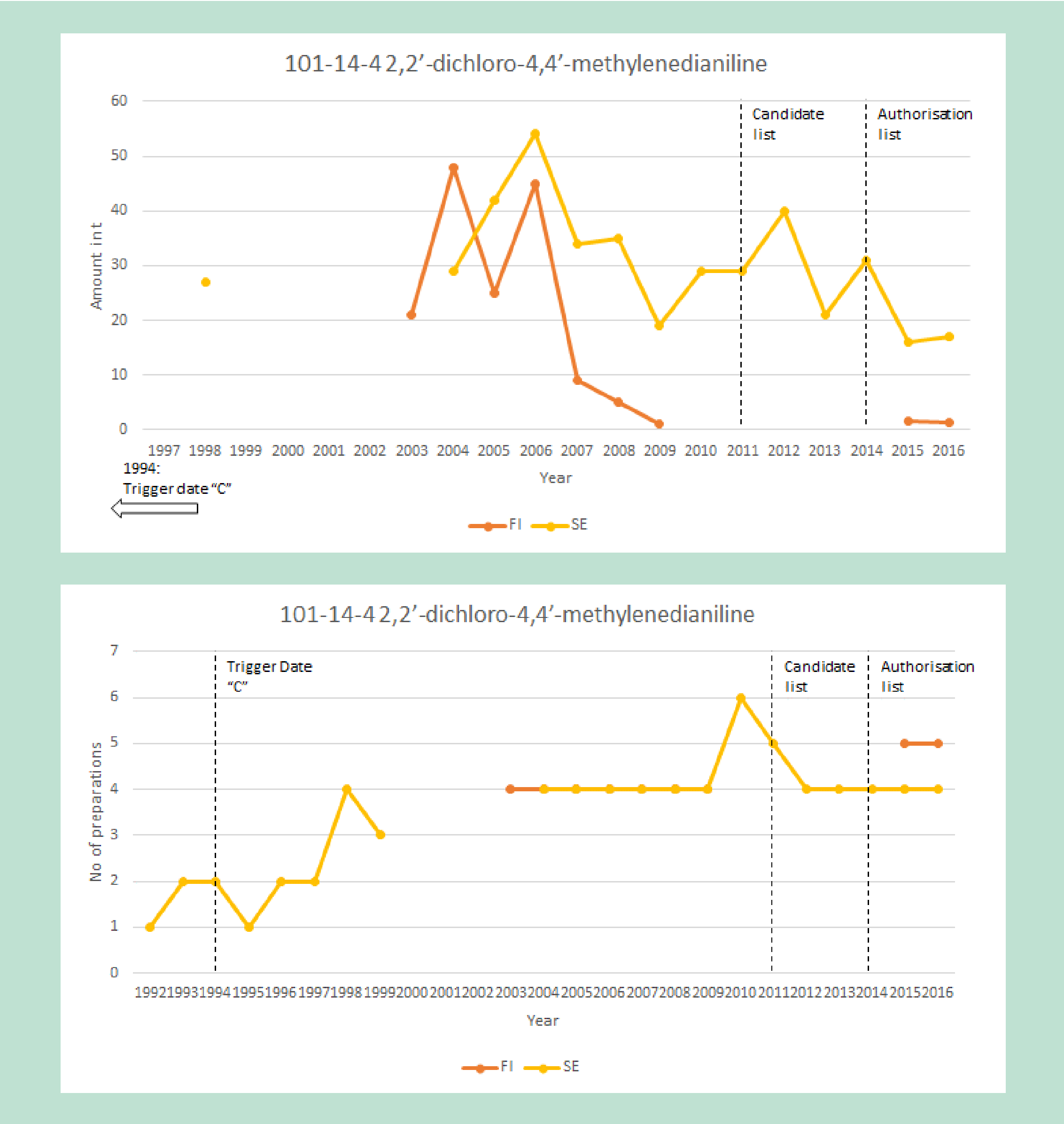

FIGURE 19. CAS no 101-14-4, 2,2'-dichloro-4,4'-methylenedianiline (MOCA)

The use of this substance in Denmark is zero throughout the period. Use in Norway is not reported. Use in Sweden begins after 2004 (although also one data point in 1998 is indicated in the pre-SPIN data provided) and decreases moderately towards the end of the period. The data for this substance shows a variable but slightly decreasing trend for Finland, starting before candidate listing, indicating that candidate listing may have led to continued reduction in use. The number of preparations listed is low in Sweden and Finland.

One application for REACH authorisation was submitted for this substance by 2016 (Backes, 2017).

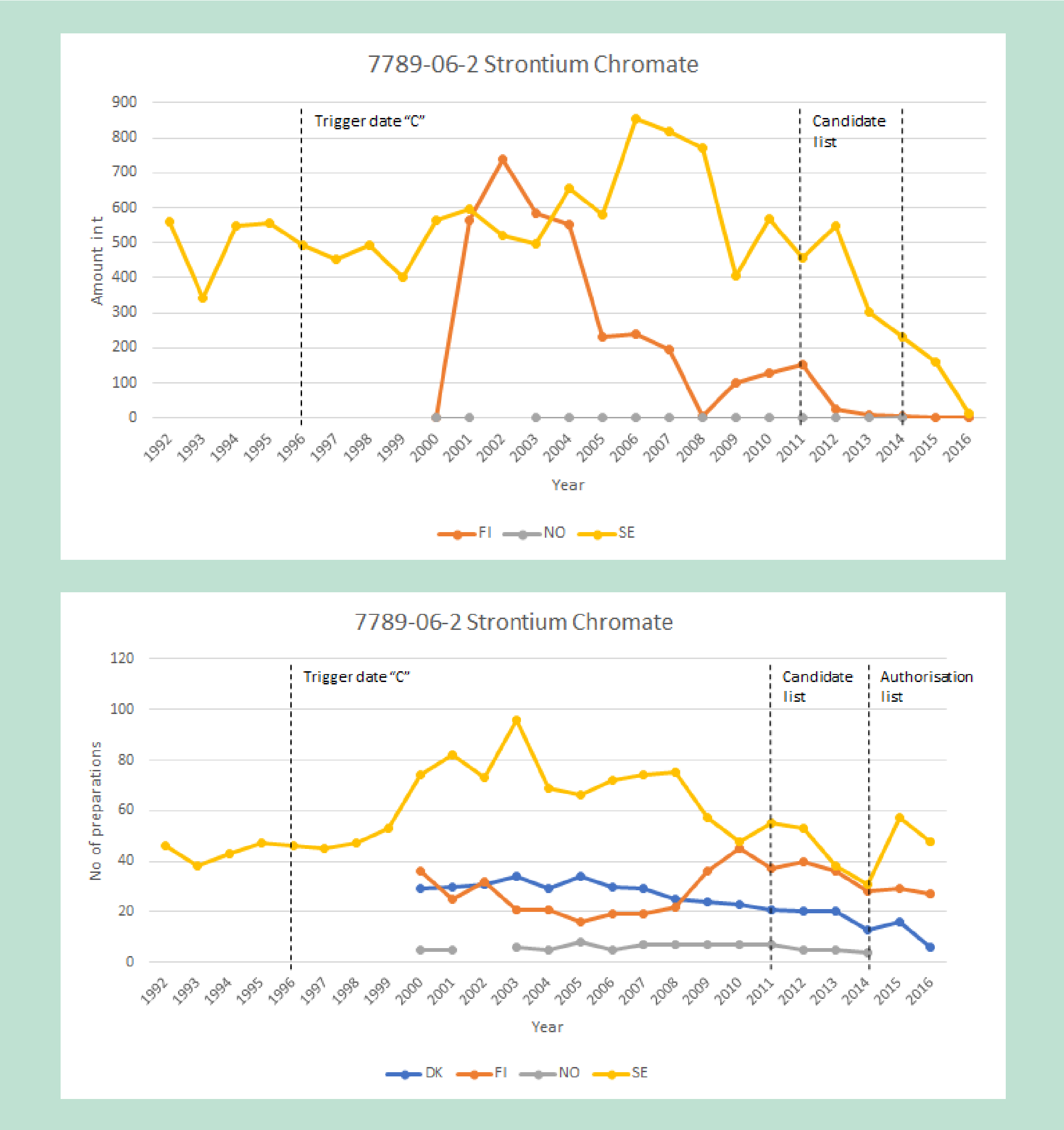

FIGURE 20. CAS no 7789-06-2, Strontium chromate

In Denmark and Norway, the use of this substance approaches zero throughout the reporting period. In Sweden and Finland, a decrease occurs before candidate listing. After this listing, volumes are further reduced until reaching zero after Annex XIV inclusion. The available pre-SPIN data for Sweden do not show an effect of the classification trigger for this substance. However, in Finland, there is a clear decrease some years before candidate listing if it is assumed that reported amounts for 2000 and 2001 are erroneous (this data are uncertain according to the Finnish product register). This indicates that there may have been an effect as a result of the classification, as well as that candidate listing and inclusion in Annex XIV have driven the amounts used to low levels.

Until 2016, two REACH authorisation applications for 13 uses had been submitted (Backes, 2017).

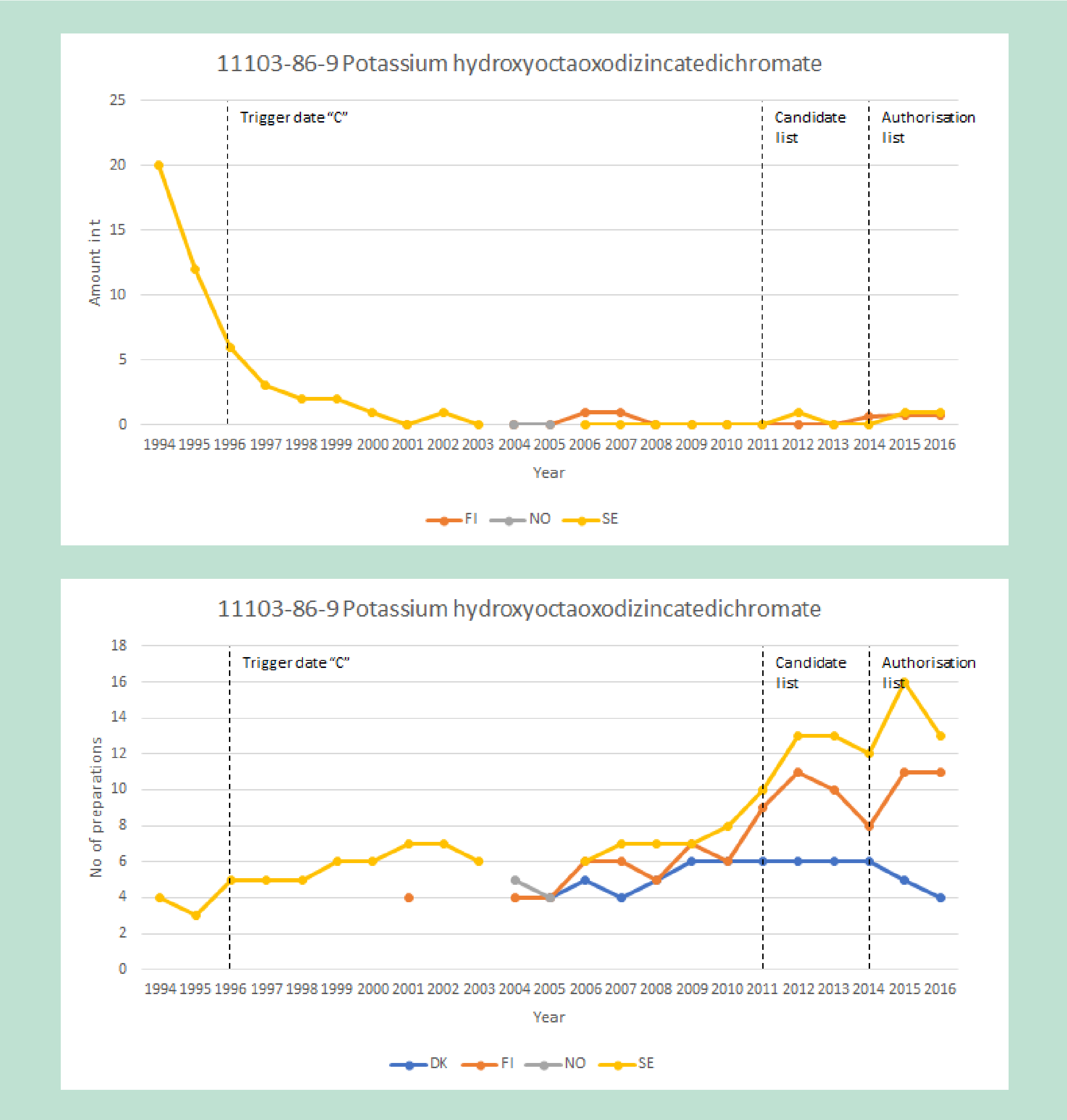

FIGURE 21. Cas no. 11103-86-9 Potassium hydroxyoctaoxodizincatedichromate

Except for Sweden, where amounts clearly decrease before the first trigger, the volumes of this substance used are close to zero in all countries throughout the period.

The number of preparations appears to increase slightly after candidate listing, which may correspond to slight increases in low volumes used in Finland and Sweden.

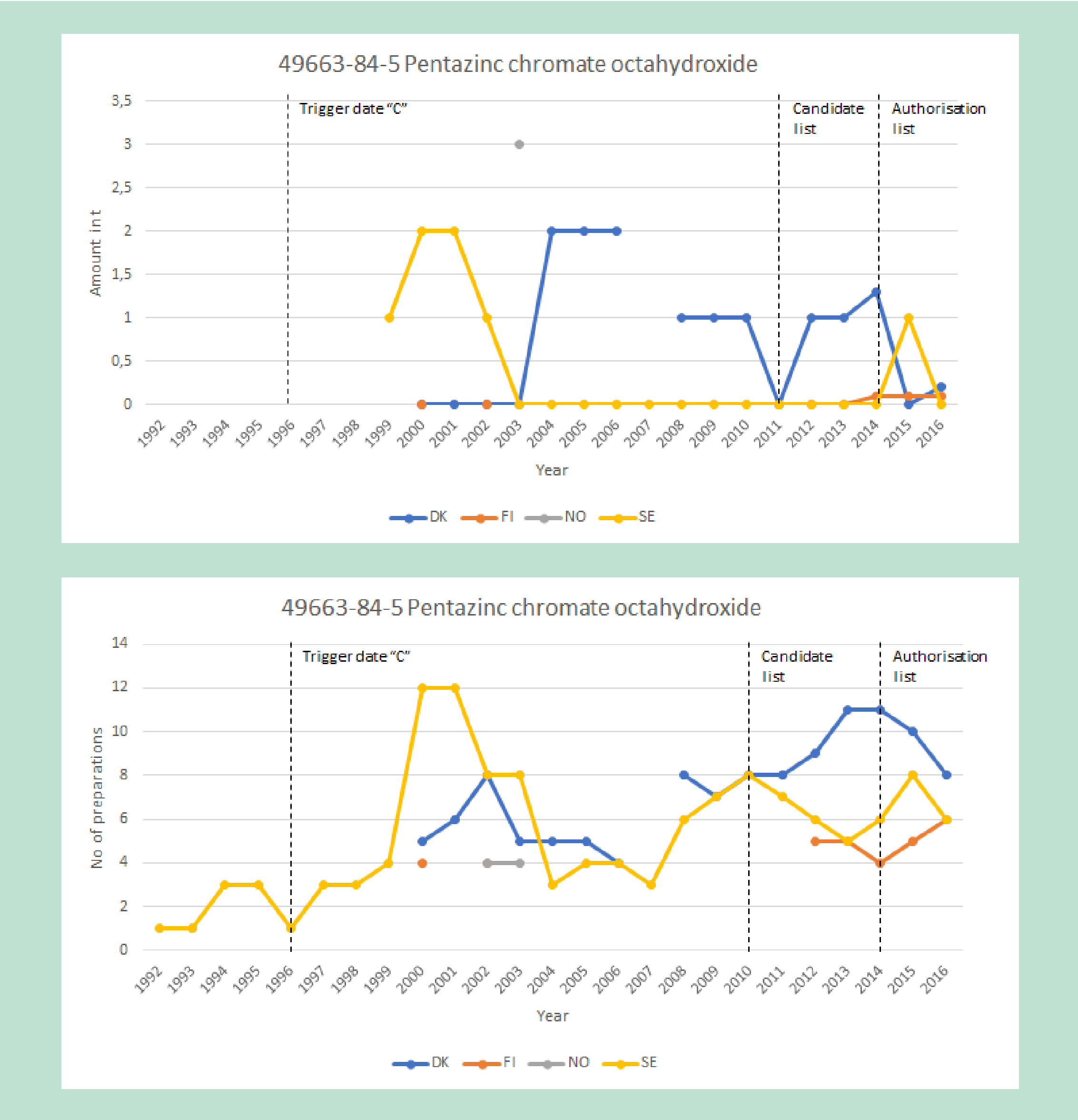

FIGURE 22. CAS no 49663-84-5 Pentazinc chromate octahydroxide

The data available about this substance show low volumes that fluctuate too much to make any assessment regarding the effect of the various regulatory interventions.

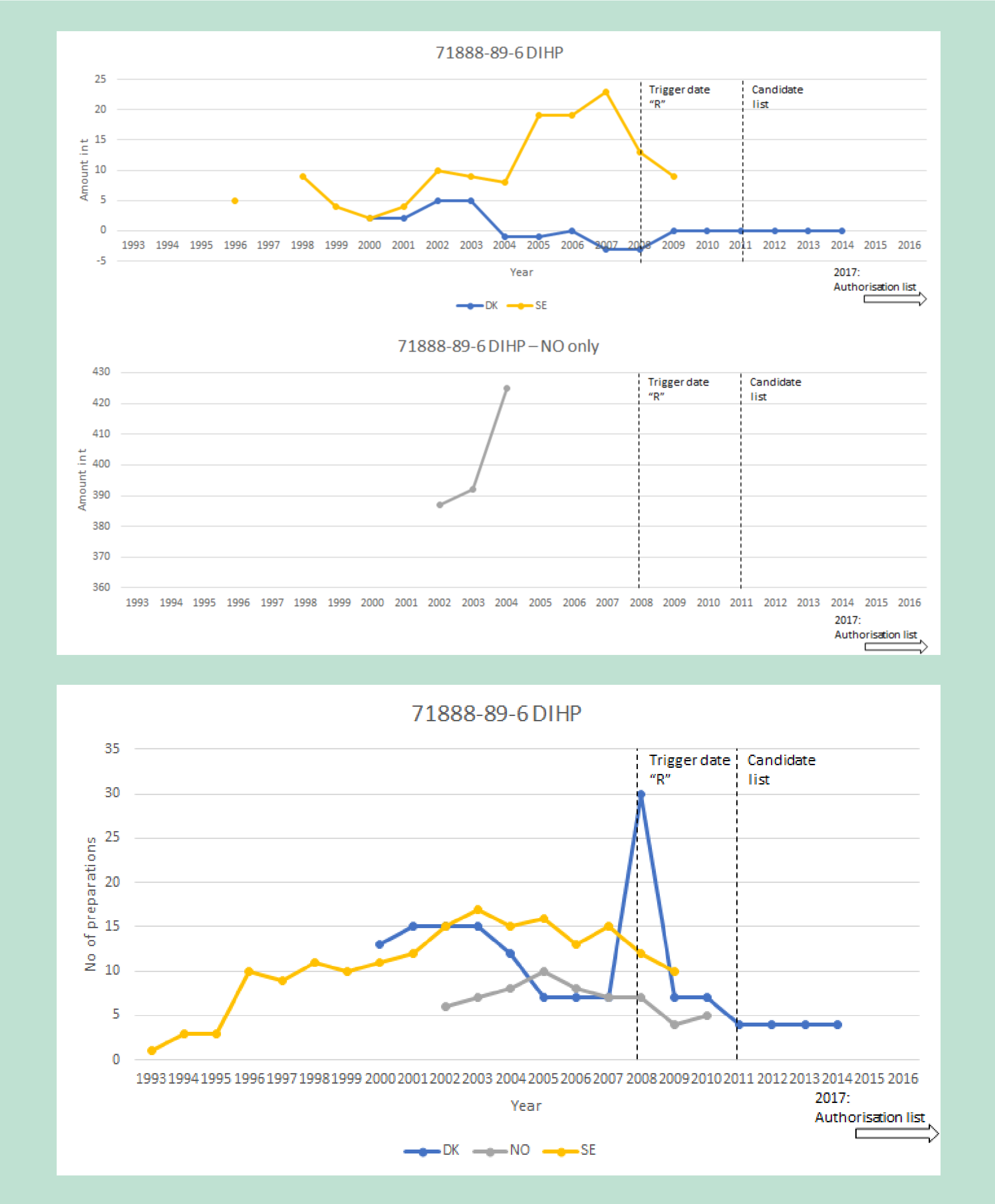

FIGURE 23. CAS no 71888-89-6, DIHP

In Norway, data about this substance are largely missing. Use in Denmark and Finland remains zero, close to zero or slightly negative (indicating net export) during the period. For Sweden, data is available until 2009, which makes it difficult to assess the effects of the different regulatory dates, although the Swedish data may indicate an effect from the classification trigger.

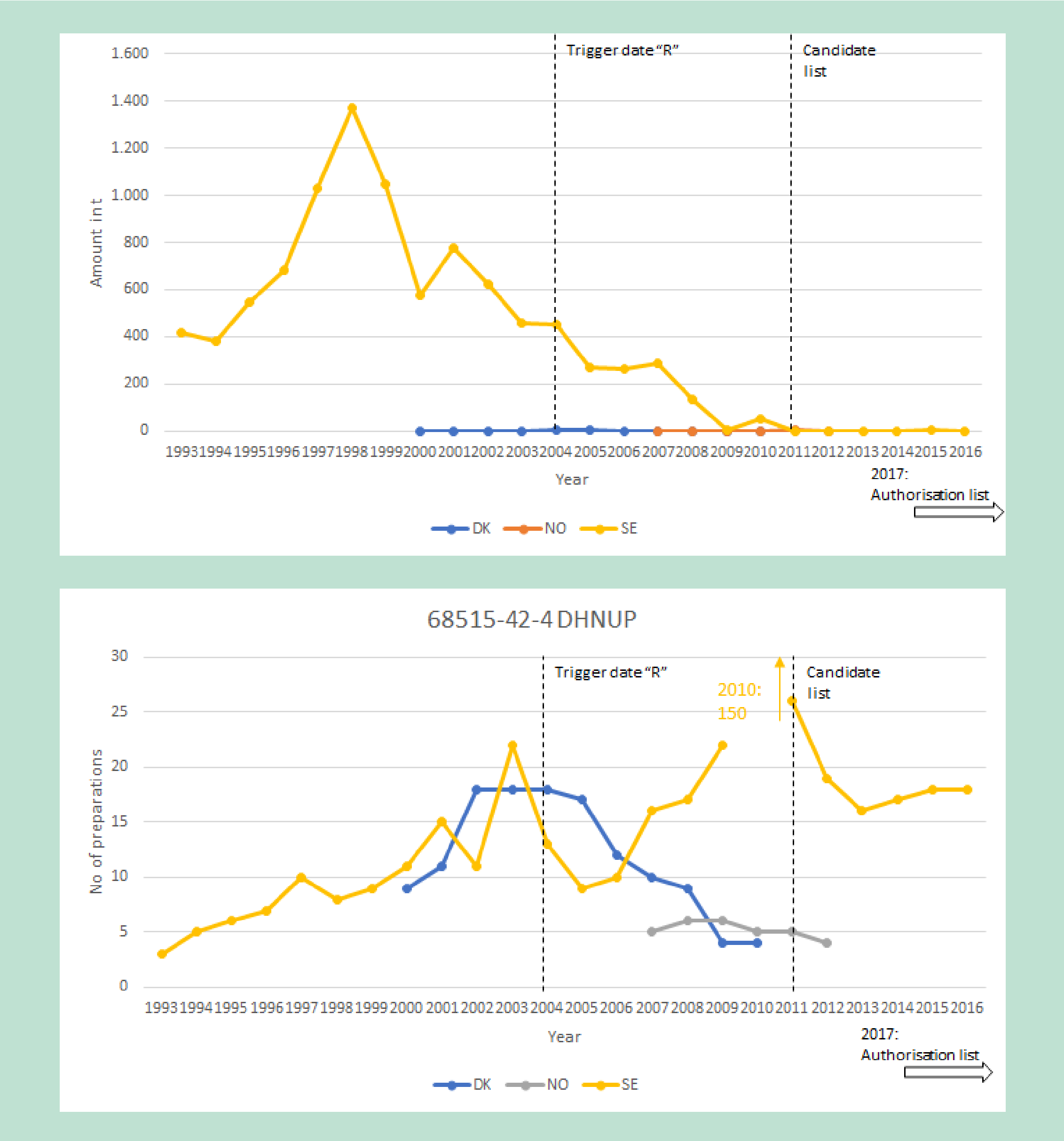

FIGURE 24. CAS no 68515-42-41, 2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)

Data on this substance from Finland are not available. In Denmark and Norway, no significant use of this substance is reported for the period. In Sweden amounts continuously decrease from well before the first trigger in 2004 until candidate listing in 2011. This pattern may constitute an example of a case where regulatory focus may have had a significant effect before the first trigger date in the Nordic countries, but where continued focus may also have led to further reduction at later dates. DHNUP is a UVCB-substance; the decrease may also indicate that companies have chosen to substitute its use with less complex substances.

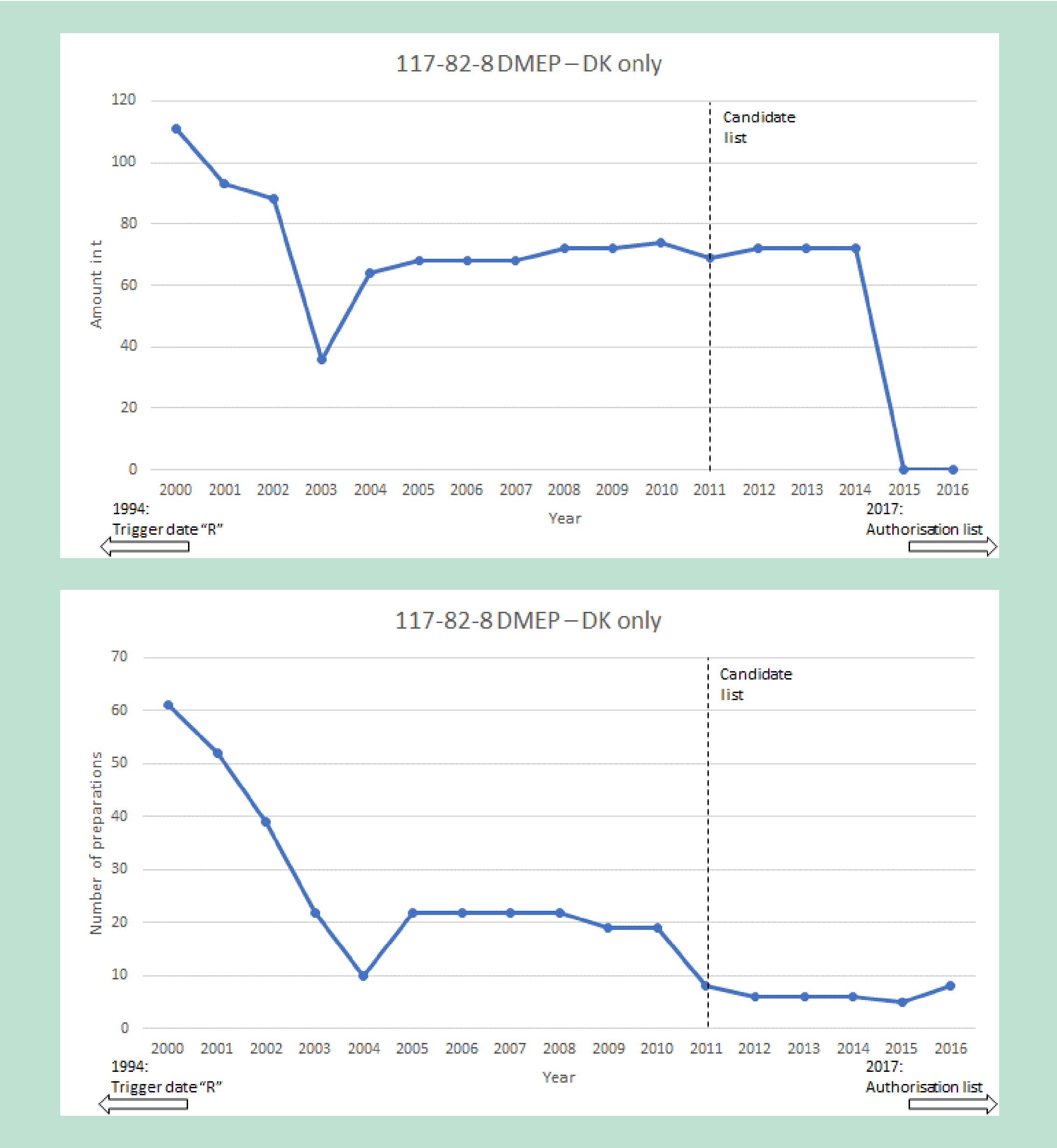

FIGURE 25. CAS no 117-82-8, Bis(2-methoxyethyl) phthalate (DMEP)

For this substance, only data from Denmark are provided. No significant use is reported in Denmark after 2014, which may be a result of candidate listing in 2011. In addition, reporting may not have been consistently updated between 2011 and 2015.

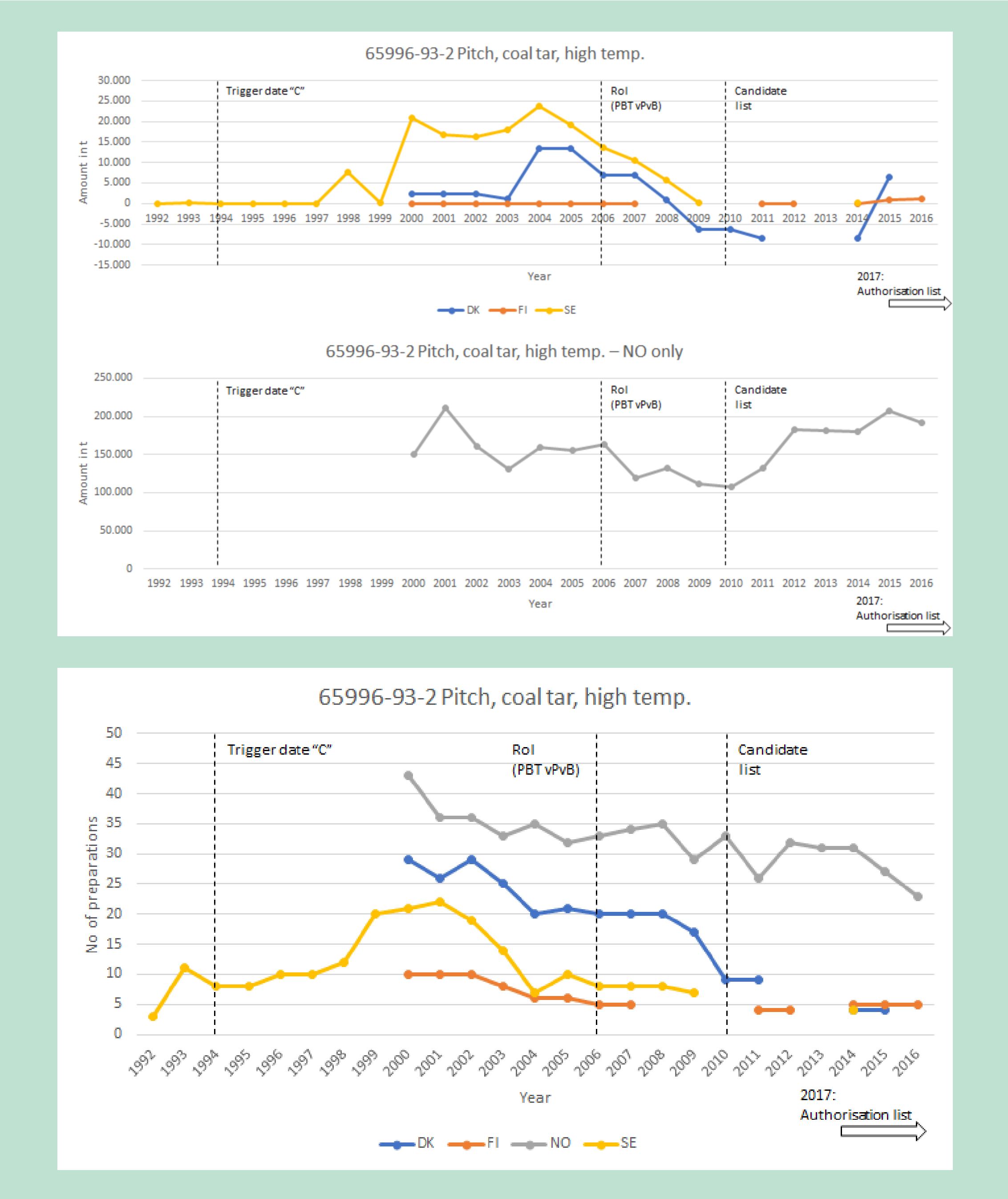

FIGURE 26. CAS no 65996-93-2, Pitch, coal tar, high temp.

The data in SPIN for this substance shows fluctuating, sometimes negative, values for Denmark, as well as high and at a later point, slightly increasing values for Norway. In Sweden, there is a decline from around 20,000 t/yr in 2000 to approx. 5,700 t/yr in 2008 to zero in 2016, and in Finland use is low but fluctuating.

The pre-SPIN data from Sweden show low volumes in the pre-SPIN period but later volumes increase. The second trigger date (PBT and vPvB), as well as subsequent inclusion in the Candidate List, seems to have affected volumes in Denmark and Sweden, but not in Norway.

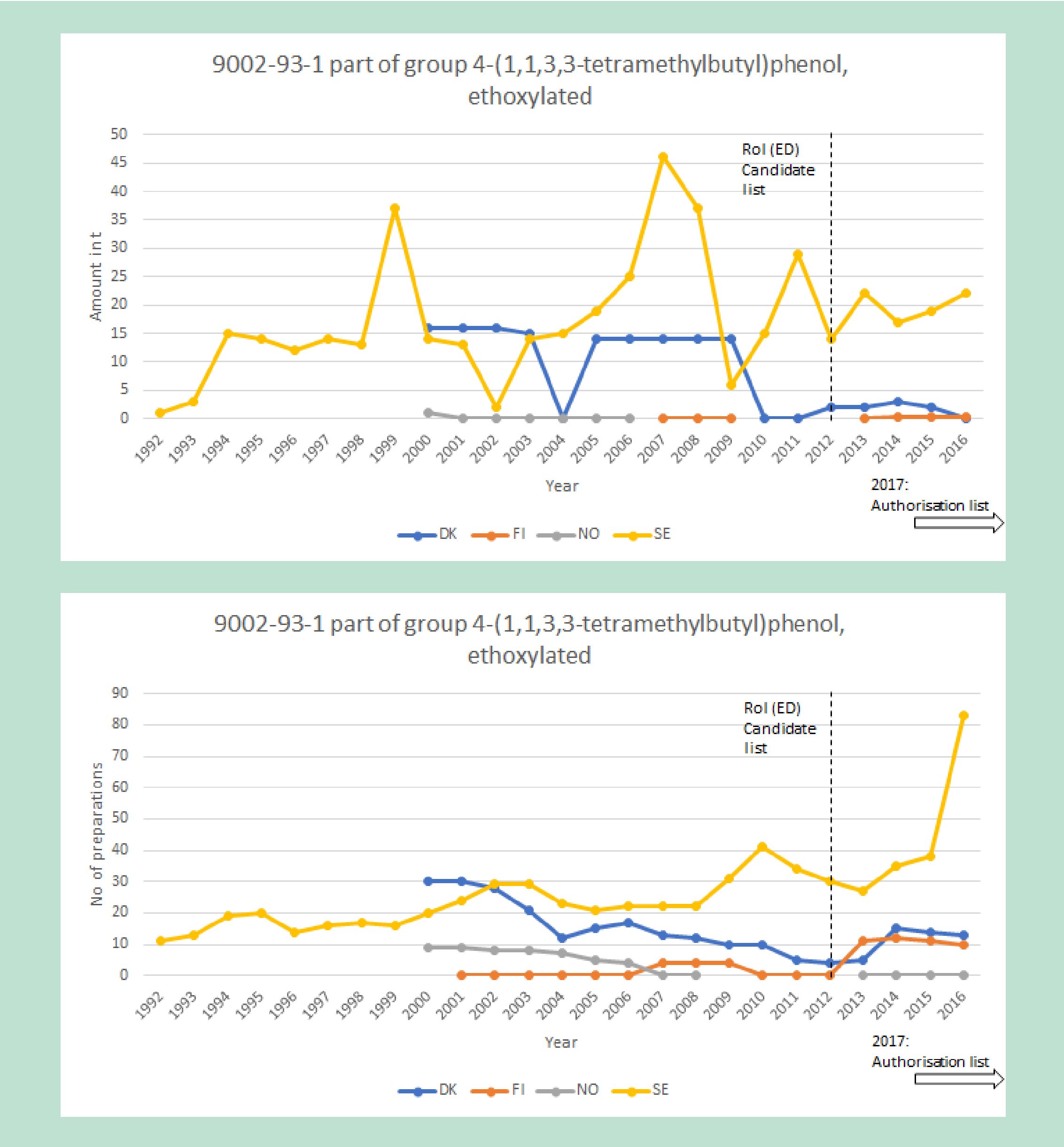

FIGURE 27. CAS no 9002-93-1, 4-tert-octylpenol ethoxylates

The two initial regulatory dates occur in the same year for this substance and inclusion in the REACH authorisation scheme occurs after the reporting period. Use in Denmark drops to zero in 2010 but increases afterward. In Norway and Finland, there is no significant use. In Sweden, the amounts fluctuate throughout the period. There appears to be a decreasing trend in the period, except for Sweden, but since both regulatory dates occurred in the same year, it is not possible to make distinctions between the two regulatory interventions. The current low volumes in Denmark are likely linked to regulatory focus on this substance group over the past decades.

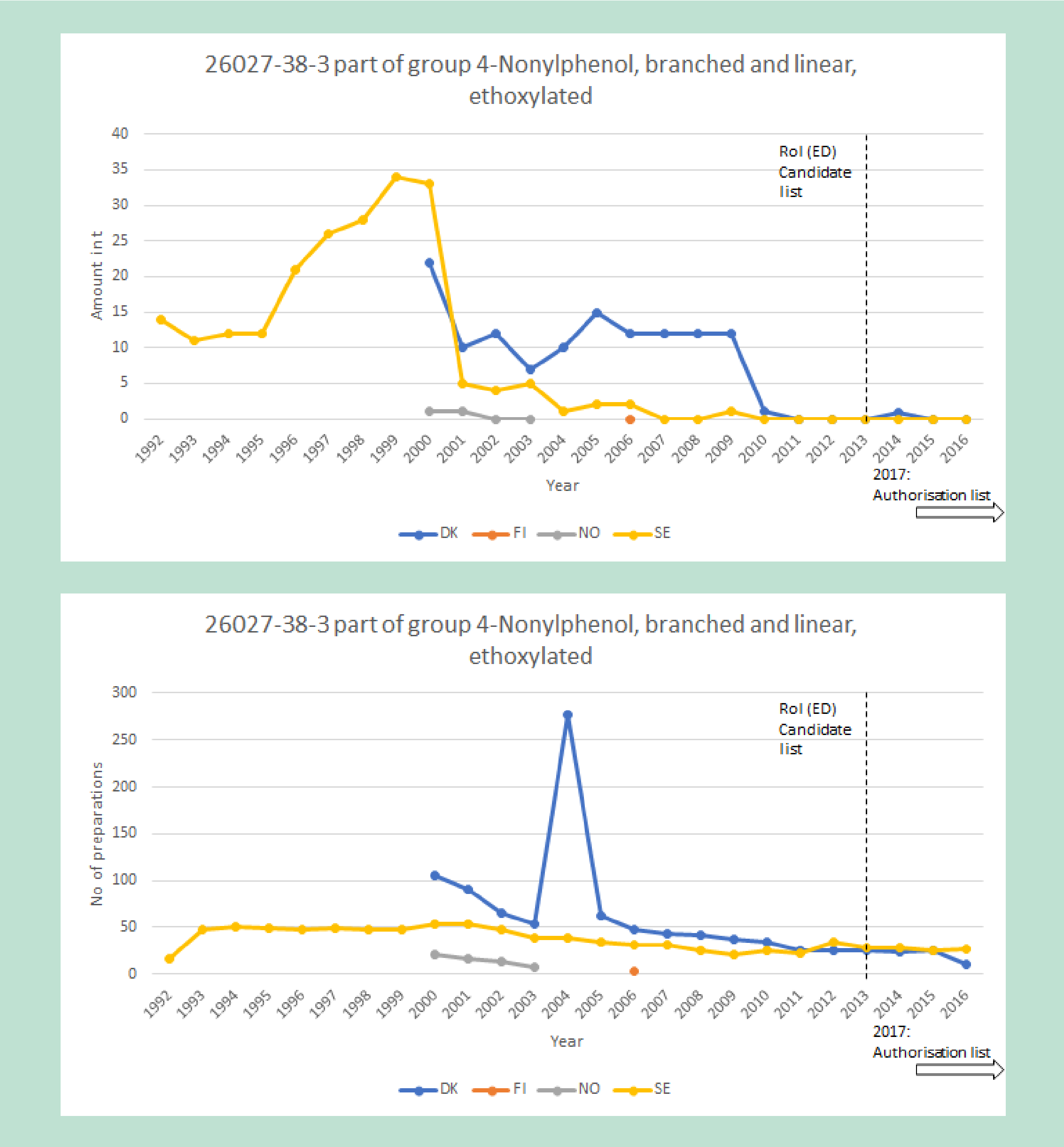

FIGURE 28. CAS no 26027-38-34, Nonyl phenol branched and linear, ethoxylated

The use of this substance is close to zero t/y for Finland and Norway, as well as for Sweden and Denmark from the years 2007 and 2011, respectively. Therefore, the volume approached zero before the first regulatory dates for all countries. However, there remain some preparations in use, so low volumes must still be on the market.

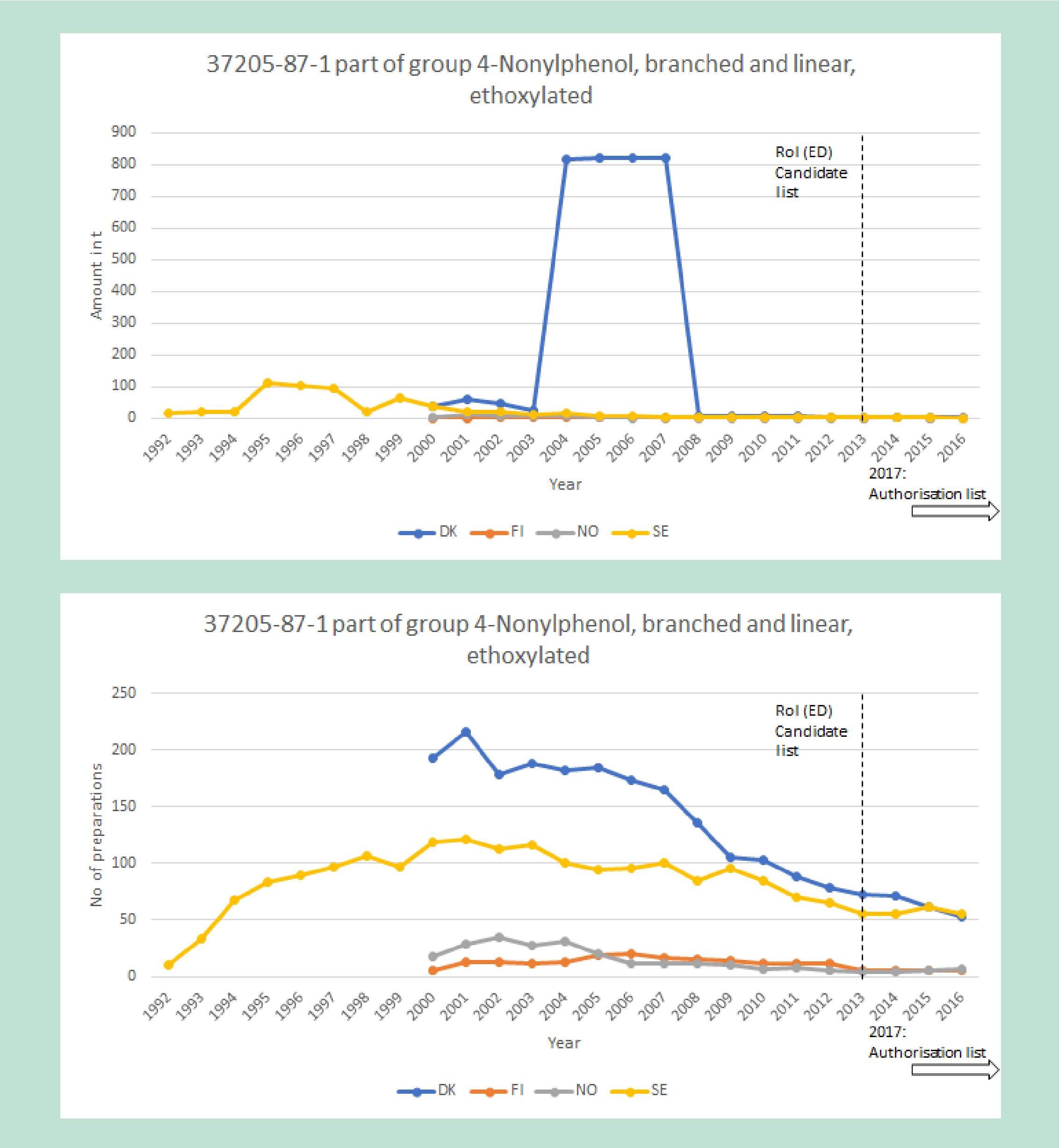

FIGURE 29. CAS no 37205-87-1, nonyl phenol branched and linear, ethoxylated

As above, the volumes of this substance reach zero before the regulatory dates in this plot. Therefore, substitution of this substance seems to have happened before the trigger date.

There are a number of apparently low volume preparations still on the market, which however also show decreasing trends.

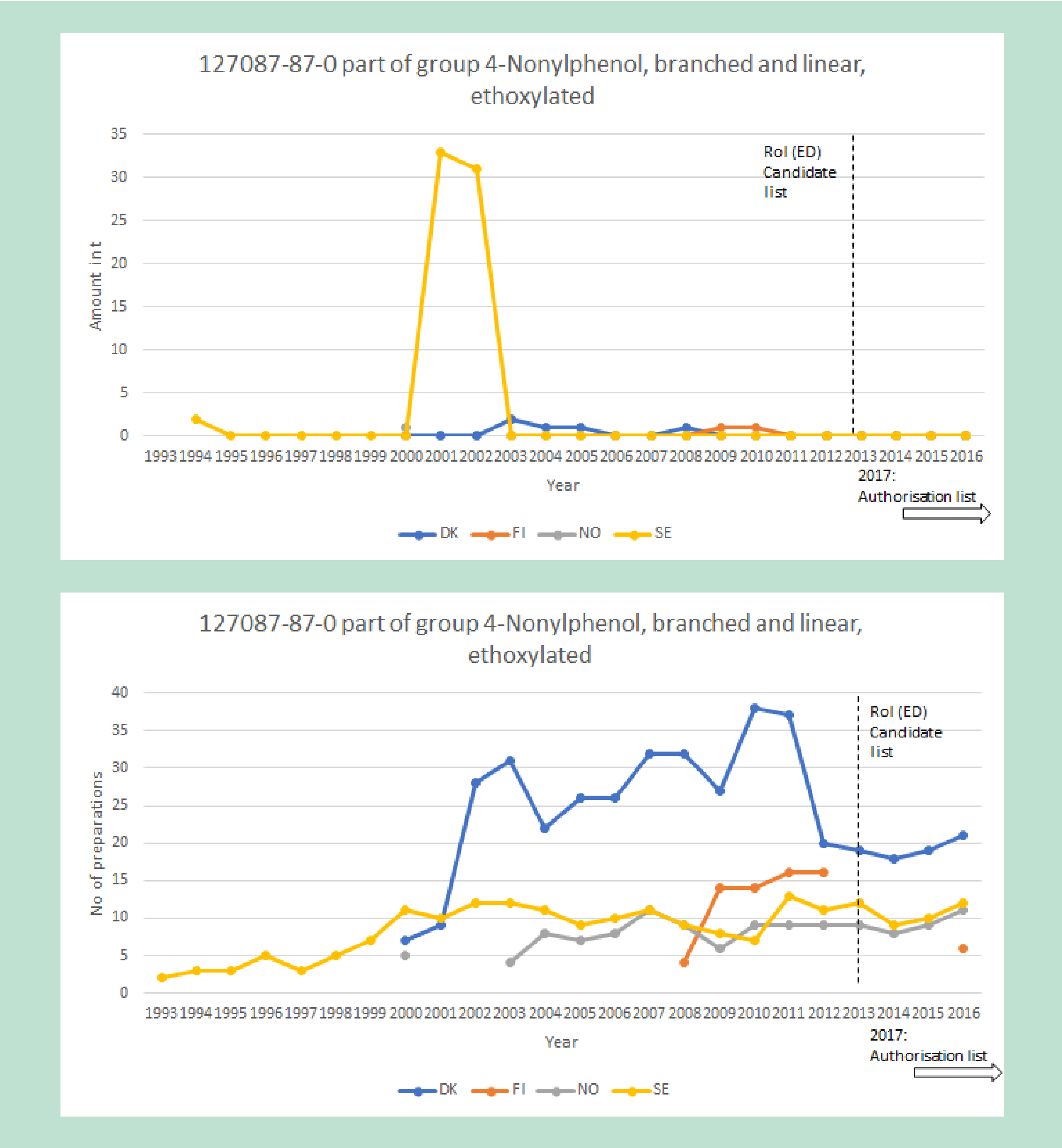

FIGURE 30. CAS no 127087-87-0, nonyl phenol branched and linear, ethoxylated

The volume for this substance is zero or close to zero in Denmark, Norway and Finland throughout the period and approaches zero for Sweden as of 2003. As for the above two CAS-numbers in this group, it appears that the decrease in volumes began well before the trigger date.

For many years, there has been a focus on the nonylphenols- and other alkylphenols and -ethoxylates in the Nordic countries because of their hormone disrupting properties and toxicity in the environment. This focus may explain why these substances are used in such small amounts. Extrapolation of these findings to other EU countries may be difficult.

3.3 Overall findings of trends in Nordic Product Register data

The general overall finding from analysing notification data from the Nordic product registers is that there are clearly decreasing volumes (or no reported use) for the Authorisation List substances in the reporting period. This decreasing trend indicates that the regulatory attention contributes to substitution and affects the market regarding the use of these substances of very high concern.

In this section, an attempt is made to analyse whether indications or tendencies can be discerned as to the relative importance of the regulatory interventions considered.

As discussed in Section 3.1 and as illustrated for several of the substances addressed in Section 3.2, SPIN data are associated with a number of uncertainties. One should therefore be careful in attempting to extract firm conclusions from the rather scattered findings in the previous section. However, various indications can still be suggested based on the data. To structure the analysis, the substances have been divided into groups based on the characteristics of the plots in Section 3.2. The results are presented in tables in Appendix 2 and below.

The four tables in Appendix 2 show where it is impossible or very difficult to conclude anything based on the plots. However, the below tables (Table 4 to Table 6) show a summary of groups of substances for which the authors have chosen to draw preliminary conclusions from the data and plots.

The four tables in Appendix 2 cover the following groups:

Errors and missing data
Some plots appear erroneous and are therefore not applicable for one or more countries for each substance. For many of the substances, only one or two plots are considered useful. The first table in Appendix 2 shows the combination of substances and countries where there are problems with one or more of the plots. These are indicated with a blue colour.

Regulatory dates very close
For some substances, the regulatory dates occur closely, making it difficult to identify the specific regulatory intervention that led to any decrease in volumes. The second table in Appendix 2 shows those substances with the specific trigger dates for each substance, as also shown in Table 3.

Low volumes
The third table in Appendix 2 shows that for 18 substances, the use is zero or close to zero in one or more of the Nordic countries. This situation might have resulted from early substitution efforts or because the substances never had a market in the Nordic countries. Moreover, substances can sometimes be notified under alternative or 'wrong' CAS numbers.

For substances where the volumes are zero, missing or erroneous for some but not all countries, the use in the remaining countries is, when otherwise deemed relevant, used in further assessment (see below). Low volumes in themselves may indicate effects of legislation; therefore, these results could constitute supportive data to information about other substances showing decreasing trends as no other information is readily available.

Substances not used any further

For five substances, the trends are not discussed further for any countries. These substances are shown in the fourth table in Appendix 2 along with a reason for not using the data.

3.3.1 Results for substances where information may support conclusions

The remaining substances and the corresponding plots in Section 3.2 are considered useful for further analysis. These have been sorted according to which legal intervention(s) appear to have influenced the observed development in the reporting period. As already stressed, the results of this analysis should be used with caution given the significant uncertainty in the data.

The tables below present a summary of the observed trends. The substances are grouped according to whether the first (or when available also the second) trigger seems to have had effect or whether subsequent regulatory interventions appear to be equally or more important. The information in the tables in this section is basically a simple and approximate overview of what was seen in the plots – and in some cases is also informed by analysis of the actual underlying data extracted as simple tables from SPIN.

When viewing the tables below, it is important to be aware that the white squares do not necessarily show that no volume decrease has occurred in reality, as plots with no data, erroneous data or volumes close to zero are also shown as white in the tables. The fact that Sweden more frequently appears with colour is partly a result of more data being available from Sweden. Moreover, it must be noted that the tables are only meant as an aid to create an overview of the general picture. The choice of colouring is expert based and therefore not fully objective as no fixed common statistical approach has been applied to the data (See Section 3.2).

Decrease in volume begins before or after classification/assignment of PBT, vPvB properties (the trigger date(s))

Table 4 shows substances where a decrease in volume in one or more of the four Nordic countries is seen in the period some years before or after classification of the substance, i.e. trigger date 1 (or where relevant trigger date 2) as designated in the plots, indicating that the trigger may have affected use. Differences are seen in how far apart trigger dates are from other regulatory dates. These differences are noteworthy since short periods between the regulatory dates make it complicated to assess whether one regulatory intervention has had more effect than another. In Table 4 the authors have included all plots where an effect of the trigger date(s) can be detected based on expert judgement.

To enable further discussion, substances classified in the 1990s are shown in bold, and those where the Swedish data from the 1990s appear to show the effect of this early classification are shown in a darker colour. Note that the pre-SPIN data from Sweden did not consistently show an effect of CMR classification in the 1990s.

Table 4: Overview of substances (indicated with blue colour) where a decreasing trend in volume can be detected in the years before or after the first trigger dates (classification). For each substance the result from each country is shown. Substances classified in the 1990s or early 2000s are shown in bold, and those where the Swedish data from the 1990s appear to show the effect of this early classification are shown in a darker colour.

Decrease in volume		**DK**	**SE**	**NO**	**FI**
Before trigger date (1st or 2nd)	4. DEHP				
	5. BBP				
	6. Dibutylphthalate				
	7. Diisobutylphthalate				
	10. Lead chromate				
	11. Pigment yellow				
	13. TCEP				
	15. TCE				
	16. Chromium trioxide				
	18b. Sodium dichromate				
	30. Potassium hydroxyoct..				
	34. DIHP				
	35. DHNUP				
	41. Coal tar				
	43a, 43b, 43 c. NPE[22]				
After trigger date (1st or 2nd)	2**. Diaminodiphenyl methane**				
	4. DEHP				
	6. Dibutylphthalate				
	8. Diarsenic trioxide				
	10. Lead chromate				
	12. Pigment read				
	15. TCE				
	16. Chromium trioxide				
	18b. Sodium dichromate				
	19. Potassium dichromate				
	27. MOCA				
	29. Strontium chromate				
	37. DMEP				
	41. Coal tar				

Table 4 indicates that for a large proportion of the substances (22), the classification trigger(s) or even attention prior to these dates in one or more countries seems to have had an effect. For others in the period between first (or second) trigger date, but before candidate listing, there has been some influence on the development in use volumes in one or more of the Nordic countries. An example of something that could influence amounts both before and perhaps

[22] There are three plots for the Nonylphenol Ethoxylates. They are all included in the assessment in this table. The substance group is included in the table although the trigger date and candidate list inclusion occur in the same year because the observed trend appears to demonstrate the effect of early attention.

alongside regulatory interventions is the Danish List of Unwanted Substances (LOUS 2009)[23], which includes substances such as the octyl- and nonylphenol ethoxylates, phthalates, pigments and lead compounds. An earlier list also included chromium compounds (LOUS 2000). However, there are also many substances (see the following tables) where a continued decreasing trend is seen, indicating that continued regulatory focus may help keep the volumes at low and sometimes continuously decreasing levels.

Decrease in volume related to candidate listing and Annex XIV inclusion

Table 5 gives an overview of substances where candidate listing and Annex XIV inclusion seem to have led to a decrease in use quantities. For many of the substances it is not possible to distinguish between trends that occur because of candidate listing or Authorisation List inclusion, as these two regulatory dates are often close. In addition, it cannot be ruled out that the classification trigger in itself can affect volumes for long periods even after its entry into force. However, the table gives an indication of how candidate listing and Annex XIV inclusion may have affected the use quantities for many substances. In addition, there is no clear trend in whether patterns change before or after any of the two regulatory interventions; as well, the observed trends vary from country to country.

Table 5: Overview of substances where a decreasing trend in volume appears related to candidate listing or inclusion in the Authorisation List.

Time of volume decrease	Substance	DK	SE	NO	FI
Before candidate listing	5. BBP	■	■		
	6. Dibutylphthalate		■		
	8. Diarsenic trioxide			■	
	16. Chromium trioxide	■	■		■
	27. MOCA		■		■
	29. Strontium chromate		■		■
	35 DHNUP		■		
	43a. NPE	■	■		
After candidate listing and before authorisation	2. Diaminodiphenylmethane	■	■	■	■
	7 Diisobutylphthalate		■		
	10. Lead chromate	■			
	19. Potassium dichromate		■		
	27. MOCA		■		
	29. Strontium chromate		■		■
	37. DMEP	■			
After Authorisation List inclusion	2. Diaminodiphenylmethane				■
	5. BBP				■
	6. Dibutylphthalate	■	■		■
	7 Diisobutylphthalate		■		
	11. Pigment yellow	■			
	16. Chromium trioxide		■		
	29 Strontium chromate		■		

The table shows that for 14 substances in total, candidate listing and Annex XIV inclusion seem to have had a visible effect on use quantities in one or more countries.

[23] https://mst.dk/service/publikationer/publikationsarkiv/2010/jul/listen-over-uoenskede-stoffer-2009/

Continued decrease indicating combined effects of all regulatory dates

Table 6 shows a summary of plots where there appears to be continued decreasing trends, indicating that more than one of the regulatory interventions have exerted an effect on the volumes. This is considered to be the case in some countries for a large proportion (15) of the substances that are still included in the assessment. In addition to the aforementioned, there are also substances where use reaches zero in some countries during the reporting period, situations that may also occur because of regulatory focus.

Table 6: Summary of plots, where there seem to be a continued decrease in quantities through the reporting period

Substance	DK	SE	NO	FI
2. Diaminodiphenylmethane				
4. DEHP				
5. BBP				
6. Dibutylphthalate				
7. Diisobutyl phthalate				
11. Pigment yellow				
12. Pigment read				
13. TCEP				
14. Dinitrotoluene				
15. TCE				
16. Chromium trioxide				
18 b. Sodium dichromate				
19, Potassium dichromate				
27. MOCA				
29. Strontium chromate				

There are also a few substances, such as no. 2 Diaminodiphenylmethane in Sweden and 42 Octylphenol ethoxylate, where an increase in volume is seen after candidate listing and/or Annex XIV inclusion. In particular, the number of preparations, which often fluctuates more than the tonnage, shows an increase in the later years of the reporting period. There is no clear explanation for this fact, which adds to the overall assessment that SPIN data should be interpreted cautiously.

Summary of the analysis

Several substances can be placed in more than one of the above groups. This grouping of substances showing various trends has helped develop the following general conclusions from the data:

- The use in the Nordic countries has been very low and close to zero for many of the substances over the entire reporting period (Table A2.3 in Appendix 2 shows that this is the case in one or more of the Nordic countries for 18 substances).

- It appears that initial identification of the hazardous properties (the trigger dates) or other factors that occurred before candidate listing of a substance leads to decreasing use volumes in many cases. Table 4 gives an overview of the trends for each substance and country.

- The 15 substances that were classified as CMR in the 1990s, before the SPIN reporting period, are generally used in low volumes throughout the period, before they were included in the Candidate List.

- Many plots show decreasing use throughout the period both before and after each regulatory date (Table 6) and in many cases, the use volume also reaches zero before the end of the study period. These patterns may indicate that the use of consecutive legal interventions (classification and subsequent inclusion in the Candidate List and Annex XIV) may work to instigate continuous efforts to substitute, but may also reflect that substitution may be challenging for the companies, as well as that effects of any given legal intervention are seen over several years, as mentioned in other reports (See Section 1.4).

- Although there is already a decreasing trend in a use of a substance, its inclusion in the Candidate and Authorisation Lists may be a final incentive to fully eliminate or minimise the use of the substance.

- The use often fluctuates and it appears that the market reacts rapidly to various conditions - whether legislative or other factors. The fluctuations are often different among the Nordic countries. These fluctuations may also be associated with irregular updates by the notifiers to the registers, or other factors such as increasing or decreasing stocks.

- There appear to be some errors in the SPIN data, constituting a drawback in this analysis. For many of the graphs a clear interpretation is impossible or difficult because of unexpected data patterns, outliers, missing data and low volumes.

4. Overall discussion

4.1 Findings in earlier studies

Several studies have investigated and discussed the effect of candidate listing and Authorisation List inclusion under REACH. Overall, these studies conclude that various stakeholders experience or believe that candidate listing and Authorisation List inclusion are important drivers for substituting SVHCs, and that these procedures lead to funding in R&D for developing alternatives - funding which may, however, depend considerably on the specific substance and its application.

There is less quantitative evidence illustrating the extent to which candidate listing and Authorisation List inclusion actually drives substitution, a situation naturally linked to the fact that the whole REACH authorisation procedure is relatively new and that its full effect cannot yet be seen. One issue may be that suitable alternatives are not yet available. It is also difficult to monitor a possible effect as REACH registration data are not regularly updated and that other data sources, e.g. EUROSTAT/PRODCOM data, have been found to be too unspecific for assessing the effect on individual substances.

A study published by the Austrian Federal Ministry of Agriculture, Forestry and Water Management (Backes, 2017) looked into SPIN for a few substances and found that regulatory focus leads to substitution in general. The study suggested that SPIN data from the Nordic Product Registers are not necessarily representative of the EU average, one issue being that Nordic countries are sometimes ahead of the EU average in substituting hazardous chemicals.

The REACH review (EC, 2018) concluded that evidence is still lacking to demonstrate that chemical legislation has led to a more fundamental development of alternative technologies and substances, new business models and non-chemical solutions. Therefore, even if the amount of an SVHC in use is decreased, it does not necessarily lead to less risk. This is also discussed in the current study where TCEP (on the Authorisation List) appears for a period to have been the substitute for various brominated flame retardants that were banned or under regulatory attention.

The REACH review (EC, 2018) concludes that the entire REACH authorisation process, in any case, contributes to the identification and control of SVHC, because of e.g. improved exposure control, which would not be reflected in data on amounts used.

Several studies also note that it is difficult to conclude that REACH, or procedures under REACH alone, lead to substitution as other market factors and other legislation, such as Occupational Health and Safety legislation, also affect use and substitution. This more complex picture may e.g. pertain to carcinogens within the scope of the CMD[24] and to the general ban of CMR substances in consumer products.

4.2 Perspectives and conclusions from the current study

Given that previous studies showed that EUROSTAT/PRODCOM and REACH registration data are not currently good indicators for trends in use of SVHC substances as defined under

[24] Directive (2004/37/EC) on carcinogens or mutagens at work of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

REACH, the current study has investigated trends in SPIN data from the Nordic product registers (Denmark, Norway, Sweden and Finland) for all substances included on their own or as a part of group entries in the REACH Authorisation List.

SPIN data have some inherent uncertainties, including data confidentiality, that data indicates 'net application' (i.e. manufacture plus import minus export), and possible erroneous reporting (See Section 3.1.2). These uncertainties *inter alia* resulted in a few substances being discarded upfront because of lack of relevant data (30 were kept in the assessment) and deselection of a further five substances following further analysis before drawing conclusions. Overall, care should be taken in drawing firm conclusions based on the current study.

One overall finding is that regulatory focus on these SVHC substances, often dating several decades back in the Nordic countries, has reduced consumption volumes over the years.

For some substances in some countries, the major decrease in amounts appears largely related to a CMR classification before candidate listing. For some substances, a significant decrease was seen associated with the candidate listing/Authorisation List inclusion. For several substances, however, the continued focus (classification, candidate listing, Authorisation List inclusion) as a whole appears to drive the amounts down. This conclusion is in line with previous studies, which also indicate combined effects of various legislation and other market drivers on substitution.

For a number of substances, the three regulatory dates are too close to conclude which one of the three is associated with the main reduction trends. The pre-SPIN 1992-1999 data cordially provided by the Swedish Product Register illustrate examples where CMR classification in the 1990s led to significant decreases in amounts applied, but there are also examples where this was not the case.

There are often differences between the timing, trends and fluctuations among the four Nordic countries; consequently, trends may be different among the countries for the same substance. This finding may be a reflection of uncertainties, but it may also be due to the fact that applications are different in Nordic countries, where for example Sweden has more chemical industries than Denmark has.

In line with the findings in previous studies, the significant differences in trends between substances is also likely linked to the possibility for substitution of that specific substance in its major applications.

The current study looked into underlying Use and Industry category (UC and IC) data in SPIN for some of the substances. These data could sometimes confirm/explain reduction of usage in a major application because of legal attention, such as substitution of DEHP as softener in soft PVC and lead pigments in paints and similar applications. However, these categories are often too unspecific to clearly specify applications and to explain differences between substances and countries.

However, further work involving UC and IC SPIN data combined with more specific research on individual substances or specific substance groups and considering application or country-specific details may provide more detailed insights on when one or another legal intervention is more powerful.

As also discussed in Backes (2017), deviations might be considerable between Nordic countries with a long tradition for focus on hazardous chemicals and the EU average. Care should therefore be taken in generalising results from the current study to the EU context.

5. Conclusion

SPIN data are associated with a range of uncertainties and are therefore difficult to interpret in some situations. Therefore, care should be taken in drawing overly firm conclusions based on these data.

The current study clearly indicates that regulatory action (including harmonised classification/assigning the SVHC designation) over the past decades on substances currently on the REACH Authorisation List has resulted in considerably reduced tonnages in the Nordic countries Denmark, Norway, Sweden and Finland. This is illustrated in reduced notified volumes to the countries' product registers. As pointed out by others, this might be more pronounced in the Nordic countries with their strong historical focus on substitution of hazardous substances than in the EU on average.

It appears that candidate listing and Authorisation List inclusion generally keep or drive tonnages to low levels and thus may function as drivers for eventual substitution in situations where it would be difficult to identify substitutes in the short term.

The findings of the project cannot support that one type of legal intervention (e.g. harmonised classification) is more or less important than another (e.g. candidate listing or Annex XIV inclusion).

The relative effects of these interventions appear to differ from substance to substance, from country to country, and from application to application and often data indicate that various legal interventions act together to reduce volumes. This finding is in line with findings in previous studies on this issue.

Further detailed analysis of the data in the current study combined with further research related to specific substances, substance groups and applications may provide further insight into when and why one legal intervention is more powerful than another.

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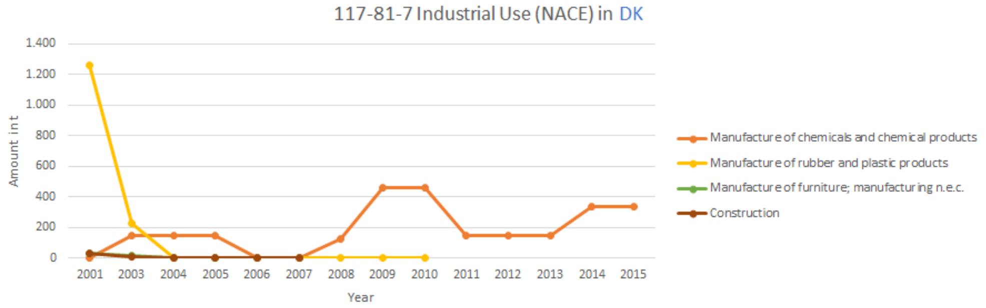
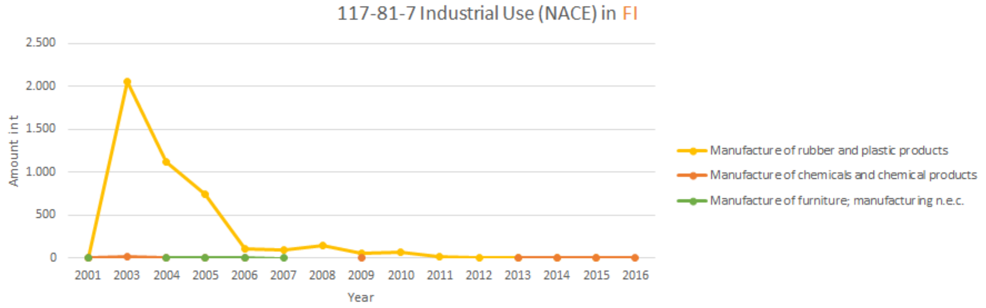
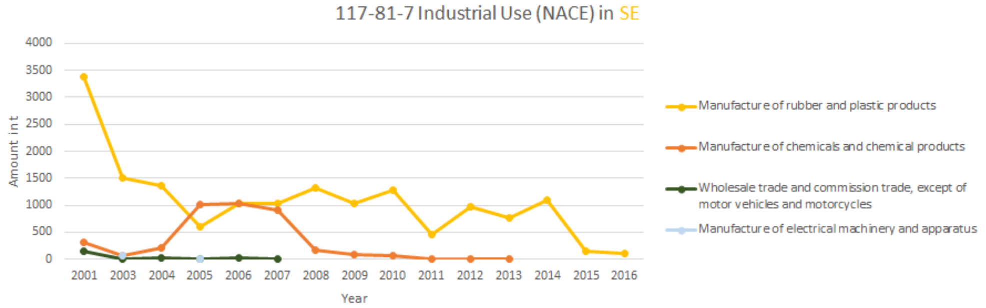
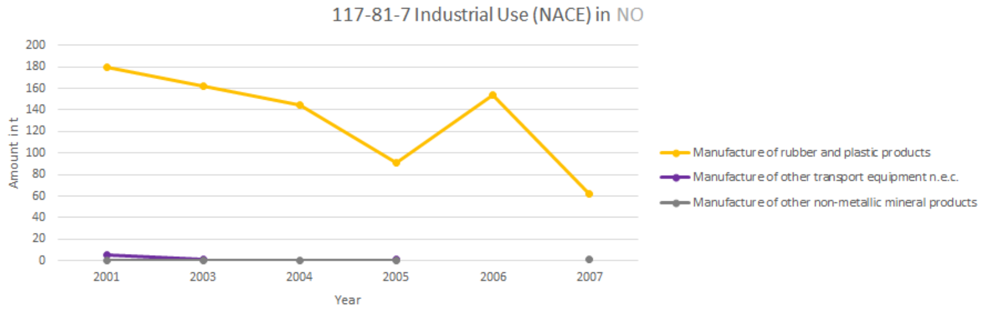
Appendix 1. Plots of tonnages in industrial and use categories for selected substances

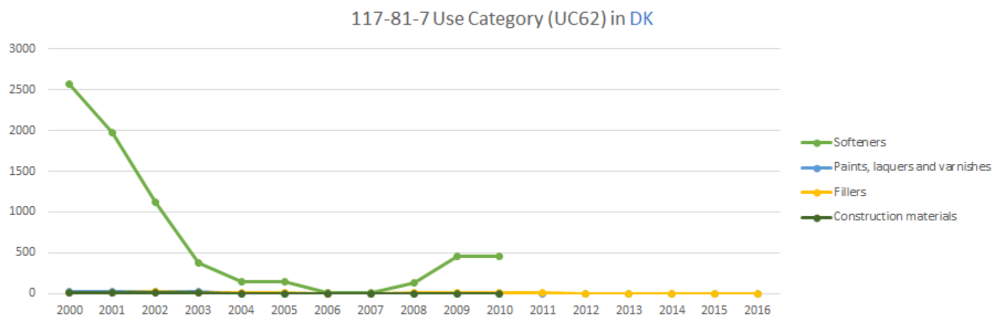
No 4, CAS no 117-81-7, Bis(2-ethylhexyl) phthalate (DEHP)

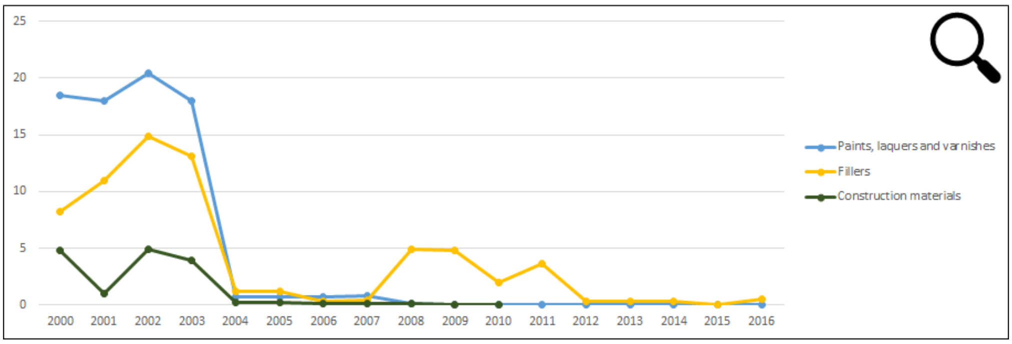


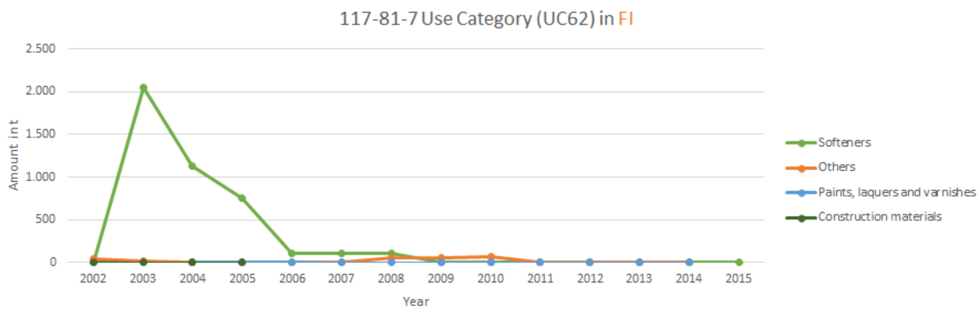


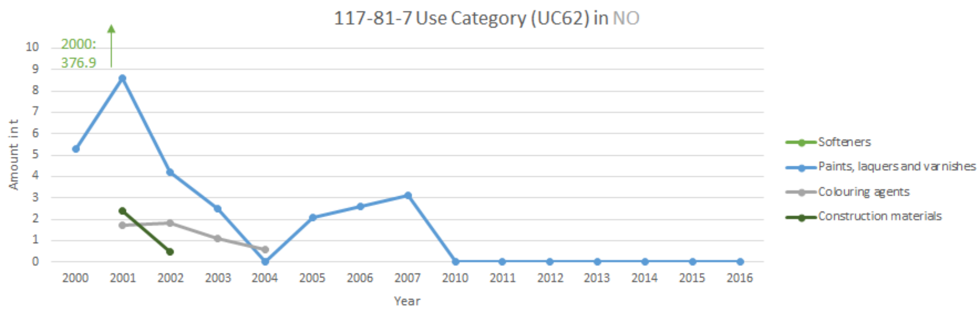


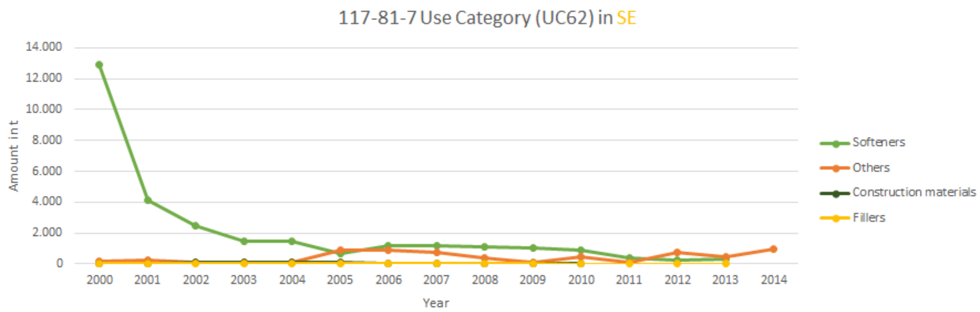



117-81-7 Use Category (UC62) in DK
Softeners
Paints, laquers and varnishes
Fillers
Construction materials

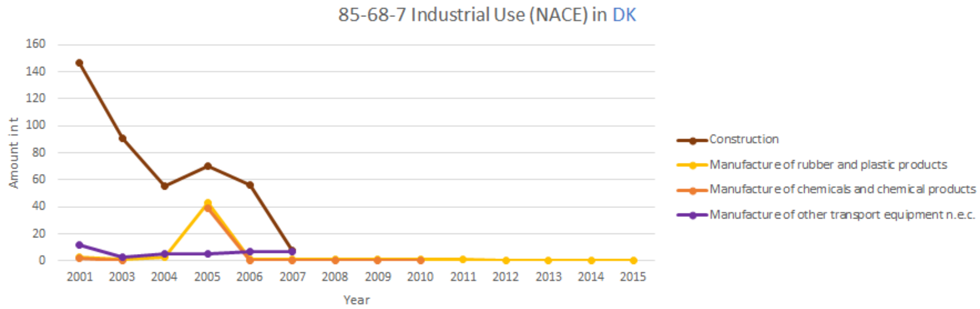

Paints, laquers and varnishes
Fillers
Construction materials

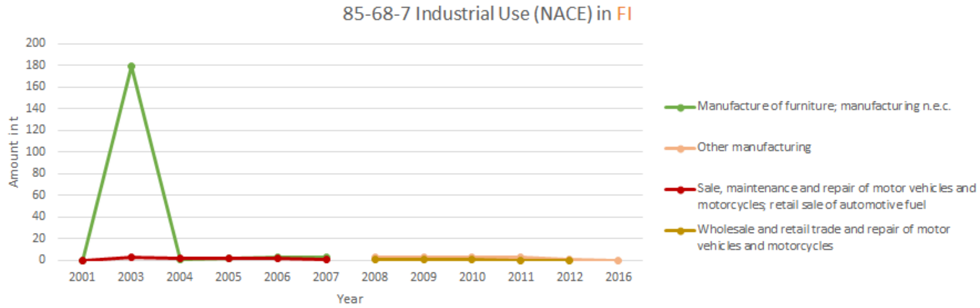

117-81-7 Use Category (UC62) in FI
Amount in t
Year
Softeners
Others
Paints, laquers and varnishes
Construction materials

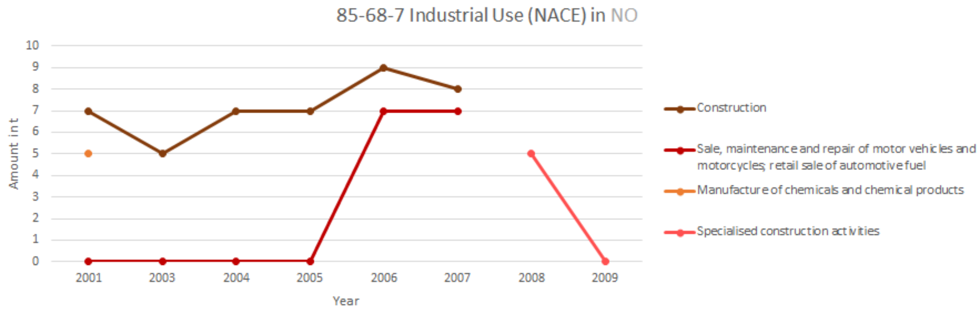

117-81-7 Use Category (UC62) in NO
2000:
376.9
Amount in t
Year
Softeners
Paints, laquers and varnishes
Colouring agents
Construction materials

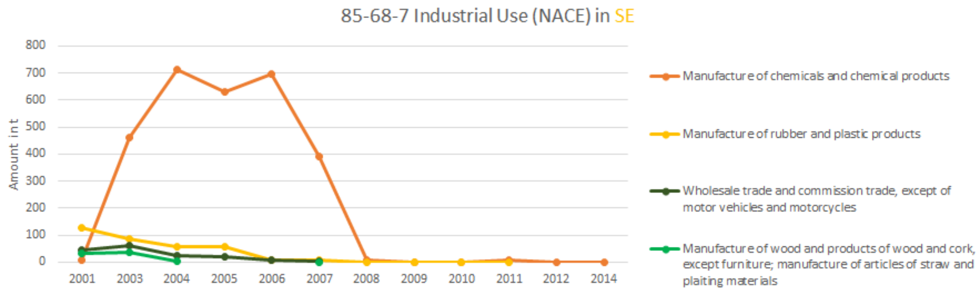

117-81-7 Use Category (UC62) in SE
Amount in t
Year
Softeners
Others
Construction materials
Fillers

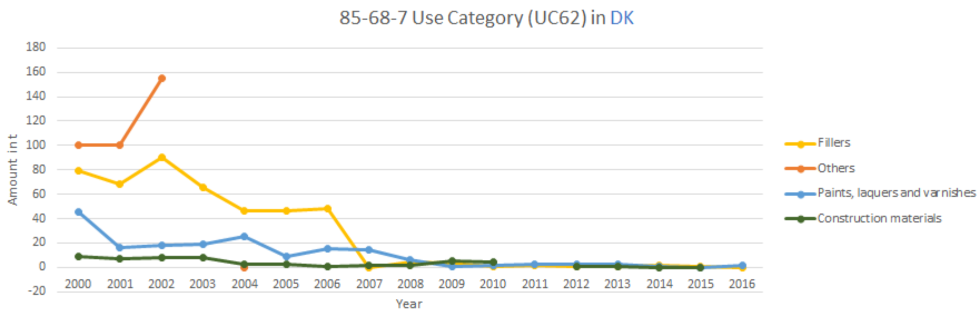
No 5, CAS no 85-68-7, Benzyl butyl phthalate

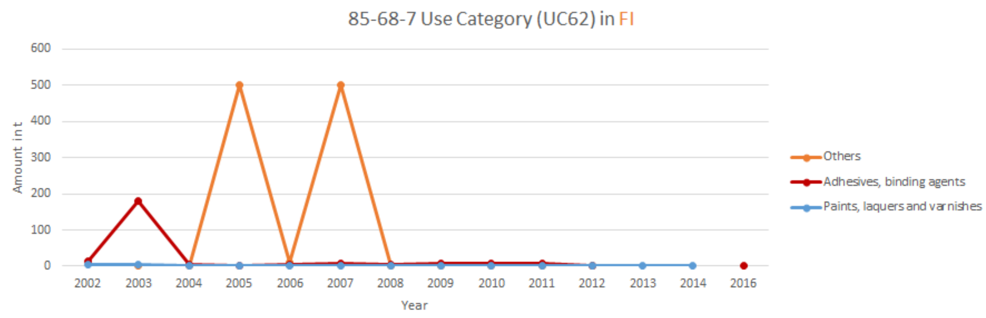


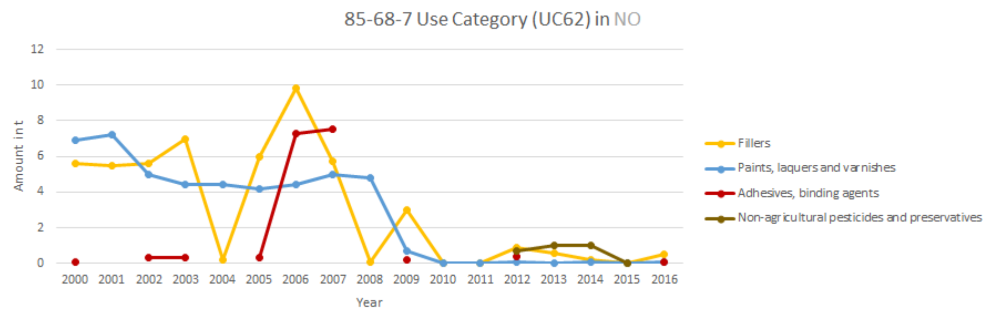


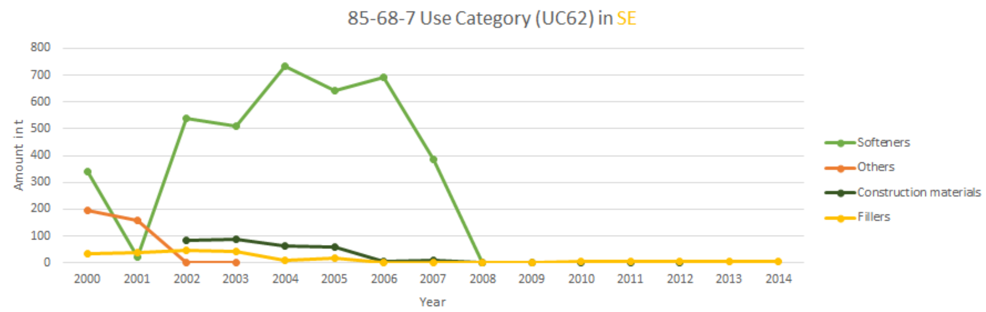




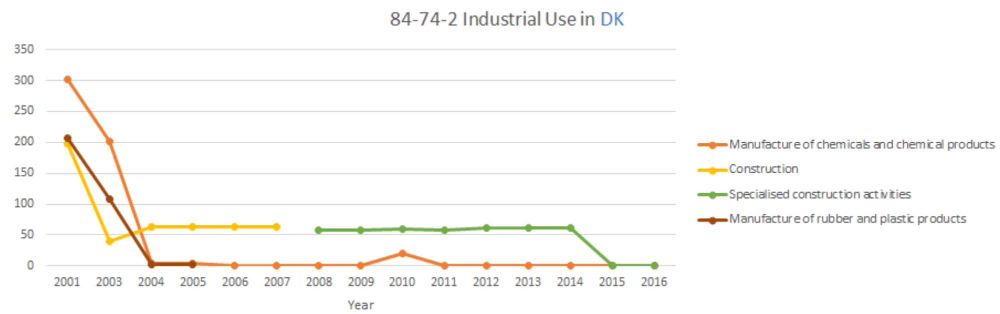


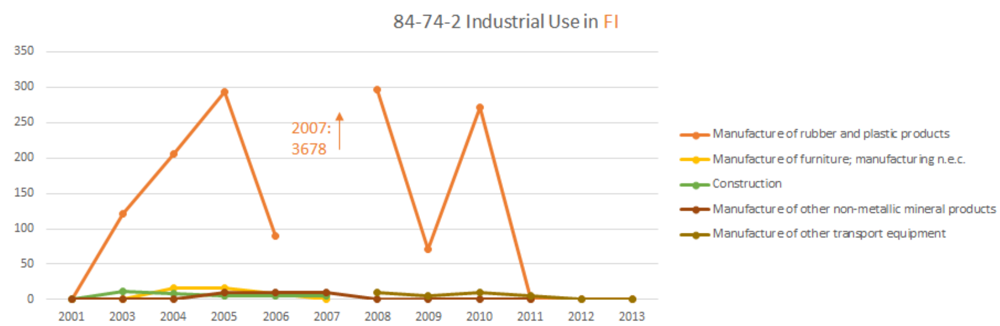


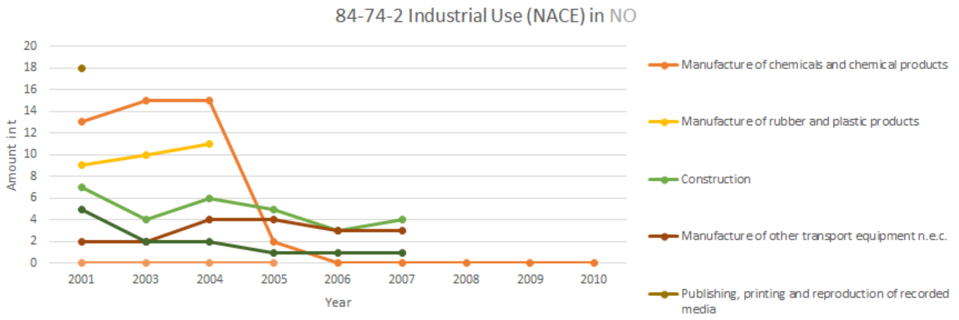


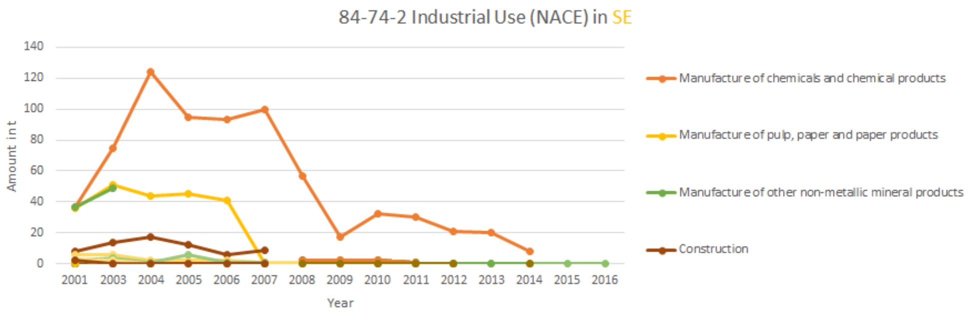


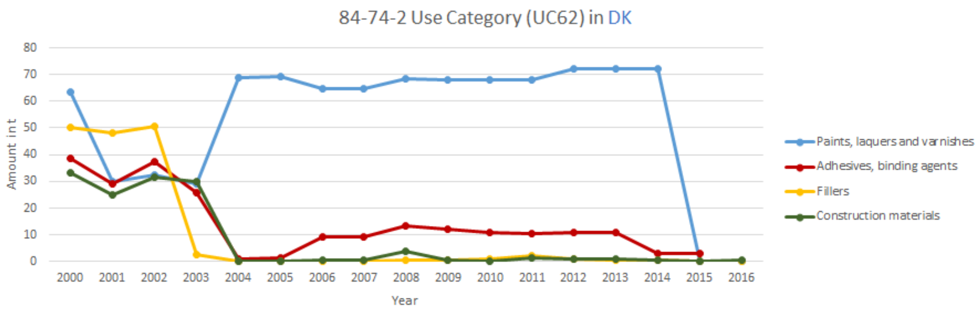
No 6, CAS no 84-74-2, Dibutyl phthalate

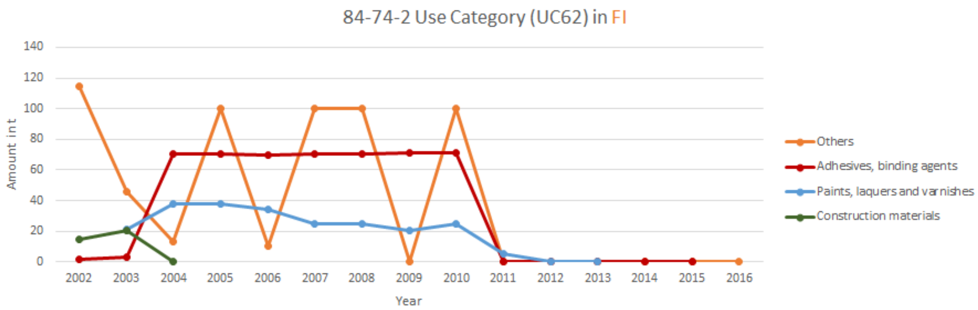


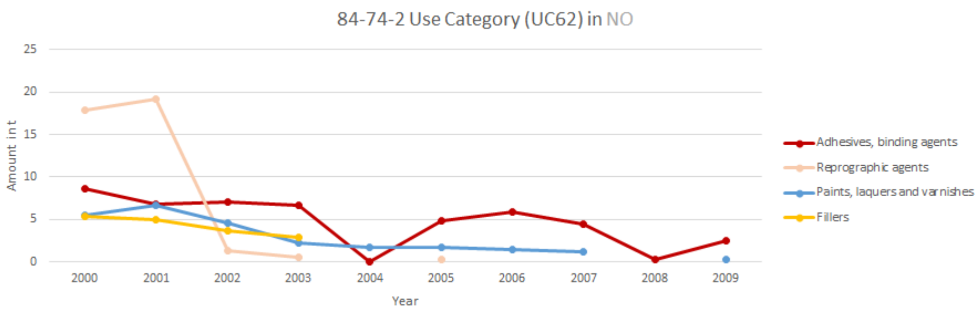


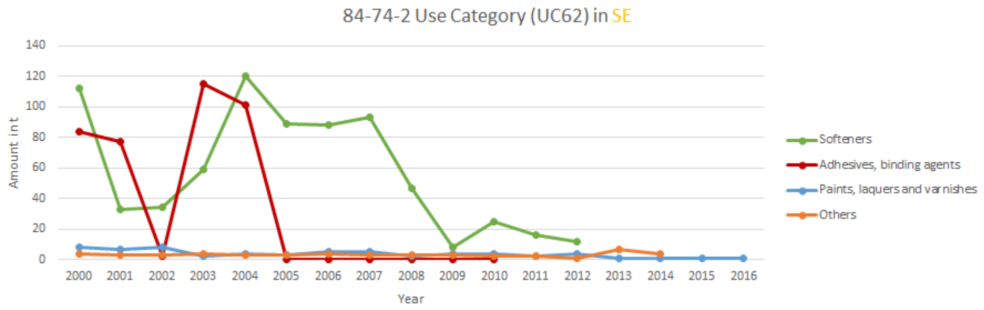

84-74-2 Industrial Use (NACE) in NO
Amount in t
Year
Manufacture of chemicals and chemical products
Manufacture of rubber and plastic products
Construction
Manufacture of other transport equipment n.e.c.
Publishing, printing and reproduction of recorded media


84-74-2 Industrial Use (NACE) in SE
Amount in t
Year
Manufacture of chemicals and chemical products
Manufacture of pulp, paper and paper products
Manufacture of other non-metallic mineral products
Construction

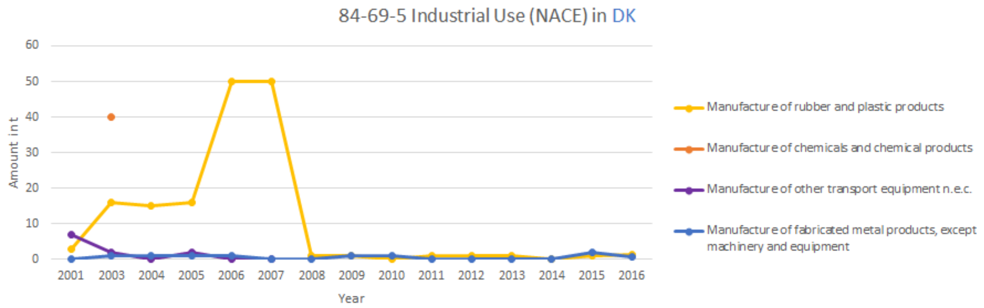

84-74-2 Use Category (UC62) in DK
Amount in t
Year
Paints, laquers and varnishes
Adhesives, binding agents
Fillers
Construction materials

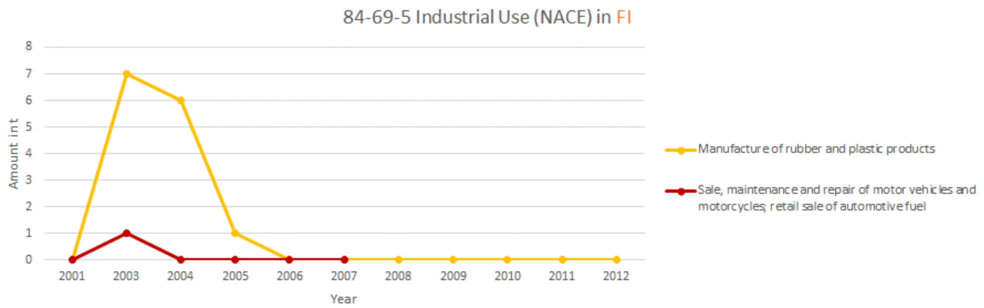

84-74-2 Use Category (UC62) in FI
Amount in t
Year
Others
Adhesives, binding agents
Paints, laquers and varnishes
Construction materials

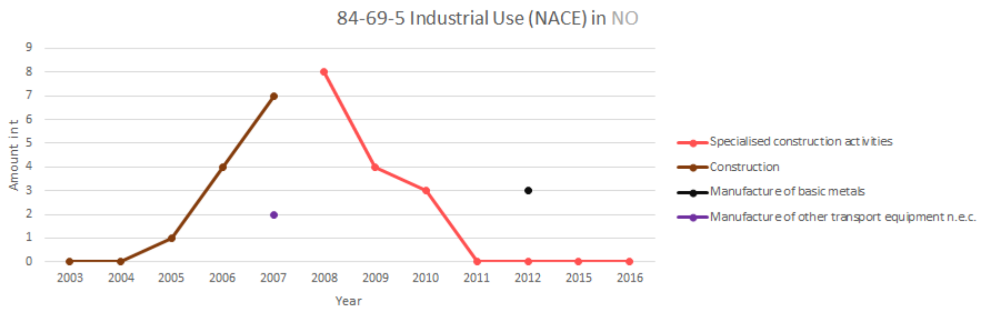

84-74-2 Use Category (UC62) in NO
Amount in t
Year
Adhesives, binding agents
Reprographic agents
Paints, laquers and varnishes
Fillers

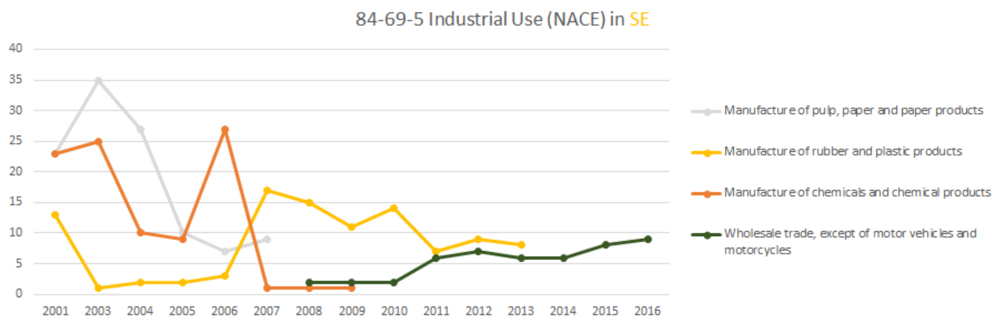


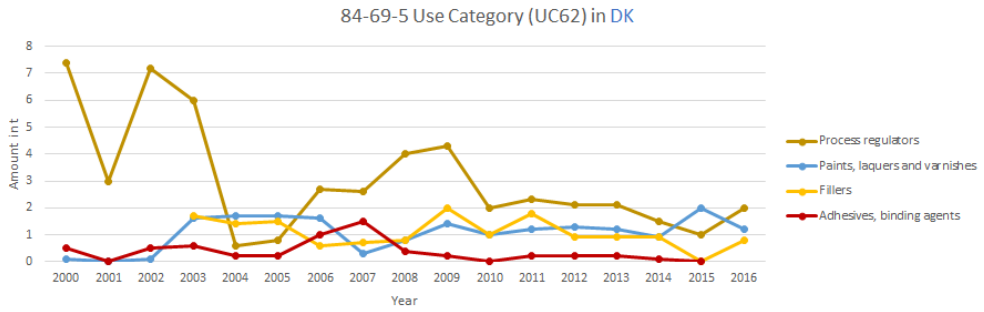
No 7, CAS no 84-69-5, Diisobutyl phthalate

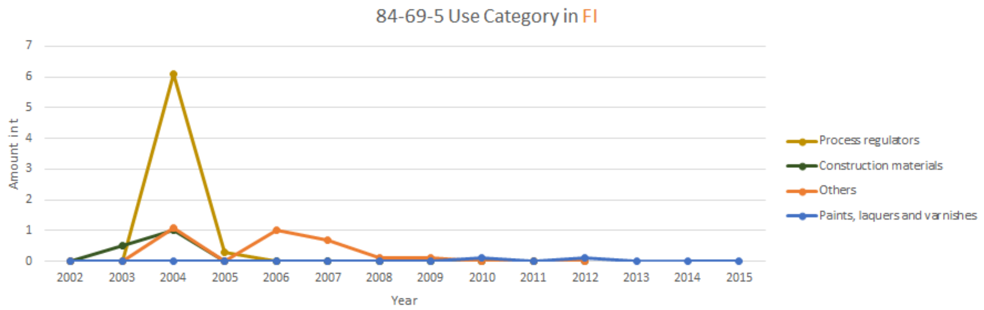


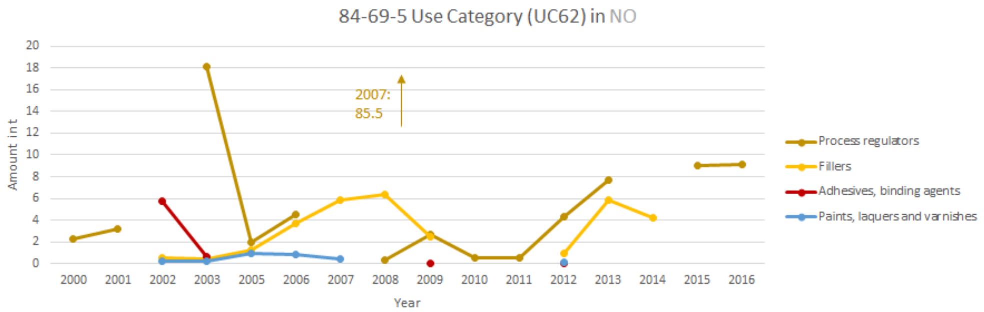


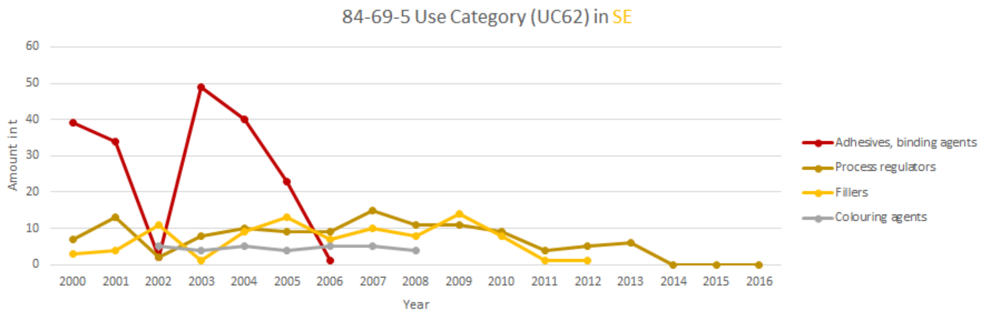




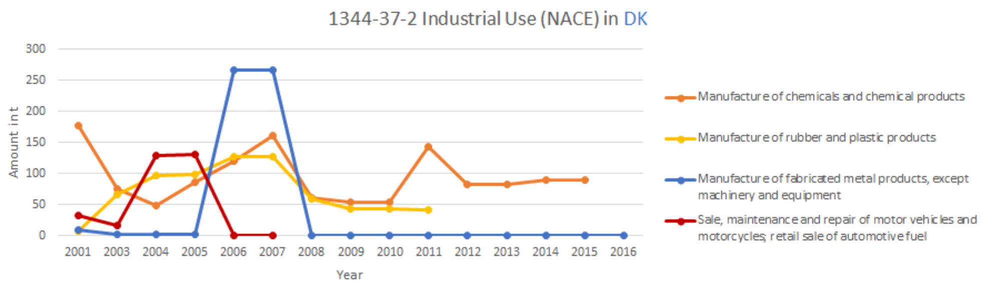


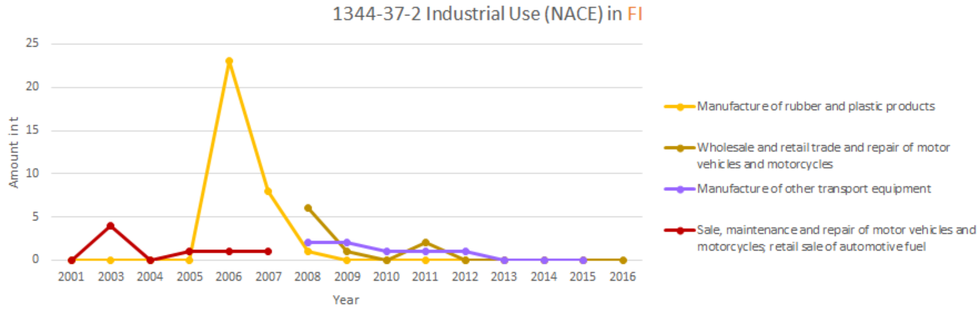


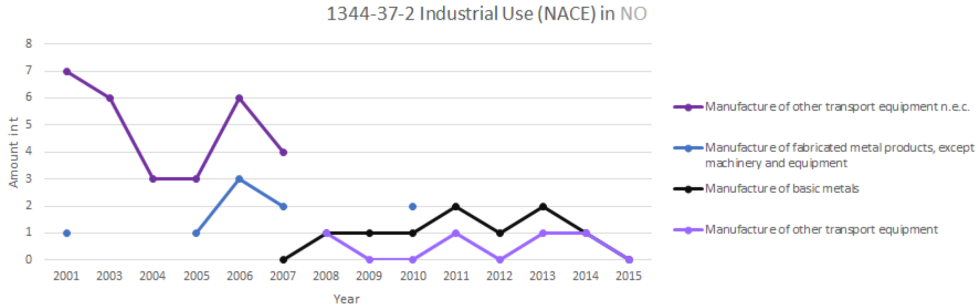


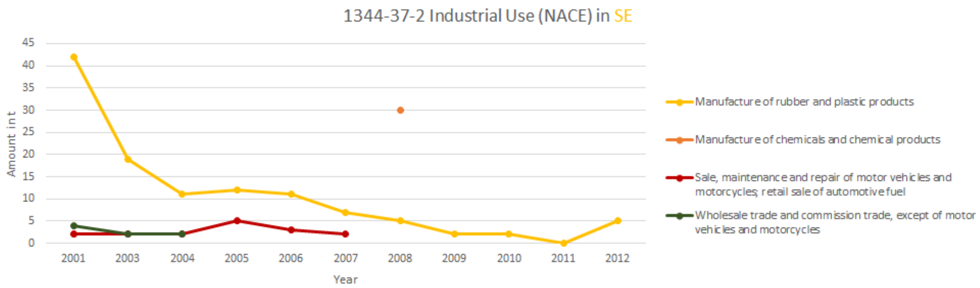


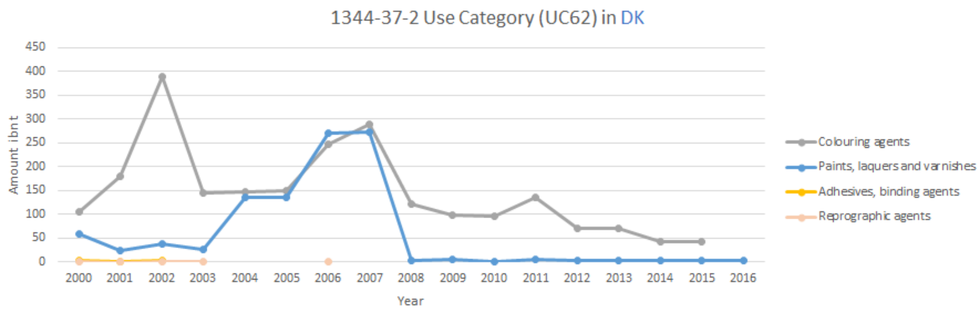
No 11, CAS no 1344-37-2, Lead sulfochromate yellow (C.I. Pigment Yellow 34)

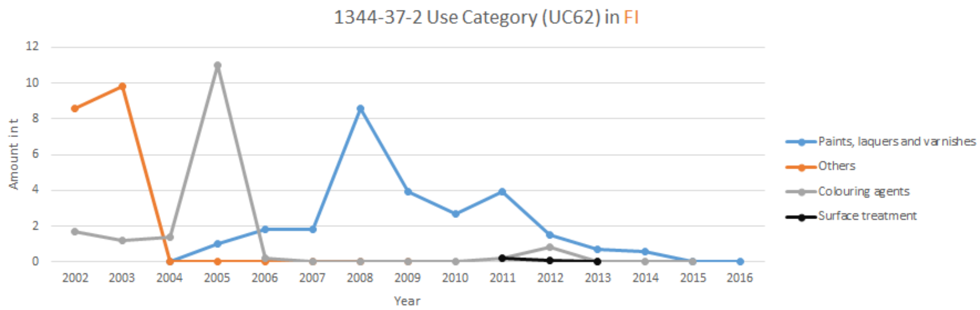


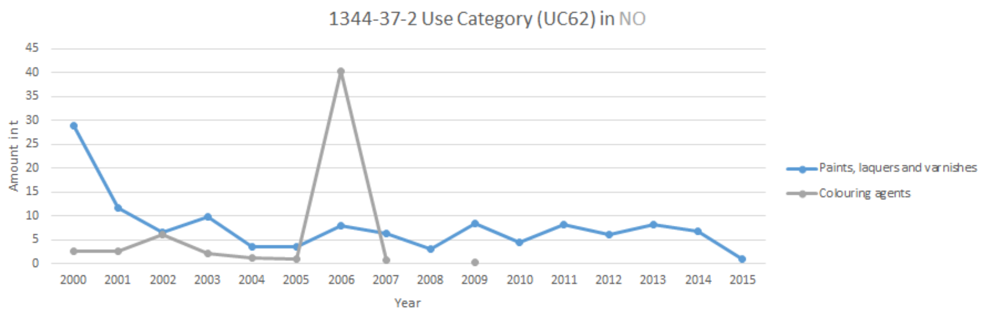

1344-37-2 Industrial Use (NACE) in FI
25
20
15
10
5
0
Amount in t
2001
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
Year
Manufacture of rubber and plastic products
Wholesale and retail trade and repair of motor vehicles and motorcycles
Manufacture of other transport equipment
Sale, maintenance and repair of motor vehicles and motorcycles; retail sale of automotive fuel

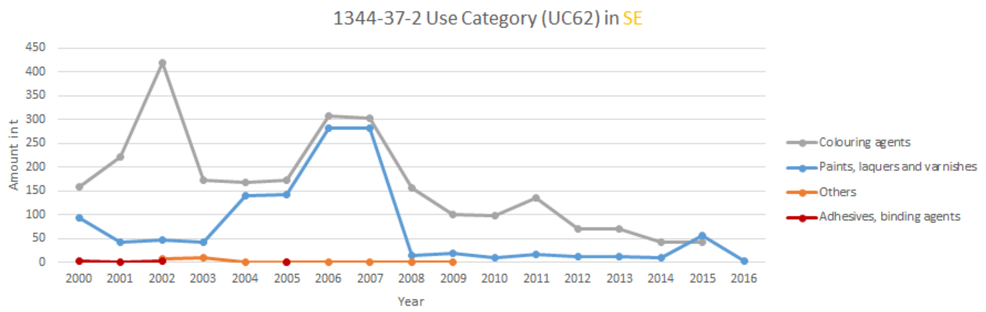

1344-37-2 Industrial Use (NACE) in NO
8
7
6
5
4
3
2
1
0
Amount in t
2001
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
Year
Manufacture of other transport equipment n.e.c.
Manufacture of fabricated metal products, except machinery and equipment
Manufacture of basic metals
Manufacture of other transport equipment


1344-37-2 Industrial Use (NACE) in SE
45
40
35
30
25
20
15
10
5
0
Amount in t
2001
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
Year
Manufacture of rubber and plastic products
Manufacture of chemicals and chemical products
Sale, maintenance and repair of motor vehicles and motorcycles; retail sale of automotive fuel
Wholesale trade and commission trade, except of motor vehicles and motorcycles

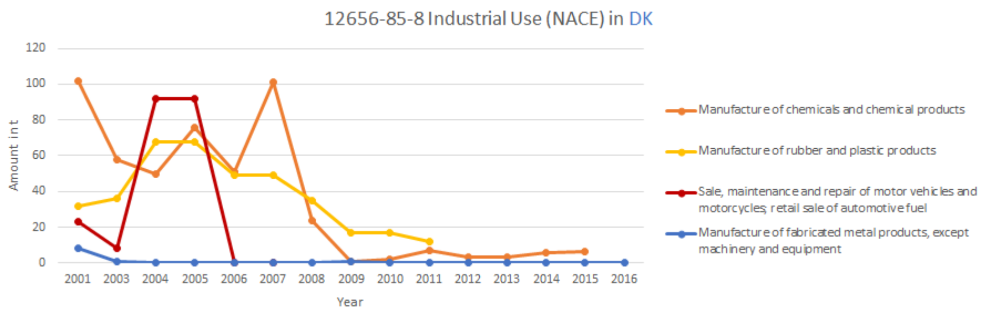

1344-37-2 Use Category (UC62) in DK
450
400
350
300
250
200
150
100
50
0
Amount in t
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
Year
Colouring agents
Paints, laquers and varnishes
Adhesives, binding agents
Reprographic agents

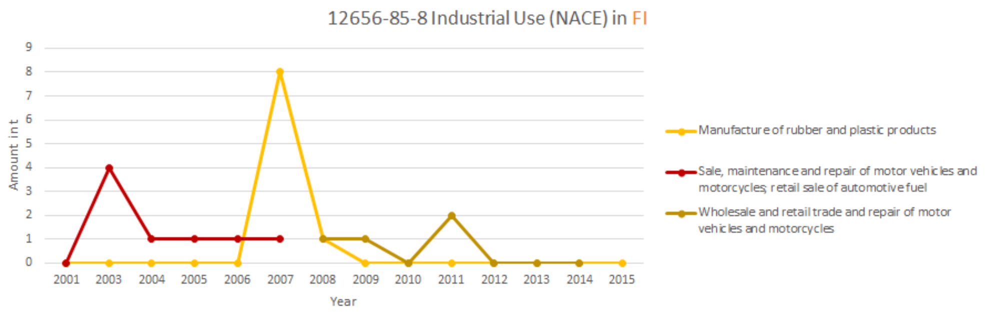

1344-37-2 Use Category (UC62) in FI
12
10
8
6
4
2
0
Amount in t
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
Year
Paints, laquers and varnishes
Others
Colouring agents
Surface treatment

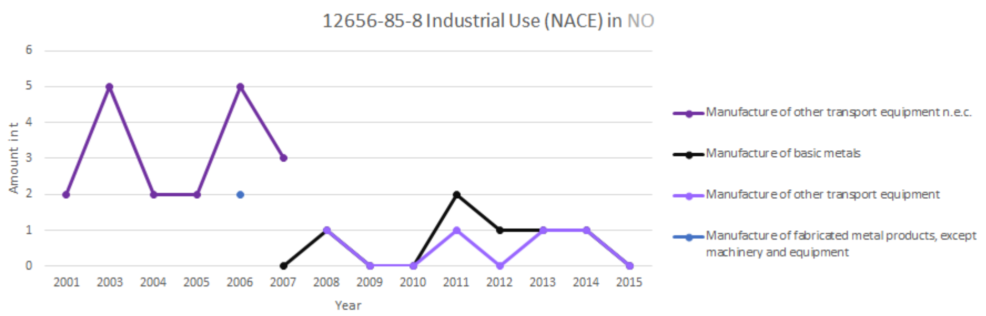


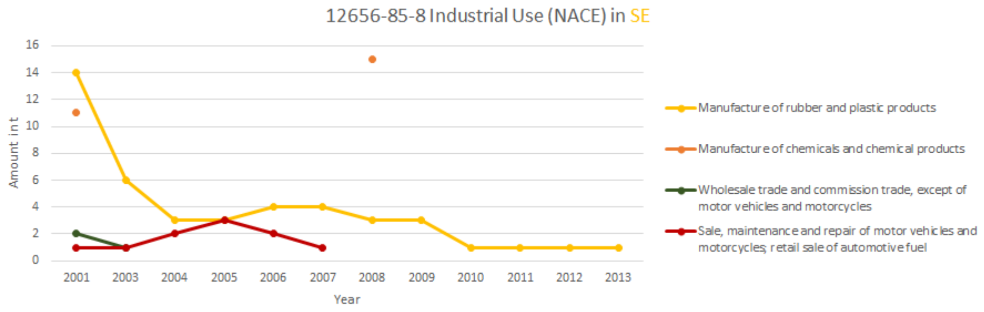


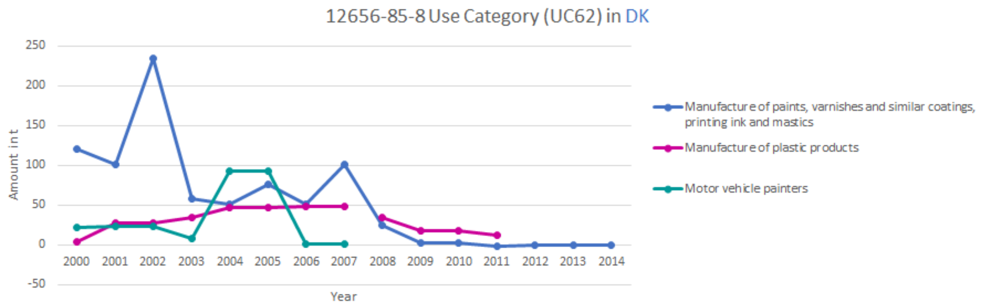
No 12, CAS no 12656-85-8, Lead chromate molybdate sulfate red (C.I. Pigment Red 104)

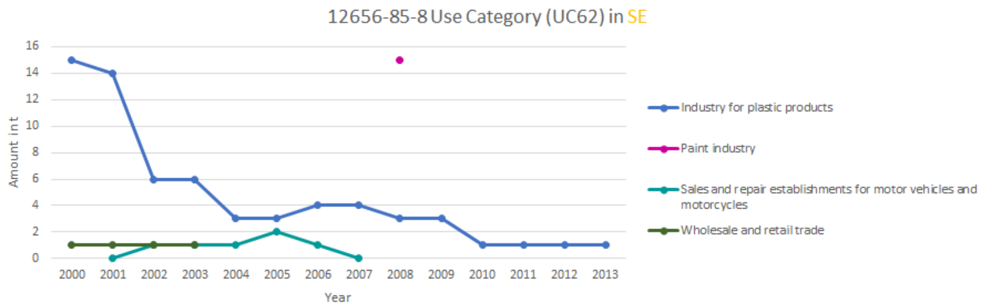




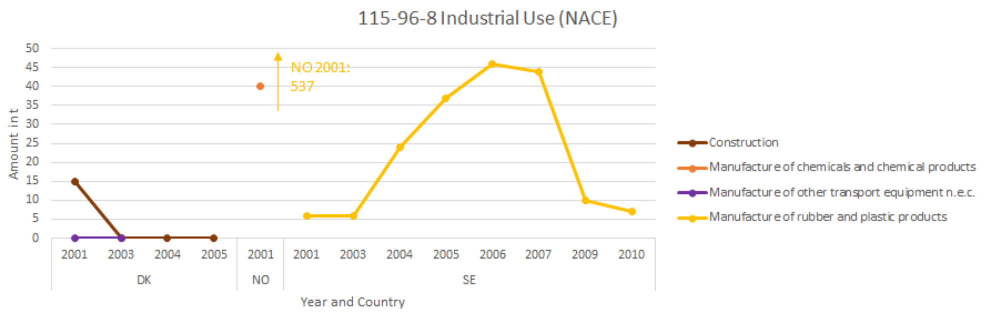


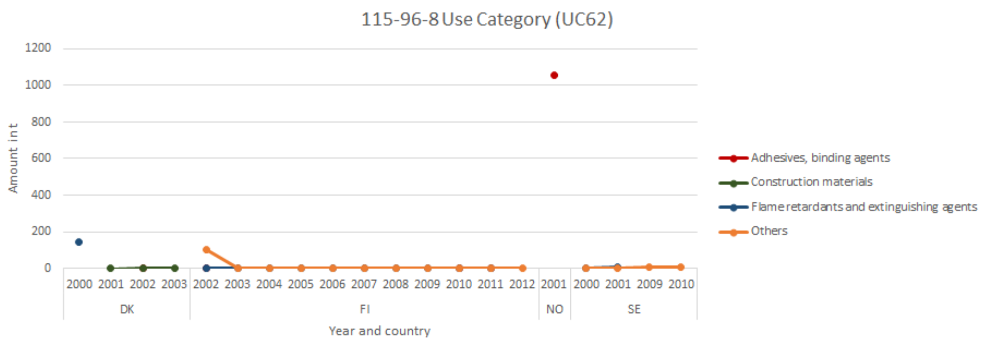




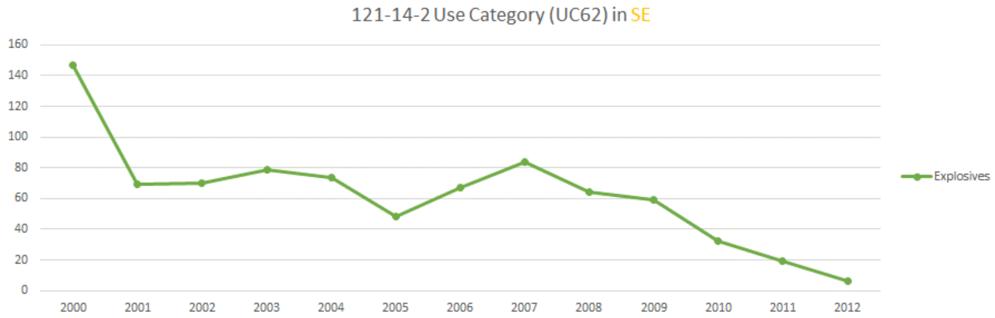


No 13, CAS no 115-96-8, Tris(2-chloroethyl)phosphate (TCEP)

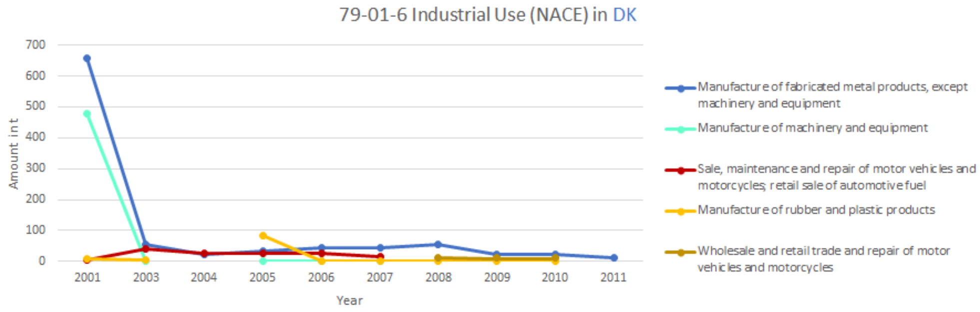


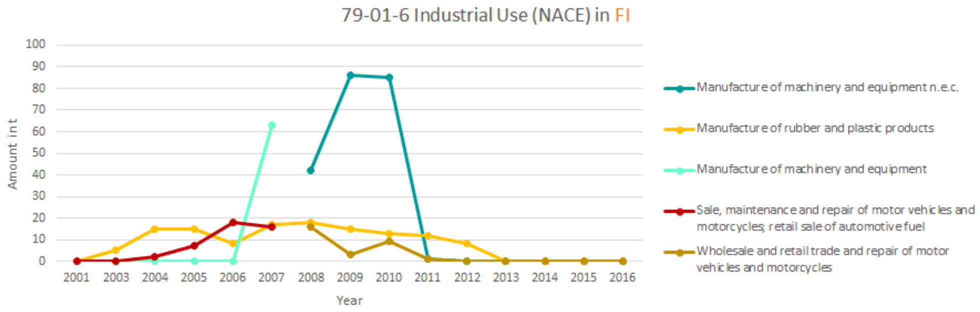


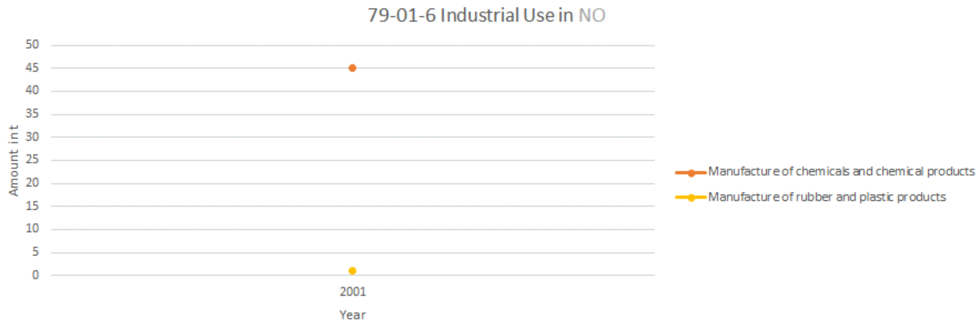
No 14, CAS no 121-14-2, 2,4-Dinitrotoluene

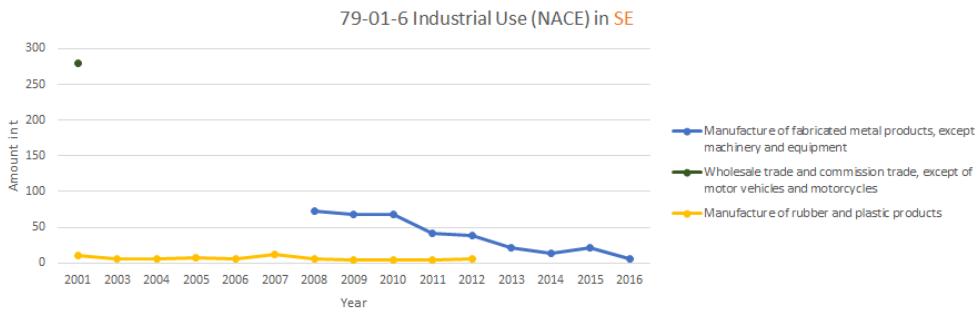


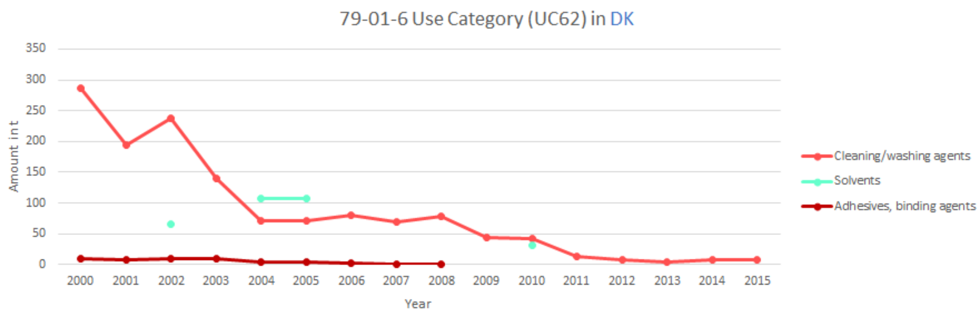
No. 15, CAS no 79-01-6, Trichloroethylene (TCE)

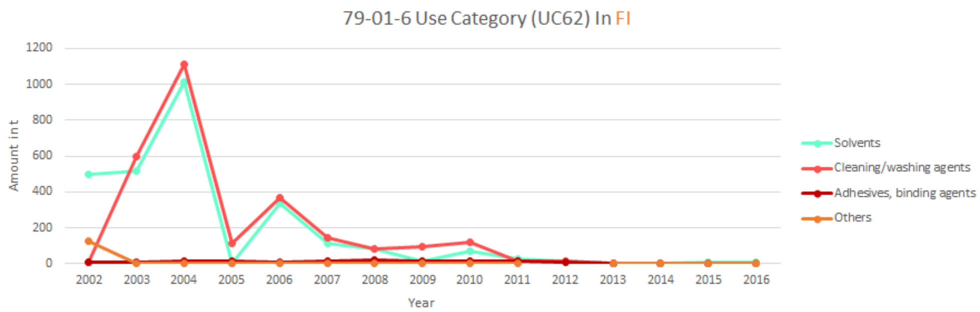


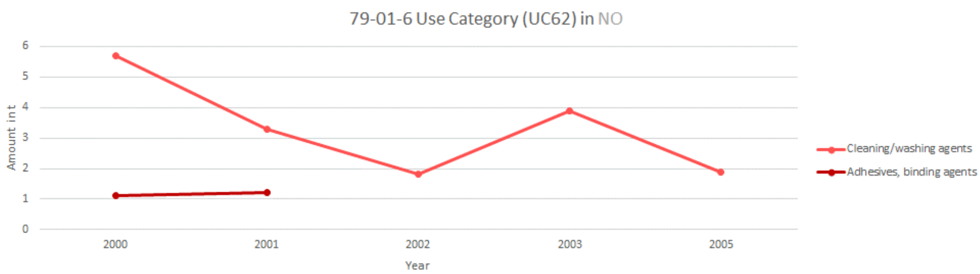


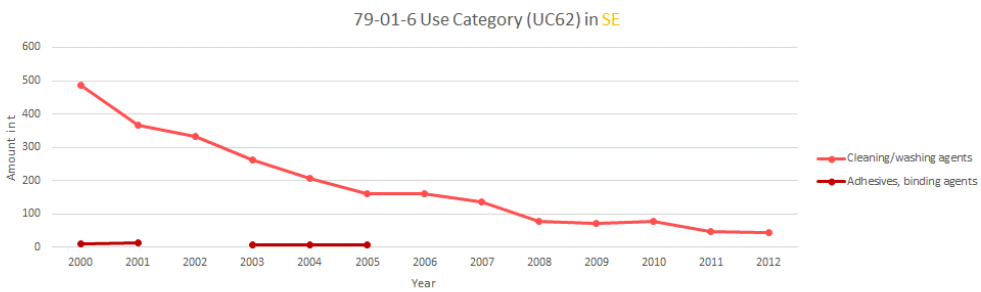




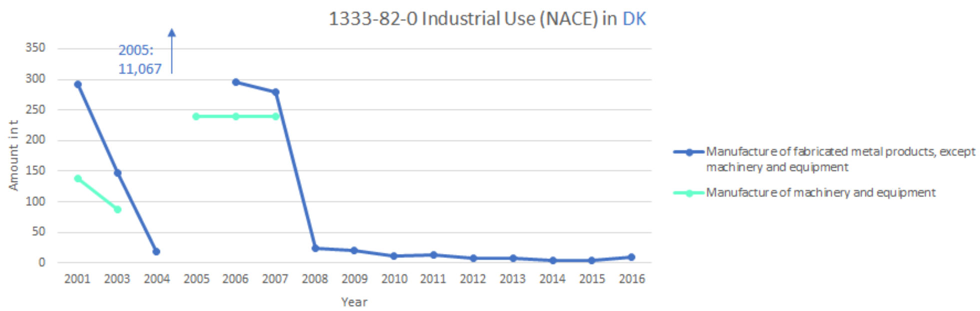


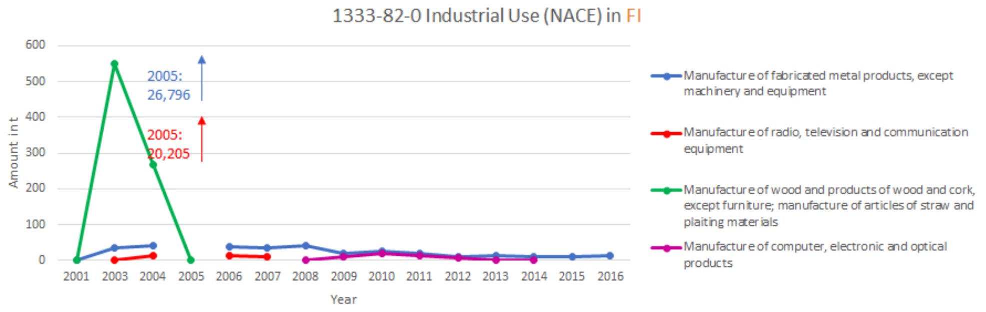


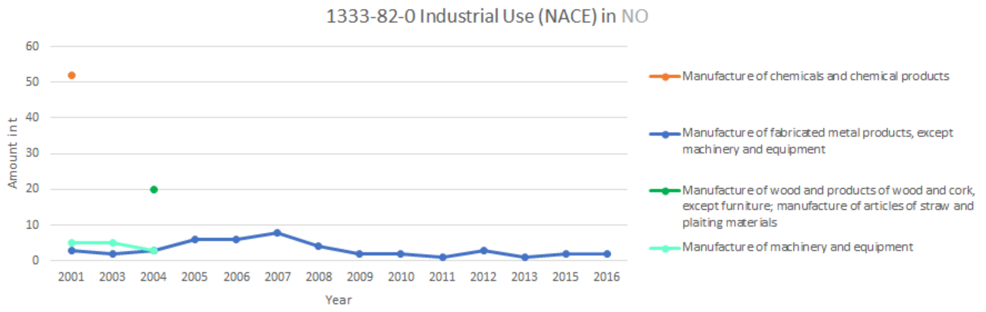


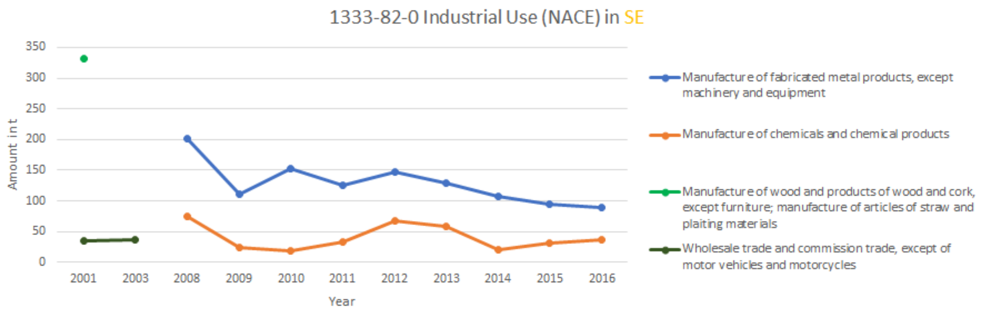


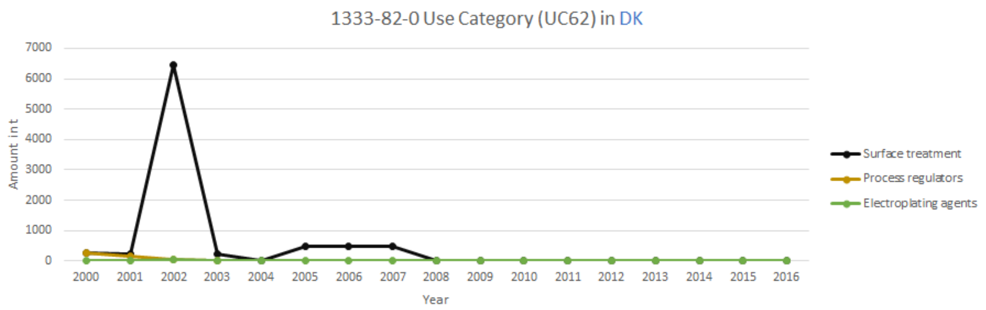
No 16, CAS no 1333-82-0, Chromtrioxide

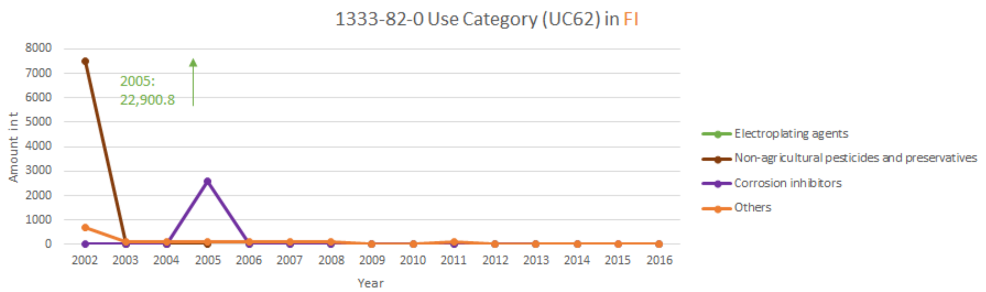


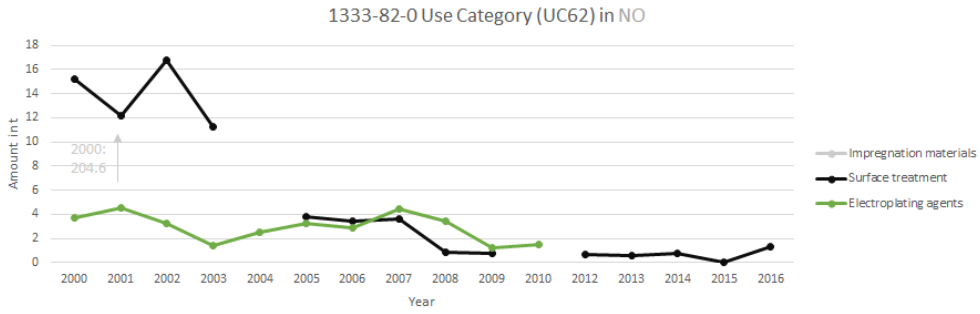

1333-82-0 Industrial Use (NACE) in FI
Amount in t
Year
2005: 26,796
2005: 20,205
Manufacture of fabricated metal products, except machinery and equipment
Manufacture of radio, television and communication equipment
Manufacture of wood and products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials
Manufacture of computer, electronic and optical products

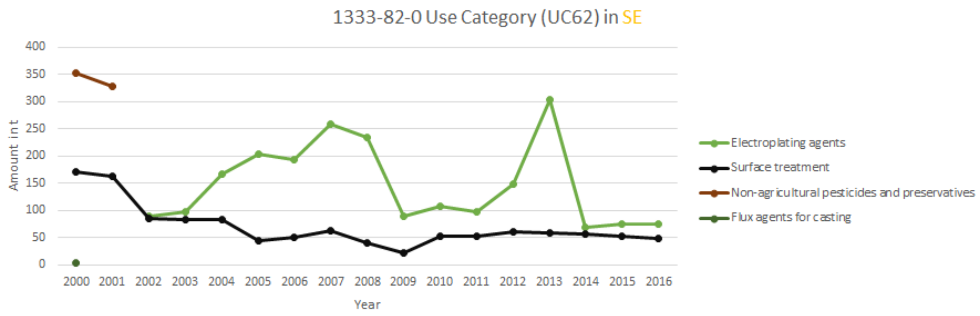

1333-82-0 Industrial Use (NACE) in NO
Amount in t
Year
Manufacture of chemicals and chemical products
Manufacture of fabricated metal products, except machinery and equipment
Manufacture of wood and products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials
Manufacture of machinery and equipment


1333-82-0 Industrial Use (NACE) in SE
Amount in t
Year
Manufacture of fabricated metal products, except machinery and equipment
Manufacture of chemicals and chemical products
Manufacture of wood and products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials
Wholesale trade and commission trade, except of motor vehicles and motorcycles

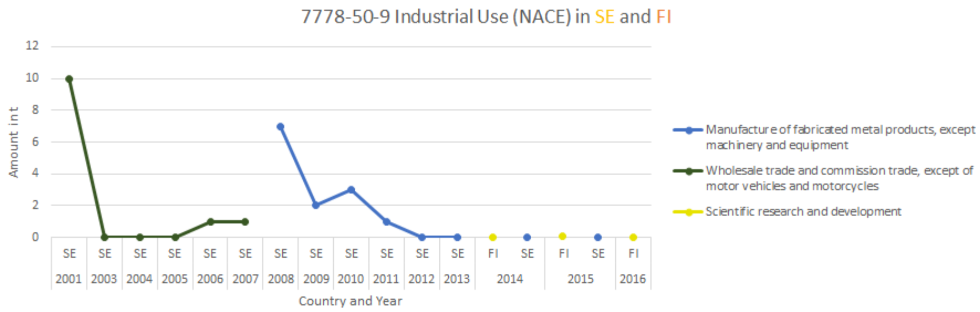

1333-82-0 Use Category (UC62) in DK
Amount in t
Year
Surface treatment
Process regulators
Electroplating agents

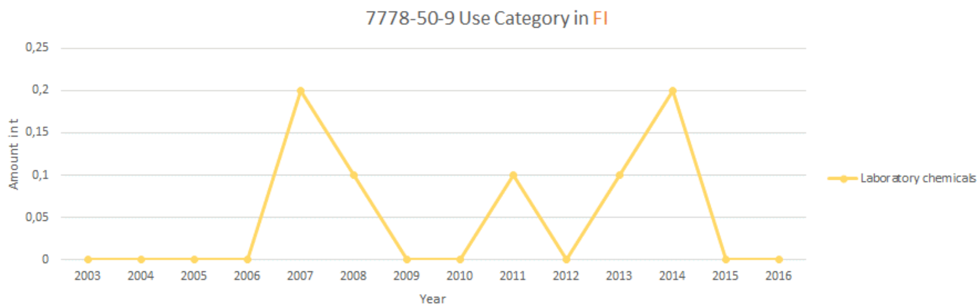

1333-82-0 Use Category (UC62) in FI
Amount in t
Year
2005: 22,900.8
Electroplating agents
Non-agricultural pesticides and preservatives
Corrosion inhibitors
Others

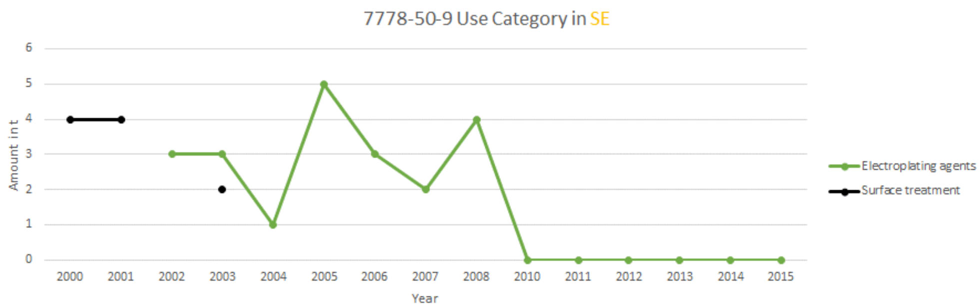




No 19, CAS no 7778-50-9, Potassium dichromate







Appendix 2. Tables of substances for which information cannot be used in the analysis for one or more countries

Errors and missing data

Table A2.1: Overview of plots where data are missing or possible errors are found.

	Substance	DK	SE	NO	FI
Plots for which data are miss-ing	*1, Musk xylene*				■
	14, Dinitrotoluene	■			■
	23, MDA	■		■	
	27, MOCA			■	
	34, DIHP		■	■	■
	35, DHNUP				■
	37,DMEP		■	■	■
Plots for which there are clear possible errors in reporting to SPIN	*2, Diaminodimethyl..*				■
	4, DEHP				■
	6, DBP				■
	10, Lead chromate	■			■
	16, Chromium trioxide	■			■
	18b, Sodium dichromate				■
	19, Potassium dichromate	■			
	26, EDC		■	■	■
	29,Strontium chromate				■
	43a, 43b, NPE	■			
	43c, NPE		■		

Very close regulatory dates

Table A2.2: Overview of substances for which the regulatory dates are very close

	Trigger 1	Trigger 2	Candidate List	Annex XIV
7, Diisobutylphthalate	2009	NA	2010	2012
10, Lead Chromate	1994	2008	2010	2012
11, Pigment yellow	1994	2008	2010	2012
12, Pigment red	1994	2008	2010	2012
13, TCEP	2009	NA	2010	2012
14, Dinitrotoluene	2009	NA	2010	2012
42, OPE	2013	NA	2013	2017
43, NPE	2013	NA	2013	2017

Low volume substances

Table A2.3: Substances where volumes are zero or close to zero. Blue colours indicate where this is the case for each country.

Substance	DK	SE	NO	FI
1, Musk xylene				
5, BBP				
7, Diisobutylphthalate				
8, Diarsenic trioxide				
14, Dinitrotoluene				
18b, Sodium dichromate				
19, Potassium dichromate				
23, MDA				
26, EDC				
27, MOCA				
29, Strontium chromate				
30, Potassium hydroxy oct..				
31, Pentazinc chrom..				
35, DHNUP				
34, DIHP				
42, OPE				
43a, NPE				
43c, NPE				

Substances not assessed any further

Table A2.4: Overview of substances not further assessed.

	DK	SE	NO	FI
1, Musk xylene				
23, MDA				
26, EDC				
31, Pentazinc chrom..				
42, OPE				

Colour code: Yellow: Low volumes Green: Missing data, Blue: Possible error data, Red: Regulatory dates too close.

Effect of some legal interventions under REACH and CLP

Previous studies have investigated and assessed the extent to which the REACH authorisation process for Substances of Very High Concern (SVHC) drives substitution of these substances. Based largely on stakeholder interviews, it is qualitatively assessed that inclusion of substances in the Candidate List and possible later inclusion in the Authorisation List (REACH Annex XIV) contribute to driving substitution and reducing exposure along with other legislation and other market factors. The current study focuses on volumes notified in the Product Registers in Denmark, Norway, Sweden and Finland as available in the SPIN database, with non-confidential registration information from the four Nordic registers. The study focuses on the 43 entries in the current Authorisation List by plotting the developments in notified amounts in the four Nordic countries over the years against three regulatory dates; trigger date, candidate-listing date and Authorisation List inclusion date. The current study clearly indicates that regulatory action (including harmonised classification/assigning the SVHC designation) over the past decades on substances currently on the REACH Authorisation List has resulted in considerably reduced tonnages in the Nordic countries. It appears that candidate listing and Authorisation List inclusion generally keep or drive ton-nages to low levels and thus may function as drivers for eventual substitution in situations where it would be difficult to identify substitutes in the short term. The findings of the project cannot support that one type of legal intervention (e.g. harmonized classification) is more or less important than another (e.g. candidate listing or Annex XIV inclusion).

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