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Preface

The purpose of this pilot project is to investigate the relationship between the implementation of classification and labelling of chemical substances and their use. Both tonnage per year and the number of products the substances occur in are used as a measure. The system that has been examined is the EU legislation for classification and labelling of chemical substances and mixtures: the Dangerous Substances Directive, DSD and the Dangerous Preparations Directive, DPD (67/548/EEC and 1999/45/EC, respectively), and the CLP Regulation (EC) No 1272/2008). The focus lies on substances with harmonised classification at European Union (EU) Community level as dangerous for the environment which by themselves or in a mixture above a certain concentration limit lead to classification and labelling with the symbol “Fish and tree” and the indication of danger *Dangerous for the environment* (N). EU Environmental hazard classification has been conducted since the mid 1990s and from the early first decade of the 21st century for chemical substances and mixtures. Now, almost 20 years after the first criteria were implemented it is interesting to look back and see whether this classification has had an impact on the use of these substances.

In addition, substances that are not classified as dangerous for the environment but classified for their health effects and that by themselves or in a mixture above a certain concentration limit lead to classification and labelling with the symbol “Skull and crossbones” and indication of danger Very toxic or Toxic (T+ or T), were also included to some extent. Carcinogenic, germ cell mutagenic and toxic to reproduction (CMR) category 1 and 2 are included in the substance classifications covering T+ and T.

Data on tonnage per year and data on the number of products that the substances occur in will be presented for substances which had one or more of these classifications a few years before and after the classification was made.

The publication has been written by Mariana Pilenvik and Jonas Falck, the Swedish Chemicals Agency. The project was managed by Stellan Fischer and Jonas Falck, the Swedish Chemicals Agency. The Nordic project group on Classification and Labelling, under the Nordic Chemicals Group, is responsible for this report and the publication has been produced and published by the Nordic Council of Ministers.

Some reports on Hazard Classification and Labelling of chemicals issued by the Nordic Council of Ministers

- “Substances and Preparations Dangerous for the Environment- A System for Classification, Labelling and Safety Data Sheet”, in Swedish (Nord 1990:087, pp. 62) and in English (Nord 1990:087E, pp. 65), respectively
- “Environmental Hazard Classification – data collection and interpretation guide”, (TemaNord 1994:589, 2nd edition 1995:581), pp. 167
- “Environmental Hazard Classification – classification of selected substances as dangerous for the environment (I)”, (TemaNord 1994:643), pp 101
- “Environmental Hazard Classification criteria for chemical substances: Terrestrial environment – Fate in the soil and soil compartment effects”, (unpublished, 1997), pp 192
- “Hazard classification of metals and metal compounds – Effect of pH on dissolution of priority substances”, COWI Report: 29855-02, (unpublished, June 1997), pp 22
- “Modelling of metal speciation in Hazard Classification”, COWI Report: 03, (unpublished, September 1997)
- “Environmental Hazard Classification – classification of selected substances as dangerous for the environment (II)”, (TemaNord 1997:549), pp 137
- “Environmental Hazard Classification – The N-CLASS Database”, CD-ROM version, (TemaNord 1999:538), pp 44 and CD-ROM
- “Transformation/Dissolution of Specified Inorganic Metal Substances”, VKI Project: 12434, (unpublished, December 1999), pp 22
- “Transformation/Dissolution Screenings Test of Inorganic Metal Compounds”, DHI project: 50602.01, (unpublished, February 2000).
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- “Human Health Hazard Classification – The H-CLASS Database”, First Internet version release (2003)
- “The N-CLASS Database”, Folder about the New Internet 5.0 version (2004)
- “Identifying relevant parameters that can be used for monitoring trends in the use of environmentally hazardous substances”, (In Danish) (unpublished, 2004), pp 87
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- “Environmental Hazard Classification of Metals and Metal Compounds – A Probabilistic Assessment of Classification Power for Data Generated by the T/D Protocol”, (TemaNord 2008:518, pp 31)
- “NKG CLP Workshop I”. Stockholm, 13–14. April 2010
- “NKG An interactive flash-presentation (2010) – Quiz about the new hazard pictograms – Published on the Nordic Competent Authorities web pages

- “Brochure and fact sheet on the new hazard pictograms (2010).
Published on the Nordic Competent Authorities web pages
- “NKG CLP Workshop II”. Helsinki, 8–9 November 2011
- “Pilot project on the influence of hazard classification on the use of chemicals”, (TemaNord 2012:507, present report)

Executive Summary

The purpose of this pilot project was to see whether the implementation of hazard classifications have had an influence on the use of chemicals. Both tonnage per year and the number of products the substances occur in are used as a measure. For this study, we used data from the Swedish products register and the Nordic SPIN database. The system that was examined is the EU legislation the Dangerous Substances Directive, DSD and the Dangerous Preparations Directive, DPD (67/548/EEC and 1999/45/EC, respectively), and the CLP-regulation ((EC) No 1272/2008). Focus is on substances classified as *Dangerous for the environment* (N). (EU Environmental hazard classification has been conducted since the mid 1990s and from the early first decade of the 21st century for chemical substances and mixtures.) In addition, substances classified as *Toxic* or *Very toxic* to human health (T or T+) including CMRs (Carcinogenic, germ cell mutagenic and toxic to reproduction) categories 1 and 2, were also included to some extent.

The results show a decrease in tonnage per year, following starting at the classification year with a decrease in mean value after classification for a significant number of substances. This decrease can be seen for several combinations of classifications, despite the fact that the total tonnage of chemical substances per year produced in or imported to Sweden during the same time period has increased with 45 per cent.

This result may be an indicator that classification apart from providing information of hazardous properties can also work as an incentive for substitution of hazardous chemicals to less hazardous ones.

There is a different trend for the number of products associated with these classified substances. The number of products is increasing after classification for a significant number of substances. This can be explained by the fact that the obligation to report components of a product to the Swedish products register changes with classification. Substances without a classification have generally only to be reported if they constitute more than 5 per cent of the product (w/w). When a classification has been made, the component must be reported irrespective of the percentage included in the product. The increased number of products associated with these classified substances is also in line with the increase in total number of products that are reported to the Swedish products register during the same time period.

The increase shows that when the substances are classified, the obligation to report them as ingredient substances also when they constitute less than 5 per cent of the product, seems complied with. The Swedish products register is also proven to be very useful when it comes to investigating the influence of hazard classification on the use of chemicals.

1. Aim and hypothesis to be tested

The purpose of this pilot project was to see whether the implementation of hazard classifications have had an influence on the reported use of chemicals. Both tonnage per year and the number of products the substances occur in are used as a measure. In order to find out, we studied data for a number of classified substances a few years before and after the year of classification.

First, to visualize changes over the years the value for each substance and year was compared with the value for the year of classification. For each substance and year, the tonnage or the number of products was divided by the tonnage or the number of products for the year of classification, in order to see a relative increase or decrease. The yearly median of all substances included in the study was then plotted to see a possible trend over time.

Secondly, for each substance, the mean value of total tonnage per year and total number of products per year a few years before the classification were compared with the mean value a few years after. The substances with increasing tonnage or increasing number of products were coded 1 and the substances with decreasing tonnage or decreasing number of products with 0. If there was no difference between the studied parameters before and after the classification there should be approximately the same number of substances coded 1 as those coded 0.

The hypothesis we tested is therefore

$$H_0: P(0) = P(1)$$

$$H_1: P(0) \neq P(1)$$

where P stands for probability.

Using this test we can only see if there is a difference before and after a classification and not how big the difference might be. A decrease in tonnage per year after classification would possibly be expected, and therefore it could have been considered to perform the statistical analyses one-sided and, thus, to test whether the decrease in tonnage was significant. In this pilot project, however, we did not want to preclude any direction of the influence the classification might have and it was therefore decided to perform the statistical analyses two-sided. The test was done for a number of different combinations of classifications, see table 1, next page.

Table 1. Explanations of the various combinations of classifications used in this project.

Combination of classifications	Explanation
N etc	Substances classified as dangerous for the environment as well as with other classifications.
T+, T, N	Substances classified as very toxic and/or toxic and/or dangerous for the environment.
solely N	Substances classified solely as dangerous for the environment.
T+, T	Substances classified as very toxic and/or toxic but <i>not</i> dangerous for the environment

2. Data selection

2.1 Data selection using the Swedish products register

The Swedish products register is a database to which manufacturers and importers are obliged to report data on chemical products, including pesticides, if the annual volume is 100 kg or more per product. Components must always be reported if they are preservatives, active substances in a plant protection product or biocidal product or classified as dangerous to health or the environment. Other components have only to be reported if they constitute more than 5 per cent of the product (w/w). For products with certain statistical Customs Tariff numbers, contaminants must be reported if they constitute more than 1 per cent of the product (w/w). In this project, data on tonnage per year and the number of products per year that a substance occurs in were collected from the register. Data on tonnage per year derived from the Swedish products register include manufacturing in and import¹ to Sweden. Data are currently available from 1992–2009.

2.1.1 *Selecting data on tonnage per year*

Substances selected for this project were collected from the list of harmonized classifications in table 3.2 of Annex VI to the CLP-regulation². These substances were then compared with data in the Swedish products register. Substances with available data on tonnage for two years or more were selected.

The year of the substance classification was assumed to be the year when the substance was latest included in an adaptation to technical progress (ATP) to the Dangerous Substance Directive, DSD³. This information was gathered from the Nordic classification databases N-Class and H-Class. Substances without reference to a specific ATP were removed since it was necessary in this project to know the year of classification.

The substances of interest were those classified and labelled with the symbol “Fish and tree” and indication of danger *Dangerous for the environment* (N) if before being put on the market by themselves or in a mixture above a concentration limit. They comprise the classifications N;

¹ Also from other EU member states.

² Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

³ Directive 67/548/EEC on the classification and labelling of Dangerous Substances.

R50, N; R50-53 or N; R51-53 (in GHS⁴ and CLP terms this corresponds to Acute aquatic hazard category Acute 1 and Long-term aquatic hazard categories Chronic 1 or Chronic 2)⁵.

In addition, substances were analysed that were not classified as dangerous for the environment but classified for their health effects and by themselves or in a mixture above a concentration limit would lead to labelling with the symbol “Skull and crossbones” and indication of danger *Very toxic* or *Toxic* (T+ or T). These include acutely very toxic and toxic substances as well as CMRs⁶ categories 1 and 2 (in GHS and CLP terms the latter corresponds to CMRs categories 1A and 1B).

Figure 1. Symbols from the Dangerous Substance Directive (DSD, 67/548/EEC) to the left and their counterparts in GHS to the right

All substances with a classification including one or more of these symbols were selected.

All substances with an index number starting with 648 or 649 were removed. These are complex coal and oil derived substances which are not subject to harmonised environmental classification at the EU Community level.

Substances with information available for five years before the classification and five years after were selected. The time period of three years before and after would give a slightly higher number of substances for each year but fewer years to study. In this case it was therefore decided that it was more useful to look at a time period of five years before and after the classification. See table 2, next page.

⁴ Globally Harmonized System of Classification and Labelling of Chemicals (See A1.6 in Appendix 1 this document).

⁵ There are three substances in Table 3.2 of Annex VI that are not classified according to these criteria, but assigned the symbol 'N' due to their classification Dangerous for the ozone layer (N; R59). These three substances were not included in the study.

⁶ Carcinogenic, germ cell mutagenic and/or toxic to reproduction.

Table 2. Number of substances with available data on (tonnage per year) for different types of classification.

Type of classification	No of substances with available information three years before and after classification	No of substances with available information five years before and after classification	No of substances with any data between 1992 to 2009
N etc	271	232	327
T+, T, N	328	275	397
solely N	13	11	22
T+, T	43	32	55

2.1.2 Selecting data on number of products

Selecting data concerning the number of products that the classified substances occurred in was done in the same manner as described above. See table 3.

Table 3. Number of substances with available information on number of products for different types of classification.

Type of classification	No of substances with available information three years before and after classification	No of substances with available information five years before and after classification	No of substances with any data between 1992 to 2009
N etc	254	214	310
T+, T, N	307	254	376
solely N	10	8	19
T+, T	39	28	51

2.2 Data selection using the SPIN data base

The SPIN database includes data on chemical products from Denmark, Finland, Norway and Sweden. Contrary to the national product registers data from the SPIN database do not include confidential data, i.e. the number of available data is reduced. Data on tonnage per year includes manufacturing and import. Data are currently available from 2000–2009 (Denmark and Norway), 2001–2009 (Finland), 1999–2009 (Sweden).

The method of data selection using the SPIN database was different from the method used with the Swedish products register. Substances selected for this project were taken from the list of harmonized classifications in table 3.2 of Annex VI to CLP. Only substances included in ATP 29 (published in 2004) were selected in order to obtain enough information a few years before and after the classification. Substances classified T+, T and/or N were selected. These substances were then linked with substance data from the SPIN database. Data were organised country by country and year by year. Substances with available information from the year 2000 (2001 for Finland) until 2009 were selected. All substances with an index number starting with 648 or 649 were removed for the same reason as mentioned above when using the Swedish products register.

The number of remaining substances can be seen in table 4.

Table 4. Number of substances with available information on number of products and tonnage per year for Denmark, Finland, Norway and Sweden.

	Denmark	Finland	Norway	Sweden
	No of substances with available information 2000–2009	No of substances with available information 2001–2009	No of substances with available information 2000–2009	No of substances with available information 2000–2009
T+, T, N	70	60	58	75

3. Results

3.1 Results using the Swedish products register

3.1.1 *Changes in tonnage per year*

Results of the first test:

To visualize the changes over a period of 11 years, five years before and after classification as *N etc*, a figure showing the median of the relative difference was made. The year of classification was set to 0, the five years before were set to “-5 to -1”, and the five years after were set to “1 to 5”, see Figure 2. The median values were used to reduce the effect of extreme outliers. For this particular exercise, three *substances* with no available information on tonnage or number of products or with 0 tonnage or 0 number of products for the year of classification were removed. This was done to have the possibility to see a trend over time in relative numbers: the tonnage or the number of products before and after the year of classification would then be divided by the tonnage or the number of products for the year of classification in order to see a relative increase or decrease. A division with 0 cannot be done.

Figure 2. The relative change of tonnage per year in relation to the year of classification, five years before and after the year of classification (0). As seen in the figure there is a decreasing trend in tonnage per year after classification

Results of the second test:

The null hypothesis was tested for the combinations of classifications as seen in table 1 page 12 for data derived the Swedish products register and as seen in table 4 page 16 for data derived the SPIN database. The statistical test, a sign test, was performed by Statisticon AB, Uppsala Sweden.

The results from the statistical tests show that there is significant difference between the mean value of tonnage per year before and after classification for substances classified *N etc.* ($P = 0.015$) and for substances classified *T+*, *T*, *N* ($P = 0.011$). Substances classified *solely N* as well as substances classified *T+*, *T* did not show a significant difference between mean values before and after classification ($P > 0.05$).

For substances classified *N etc.*, 97 substances increased in tonnage per year after classification and 135 decreased in tonnage per year after classification, see Figure 3.

Figure 3. The number of substances classified *N etc* with increasing tonnage per year after classification compared with the number of substances classified *N etc* with decreasing tonnage per year after classification ($P = 0.015$)

For substances classified *T+*, *T*, *N* 116 substances increased in tonnage per year after classification and 159 substances decreased in tonnage per year after classification, see Figure 4, next page.

Figure 4. The number of substances classified T+, T, N with increasing tonnage per year after classification compared with the number of substances classified T+, T, N with decreasing tonnage per year after classification. ($P = 0.011$)

3.1.2 Changes in number of products

Results of the first test:

Another figure was made to visualize the relative changes of number of products that the substances occur in over a period of eleven years, five years before and after classification. This figure was made in the same manner as the one mentioned above concerning tonnage per year. However the mean values were used since there were no extreme outliers, see

Figure 5. The relative change in number of products the substances occur in per year in relation to the year of classification. The figure show five years before and after the year of classification (0). As seen in the figure there is an increasing trend of number of products after classification

Results of the second test:

The difference was tested statistically between the number of substances for which the amount of products increased as opposed to decreased. The results from the tests showed that there is a significant difference between the mean value of number of products before and after classification for substances classified *N etc.* ($P = 0.002$), for substances classified *T+*, *T*, *N* ($P = 0.0002$) and for substances classified *T+*, *T* ($P = 0.02$). Substances classified *solely N* did not show a significant difference between the mean value before and after classification ($P > 0.05$).

For substances classified *N etc.*, 118 substances were included in an increasing number of products, 75 in a decreasing number of products and for 21 substances there were no change, see Figure 6.

Figure 6. A comparison of the number of substances classified *N etc.* with increasing, decreasing or unchanged number of products which the substances occur in after classification. ($P = 0.002$)

For substances classified *T+*, *T*, *N*, 144 substances were included in an increasing number of products, 87 in a decreasing number of products and for 23 substances there were no change, see Figure 7, next page.

Figure 7. A comparison of the number of substances classified T+, T, N with increasing, decreasing or unchanged number of products which the substances occur in after classification ($P = 0.0002$)

For substances classified T+, T, 20 substances were included in an increasing number of products, 7 in a decreasing number of products and for 1 substance there was no change, see Figure 8.

Figure 8. A comparison of the number of substances classified T+, T with increasing, decreasing or unchanged number of products which the substances occur in after classification ($P = 0.02$)

3.2 Results using the SPIN data base

The results with regard to the limited information⁷ given in the SPIN database only showed a significant difference between the mean value for number of products before and after classification in Norway ($P = 0.049$), see table 4.

Table 5. Number of substances that increases, decreases or stays unchanged after classification regarding tonnage per year and the number of products that the substance occurs in. Denmark, Norway and Sweden (year 2000–2009) and Finland (year 2001–2009) based on the limited information given in the SPIN database.

Country	Change after classification	Tonnage per year (No of substances)	Number of products that the substance occurs in (No of substances)
Sweden	Increasing	39	41
	Decreasing	36	34
	Unchanged	0	0
Denmark	Increasing	34	46
	Decreasing	35	23
	Unchanged	1	1
Norway	Increasing	24	37
	Decreasing	34	20
	Unchanged	0	1
Finland	Increasing	32	37
	Decreasing	27	22
	Unchanged	1	1

⁷ Contrary to the national product registers, data from the SPIN database do not include confidential data, i.e. the extent of available data is reduced.

4. Discussion

EU Environmental hazard classification has been conducted since the mid 1990s and from the early first decade of the 21st century for chemical substances and mixtures. (see A1.8 in Appendix 1 of this document). Now, almost 20 years after the first criteria were implemented it is interesting to look back and see whether this classification has had an impact on the use of these substances.

For environmentally hazardous substances (*N etc*), there is a decreasing trend in tonnage per year, following from the year of classification (see Figure 2), with a significant decrease in mean value after classification (see Figure 3). This significant decrease in tonnage per year can still be seen when adding substances classified as *T+*, *T* (Figure 4).

There is an increasing trend from the year of classification in number of products associated with these environmentally hazardous substances (Figure 5). The number of substances with an increased number of associated products is significantly larger than the number of substances with a decreased number of associated products. This is verified for *N etc*, for *T+*, *T*, *N* and for *T+*, *T* (Figures 6 to 8).

Based solely on the observed increase in number of products one would for these substances expect that this should lead to a slight increase in tonnage per year of products reported to the Products Register. Still, the tonnage per year for these classified substances is decreasing (see above). Consequently the decrease of tonnage as a result of classification is large enough even to cover an expected increase. One explanation for this could be that in order to avoid a certain classification and labelling of a mixture, the concentration of a hazardous ingredient may be assured to be less than the concentration limits which triggers classification and subsequent labelling of the mixture. The concentration limits are with regard to the included substances not taken into consideration before they are classified. Therefore, in relation to these hazardous substances, the classification may result in less concentrated and hence less hazardous mixtures. The decreased concentrations would then be reflected in the decrease of tonnage per year.

It should be mentioned that the total tonnage per year of manufacture in and import to Sweden⁸ (classified and non-classified substances) has increased from 1995 to 2009 by 45 per cent. In the light of this, the significant decrease in tonnage per year after classification observed for these substances is even more evident.

⁸ Also from other EU member states.

Consequences of classification are greater than just a hazard communication label or a safety data sheet in that it also has a direct effect on the management of associated risks. More than 20 legal acts rely on classification in one way or the other (see A1.3, Appendix 1, this document). It could be expected that as a consequence of this the number of products associated with these substances would decrease (just as is the case with the tonnage per year). Still, the number of products reported to contain these classified substances is increasing (see above).

The increase in number of products associated with the classified substances can be explained by the obligation to report components of a product to the Swedish products register changes with classification. Substances without a classification must only be reported if they constitute more than 5 per cent of the product (w/w). When a classification has been made the component must be reported irrespective of the percentage included in the product. This can clearly be a reason for the observed increase in the products register of the number of products associated with these substances classified for environmental or health hazards.

Since the year of classification in this study has been normalised to be the same (0), whether it is classified early or late in the observed period, the influence is minimised of other parameters like a general change of the situation in the world or in Swedish economy. Therefore it is likely that the change is due to the classification.

Hardly any significant trends could be seen in data from the Nordic SPIN database. Clearly, there are too many factors affecting this data to make it useful in the current form and for this type of investigation. For example, confidentiality limits the sample size. In addition only one year of classification, 2004, could be used since the database is rather new. The consequence of this was that influences of other parameters than classification could not easily be excluded.

4.1 Conclusions

The results of this pilot project show:

- That an environmental and/or health classification of a substance does influence the use of the substance
- That tonnage per year is decreasing for a significant number of substances after the year of classification
- That this may be an indicator that classification apart from providing information on hazardous properties can also be an incentive for substitution of hazardous chemicals to less hazardous ones
- An increase in number of products associated with these substances in the Swedish products register from the year of classification
- That this increase shows that the obligation to report the substances as included substances even when they constitute less than 5 per cent of the product seems to be working

- That the Swedish products register is very useful when it comes to investigating the influence of hazard classification on the use of chemicals

4.2 Ideas for future work

It could be interesting:

- To do similar studies with data selected from other national product registers (e.g. in Denmark, Finland and Norway)
- Possibly to see whether there is a greater difference between several different classifications (physical, health and environmental hazards)
- Possibly to distinguish differences between different types of products. Where does classification have a great effect on the use pattern and where and why does it not give the effect expected?

5. Literature

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6. Svensk sammanfattning (Summary in Swedish)

EU-klassificering av miljöfarliga ämnen har bedrivits sedan mitten av 1990-talet för ämnen och sedan början av 2000-talet för blandningar.

Syftet med det här pilotprojektet har varit att nu, 15–20 år efter de första miljöfaroklassificeringarna, studera huruvida dessa klassificeringar påverkar användningen av kemikalier. Både ton per år och antalet produkter som ämnet finns med i per år har använts för att få ett mått på kemikalieanvändningen. Systemet som studerats är EU:s ämnes- och preparatdirektiv (67/548/EEC och 1999/45/EC) samt CLP-förordningen ((EG) Nr 1272/2008). Studien har fokuserat på ämnen med miljöfaroklassificering (N) men till viss del har även hälsofarliga ämnen (T eller T+) ingått. Bland dessa finns så kallade CMR-ämnen (carcinogena, mutagena och reproduktionstoxiska) kategori 1 och 2.

Resultatet visar att mängder räknat i ton per år minskar efter klassificering för ett signifikant antal ämnen. Den här minskningen kan ses för flera kombinationer av klassificeringar trots det faktum att det totala tonnaget av kemiska ämnen per år räknat i tillverkning i och import till Sverige har ökat med 45 %.

Resultaten från den här studien visar på att klassificering inte bara bidrar till att sprida information om kemikaliers farliga inneboende egenskaper utan även kan fungera som ett incitament för att man ska byta ut mer farliga mot mindre farliga kemikalier.

För antalet produkter som klassificerade ämnen till det svenska produktregistret rapporteras finnas i ser vi en motsatt trend. Dessa ökar för ett signifikant antal ämnen. Detta stämmer väl överens med att det totala antalet produkter ökat under samma period.

Ökningen i det svenska produktregistret av antalet produkter som innehåller miljö- och hälsofarliga ämnen visar på att skyldigheten att rapportera in dessa ämnen som ingredienser i en produkt, även om de utgör mindre än 5 % av produkten, verkar efterlevas.

Det svenska produktregistret har visat sig vara ytterst användbart för att undersöka faroklassificeringars påverkan på kemikalieanvändningen.

7. Appendix 1: Background⁹

7.1 Classification, labelling and safety data sheets

The lack of knowledge of intrinsic hazardous properties of chemical substances and mixtures can pose a threat to both human health and the environment. The aim of classification and labelling is to identify these hazardous properties and to communicate these through appropriate warnings together with information on safety measures, to ensure that receivers and users will have the information necessary for adequate protection. Apart from labelling (information on hazard classification provided on the packaging), the more detailed information shall also be provided to professional users through safety data sheets (SDS). Since classification is based on intrinsic *hazardous* properties and not on assessment of risk, the obligation to inform users applies irrespective of the intended use of the product and the *risks* connected with a particular use.¹⁰ Hazard classification and communication through labelling and SDS is thereby a hazard based tool for risk management and risk reduction.

7.2 A tool for risk reduction and risk management

Figure A1. While thousands of substances have a harmonised classification listed in Annex VI to the CLP Regulation, there are tens of thousands of substances on the market and which are subject to industry self-classification. The number of products (mixtures/preparations) all subject to industry self-classification is estimated to be in millions

⁹ The background is partly based on the publications in the literature list.

¹⁰ It is important to distinguish between hazard and risk. While hazard is the ability to cause damage or harm, the risk is the probability for damage or harm to occur.

For the majority of chemicals on the market, chemicals management builds on knowledge, information and communication demands entirely placed on the actors in the supply chains: Generation of knowledge, sharing of test-data, spread of information, exchange of safety and exposure data, enhanced contacts and communication between the actors in the supply chains – are all based on industry obligations laid down in the overall interest of EU-development. Key instruments for having this system in place and work are: Classification & labelling and safety data sheets.

7.3 Measurements in downstream legislation

Consequences of classification are, however, greater than just a hazard label or a safety data sheet in that it also has a direct effect on the management of associated risks. Because of the high EU-concern for chemicals risks there are complementary procedures for regulatory action in certain cases, like authorization demands, substitution demands, bans and restrictions.

More than 20 legal acts rely on classification in one way or the other.

Figure A2. A network of EU legislation relies on classification in one way or the other. In this figure some areas are given as examples.

7.4 CLP and REACH

Classification plays a key role in REACH¹¹; it must be included in the registration dossier for a substance and it triggers certain provisions such as the performance of an exposure assessment and risk characteri-

¹¹ Regulation (EC) No 1907/2006 of the European Parliament of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

sation as part of the chemical safety assessment (CSA) and the obligation to provide a safety data sheet. Classification of a substance as mutagenic, carcinogenic or toxic to reproduction may also lead to restrictions and the need to apply for authorisation.

Figure A3. The CLP- and REACH-regulations build up the system for chemicals risk management today in the EU Member States. They are the two core regulations regarding industrial chemicals and consumer chemicals but do also direct the management of biocidal products and plant protection products

7.5 A1.5 The interface between self-classification and harmonised classification

To the complementary procedures for regulatory action one can also add classifications harmonised at the EU-community level. Hazardous properties that are prioritised for harmonised classification are mainly carcinogenicity, germ cell mutagenicity, toxicity to reproduction and respiratory sensitisation but other properties may also fall into this category if a harmonised classification can be motivated. In addition, substances regulated under the Biocidal Products Directive (98/8/EC) or under the Plant Protection Products Regulation (EC no 1107/2009) are normally subject to harmonised classification concerning all properties. All substances with a harmonised classification can be found in Annex VI to the CLP Regulation.

Annex VI to CLP contains two tables; table 3.1 with a list of substances classified according to CLP and 3.2 with a list of substances classified according to the dangerous substances directive (DSD, 67/548/EEC). If a harmonised classification exists for a substance this must always be used by the manufacturer, importer or downstream user.

The chemical industry in the form of manufacturers, importers and downstream users are responsible for classification of all substances that are not included in Annex VI to CLP. The industry is also responsible for classifying substances with harmonised classifications for those hazard classes and differentiations that are not already included in Annex VI to CLP. In addition, they are also responsible for classification of mixtures. Therefore, the industry is responsible for most of the classifications made.

7.6 A1.6 The implementation of a globally harmonized system (GHS)

With CLP and parts of REACH the standard of the Globally harmonized system for Classification and Labelling (GHS¹²) was implemented into EU law. As explained, they present the fundamental base for the legislation on chemicals management for an overwhelming majority of all chemicals.

Before GHS became effective, a number of countries and organisations all over the world developed their own versions of laws and regulations on chemical labelling and information conveyed to chemical users. Regulations and classifications in different countries did have similarities but were different enough to result in different labels and safety data sheets for the same product. The need for a globally harmonised system was discussed during the 1992 United Nations Conference on Environment and Development (UNCED) where the international mandate that provided the impetus for completing the work was adopted, as reflected in Agenda 21, para 19.27:

“A globally harmonized hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000”.

The purpose of the new harmonised system was to facilitate international trade of chemicals, while at the same time increase the protection of human health and the environment. Additionally, it provided a legal framework for countries lacking existing systems for chemical regulations and since test results and classifications can be used more broadly it reduced the need for testing and evaluation of chemicals. The first version of the globally harmonized system for classification and labelling of chemicals (GHS) was published in 2003. Since then, the GHS has been updated every two years as needs arise and experience is gained with its implementation.

The GHS was implemented in the EU Community in 2009 through the CLP Regulation. Directives 67/548/EEC (Dangerous Substances Directive, DSD) and 1999/45/EC (Dangerous Preparations Directives, DPD) on classification and labelling will be in force until 1 June 2015. Until they will be repealed in their entirety on 1 June 2015, their provisions will be replaced in a stepwise approach during a transitional period which is set out in the CLP Regulation.

¹² The UN Globally Harmonized System of Classification and Labelling of Chemicals

7.7 A1.7 The scope of the system with classification, labelling and safety data sheets

The EU law on classification, labelling and safety data sheets apply to chemical substances and mixtures, which are placed on the market. This includes industrial chemicals as well as plant protection products and biocides. If substances are subject to registration or notification under the REACH Regulation they are also subject to classification even if they are not placed on the market. There are a number of substances and mixtures that are exempted from the classification requirements e.g. radioactive substances and mixtures or substances and mixtures which are in the finished state, intended for a final use as human or animal pharmaceuticals, cosmetics or food products.

The system consists of hazard classes which communicate the type of hazard; physical, health or environmental. Each class is divided into hazard categories, with different criteria, to communicate the severity of the hazard. Information on hazard classification provided on the packaging shall include hazard pictograms, signal word, hazard and precautionary statements (according to CLP) or danger symbols, danger indications and risk and safety phrases (according to the Dangerous Substance Directive, 67/548/EEC and Dangerous Preparations Directive, 1999/45/EC). It is recognised that the hazard communication needs of the various end users may differ. Consumers are primarily dependent on the label of a substance or a mixture as a source of hazard and precautionary information, while the requirement for provision of a safety data sheet with more detailed information is primarily applicable to professional users.

7.8 A1.8 From physical and acute health hazards of substances to environmental hazards of mixtures

The EU has had a system for classification and labelling of dangerous substances for over 40 years. At first the system focused on acute effects: (i) Explosive, (ii) Oxidizing, (iii) Flammable, (iv) Toxic and Harmful, and (v) Corrosive and Irritant and the classifications were conducted by the authorities. With the 6th amendment of the Dangerous Substance Directive the principle of industry self-classification and labelling was introduced in 1981 and it was not until later in the 1980s that classification for chronic effects came into the system. Criteria for classifying CMRs (carcinogenic, mutagenic or toxic for reproduction) largely as we know them today were not implemented until the late 1980s and in 1988 the EU directive on classification and labelling of dangerous preparations came into force.

Classification and labelling of substances as dangerous for the environment was added in 1992/93 and it was not until 1999 that environmental classification of preparations (or mixtures as we know them today) was introduced. With the new preparations directive, DPD, classifi-

cation and labelling of plant protection products and biocidal products were brought into the same legislation as the non-pesticides. The labelling requirements as dangerous for the environment for non-pesticidal preparations entered into force in 2002 and for plant protection products and biocidal products in 2004.

Hence, EU environmental hazard classification has been conducted since the mid 1990s and from the early first decade of the 21st century for chemical substances and mixtures. Now almost 20 years after the first criteria were implemented, it is interesting to measure the influence this implementation has had on the use of chemicals.

The influence of hazard classification on the use of chemicals

The purpose of this pilot project is to investigate the relationship between the implementation of classification and labelling of chemical substances and their use. The system that has been examined is the EU legislation for classification and labelling of chemical substances and mixtures. The focus lies on substances with harmonised classification at European Union (EU) Community level as dangerous for the environment which by themselves or in a mixture above a certain concentration limit lead to classification and labelling with the symbol “Fish and tree” and the indication of danger Dangerous for the environment (N). Other effects were also included to some extent. EU Environmental hazard classification has been conducted since the mid 1990s and from the early first decade of the 21st century for chemical substances and mixtures. Now, almost 20 years after the first criteria were implemented it is interesting to look back and see whether this classification has had an impact on the use of these substances.