Danish Ministry of the Environment
Environmental Protection Agency

Survey of Formaldehyde

A LOUS review project

Consultation draft

Title:

Survey of Formaldehyde

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Published by:

The Danish Environmental Protection Agency
Strandgade 29
1401 Copenhagen K
Denmark
www.mst.dk/english

Photography:

[Name]

Illustration:

[Name]

Year:

2014

Map:

[Name]

ISBN no.

[xxxxxx]

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Preface

Background and objectives

The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) is intended as a guide for enterprises. It indicates substances of concern whose use should be reduced or eliminated completely. The first list was published in 1998 and updated versions have been published in 2000, 2004 and 2009. The latest version, LOUS 2009 (Danish EPA, 2011) includes 40 chemical substances and groups of substances which have been documented as dangerous or which have been identified as problematic using computer models. For inclusion in the list, substances must fulfil several specific criteria. Besides the risk of leading to serious and long-term adverse effects on health or the environment, only substances which are used in an industrial context in large quantities in Denmark, i.e. over 100 tonnes per year, are included in the list.

Over the period 2012-2015 all 40 substances and substance groups on LOUS will be surveyed. The surveys include collection of available information on the use and occurrence of the substances, internationally and in Denmark, information on environmental and health effects, on alternatives to the substances, on existing regulation, on monitoring and exposure, and information regarding ongoing activities under REACH, among others.

On the basis of the surveys, the Danish EPA will assess the need for any further information, regulation, substitution/phase out, classification and labelling, improved waste management or increased dissemination of information.

This survey concerns formaldehyde (CAS 50-00-0). This substance was included on LOUS in 2009. The main reason for the inclusion in LOUS is formaldehyde´s classification as Carc3; R40 and R43. According to the CLP classification (Classification, Labelling and Packaging Regulation) this corresponds to Carc. 2 (H351) and Skin Sens. 1 (H317). Furthermore formaldehyde is included on the LOUS list because it is used in a quantity > 100 tonnes per year in Denmark.

The main objective of this study is, as mentioned, to provide background for the Danish EPA's consideration regarding the need for further risk management measures.

The process

The survey has been undertaken by DHI from September 2013 to April 2014. The project team was:

- Dorthe Nørgaard Andersen, DHI, Project Manager
- Tina Slothuus, DHI, contributor
- Poul Bo Larsen, DHI, Quality supervisor

The work has been followed by an advisory group consisting of:

- Louise Grave-Larsen, Danish EPA, Project Manager
- Lea Tobiassen, Danish EPA
- Anne-Louise Jørgensen Rønlev, Danish EPA
- Hilde Balling, Danish Health and Medicines Authority
- Nikolai Stubkjær Nilsen; Danish Industry
- Mette Holm, Danish Veterinary and Food Administration
- Nanna Rosted Vind, Danish Working Environment Authority

Data collection
The survey and review is based on the available literature on the substances, information from databases and direct inquiries to trade organisations and key market actors.

The data search included (but was not limited to) the following:

- Legislation in force from Retsinformation (Danish legal information database) and EUR-Lex (EU legislation database);
- Ongoing regulatory activities under REACH and intentions listed on ECHA's website (incl. Registry of Intentions and Community Rolling Action Plan);
- Data on harmonised classification (CLP) and self-classification from the C&L inventory database on ECHAs website;
- Data on ecolabels from the Danish ecolabel secretariat (Nordic Swan and EU Flower) and the German Angel.
- Relevant documents regarding International agreements from HELCOM, OSPAR, the Stockholm Convention, the PIC Convention, and the Basel Convention. Production and external trade statistics from Eurostat's databases (Prodcom and Comext);
- Export of dangerous substances from the Edexim database;
- Data on production, import and export of substances in mixtures from the Danish Product Register (confidential data, not searched via the Internet);
- Date on production, import and export of substances from the Nordic Product Registers as registered in the SPIN database;
- Information from Circa on risk management options (confidential, for internal use only, not searched via the Internet)
- Monitoring data from the National Centre for Environment and Energy (DCE), the Geological Survey for Denmark and Greenland (GEUS), the Danish Veterinary and Food Administration, the European Food Safety Authority (EFSA) and the INIRIS database.
- Waste statistics from the Danish EPA;
- Chemical information from the ICIS database;
- Reports, memorandums, etc. from the Danish EPA and other authorities in Denmark;
- Reports published at the websites of:
  - The Nordic Council of Ministers, ECHA, the EU Commission, OECD, IARC, IPCS, WHO, OSPAR, HELCOM, and the Basel Convention;
  - Environmental authorities in Norway (Klif), Sweden (KemI and Naturvårsverket), Germany (UBA), UK (DEFRA and Environment Agency), the Netherlands (VROM, RIVM), Austria (UBA). Information from other EU Member States was retrieved if quoted in identified literature.
  - US EPA, Agency for Toxic Substances and Disease Registry (USA) and Environment Canada.
- PubMed and Toxnet databases for identification of relevant scientific literature.

Besides, direct enquiries were sent to Danish and European trade organisations and a few key market actors in Denmark

Summary and conclusions

The Danish EPA has included formaldehyde on the LOUS list (2009) based on its former classification as Carc. 2 (H351) and Skin Sens. 1 (H317). Furthermore, formaldehyde is used in a quantity > 100 tonnes on the Danish market, and it is applied in a large number of products. The use of formaldehyde ranges from resin production (e.g. phenolic, urea, and melamine resins, which have wide uses as adhesives and binders in the wood-production, pulp-and-paper, and the synthetic vitreous fibre industries, in the production of plastics and coatings, and in textile finish) to cosmetics, cleaning agents and biocide and pesticide products.

Regulation

Formaldehyde is regulated through both national and EU legislation. Legislation includes registration under REACH (registered at a tonnage band of 1,000,000 + tonnes). Formaldehyde is classified according to the CLP regulation as: Acute tox. 3 (H301, H311, H331), Skin Corr. 1B (H314), Skin Sens. 1 (H317), Mut2 (H341) and Carc. 1B (H350). The classification as Carc 1B and Mut2 were agreed on in December 2013, as before formaldehyde was classified as Carc 2. The new classification has not yet been applied in all regulations.
Formaldehyde was included on in the list for substance evaluation under REACH (the Community Rolling Action Plan (CoRAP)) in 2013. However, formaldehyde is neither on the Candidate List of Substances of Very High Concern for Authorisation nor on the list of restrictions.

Furthermore, formaldehyde is strictly regulated in a variety of regulatory sectors covering biocides, cosmetics, toys, occupational environment, food additives and food contact materials. Regarding the use of formaldehyde in consumer products, formaldehyde is addressed in the Directive 2009/48/EC on the safety of toys as well as the Cosmetic Regulation (EC) No 1223/2009, setting limits for the content of formaldehyde in the final products. Most eco labelling criteria (EU flower and Nordic swan) exclude the use of formaldehyde due to its classification as carcinogenic. Also there are EU regulations for formaldehyde in food additives and in food contacts materials.

Formaldehyde is included in the Danish order on the control of major-accident hazards involving dangerous substances. The Danish Environmental Quality Standard for marine- and freshwater is 9.2 µg/L and for short term releases 46 µg/L. Also there are national regulations on the content of formaldehyde in textiles.

Production and use

In 2010, 29 million tonnes of formaldehyde (37 % solution) were produced globally. The European Union is the second largest producer of formaldehyde (23 %) after Asia (with China as the main producer) which has approximately 50 % of the global capacity. Within Europe, Germany (of the 22 EU Member states producing formaldehyde) has the highest formaldehyde manufacturing capacity with approximately 5 % of the global production capacity and 23 % of the European production capacity.

The use of formaldehyde ranges widely from use as an intermediate to use in consumer products. The use as an intermediate is mainly within the chemical industry for the production of condensed resins for the wood, paper and textile processing industries and in chemical synthesis.
Formaldehyde plastic is a common name for a wide range of plastics materials, which are formed by the reaction of formaldehyde with, for example, urea, melamine, phenol or furfuryl alcohol.

Aqueous solutions of formaldehyde are employed as germicides, bactericides and fungicides (in Denmark for instance formaldehyde is applied in aquaculture).
Furthermore, formaldehyde is used as a preservative in a large number of consumer products, such as cosmetics and household cleaning agents. Information from the Nordic SPIN database shows that in Denmark (2011) formaldehyde is especially contained in raw materials applied for synthesis and intermediate products with a tonnage of more than 13 000 tonnes. Denmark has a rather large production of chipboards, and formaldehyde is used in this production. In Denmark there has been a decline in the number of different preparations which contain formaldehyde. However, the tonnage of preparations has been quite constant from 2009 and forward (important to note that SPIN data is not including consumer product but only products for professionals).

Waste
Releases of formaldehyde into the environment are likely to occur during production and processing as intermediate as well as from use of products such as cleaning agents which can contain the substance. Formaldehyde released to the sewer is expected to stay in the water phase, not to bind to sludge, and biodegrade rapidly. Exposure of formaldehyde to the soil compartment through the application of sludge on agricultural soil is therefore not expected. Formaldehyde is evaluated as an A-substance according to the Danish EPA's Guidance Document on "Connecting industrial wastewater to municipal wastewater treatment plants"; this is due to the Carc. 2 classification. Re-classification as a Carc. 1B substance will not change this evaluation (as both R40 and R45 will cause a substance A categorization). Waste is considered hazardous if it contains ≥1% of formaldehyde. This limit is also triggered by the Carc. 2 classification. After re-classification to Carc. 1B, this will change to ≥ 0.1%. When formaldehyde is used as a reactant within the chemical industry, almost all formaldehyde is converted leaving a limited fraction of waste.

Environment
Formaldehyde does not meet the criteria for Persistent, Bioaccumulative and Toxic (PBT), and there is no harmonised classification addressing the environment.
Both acute and chronic toxicity data are available for fish, invertebrate and algae. A Predicted No Effect Concentration $PNEC_{aqua}$ of 5.8 µg/L was calculated in the OECD SIDS report on formaldehyde and a Negligible Concentration (NC) = 0.0018 mg/L was calculated in the report by RIVM. These values are above the concentrations reported for monitoring data from ground water, rain water, and atmospheric water (15 year old data).
A degree of dilution of atmospheric water must be anticipated when entering aquatic ecosystems. It is not known if this dilution will be enough to reach a final concentration below the calculated $PNEC_{aquatic}$ and the NC. A predicted environmental concentration in freshwater was calculated in the assessment performed by the Australian Government. Calculations were done for emission levels reported for 2001-2002 and 2002-2003 and resulted in concentrations of 0.14 µg/L and 0.7 ng/L for two different scenarios. Applying this value and the calculated $PNEC_{aqua}$ of 0.0058 mg/L indicates no risk to the water compartment.
Formaldehyde is not anticipated to distribute to the sediment compartments, no monitoring data are available.

Formaldehyde has a low toxicity to birds exposed to formaldehyde in food, but formaldehyde in air and water fog has potentially adverse effects on some plant species when exposed.
Soil concentrations of formaldehyde are reported in the mg/kg range at local-production sites (not at non-production sites) and therefore in some cases above the NC for soil. Therefore at production sites no risk can be excluded. Transport to agricultural soil through the application of sludge is however unlikely.

Sewage micro-organisms have been reported to be impaired at high concentrations (30 mg/L). Releases into the environment are likely to occur during production and processing as intermediate as well as from use of products containing the substance. When released formaldehyde is ready biodegradable according to OECD Guideline no. 301 and can also be photodegraded in air either directly (half-life 4.1 hours) or indirectly by reaction with OH-radicals, with a half-life of 1.71 d. Half-lives between 1-7 d and 2-14days are reported for surface- and ground water. The half-life for soil is between 1-7 days.

Human health

In humans, as in other animals, formaldehyde is an essential metabolic intermediate in all cells. Formaldehyde is highly reactive and is a known skin- and eye- and respiratory tract irritant. Moderate to severe eye, nose and throat irritation occurs at exposure levels in air from 2 to 3 ppm. In humans, transient and reversible sensory irritation of the eyes and respiratory tract has been observed in clinical studies and epidemiological surveys. Consequently, formaldehyde is classified for its irritating potential.

Formaldehyde is also a skin sensitiser, and despite the fact that formaldehyde concentration for induction of allergy to is not exactly known, it is believed to be lower than 5%. Elicitation of allergy is observed in formaldehyde-sensitive persons in concentrations as low as 0.05% formaldehyde. Due to the high reactivity of formaldehyde at site of contact, the substance is not subject to systemic absorption either from dermal, oral or inhalational exposure, and there is no evidence of systemic toxicity or of a systemic target organ after prolonged exposure to formaldehyde. From rats exposed via drinking water a NOAEL of 15 mg/kg bw/day was established based on a 2-year study. From this study an oral reference dose of 0.2 mg/kg bw/day was set by the US EPA. WHO has concluded 2.6 mg formaldehyde/L in drinking water to be a tolerable concentration. The NOAEL for sensory irritation was a vapour concentration of 0.5 ppm (0.6 mg/m^3) (Nielsen et al, 2013). A DNEL (derived no effect level) of 0.5 mg/m^3 for long term inhalation exposure and 1 mg/m^3 for short term inhalation exposure for workers was given in the formaldehyde REACH dossier.

As the eye irritation is the most sensitive parameter, the onset of eye irritation is believed to provide a safety margin to the onset of irritation-induced cytotoxicity and cell proliferation. A maximum indoor air formaldehyde concentration of 100 µg/m^3 was established by WHO in 2010 also based on NOELS for the eye irritation as a sensitive, and preventive, parameter for more severe effects of formaldehyde.

In workers exposed to formaldehyde an associations have been found to the induction of and several cancers, including nasopharyngeal cancer and leukaemia.

In 2006, IARC evaluated formaldehyde to be carcinogenic to humans (IARC group 1). This classification was based on “sufficient evidence of nasopharyngeal cancer in humans, strong but not sufficient evidence of leukemia in humans, and limited evidence of sinonasal cancer in humans”. In 2009, IARC reaffirmed this Group 1 classification and also concluded that there was sufficient evidence of leukaemia in humans. EU has recently also strengthened the classification of formaldehyde from Carc 2 to Carc 1b and Muta 2.

The general population is exposed to formaldehyde from many sources and based on the extensive use of formaldehyde in many different areas, the exposure to the substance is very complex. One of the main formaldehyde exposure routes for the general public are indoor air formaldehyde originating from different source like building materials such as pressed wood products, insulation and carpets. Large investigations of indoor air concentration in houses in Europe have shown that the average indoor concentration is about 20 – 40 µg/m^3. This concentration is regarded as safe as it is below the WHO limit of 100 µg/m^3. Although low average values, there are indications that still about 10 % of the homes exceed the limit value of 100 µg/m^3, which indicate concern for a rather high fraction of the population. Thus, higher concentrations may be measured in a period where formaldehyde is evaporating from new products, indicating that humans may be exposed to formaldehyde concentrations possibly giving a risk of health effects at certain periods. Some people are very sensitive to formaldehyde, whereas others have no reaction to the same level of exposure. Thus temporary higher indoor concentrations in periods could pose risk to especially sensitive people.

Another exposure to formaldehyde is via food and indirect via food contact materials containing formaldehyde. The natural content of formaldehyde in food is in a range of 1.6 mg/kg bw/day (1.4 from food and 0.2 from food contact material). This contribution to the formaldehyde exposure from food is evaluated to be safe, as it is at least 600 times lower than the endogenous turnover of formaldehyde.
Other exposures originate from consumer product like cosmetics, cleaning agents and textile, where allergy is the main risk. Because of a low elicitation concentration to formaldehyde the exposure to formaldehyde during use of consumer products may pose a risk for allergy to consumers, and especially sensitive individuals.

For workers, inhalation is the most pronounced exposure followed by dermal exposure. Because of the varied use of formaldehyde, exposure to formaldehyde in the workplace may take place in many different industries. Due to the severe health effects of formaldehyde, keeping the exposure level at a minimum in the working environment is regarded as critical. Investigations in different working environments indicate that the air concentration is decreasing and operational conditions and Risk Management Measures, e.g. reduction of duration of activities to below four hours/day or the use of respiratory protection, are being introduced to keep the formaldehyde exposure low. Furthermore, the very low OEL values established are an expression of the effort to protect workers against the substance. Also, handling formaldehyde solutions and materials containing formaldehyde (or residual amounts of formaldehyde) may pose a risk for dermal exposure.

In developing any strategy for reducing the risks relating to a given substance, it is important to consider the availability of alternatives for the applications of concern, where this includes alternative substances, technologies and/or processes. Such considerations are important since any proposed risk management measures may initiate a shift to such alternatives.
Alternative preservatives and holding solutions for biological specimens to formaldehyde, which were identified, include substances such as 2-Amino-2-Ethyl-Propanediol (AEPD), ethylene glycol phenyl ether, propylene glycol and phenol. These substances do not have environmental classifications, except propylene glycol, but they do have classifications regarding human health. However, no classification as carcinogenic is included for the identified substances.
Major approaches to reduce the problem of exposure to formaldehyde from binders include initiatives to reduce emissions of formaldehyde rather than a substitution with a substance of less concern.
In conclusion, due to the large use of formaldehyde for many different purposes, it seems difficult to identify individual alternatives that generally can substitute formaldehyde. The substitution may have to be assessed case-by-case to suit the different application forms.

Overall conclusion
Formaldehyde is widely used for many different applications ranging from industry production/processes to professional use and also indifferent product and articles for consumers. The substance has been extensively studied and many reviews describing the effects of formaldehyde are available in open literature. Regulatory wise, the substance is regulated through both national and EU legislation. Formaldehyde was recently re-classified for its carcinogenic effect as Carc 1B, but formaldehyde is neither on the Candidate List of Substances of Very High Concern for Authorisation nor on the list of restrictions.
In relation to environmental effects, formaldehyde does not meet all the criteria for being persistent, bioaccumulative and toxic (PBT), and there is no harmonised classification addressing the environment. The human health effects are the most critical effects of formaldehyde as formaldehyde is a well-known dermal irritant and sensitiser. Furthermore, low-levels vapour exposure may cause eye- and respiratory tract irritation and long term exposure at higher level may cause cancer in the respiratory tract. In the occupational environment a stringent occupational exposure limit of 0.4 mg/m^3 has been established in order to protect the workers.

Still, formaldehyde exposure during use of consumer products or elevated in-door air concentrations may pose a risk to consumers especially sensitive individuals in relation to both dermal effects (irritation and/or sensitisation) and irritation of eye and the upper respiratory tract. Dermal exposure to formaldehyde in consumer products like cosmetic, household products or textile can pose a risk of allergy in sensitive individuals as a very low concentration may trigger allergy.
The new classification as Carc 1B of formaldehyde will put further pressure on the use of the substance – especially for the consumer use, however, it is not possible at this point in time to exactly asses how much this will influence and reduce the exposure of the population.

Also, due to the use of formaldehyde for many different purposes, it seems difficult to identify individual alternatives that can generally substitute formaldehyde. The substitution may have to be assessed case-by-case to suit the different application forms.

Sammenfatning og konklusion

Den danske Miljøstyrelse har medtaget formaldehyd på LOUS listen (2009) baseret på den tidligere klassificering som Carc. 2 (H351) og Skin Sens 1 (H317). Desuden bruges formaldehyd i en mængde > 100 tons på det danske marked, og det anvendes i en lang række produkter. Brugen af formaldehyd spænder fra harpiksproduktion (phenol, urinstof, og melaminharpikser, som har udbredt anvendelse som klæbemidler og bindemidler i træproduktion, papirmasse-og-papir, og i syntetisk glasagtig fiber industrier, i produktionen af plast og belægninger, og i tekstiloverflader) til kosmetik, rengøringsmidler og biocid- og pesticidprodukter.

Regulering
Formaldehyd er reguleret både gennem national og EU-lovgivning. Lovgivningen omfatter registrering i henhold til REACH (ved et mængdeinterval på 1.000.000 + t). Formaldehyd er klassificeret i henhold til CLP-forordningen som: Acute Tox. 3 (H301, H311, H331), Skin Corr. 1B (H314), Skin Sens 1 (H317) Aquatic Tox. 3, Mut2 (H341) og Carc. 1B (H350). Klassificeringen som Carc 1B og Mut2 blev aftalt i december 2013, da formaldehyd tidligere var klassificeret som Carc 2. Den nye klassificering er endnu ikke blevet anvendt i alle regulativer.
Formaldehyd blev optaget på listen for vurdering af stoffer under REACH (EF rullende handlingsplan (CoRAP) i 2013, men formaldehyd er hverken på kandidatlisten over særligt problematiske stoffer til godkendelse eller på listen over begrænsninger.

Desuden er formaldehyd strengt reguleret på en række områder, der omfatter biocider, kosmetik, legetøj, arbejdsmiljø, tilsætningsstoffer og materialer i berøring med fødevarer. Hvad angår anvendelsen af formaldehyd i forbrugerprodukter, er formaldehyd behandlet i Direktiv 2009/48/EF om sikkerhedskrav til legetøj samt Kosmetikforordning (EF) nr. 1223/2009, som fastsætter grænser for indholdet af formaldehyd i de endelige produkter. De fleste miljømærkningskriterier (EU Blomsten og den nordiske Svane) udelukker brugen af formaldehyd på grund af klassificeringen som kræftfremkaldende. Der er også EU-regler for formaldehyd i fødevaretilsætningsstoffer og i fødevarekontaktmaterialer.

Formaldehyd er medtaget i den danske bekendtgørelse om kontrol af risikoen for større uheld med farlige stoffer. Den danske Miljøkvalitetsstandard for hav- og ferskvand er 9,2 ug/L og for kortsigtet frigivelse 46 pg/L. Der er også nationale regler om indholdet af formaldehyd i tekstiler.

Produktion og anvendelse
I 2010 blev der globalt produceret 29 millioner tons formaldehyd (37 % opløsning). EU er den næststørste producent af formaldehyd (23 %) efter Asien (med Kina som den største producent), som har omkring 50 % af den globale kapacitet. I Europa har Tyskland (af de 22 EU-medlemsstater, der producerer formaldehyd) den højeste produktionskapacitet af formaldehyd med ca. 5 % af den globale produktionskapacitet og 23 % af den europæiske produktionskapacitet.

Anvendelsen af formaldehyd spænder bredt fra anvendelse som mellemprodukt til anvendelse i forbrugerprodukter. Anvendelse som mellemprodukt er primært inden for den kemiske industri til fremstilling af kondenserede harpikser til træ-, papir- og tekstil-forarbejdningsindustrien og i kemisk syntese. Formaldehydplast er en fælles betegnelse for en lang række plastmaterialer, som er dannet ved reaktion af formaldehyd med for eksempel urea, melamin, phenol eller furfurylalkohol.

Vandige opløsninger af formaldehyd anvendes som germicider, baktericider og fungicider (i Danmark anvendes formaldehyd for eksempel i akvakultur).
Desuden anvendes formaldehyd som konserveringsmiddel i en lang række forbrugerprodukter, såsom kosmetik og rengøringsmidler. Information fra Nordisk SPIN-databasen viser, at formaldehyd i Danmark (2011) især er indeholdt i råvarer, der anvendes til syntese og mellemprodukter med en tonnage på mere end 13.000 tons. Danmark har en temmelig stor produktion af spånplader, og formaldehyd anvendes i produktionen. I Danmark har der været et fald i antallet af forskellige præparater, der indeholder formaldehyd. Imidlertid har tonnagen af præparater været ganske konstant fra 2009 og frem (vigtigt at bemærke, at SPIN data ikke inkluderer forbrugerprodukter, men kun produkter til erhvervsmæssigt brug).

Affald
Frigivelse af formaldehyd til miljøet forventes at forekomme under produktion og forarbejdning til mellemprodukt samt ved brug af produkter såsom rengøringsmidler, der kan indeholde stoffet. Formaldehyd, som frigives til kloaker, forventes at forblive i vandfasen, ikke binde sig til slam og nedbrydes hurtigt. Formaldehydeksponering af jordmiljøet ved anvendelse af slam på landbrugsjord forventes derfor ikke. Formaldehyd er vurderet som et A-stof i henhold til den danske Miljøstyrelsens Vejledning om "Tilslutning af industrispildevand til kommunale renseanlæg"; dette skyldes Carc. 2-klassificeringen. Re-klassificering til et Carc. 1B-stof vil ikke ændre denne vurdering (da både R40 og R45 vil medføre en kategorisering som A-stof). Affald betragtes som farligt, hvis det indeholder ≥ 1 % formaldehyd. Denne grænse udløses også af Carc. 2-klassificeringen. Efter re-klassificering til Carc. 1B vil dette ændre sig til ≥ 0,1 %. Når formaldehyd anvendes som reaktant i den kemiske industri, vil næsten al formaldehyd reagere, og dermed begrænse mængden af affald.

Miljø
Formaldehyd opfylder ikke kriterierne for Persistent, Bioakkumulerende og Toksisk (PBT), og der er ingen harmoniseret klassificering for miljøet.
Både akutte og kroniske toksicitetsdata er tilgængelige for fisk, hvirvelløse dyr og alger. En Predicted No Effect Concentration $PNEC_{vand}$ på 5,8 ug/L blev beregnet i rapporten fra OECD SIDS på formaldehyd, og en Negligible Concentration (NC) = 0,0018 mg/L blev beregnet i rapporten fra RIVM. Disse værdier er over de koncentrationer, der er rapporteret for overvågningsdata fra grundvand, regnvand, og atmosfærisk vand (15-årige data).
Der må påregnes en vis udvanding af atmosfærisk vand, når det kommer ind i akvatiske økosystemer. Det vides ikke, om denne udvanding vil være nok til at nå en endelig koncentration under den beregnede $PNEC_{vand}$ og NC. En forudsagt miljømæssig koncentration i ferskvand blev beregnet i en vurdering udført af den australske regering. Beregninger blev udført for emissionsniveauer indberettet for 2001-2002 og 2002-2003 og resulterede i koncentrationer på 0,14 mg/L og 0,7 ng/L for to forskellige scenarier. Anvendelsen af denne værdi og den beregnede $PNEC_{vand}$ på 0,0058 mg/L tyder ikke på risiko for vandsegmentet.
Formaldehyd forventes ikke at distribuere til sedimentsegmenterne; der er ingen tilgængelige overvågningsdata.

Formaldehyd har en lav toksicitet for fugle eksponeret for formaldehyd i foder, men formaldehyd i luft og tåge har potentielt skadelige virkninger på visse plantearter ved eksponering. Jordkoncentrationer af formaldehyd er rapporteret i mg/kg ved lokal-produktionssteder (ikke på ikke-produktionssteder) og er derfor i nogle tilfælde over NC for jord. Derfor kan risiko ikke udelukkes på produktionssteder. Transport til landbrugsjord ved anvendelse af slam er imidlertid usandsynligt.

Mikroorganismer fra spildevand er blevet rapporteret at være forringet ved høje koncentrationer (30 mg/L).

Frigivelse til miljøet forventes at forekomme under produktion og forarbejdning til mellemprodukt samt ved brug af produkter, der indeholder stoffet. Frigivet formaldehyd er let biologisk nedbrydeligt i henhold til OECD Guideline no. 301 og kan også fotonedbrydes i luft enten direkte (halveringstid 4,1 timer) eller indirekte ved reaktion med OH-radikaler, med en halveringstid på 1,71 d. Halveringstider mellem 1-7 dage og 2-14 dage er rapporteret for overflade-og grundvand. Halveringstiden for jord er mellem 1 og 7 dage.

Sundhed

Hos mennesker, som hos andre dyr, er formaldehyd et vigtigt metabolisk mellemprodukt i alle celler.

Formaldehyd er meget reaktivt og er et kendt hud-, øjen- og luftvejsirriterende stof. Moderat til svær øjen-, næse- og halsirritation opstår ved eksponeringsniveauer i luften fra 2 til 3 ppm. Hos mennesker er forbigående og reversibel sensorisk irritation af øjne og luftveje blevet observeret i kliniske og epidemiologiske undersøgelser. Derfor er formaldehyd klassificeret for sit irriterende potentiale.

Formaldehyd er også hudsensibiliserende, og trods det at formaldehydkoncentrationen for induktion af allergi ikke er nøjagtigt kendt, menes den at være mindre end 5 %. Fremkaldelse af allergi er observeret i formaldehyd-overfølsomme personer i koncentrationer så lave som 0,05 % formaldehyd.

På grund af den høje reaktivitet af formaldehyd på kontaktstedet er stoffet ikke omfattet af systemisk absorption fra enten dermal, oral eller inhalationseksponering, og der er ingen tegn på systemisk toksicitet eller et systemisk målorgan efter langvarig eksponering for formaldehyd. Ud fra et 2-årigt rotte-studie, hvor de blev eksponeret via drikkevand blev en NOAEL på 15 mg/kg legemsvægt/dag fastsat. Ud fra denne undersøgelse blev en oral referencedosis på 0,2 mg/kg legemsvægt/dag fastsat af US EPA. WHO har konkluderet, at 2,6 mg formaldehyd/L i drikkevand er en tolerabel koncentration. NOAEL for sensorisk irritation var en dampkoncentration på 0,5 ppm (0,6 mg/m^3) (Nielsen *et al*, 2013).

Da øjenirritation er den mest følsomme parameter, menes øjenirritation at give en sikkerhedsmargen til udbrud af irritationsinduceret cytotoksicitet og celleproliferation. En maksimal indendørs formaldehydkoncentration i luft på 100 µg/m^3 blev fastsat af WHO i 2010 også baseret på NOELs for øjenirritation som en følsom - og forebyggende - parameter for mere alvorlige virkninger af formaldehyd.

Hos arbejdere, der udsættes for formaldehyd, er der fundet associationer til induktion af flere kræftformer, herunder nasopharyngeal cancer og leukæmi.

I 2006 vurderede IARC formaldehyd til at være kræftfremkaldende for mennesker (IARC gruppe 1). Denne klassificering er baseret på "*tilstrækkelig evidens for nasopharyngal kræft hos mennesker, stærk, men ikke tilstrækkelig dokumentation for leukæmi hos mennesker og begrænset evidens for sinonasal kræft hos mennesker*." I 2009 bekræftede IARC igen denne gruppe 1-klassificering og konkluderede også, at der ikke var tilstrækkelig evidens for leukæmi hos mennesker. EU har for nylig også styrket klassificeringen af formaldehyd fra Carc 2 til Carc 1b og Muta 2.

Befolkningen er udsat for formaldehyd fra mange kilder, og baseret på den omfattende brug af formaldehyd på mange forskellige områder er eksponeringen for stoffet meget kompleks. En af de vigtigste formaldehydeksponeringskilder for befolkningen er formaldehyd i indendørs luft, der stammer fra forskellige kilder såsom byggematerialer, fx pressede træprodukter, isolering og tæpper. Store undersøgelser af indeklimakoncentrationer i huse i Europa har vist, at den gennemsnitlige indendørs koncentration er omkring 20 til 40 µg/m^3. Denne koncentration betragtes som sikker, da den er under WHO's fastsatte grænse på 100 µg/m^3. Selv med de lave gennemsnitlige værdier er der tegn på, at der stadig er omkring 10 % af boligerne, der overskrider grænseværdien på 100 ug/m^3, hvilket indikerer betænkelighed for en ret stor del af befolkningen. Således kan der måles højere koncentrationer i en periode, hvor formaldehyd fordamper fra nye produkter, hvilket indikerer, at mennesker kan blive eksponeret for formaldehyd-koncentrationer, som muligvis kan udgøre en risiko for sundhedsmæssige effekter i visse perioder. Nogle mennesker er meget følsomme over for formaldehyd, mens andre ikke har nogen reaktion på det samme eksponeringsniveau. Således kan midlertidigt højere indendørs koncentrationer i perioder udgøre en risiko for særligt følsomme personer.

En anden eksponeringsvej for formaldehyd er via fødevarer og indirekte via fødevarekontaktmaterialer, der indeholder formaldehyd. Det naturlige indhold af formaldehyd i fødevarer er ca. 1,6 mg/kg legemsvægt/dag (1,4 fra mad og 0,2 fra fødevarekontaktmateriale). Dette bidrag til formaldehydeksponering fra fødevarer vurderes at være sikkert, da det er mindst 600 gange lavere end den endogene omsætning af formaldehyd.
Anden eksponering stammer fra forbrugerprodukter som kosmetik, rengøringsmidler og tekstiler, hvor allergi er den største risiko. På grund af en lav elicitationskoncentration af formaldehyd kan formaldehydeksponeringen under brug af forbrugerprodukter udgøre en risiko for allergi for forbrugerne, og især følsomme personer.

For arbejdere er inhalation den mest udtalte eksponeringsvej efterfulgt af dermal eksponering. På grund af den varierede anvendelse af formaldehyd kan eksponering for formaldehyd på arbejdspladsen finde sted i mange forskellige industrier. På grund af de alvorlige sundhedsmæssige effekter af formaldehyd, betragtes det som kritisk at holde eksponeringsniveauet på et minimum i arbejdsmiljøet. Undersøgelser i forskellige arbejdsmiljøer indikerer, at luftkoncentrationen er faldende, og driftsmæssige forhold og risikohåndteringsforanstaltninger, fx reduktion af varigheden af aktiviteter til fire timer/dag eller brug af åndedrætsværn, bliver indført for at holde formaldehydeksponeringen lav. Desuden er de meget lavt fastsatte OEL værdier et udtryk for indsatsen for at beskytte arbejderne mod stoffet. Desuden kan håndtering af formaldehydopløsninger og materialer, der indeholder formaldehyd (eller restmængder af formaldehyd), udgøre en risiko for dermal eksponering.

I udviklingen af en strategi til reducering af risici i forbindelse med et givet stof er det vigtigt at overveje tilgængeligheden af alternativer til problemanvendelser, hvor dette omfatter alternative stoffer, teknologier og/eller processer. Sådanne overvejelser er vigtige, da de foreslåede risikohåndteringsforanstaltninger kan igangsætte et skift til sådanne alternativer.
Alternative konserveringsmidler og opløsninger til formaldehyd, der blev identificeret, omfatter stoffer som 2-amino-2-ethyl-propandiol (AEPD), ethylenglycol phenylether, propylenglycol og phenol. Disse stoffer har ikke miljøklassificeringer, undtagen propylenglycol, men de har sundhedsklassificeringer. Ingen af de identificerede stoffer er imidlertid klassificeret som kræftfremkaldende.
Tiltag til mindskning af problemet med formaldehydeksponering fra bindemidler omfatter initiativer til at reducere udledningen af formaldehyd snarere end en substitution med et mindre problematisk stof.
Det konkluderes, at det er vanskeligt på grund af den omfattende brug af formaldehyd til mange forskellige formål at identificere individuelle alternativer, som generelt kan erstatte formaldehyd. Substitution skal måske vurderes fra sag til sag, så den passer til de forskellige ansøgningsskemaer.

Overordnet konklusion
Formaldehyd anvendes i vid udstrækning til mange forskellige formål lige fra industriproduktion/-processer til erhvervsmæssig brug, og også indifferente produkter og artikler til forbrugerne. Stoffet er blevet grundigt undersøgt, og mange rapporter, der beskriver virkningerne af formaldehyd, er tilgængelige i den åbne litteratur. Med hensyn til regulering er stoffet reguleret både gennem national og EU-lovgivning. Formaldehyd blev for nylig re-klassificeret som Carc 1B for sin kræftfremkaldende virkning, men formaldehyd er hverken på kandidatlisten over særligt problematiske stoffer til godkendelse eller på listen over begrænsninger.
I relation til miljøeffekter opfylder formaldehyd ikke alle kriterier for at være Persistent, Bioakkumulerende og Toksisk (PBT), og der er ingen harmoniseret miljøklassificering.

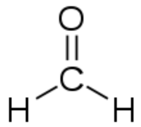
De sundhedsmæssige effekter er de mest kritiske for formaldehyd, da formaldehyd er et velkendt irriterende og sensibiliserende stof. Desuden kan lav-niveau eksponeringsdampe medføre øjen- og luftvejsirritation, og langvarig eksponering på højere niveau kan medføre kræft i luftvejene. I arbejdsmiljøet er der etableret en streng grænseværdi på 0,4 mg/m^3 for at beskytte arbejderne. Alligevel kan formaldehydeksponering under anvendelse af forbrugerprodukter eller forhøjede indendørs luftkoncentrationer udgøre en risiko for forbrugerne, især følsomme personer, både i forhold til hudeffekter (irritation og/eller overfølsomhed) og irritation af øjne og øvre luftveje. Dermal eksponering for formaldehyd i forbrugerprodukter som kosmetik, husholdningsprodukter og tekstil kan udgøre en risiko for allergi hos følsomme personer, da en meget lav koncentration hos sensitive individer kan udløse allergi.
Den nye klassificering af formaldehyd som Carc 1B vil lægge yderligere pres på anvendelsen af stoffet - især forbrugeranvendelse, dog er det ikke muligt på nuværende tidspunkt at vurdere præcist, hvor meget dette vil påvirke og reducere eksponeringen af befolkningen.

Det synes vanskeligt at identificere de enkelte alternativer, som generelt kan erstatte formaldehyd, på grund af formaldehyds anvendelse til mange forskellige formål. Substitution skal måske vurderes fra sag til sag, så den passer til de forskellige ansøgningsskemaer.

1. Introduction to the substance

1.1 Definition of the substance

TABLE 1-1
NAME AND OTHER IDENTIFIERS OF FORMALDEHYDE (OECD SIDS 2002; REACH REGISTRATION DATA 2013)

Formaldehyde	
EC number	200-001-8
CAS number	50-00-0
Synonyms	Formaldehyde solution Formaldehyde, gas Formalin Formalith Formol Formic aldehyde Methaldehyde Morbicid Oxomethane Paraform Methanal Methylene oxide
Molecular formula	CH_2O
Molecular weight	30.03 g/mol
Structure	

1.2 Physical and chemical properties

Formaldehyde is a colourless gas with pungent odour. The molecular mass of formaldehyde is 30.03 g/mol and the relative gas density is 1.03-1.10 g/mL. Formaldehyde is highly soluble in water. Formalin is a solution of formaldehyde gas in water. Aqueous solutions containing more than 30%

(w/w) formaldehyde becomes cloudy at room temperature due to formation of larger poly(oxymethylene)glycols. However, at room temperature aqueous solutions contain formaldehyde in the form of methylene glycol $HOCH_2OH$ and its oligomers.
The calculated vapour pressure at 25°C is 5,176 hPa and in good agreement with a measured value of 5,185 hPa quoted in the literature. The vapour pressure of the liquid solution is between 22.6 and 26.6 hPa (Table 1-2) (EHS, 1989; OECD SIDS, 2002).

TABLE 1-2
PHYSICAL-CHEMICAL PROPERTIES FOR FORMALDEHYDE GAS AND FORMALIN (37% AQUEOUS SOLUTION OF FORMALDEHYDE) (EHS*, (1989); OECD SIDS, (2002), AUSTRALIAN GOVERNMENT** (2006))

Property	Formaldehyde (gas)	Formalin (37% formaldehyde solution)
Physical state	Colourless gas	Aqueous solution
Molecular weight	30.03	30.03**
Melting point	- 92 °C	NA
Freezing point	-118 °C*	NA
Boiling point	-19.2 °C	96 °C**
Relative density	NA	1.03-1.10 g/mL**
Vapour pressure	5,176 hPa at 25 °C (calculated) 5,185 hPa (measured)	22.6 to 26.6 hPa**
Water solubility (mg/L)	400-550 mg/mL 25 °C**	≥ 100 mg/mL at 20.5 °C**
Log P (octanol/water)	0.35 at 25 °C	NA
Henry's Law Constant	0.034 Pa*m³* mol-1 at 25 °C	NA
Conversion factor	1 ppm = 1.23 mg/m³	-

NA: NOT AVAILABLE

1.3 Impurities

The sales product in aqueous solution contains in general 35 – 55 % formaldehyde. The 49 - 49.3 % sales solution of BASF product of formaldehyde contains the following impurities (OECD SIDS, 2002):

Methanol: 0.5 – 2 % w/w
Formic acid: about 0.3 % w/w
Iron: < 0.0001 - % w/w

To reduce the intrinsic polymerisation of formaldehyde, stabilisers, such as methanol and various amine derivatives, are added to the solution (Australian Government, 2006).

2. Regulatory framework

This chapter gives an overview of how formaldehyde is addressed in existing and forthcoming EU and Danish legislation, international agreements, eco-label criteria etc. The overview reflects the findings from the data search.

Appendix 1 provides a brief overview of and connections between legislatives instruments in EU and Denmark. The appendix also gives a brief introduction to chemicals legislation, explanation for lists referred to in chapter 3, as well as a brief introduction to international agreements and the aforementioned eco-label schemes.

2.1 Existing legislation

The Danish EPA has included formaldehyde on the LOUS list (2009) based on its classification as Carc. 2 (H351) and because formaldehyde is applied on the Danish market in a quantity > 100 tonnes.

Table 2-1 includes regulatory measures in relation to formaldehyde with different regulatory sectors e.g. industrial chemicals and chemical products, articles, biocides, cosmetics, toys, food, occupational environment, drinking water, environment etc.

TABLE2-1
LEGISLATION ADRESSING FORMALDEHYDE

Legal instrument	Reference	Requirement as concerns formaldehyde and national implementation	Consequences of reclassification of formaldehyde from carc. 2 to carc. 1B
General legislation			
REACH regulation	REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Registration of production import and uses. Tonnage band: 1,000,000 + tonnes per year	
CLP regulation	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16	EU harmonised classification. Please refer to Table 2-3 page 22.	According to the 6th ATP a re-classification as Carc. 1B is expected to be implemented in the summer of 2014

Legal instrument	Reference	Requirement as concerns formaldehyde and national implementation	Consequences of reclassification of formaldehyde from carc. 2 to carc. 1B
	December 2008 on classification, labelling and packaging of substances and mixtures		
Regulation addressing substances and products (workers and consumers)			
Danish Statutory Order limiting the content of formaldehyde in particle board, plywood and similar plates, which are used in furniture, fixtures and similar	Bekendtgørelse om begrænsning af formaldehyd i spånplader, krydsfinerplader og lignende plader, som anvendes i møbler, inventar og lignende BEK nr 289 af 22/06/1983 (under revision)	Max. release at equilibrium: 0.15 mg/ m^3 air (when tested in a climate chamber) Max. content in the product of 25 mg/ 100 g dw.	Not known
Biocidal Regulation	REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products	Formaldehyde is included in the review process on product type 2 (Disinfectants and algaecides not intended for direct application to humans or animals), 3 (Veterinary hygiene) and 22 (Embalming and taxidermist fluids) for possible inclusion on the positive list as active substance in these product types.	A biocidal product shall not be authorised for making available on the market for use by the general public where it meets the criteria according to Regulation (EC) No 1272/2008 for classification as: category 1A or 1B carcinogen
Cosmetic	REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products	*ANNEX III:* List of prohibited or restricted substances for use in cosmetic products. Nail hardeners: Maximum authorized concentration in the finished cosmetic product 5 % calculated as formaldehyde *ANNEX V: All finished products containing* formaldehyde or substances which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0.05 %.*Oral products: 0.1%* *Other products: 0.2%*	The regulation states "Given the hazardous properties of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2,... their use in cosmetic products should be prohibited... *However*, as a hazardous property of a substance does not necessarily always entail a risk, there should be a possibility to allow the use of substances classified as CMR 2 substances where, in view of exposure and concentration, they have been found safe for use in cosmetic products. *After a reclassification to Carc. 1B the latter will no longer apply to*

Legal instrument	Reference	Requirement as concerns formaldehyde and national implementation	Consequences of reclassification of formaldehyde from carc. 2 to carc. 1B
			formaldehyde and it is expected that the limits listed will no longer be applicable.
Food contact material	COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food	Formaldehyde is included on Annex I of the regulation as monomer and additive. The specific migration limit applicable for the substance is 15 mg substance per kg food.	Not known
Food additive Specifications	Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council	Limits for formaldehyde in certain food additives: Formaldehyde in the food additives (E 200), (E 202), (E 203) and (E 280) not more than 0.1 % of the food additive. Formaldehyde in the food additives (E 400), (E 402), (E 403), (E 404) and (E 405): Not more than 50 mg substance per kg food additive. Formaldehyde as non-intentional impurity in (E 407) and (E 407a): Not more than 5 mg substance per kg food additive.	Not known
Food Additive Regulation	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives	E 239 hexamethylentetramin can cleave off formaldehyde. The additive is only to be used in a certain cheese (Provelone). The maximum limit is 25 mg per kg food.	Not known
Toys Directive	DIRECTIVE 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys	Substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.	No change
Regulation addressing working environment			
Directive on Chemicals Agents at Work	COUNCIL DIRECTIVE 98/24/EC of 7 April 1998	On the protection of the health and safety of workers from the	No change

Legal instrument	Reference	Requirement as concerns formaldehyde and national implementation	Consequences of reclassification of formaldehyde from carc. 2 to carc. 1B
	on the protection of the health and safety of workers from the risks related to chemical agents at work.	risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). *Implemented in Denmark by: Statutory Order No. 292; 26. April 2001. "Bekendtgørelse om arbejde med stoffer og materialer (kemiske agenser)"* and amendments (the deployment of chemical agents Directive). It describes, among other things for which substances and materials that are requirements for safety data sheets, requirements for workplace instructions, requirements for substitution and preparation of the special chemical risk assessment.	
Danish executive order: on the Performance of Work	Danish Executive Order No. 559 of 17 June 2004	Section 16. Any unnecessary effect of substances and materials shall be avoided. Therefore, the effect of substances and materials during work shall be reduced to the lowest level reasonably practicable taking account of technical progress, and any limit values fixed shall be complied with.	No change since both classifications, H351 (R40) and H350 (R45), are already included equally in this executive order.
Danish Executive order on measures to prevent exposure to carcinogenic substances and materials.	Danish Executive order no. 908 of 27/09/2005	Appendix 1 section A; determines the percentage of the substance, a material must contain in order to be covered by this notice. The limits for formaldehyde are 0.1-5% for the product groups: All-purpose cleaners, disinfectants, paints, varnishes, glues, hardener, inks etc,, impregnating agents, raw materials for synthesis, fixation agents, preservatives, stabilizers used in the manufacturing processes, binders used in the manufacture of paints, plastic products etc., laboratory use and other	Not known

Legal instrument	Reference	Requirement as concerns formaldehyde and national implementation	Consequences of reclassification of formaldehyde from carc. 2 to carc. 1B
		application	
Danish executive order on working with code-numbered products,	Danish Executive order no-302 of May 13, 1993 and Danish executive order laying down the code numbers, No. 301, May 13, 1993, as amended (*bekendtgørelse om arbejde med kodenummererede produkter og bekendtgørelse om fastsættelse af kodenumre*).	The notice includes work with those in Annex 1 named products including glue, as well as preparation and clearance of these works (formaldehyde is not directly mentioned)	Not known
Danish executive order: Order amending the Order on limit values for substances and materials	Danish Executive order no. 986 of 11/10/2012 (Bekendtgørelse om ændring af bekendtgørelse om grænseværdier for stoffer og materialer)	The notice shall include any work with substances and materials, including production, use and handling, and any risk of exposure in the workplace substances and materials. Exposure limits for air pollution. Annex II, set exposure limits for gases, vapors and particulate pollution. For formaldehyde these limits are: 0.3 ppm 0.4 m^3 (Further the appendix has the following remarks L = the threshold is a limit value, which should never be exceeded. And K = the substance is considered to be carcinogenic.	Not known
Danish Statutory order on the control of major-accident hazards involving dangerous substances. Implementing the SEVESO III Directive (2012/18/EU)	BEK nr 1666 af 14/12/2006 Gældende. Bekendtgørelse om kontrol med risikoen for større uheld med farlige stoffer	The notice provides for the prevention of major accidents in and around companies including its installations, warehouses where hazardous substances may occur, and rules concerning the mitigation of major accidents Qualifying quantity (tonnes) for the use of Formaldehyd (koncentration ≥ 90 %) 5 tonnes (lower tier requirements)	Not known

Legal instrument	Reference	Requirement as concerns formaldehyde and national implementation	Consequences of reclassification of formaldehyde from carc. 2 to carc. 1B
		and 50 tonnes (higher tier requirements)	
Danish Statutory order BEK nr 20 af 12/01/2006 Order on the control of the working environment at risk of major accidents involving dangerous substances	BEK nr 20 af 12/01/2006 Bekendtgørelse om kontrol med arbejdsmiljøet ved risiko for større uheld med farlige stoffer	Qualifying quantity (tonnes) for the use of Formaldehyde (koncentration ≥ 90 %) 5 tonnes (must prepare safety documentation and a safety report) and 50 tonnes (must prepare safety documentation and a contingency plan)	Not known
Regulation addressing waste			
Waste framework directive	DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives	Formaldehyde is as a consequence of its classification as Carc. 2 included in ANNEX III: Properties of waste which render it hazardous. Implemented in Denmark by; BEK nr 1309 af 18/12/2012 Gældende(Affaldsbekendtgørelsen)	This directive addresses carcinogenic substances without reference to classification. Therefore no change is expected. According to the Danish order waste is considered hazardous if it contains ≥1% of formaldehyde. This limit is triggered by the substance property as a carcinogenic (Carc. 2). Re-classification of formaldehyde to Carc. 1B will change this limit to ≥ 0.1%.
Basel Convention	On the control of transboundary movements of hazardous wastes and their disposal	ANNEX III List of hazardous substance characteristics. *Substances or wastes which, if they are inhaled or ingested or if they penetrate the skin, may involve delayed or chronic effects, including carcinogenicity. Formaldehyde is classified as carcinogenic, and therefore included.*	Carcinogenic substances are addressed without reference to classification. Therefore no change is expected.

Legal instrument	Reference	Requirement as concerns formaldehyde and national implementation	Consequences of reclassification of formaldehyde from carc. 2 to carc. 1B
Regulation addressing emissions to the environment			
Danish Statutory Order on water quality and monitoring of water supply systems:	Bekendtgørelse om vandkvalitet og tilsyn med vandforsyningsanlæg. BEK nr. 1024 af 31/10/2011.	A limit value for total formaldehyde in drinking water (at water works and at the consumer's tap) has been set at 10 µg/L and 50 µg/L water respectively.	Not known
Water Framework Directive	DIRECTIVE 2000/60/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2000 establishing a framework for Community action in the field of water policy	Formaldehyde is as a consequence of its classification as Carc. 2 included in the ANNEX VIII Indicative list of the main pollutants	Carcinogenic substances are addressed without reference to classification. Therefore no change is expected.
Environmental Quality Standards	Danish executive order no. 1022 of 25/08/2010	Environmental Quality Standards = 9.2 µg/L (fresh- and marine water) Short term release =46 µg/L	When setting the Environmental Quality Standards for fresh- and marine waters any factor that may contribute to the danger of a substance shall be taken into account when calculating. Specifically, they mention as examples carcinogenic properties and effects on populations and communities. It is therefore anticipated that this effect has been considered.
Danish guidance document	Vejledning fra Miljøstyrelsen Nr. 2 2002 "B-værdivejledningen"	B-value formaldehyde = 0.01 mg/m^3 B-value (contribution value) is, according to this guidance document a limit for each company's contribution to air pollution in the environment. B-values are used to protect the public from harmful effects	

According to the Danish Veterinary and Food Administration (personal communication), there is currently a special focus on kitchen ware from China and Hong Kong made of melamine which may contain residual amounts of formaldehyde. These products are subject to specific restrictions on import into the EU, where formaldehyde is included on Annex I of the regulation as monomer and additive. The specific migration limit applicable for formaldehyde is 15 mg formaldehyde per kg food. This means that all kitchen ware entering the EU must be notified in advance, and a documentary of all parties has to be made, including analytical control of 10% of the lots which should be checked for migration of formaldehyde. No results from the control are published but approximately 2% of the analysed batches do exceed the migration limit and are rejected before entering the market (personal communication).

The European Commission (IPF, 2013) has recently published a report on the potential impact on industrial competitiveness of restrictions on certain CMR 1A and 1B substances in articles". The report also includes information on formaldehyde. Here it is stated that the acceptable levels of formaldehyde emission from composite wood products have been continuously reduced over the last years. Also, many countries have legislation in place to regulate formaldehyde emissions from articles and furthermore they have developed an obligatory emission class E1 (0.1 ppm boards) for wood-based panels.
According to the report, Europe has established the emission classes E1 and E2 (European Standard EN 13986) regarding wood products used in construction. As such, in 2006, emission class E1 became obligatory for panel production. Europe's harmonised standard includes two emission classes - namely E1 and E2 (E1 ≤ 8mg/100g dry board; E2 >8 - ≤ 30 mg/100g dry board).
Individual member states including Germany, Austria, Denmark and Sweden require compliance with emission limits of 6.5 mg/100g dry board.
The European panel federation (EPF7) also has its own standard - the EPF-S [designed for Particle Board (PB): 4mg/100g and for medium density fibreboard (MDF) (with > 8 mm thickness)): 5 mg/100g]. In 2011, EPF agreed on a reduction in formaldehyde emissions for CE-labelled, uncoated wood panels for construction (EN 13986). The new limit value has been set at 0.065ppm.

2.1.1 Occupational exposure limit

An occupational exposure limit is an upper limit on the acceptable concentration of a hazardous substance in workplace air. Most of the OEL values are Time Weighted Averages (TWA) for 8 hours of exposure. However a few countries report their limits as 15 minutes values. Reported values for European countries are presented in Table 2-2 below. The conversion factor 1 ppm ≈ 1.23 mg/m³, has been applied in order to compare the TWA values (SCOEL, 2008).

TABLE 2-2
OCCUPATIONAL EXPOSURE LEVELS (OEL) FOR EUROPEAN COUNTRIES REPRESENTED AS TIME WEIGHTED AVERAGES (TWA) 15 MINUTES AND 8 HOURS DEPENDING ON THE COUNTRY.

Country	TWA Limit (8 h)	Reference
Denmark	0.4 mg/m³	Danish Work Authority, 2012
Austria	0.6 mg/m³	Grenzwerteverordnung 2006 - GKV 2006)
France	0.6 mg/m³	INRS, 2012
Netherland	0.2 mg/m³	Dutch OEL Databank, 2013

Country	TWA Limit (8 h)	Reference
Switzerland	0.7 mg/m3	Dutch OEL Databank
Finland	1.2 mg/m3	Dutch OEL Databank
Spain	0.4 mg/m3	Dutch OEL Databank
Belgium	0.4 mg/m3	Dutch OEL Databank
Norway	0.6 mg/m3	Dutch OEL Databank
Sweden	0.7 mg/m3	Dutch OEL Databank
England	2.5 mg/m3	Dutch OEL Databank
Germany, Italy	No limit	Dutch OEL Databank

*TWA for 15 minutes.

SCOEL (2008) has recommended an 8-hr TWA value of 0.2 ppm or 0.2 mg/m3 and a short term (15-mintues value) STEL of 0.4 ppm or 0.5 mg/m3.

2.1.2 Classification and labelling

2.1.2.1 Harmonised classification in the EU

Formaldehyde has previously been evaluated as a probable carcinogenic to humans. This evaluation was based on experimental animal data and limited human data, but new information from workers and occupational exposure to formaldehyde has increased the overall weight of the evidence. Thus, IARC (International Agency for Research on Cancer) reclassified formaldehyde as carcinogenic to humans (group 1) in 2010 (IARC 2009).

A harmonized classification and labelling is appointed to Formaldehyde according to Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). Formaldehyde is classified as presented in Table 2-3 below.

However, in the opinion of the RAC (Committee for Risk Assessment), it is recommended to classify formaldehyde as Carc. 1B (H350: May cause cancer) and Muta 2, (H341: Suspected of causing genetic defects) (ECHA, 2012). The 6th ATP for formaldehyde as a Carc 1B was agreed on in a meeting held 17th December 2013 in EU (Draft Commission Regulation, 2013).

The classification as Carcinogen Category 1B could lead to further regulation e.g. identification as a SVHC substance and possible inclusion on annex XIV (the authorisation list) or (maybe more probable) lead to restrictions on consumer use of formaldehyde.

TABLE 2-3
HARMONISED CLASSIFICATION OF FORMALDEHYDE (CAS: 50-00-0) (ANNEX VI TO CLP SEPTEMBER 2013 AND INCLUDING ADOPTED 6TH ATP REGARDING RE-CLASSIFICATION AS CARC 1B WHICH IS EXPECTED TO BE IMPLEMENTED IN THE SUMMER 2014)

Chemical identification (CAS No)	Classification	
	Hazard Class and Category Code(s)	Hazard statement Code(s)
Formaldehyde (50-00-0)	Acute Tox. 3.	H301
	Acute Tox. 3.	H311

Chemical identification (CAS No)	Classification	
	Hazard Class and Category Code(s)	Hazard statement Code(s)
	Skin Corr. 1B	H314
	Skin Sens. 1	H317
	Acute Tox. 3.	H331
	Mut2	H341
	Carc. 1B	H350

H301: Toxic if swallowed; H311: Toxic in contact with skin; H314: Causes severe skin burns and eye damage; H317: May cause an allergic skin reaction; H331: Toxic if inhaled; H341: Suspected of causing genetic defects; H350: May cause cancer.

Further it needs to be labelled with warning pictograms:

Skull and crossbones

Corrosion

Health Hazards

2.1.2.2 Notified classification in the EU

According to the current CLP regulation companies putting chemical substances or chemical mixtures on the market in EU are obliged to notify the classification they apply for the substances to the European Chemicals Agency, ECHA.
The classifications used (and notified) by the companies can be searched at the ECHA website in the CLP inventory database. There are 2,551 notifications available for formaldehyde (CAS: 50-00-0) 1,788 of these notified classifications are in accordance to the harmonized classification presented above.

2.2 REACH

2.2.1 REACH registration, evaluation, authorisation, restriction

Formaldehyde has been registered under REACH at a tonnage band of 1,000,000 + tonnes per year. Formaldehyde was included in the list of substances included in the Community Rolling Action Plan (CoRAP) in 2013. The grounds of concern are human health concerns (CMR), worker exposure and wide dispersive use as well as high aggregated tonnage.
France and the Netherlands will lead the evaluation of formaldehyde as rapporteur and co-rapporteur, and will have one year to do so. Within this year they have to decide whether there is a need to request further information from the registrants to clarify the concern. This request might go beyond the standard information requirements of REACH (Annexes VII to X) and may pertain to the intrinsic properties of the substance or its exposure.

Formaldehyde is not on the Candidate List of Substances of Very High Concern for Authorisation. Formaldehyde is not included on the list of restriction. The list of restrictions contains those substances (on its own, in a mixture or in an article) for which manufacture, placing on the market or use is limited or banned in the European Union.

2.2.2 EU risk assessment and Annex XV transitional report

No EU risk assessment report or Annex XV transitional[1] report has been developed for formaldehyde.

2.2.3 Other legislation/initiatives

Formaldehyde is listed on the Organisation for Economic Cooperation and Development's (OECD) List of High Production Volume (HPV) chemicals, i.e. production volume of 1,000 tonnes or more (OECD, 2004). An OECD SIDS (Screening Information Dataset) Report is available for formaldehyde (OECD SIDS, 2002). The document contains the information gathered and an Initial Assessment performed under the framework of the OECD HPV Chemicals Programme (substance evaluated prior to 2007).

2.3 International agreements

There are international initiatives on authority level specifically addressing the use of formaldehyde. Table 2-4 below summarises the level of formaldehyde permitted in textiles in different countries.

TABLE 2-4
REGULATION OF FORMALDEHYDE IN TEXTILES (AUSTRALIAN COMPETITION AND CONSUMER COMMISSION, 2008) (PPM = PARTS PER MILLION).

Country	Regulation
EU	Regulations in the EU limit formaldehyde in children's clothing to 30 ppm.
Netherland	The Netherlands has the following regulations for limits on formaldehyde in textiles that come in direct contact with the skin: • any containing more than 120 ppm formaldehyde must be labelled 'Wash before first use' • after washing, these products must not contain more than 120 ppm.
Finland	• textiles for babies under 10 years old—30 ppm • textiles in direct skin contact—100 ppm • textiles not in direct skin contact—300 ppm.
Norway	• textiles for babies under 10 years old—30 ppm • textiles in direct skin contact—100 ppm • textiles not in direct skin contact—300 ppm.
France	• textiles in baby products intended to come in contact with skin—20 ppm • textiles in direct skin contact—100 ppm • textiles not in direct skin contact—400 ppm.
Germany	In Germany, textiles that normally come in direct contact with the skin and release more than 1500 ppm formaldehyde must bear a label that states: 'Contains formaldehyde. Washing this garment is recommended prior to first time use in order to avoid irritation of the skin.'

[1] Annex XV transitional reports of existing substance risk assessments and risk reduction strategies developed under Regulation (EEC) No 793/93, where the work was not finalised by 1 June 2008.

Country	Regulation
Austria	In Austria, textiles that contain 1,500 ppm or above have a label stating this.
China	• textiles for infants and babies—less than 20 ppm • textiles in direct skin contact—less than 75 ppm • textiles not in direct skin contact—less than 300 ppm.
Japan	• textiles for infants—must not be detectable (20 ppm) • textiles in direct skin contact—75 ppm • clothing supplied for children aged from birth to three years old must have no detectable residue of formaldehyde.
Australia	• infants' clothing—30 ppm • clothing specifically marketed as suitable for people with sensitive skin—30 ppm • garments which contact the skin—100 ppm • other garments or fabrics—300 ppm.
New Zealand	• clothes for babies and infants under two years old—no greater than 30 ppm or 30 ppm • clothing specifically designed and marketed for children and adults with sensitive skin or to avoid any sensitive reaction with skin—no greater than 30 ppm • clothing and textiles in direct contact with skin—no greater than 100 ppm or no greater than 100 ppm after wash if there is a label or instruction recommending to wash before first use • clothing and textiles not in direct contact with skin—no greater than 300 ppm.

In Denmark, there are no rules on formaldehyde in textiles as such, in the form of limits, the Danish EPA however state on their website that, "*Formaldehyde can cause allergies, and therefore it is a good idea to wash new clothes before you use it. There is such a small quantity of formaldehyde in clothes that it does not pose a risk in relation to cancer. Studies by the Danish EPA show that you can avoid being exposed to formaldehyde by washing new textiles before use, as it reduces the content significantly*."

2.4 Eco-labels

The general approach taken in eco-label criteria (the Nordic Swan, the EU Flower and the German Blue Angel) adopted to date is to exclude eco-labelling when the products contain chemicals which have certain specific properties (classification and risk phrases).

Generally criteria documents do not permit formaldehyde as an ingredient in eco-labelled products due to its classification or limit the inclusion of formaldehyde or substances in general which are classified as carcinogenic.

The criteria document for toys (Nordic Swan) state that: *The content of free formaldehyde must not exceed the following threshold values as determined using the applicable version of EN-120, the Perforator Method: In the case of individual values: ≤ 8 mg formaldehyde/100 g dry substance. In the case of the six-monthly mean value: ≤ 6.5 mg formaldehyde/100 g dry substance.*

The requirements apply to panels made of wood with a moisture content of H = 6.5%.

2.5 Other lists

Formaldehyde is included as a substance in the SIN-list database developed by the Chemical Secretary (ChemSec.) (Data search September 26, 2013). The SIN-list includes substances which are identified by ChemSec as fulfilling the criteria for Substances of Very High Concern as defined in the REACH regulation.

Formaldehyde is also included on the PRIO-list developed by KEMI (the Swedish Chemical Agency) which is a web-based tool intended to be used to preventively reduce risks to human health and the environment from chemicals.

Formaldehyde is not included on the EU list of 146 substances with endocrine disruption classifications (EU, 2000).

2.6 Summary and conclusions

The Danish EPA has put formaldehyde on the LOUS list (2009) based on its former classification as Carc. 2 (H351) (now a higher more stringent carcinogenic classification as Carc 1B; H350 has been decided for the substance) and because formaldehyde is applied on the Danish market in a quantity > 100 tonnes. Another reason is the broadly use of formaldehyde in a large numbers of products ranging from resin production (Phenolic, urea, and melamine resins have wide uses as adhesives and binders in the wood-production, pulp-and-paper, and the synthetic vitreousfibre industries, in the production of plastics and coatings, and in textile finish) to cosmetics and biocide and pesticide products.

In 2006, IARC moved formaldehyde from IARC Group 2A (probable human carcinogen) to IARC Group 1 (carcinogenic to humans), and in 2009, this Group 1 classification was reaffirmed. In EU the opinion of the RAC (Committee for Risk Assessment) concluded to classify formaldehyde as Carc. 1A (H350: May cause cancer). A voting for this classification for formaldehyde took place in the end of 2013, and a classification as Carc 1B was decided.

Formaldehyde is regulated through EU legislation that is enforced through the Danish national legislation. Legislation includes registration under REACH (at a tonnage band of 1,000,000 + tonnes), classification according to the CLP regulation (Classifying formaldehyde as: Acute tox. 3, Skin Corr. 1B, Skin Sens. 1, Aquatic Tox. 3 and Carc. 2[2].) and the regulation of the use of chemicals in the working environment, i.e. the exposure to chemicals agents at work places as well as the exposure to carcinogens at work places. Furthermore the exposure of workers to formaldehyde in air is regulated through national Occupational Exposure Limits (OEL-values). Formaldehyde was included in the list of substances included in the Community Rolling Action Plan (CoRAP) in 2013 but is not on the Candidate List of Substances of Very High Concern for Authorisation and also not on the list of restrictions.

Formaldehyde is also addressed in the Directive 2009/48/EC on the safety of toys as well as the Cosmetic Regulation (EC) No 1223/2009, setting limits for the content of formaldehyde in the final products. Also there are national regulations on the content of formaldehyde in textiles and regulations for formaldehyde in food additives. Formaldehyde is also included in the Danish order on the control of major-accident hazards involving dangerous substances.
The Environmental Quality Standard for marine- and freshwater is 9.2 µg/L and for short term releases 46 µg/L.
Most eco labelling criteria (EU flower, Nordic swan and the German Blue Angel) exclude the use of formaldehyde as an ingredient due to its classification as carcinogenic.

[2] The new classification as Carc. 1B and Mut2 is still not published in CLP

3. Manufacturing and uses

3.1 Manufacturing

3.1.1 Manufacturing processes

Formaldehyde is technically produced as an aqueous solution (50-55% w/w) by oxidative dehydrogenation of methanol with air (OECD SIDS, 2002).

3.1.2 Manufacturing sites

The manufacturer of formaldehyde reported in the OECD SIDS on formaldehyde (2002) is BASF AG, Ludwigshafen (Germany), Methanova (Germany), and Mainz-Mombach (Germany).

Furthermore the following manufacturers and production volumes were identified for formaldehyde (formalin):

Name	Annual production volume, thousand tonnes
Dynea, the Netherlands	720
BASF, Germany	650
Perstorp Formox, the Netherlands	550
Degussa, Germany	519
Ercros, Spain	400
Hexion, the Netherlands - Germany	390
Bayer, Germany	271
Sadepan Chimica, Italy	250
Ticona Polymerwerke, Germany	238
Dynochem, Great Britain	225
Sonae, Португалия	220
Caldic Chemie, the Netherlands	215
Krems Chemie, Austria	175
Chimica Pomponesco, Italy	160
Perstorp, Italy	140
Polioli, Italy	140
Osterreichische Hiag-Werke, Austria	125
Forestales Atlanticos, Spain	120
Nordalim, Denmark	115
Akzo Nobel, Sweden	110
Farcoll, Italy	110
Foresa, Spain	100

(information retrieved from www.export.by, (2013))

3.1.3 Manufacturing volumes

The global production of formaldehyde in 1999 was estimated to 5-6 million tonnes according to the OECD SIDS (2002). These production volumes were distributed as follows:

Asia: 1–1.5 million tons,
North America: 1-1.5 million tons,
Western Europe: 2-2.5 million tons
Total: 4-5.5 million tons

In 2006, production of pure formaldehyde in Europe was over 3 million tonnes (ICF, 2013); in 2010, this had decreased to around 2.3 million tonnes (ICF, 2013).
In the EU, formaldehyde is manufactured and used as an aqueous formaldehyde solution, known as formalin, which usually does not contain more than 3% methanol. Formaldehyde is not commonly purchased in its pure form due to the fact that it is not stable in this form. Available data on the production and use of formaldehyde therefore refer to a 37% formaldehyde solution.

In 2010, 29 million tonnes of formaldehyde (37%) were produced globally, of which Europe accounted for 23% (6.7 million tonnes). The European Union is the second largest producer of formaldehyde after Asia which has approximately 50% of global capacity (Merchant Research and Consulting, 2012). China manufactures, on average, an estimated 12 million tonnes annually (Tang, *et al.*, 2009). Within Europe, Germany (of the 22 EU Member states producing formaldehyde) has the highest formaldehyde manufacturing capacity with 2.2 million tonnes per year which is approximately 5% of global production capacity and 23% of European production capacity (ICF, 2013). Germany is followed by followed by Italy, Spain, the Netherlands and the UK (Formacare, 2010c).
Global formaldehyde production is expected to have reached 32.5 million metric tonnes in 2012 (ICF, 2013). Figure 3-1 shows global formaldehyde production and consumption by major regions.

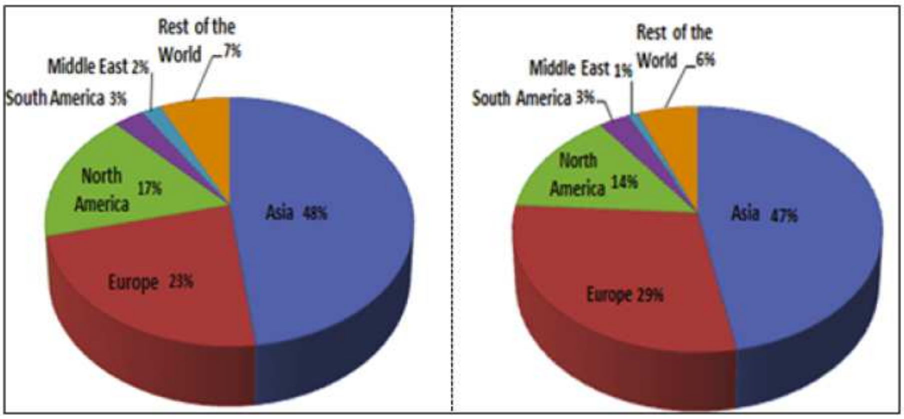


FIGURE 3-1
GLOBAL FORMALDEHYDE PRODUCTION (LEFT FIGURE) AND CONSUMPTION (RIGHT FIGURE) BY MAJOR REGIONS IN 2008 (FIGURE TAKEN FROM ICF, 2013).

3.2 Production and use

Formaldehyde is present in the environment as a result of natural processes and from man-made sources. The major source of atmospheric formaldehyde is the photochemical oxidation and incomplete combustion of hydrocarbons.

Uses of formaldehyde include:

- intermediate in the chemical industry for the production of condensed resins for the wood, paper and textile processing industries
- synthesis of methylene dianiline (MDA), diphenylmethane diisocyanate (MDI), hexamethylenetetraamine (HTMA), trimethylol propane, neopentylglycol, pentaerythritol and acetylenic agents.
- aqueous solutions of formaldehyde are employed as germicides, bactericides and fungicides (in Denmark for instance in aquacultures[3] . The use of formaldehyde as biocide and in other applications is estimated to be 1.5 % of

[3] Since formaldehyde is carcinogenic, special rules apply when using formalin with more than 0.1% formaldehyde (Dansk Akvakultur, 2013)

the total production, i.e. 75,000 to 90,000 t/year related to the worldwide production amount (Dansk akvakultur 2013; DMU, 2008).
- as a preservative in a large number of consumer products, such as cosmetics and household cleaning agents.
- urea-formaldehyde foam insulation.
- formaldehyde-containing disinfectants.
- formaldehyde resin products used in the textile industry including printing inks, dyes and textile finishing products. The concentrations of free formaldehyde in these products are generally less than 2%. These formaldehyde-based materials help bind dyes and pigments to fabrics, prevent colours from running, improve a fabric's resistance to wrinkles, ease clothing care and maintenance and prevent mildew.

(OECD SIDS, 2002; Australian Government, 2006).

Formaldehyde (or, in its commercialized state as, formalin) is primarily used in the production of thermosetting resins. These account for almost two thirds of the use of formalin. The three major commercially-used resins globally are:
- Urea-Formaldehyde (UF);
- Melamine-Formaldehyde (MF); and
- Phenol-Formaldehyde (PF) resins (In Denmark PF is applied in insulating material (Rockwool).

According to recent data, UF, MF and PF resins account for approximately 63% of world consumption for formaldehyde (Figure 3-2) (Formacare, 2010d).

UF resins are primarily used as binders in non-structural wood-based panels. Most UF resins that are manufactured in the EU are currently used to make building materials such as particle board, interior PW and MDF (Formacare, 2010d). In 2004, UF resins accounted for 55% (i.e. about 5.4 million metric tonnes) of EU 25 plus Norwegian formaldehyde consumption (ICF, 2013).

MF resins are used predominantly as paper impregnating resins for surfacing of panels, for example in laminate flooring. They are also used as binders and adhesives where improved water resistance is required. The automobile industry, for instance, consumes MF resins in the form of clear coats (lacquer). MF consumption in the EU25 and Norway was estimated at about 1.3 million tonnes in 2004 (Subsport, 2013).

Equally water-resistant, PF resins are used as durable binders and adhesives in structural wood panels and as binders in mineral wool insulation. Their high thermal stability and fire-resistant properties are particularly well-suited to a wide spectrum of uses in the automotive and construction industries. In 2004, PF resin consumption in the EU25 and Norway has been estimated at about 75,000 metric tonnes (ICF, 2013).

Formaldehyde is also used as an intermediary in the production of polyacetal resins [or polyoxymethylene (POM)]. Polyacetals are inherently self-lubricating and are particularly suited to a variety of applications such as replacing metal parts in electrical, electronic, automotive, and consumer applications. The demand for polyacetals in Europe is said to have grown by 10% from 2003 and 2008 and is estimated at about 220,000 tonnes a year (ICIS, 2009).

Another rapidly-growing formaldehyde derivative market is that of methylene diphenyl diisocyanate (MDI). MDI constitutes an important material for the manufacturing of polyurethane products, which are widely used in the footwear, household appliance, construction, automotive and furniture manufacturing industries. The global annual MDI production was estimated at about

5.9 million tonnes in 2010, of which Europe contributes an estimated 2.55 million tonnes every year (i.e. about 43% of total global MDI output) (ICF, 2013).

Similarly, butanediol (BDO) and pentarythritol are other industrial chemicals that are currently manufactured using formaldehyde. BDO is primarily used to produce intermediates for downstream production of polyester thermoplastics resins. These are in turn used in the textile fibres, electronics and automotive markets. On the other hand, pentarythritol – an alcohol produced from formaldehyde and acetaldehyde – is increasingly used in the EU for the production of alkyd resins and neopolyol esters.
Alkyd resins are typically found in architectural coatings like paints and product finishes for automobiles whilst neopolyol esters constitute an important ingredient in engine lubricants for aeroplane turbines and automobile engines. Germany remains a major player of the EU's alkyd resins market, covering 37% of EU production and consumption. In 2010, it produced 190,000 tonnes of alkyd resins, and provided 45,000 tonnes for export. Other significant Western European manufacturing facilities are concentrated in Italy and France (ICF, 2013).

Hexamine and paraformaldehyde are also derived from formaldehyde. Hexamine is primarily used in the production of vulcanized rubber for automobiles whilst paraformaldehyde is mainly used as a fungicide and/or disinfectant. As of 2012, nearly 145,000 tonnes of paraformaldehyde were produced in the EU.

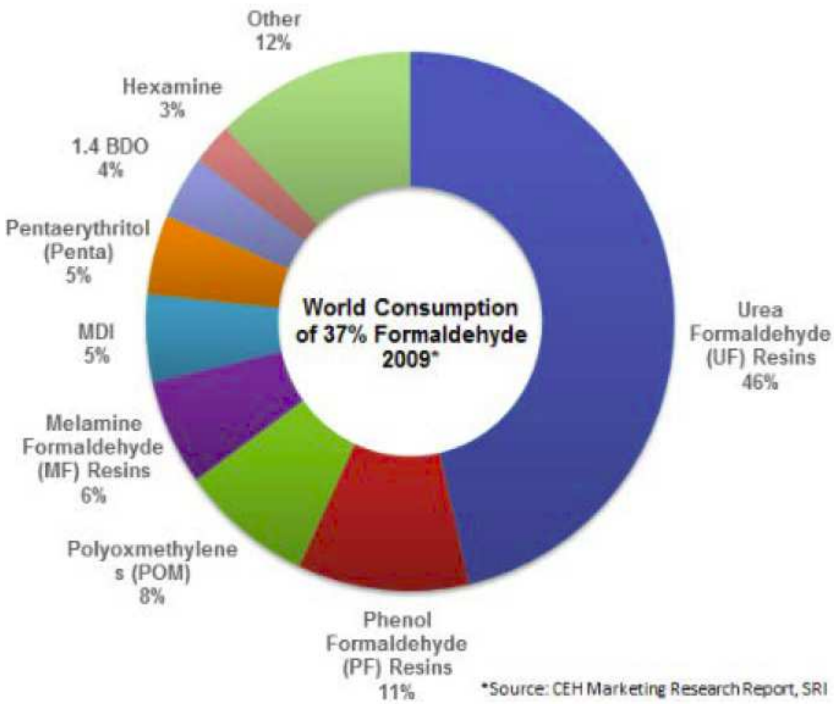


FIGURE 3-2
WORLD CONSUMPTION OF FORMALDEHYDE FOR USE IN THE PRODUCTION OF FORMALDEHYDE RESINS AND SPECIALTY CHEMICALS (FIGURE TAKEN FROM ICF, 2013)

Formaldehyde-based adhesives are used in the manufacture of particle board, plywood and MDF and a variety of agents which are used to treat wood surfaces. The benefits of using formaldehyde are in particular to increase the lifetime and improve the performance characteristics of the product (Højteknologifonden, 2012).

Formaldehyde plastics, a common name for a wide range of plastics materials, which are formed by the reaction of formaldehyde with, for example, urea, melamine, phenol or furfuryl alcohol. Phenol plast is also referred to as Bakelite (Plastindustry Denmark, 2008).

The Nordic countries

From the Nordic SPIN database ("Substances in Preparations in the Nordic Countries") information of use volumes and information on the distribution of substances in preparation in the Nordic countries has been retrieved for formaldehyde (CAS No. 50-00-0). The SPIN database is the result of a common Nordic initiative to gather non-confidential, summarized information from the Nordic product registers on the common use of chemical substances in different types of products and industrial areas.

Table 3-1 presents the uses of formaldehyde in Denmark in 2011 (SPIN database, 2013). From the information retrieved it can be seen that formaldehyde is contained in especially raw materials applied for synthesis and intermediate products with a tonnage of 13,262tonnes. The next most important sector is private and public health area, where formaldehyde is included in disinfectants and biocidal products, with a total tonnage of 176 tonnes.

TABLE 3-1
USES OF FORMALDEHYDE IN PREPARATIONS FOR OCCUPATIONAL USE ON THE DANISH MARKET IN 2011 (SPIN DATABASE, 2013)

Use category	Numbers of preparations	Tonnes
Private area and public health area disinfectants and other biocidal products	16	175.5
Binding agents for paints, adhesives etc.	41	0.6
Other binding agents	34	2.8
Other fixing agents	5	0.7
Sequestering agents	12	0.6
Cement/concrete/mortar	37	2.1
Paint and varnish Water based Decorative/protection Industrial use	34	0.1
Paint and varnish Volatile organic thinner Decorative/protection Industrial use	128	0.4
Paint and varnish Volatile organic thinner Decorative/protection Other (including road-, art-, furniture-, autopaint)	8	0.6
Non-galvanic metal surface coatings (chromatisizing agents)	8	0.7
Raw materials for synthesis and intermediate products	15	13,261.6
Stopping material	20	4.0

Information on the numbers of preparations in the Nordic countries which contain formaldehyde is presented in Figure 3-3 and Figure 3-4 shows the corresponding volumes. From these figures it can be seen that in Denmark there has been a decline in the number of different preparations which contain formaldehyde. Furthermore, in Denmark products with less than 0.1% formaldehyde may be included in the number of preparation because you do not want to exclude that there may be

residual monomers of formaldehyde in the product, which could be the reason why Denmark has the highest number of preparations in Scandinavia. Though one can see a decrease in the number of preparation during the last 10 years the tonnage has been quite constant at about 13000 tonnes from 2009 and forward. In Denmark a large production of chipboards takes place in which formaldehyde indirectly is used in the production of resins used to produce chipboards.
Due to the widespread and dispersive use of formaldehyde additional tonnage levels may be used in consumer products that have not been registered into the Danish Product Registry and SPIN.

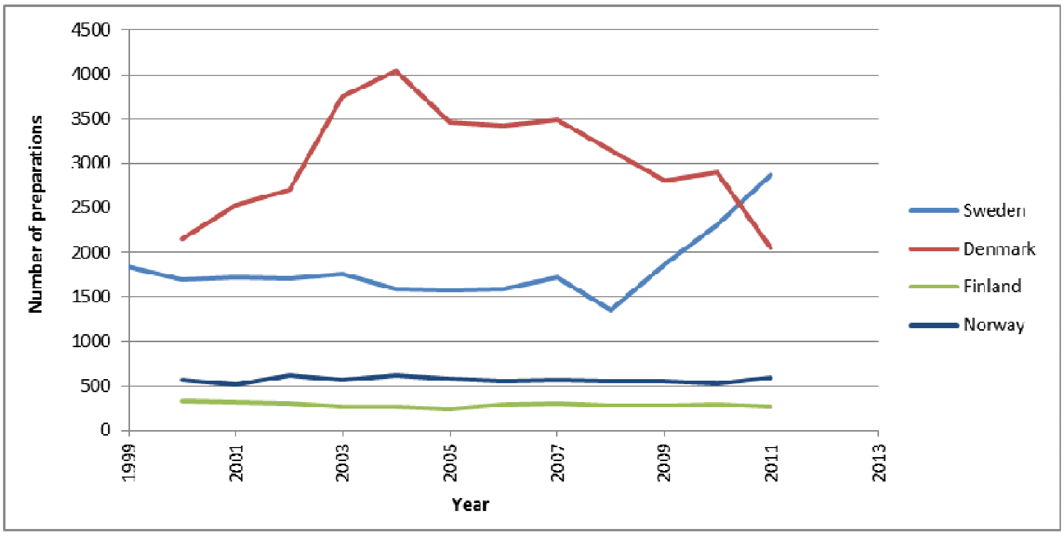


FIGURE 3-2
THE TOTAL NUMBER OF PREPARATIONS CONTAINING FORMALDEHYDE (CAS. NO. 50-00-0) IN THE NORDIC COUNTRIES FROM 1999 TO 2011 (DATA RETRIEVED FROM THE SPIN DATABASE).

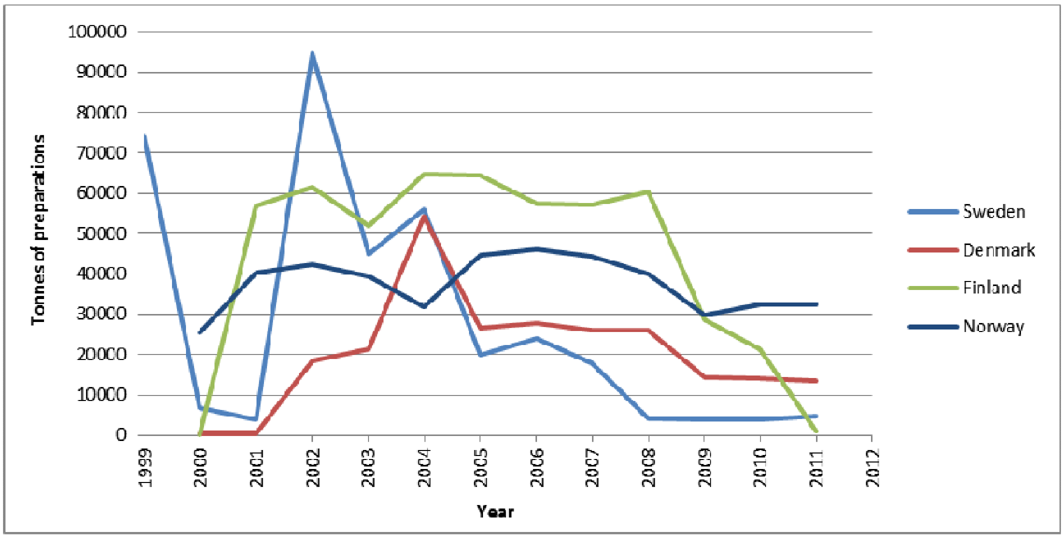


FIGURE 3-3
TOTAL TONNES OF FORMALDEHYDE (CAS. NO. 50-00-0) INCLUDED IN PREPARATIONS ON THE DANISH MARKET FROM 2000 TO 2011. 2005 (DATA RETRIEVEDFROM THE SPIN DATABASE).

Personal communication with Danish Industries reveals that liquid formalin is applied for special rehabilitation tasks in animal husbandry where housing/stable facilities, following a particularly undesirable infection/disease, are treated. Formalin is however not a part of the general bio-security program.

3.3 Historical trends in use

According to the SPIN Database the use of formaldehyde was at its highest around 2004. That year the reported amount of formaldehyde applied in preparations on the Danish market was just below 55.000 tonnes. And the numbers of preparations were 4.035. Both the amount applied in preparations and the numbers of preparations including formaldehyde has been decreasing since (SPIN Database, 2013).

3.4 Summary and conclusions

In 2010, 29 million tonnes of 37% formaldehyde were produced globally, of which Europe accounted for 23% (6.7 million tonnes). The European Union is the second largest producer of formaldehyde after Asia which has approximately 50% of global capacity. Within Europe, Germany (of the 22 EU Member states producing formaldehyde) has the highest formaldehyde manufacturing capacity with 2.2 million tonnes per year which is approximately 5% of global production capacity and 23% of European production capacity. In Asia China is a main producer with an estimated 12 million tonnes annually.

Formaldehyde is mainly used as an intermediate in the chemical industry for the production of condensed resins for wood, paper and textile processing industries and in chemical synthesis.

Formaldehyde plastic is a common name for a wide range of plastics materials, which are formed by the reaction of formaldehyde with, for example, urea, melamine, phenol or furfuryl alcohol.

Aqueous solutions of formaldehyde are employed as germicides, bactericides and fungicides (in Denmark for instance formaldehyde is applied in aquacultures).

Furthermore formaldehyde is used as a preservative in a large number of consumer products, such as cosmetics and household cleaning agents.

Formaldehyde (or, in its commercialized state as, formalin) is primarily used in the production of thermosetting resins. In Denmark Phenol-Formaldehyde (PF) resins is used in insulating material (Rockwool).

Based on information from the Nordic SPIN database it can be seen that in Denmark (2011) formaldehyde is contained in especially raw materials applied for synthesis and intermediate products with a tonnage of 13,261.6 tonnes, and a large amount of this is properly used in the chipboard production. The next most important sector being the private and public health area, where formaldehyde is included in disinfectants and biocidal products, with a total tonnage of 175.5 tonnes. In Denmark there has been a decline in the number of different preparations which contain formaldehyde however the tonnage which is applied has been rather constant at about 13000 tonnes since 2009.

4. Waste management

4.1 Waste from manufacture and use of formaldehyde

Releases into the environment are likely to occur during production and processing as intermediate as well as from use of products containing the substance. During production and internal processing at BASF AG, Ludwigshafen (Germany), approx. 21 tons formaldehyde was emitted into the air in 2000. No information on the emission into wastewater or surface water is available for this site. At the production site of Methanova (two factories), Mainz-Mombach (Germany), less than 5 tons are emitted per year during production and processing to para-formaldeyde. No emission of formaldehyde into wastewater treatment plant occurs during production and processing (OECD SIDS, 2002).

It can be estimated that formaldehyde contained in consumer products, like cleaning agents is released completely into the wastewater. In addition, reported use of formaldehyde in fish farming and animal husbandry may lead to a significant environmental exposure (OECD SIDS, 2002).

Transport and distribution modelling using Mackay Level I indicates water to be the main target compartment for formaldehyde (99%) (OECD SIDS, 2002) The measured log P_{OW} of 0.35 at 25°C dictates that formaldehyde once released with waste water is expected to remain in the water phase and not to be retained in sludge. Transport of formaldehyde to the soil compartment through the application of sludge on agricultural soil is therefore not expected.

According to the Danish EPA´s Guidance Document on "Connecting industrial wastewater to municipal wastewater treatment plants" (Danish EPA, 2002), formaldehyde is evaluated as an A-substance based on the classification as carcinogenic. Substances are classified as A-substances if they possess characteristics which render them as unwanted in the sewage system and A-substances should be reduced to a minimum or preferably substituted.

4.2 Waste treatment

4.2.1 Classification of waste

A waste is considered hazardous if it exhibits one or more of the characteristics listed in Table 1 of the Danish statutory order on waste (Bek. 1309 of 18/12/2012) in % limit, as indicated in Table 2 of the order. Below is indicated the various concentration limit for the various classifications that have been applied for formaldehyde (please refer to Table 2-3) (the limits applicable for the previous classification of formaldehyde will still apply at this point for waste containing formaldehyde):

Acut tox 3 ≥ 3%

Skin.Corr. 1B ≥ 5%

Skin Sens. 1 ≥ 1%

Carc 2. 1%

(When re-classified to Carc 1≥ 0.1%)

The limit for classification as hazardous waste would be a content of 1% in the waste, which is triggered both as a consequence of the classification as Skin Senc. 1 and the classification as Carc. 2..

A previously mentioned a re-classification of formaldehyde (to Carc. 1B) is expected to be implemented in the summer of 2014. This reclassification will change the concentration limit to ≥ 0.1%.

For chemical product waste containing formaldehyde the classification as hazardous waste will also depend on whether the products contain other hazardous substances to an extent that result in a hazard classification of the product.

4.2.2 Treatment of waste

Formaldehyde is present in low concentrations in a wide variety of consumer products. These products include household cleaning products, such as dishwashing liquids, disinfectants, and cosmetics products, such as shampoos, conditioners, and shower gels etc. (please refer to section 3) Many of these products are released directly into wastewater streams during their use (the fate of this is discussed in the next chapter). Aqueous formaldehyde released into water is expected to remain dissolved in the aquatic compartment where it would enter sewage treatment facilities. The vapour pressure of formaldehyde indicates a high volatility (516 kPa at 25°C), the Henry's Law Constant (0.022-0.034 Pa*m^3/mol) indicates only a moderate volatility from water Formaldehyde emissions to soils are most likely to occur through disposal of solid wastes containing formaldehyde to landfills.

4.3 Recycling

Chemical recycling is not applicable to formaldehyde due to its high reactivity, and as it is mainly used as an intermediate in chemical synthesis and therefore converted into other substances.

4.4 Summary and conclusions

Releases of formaldehyde into the environment are likely to occur during production and processing as intermediate as well as from use of products such as cleaning agents which can contain the substance. Formaldehyde released to the sewer is expected to stay in the water phase, not to bind to sludge, and biodegrade rapidly. Exposure of formaldehyde to the soil compartment through the application of sludge on agricultural soil is therefore not expected. Formaldehyde is evaluated as an A-substance according to the Danish EPA's Guidance Document on "Connecting industrial wastewater to municipal wastewater treatment plants"; this is due to the Carc. 2 classification. Re-classification as a Carc. 1B substance will not change this evaluation (as both R40 and R45 will cause a substance A categorization). Waste is considered hazardous if it contains ≥1% of formaldehyde. This limit is also triggered by the Carc. 2 classification. After re-classification to Carc. 1B, this will change to ≥ 0.1%. When formaldehyde is used as a reactant within the chemical industry, almost all formaldehyde is converted leaving a limited fraction of waste.

5. Environmental effects and exposure

5.1 Environmental risk and hazard

There are several reports and a large amount of data on the environmental effects of formaldehyde. Overall, the data do not indicate a need for classification for environmental hazards. However, the conclusion on environmental hazard reached in the OECD SIDS[4] (2002) is that formaldehyde is a candidate for further work. It is assumed that from the use of 1.5 % of the worldwide production volume (5 to 6 mio t/year) as biocide (e.g. from fish and livestock farming) and in other applications i.e. 75, 000 – 90,000 t/year a high amount of formaldehyde is released into the environment. Product register information shows that formaldehyde is contained in a large number of consumer products, like cleaning agents, detergents, soaps etc. For these applications it can be estimated that the whole amount is released into the waste water. Due to the low Predicted No Effect Concentration ($PNEC_{aqua}$) of 5.8 µg/L a risk to the aquatic environment cannot be excluded. Therefore, an exposure assessment is recommended (OECD SIDS, 2002).

Furthermore RIVM has prepared a report in 2002 presenting Environmental Risk Limits (ERL) for selected chemicals for the compartments air, ground(water), sediment and soil. The ERLs serve as advisory values for Environmental Quality Standards (EQS). In this report further aquatic toxicity data (acute and chronic) are reported for formaldehyde. RIVM further concludes that since there are no monitoring data no risk analysis can be performed (RIVM, 2002).

The conclusions from the report on formaldehyde prepared by the Australian Government (2006) are: Formaldehyde is water soluble and biodegradable. Its major environmental release is to the atmosphere, where it breaks down in a short period of time. Direct release to the aquatic compartment and soil is expected to be minor and significant removal occurs through biodegradation. The short atmospheric lifetime of formaldehyde and worst-case predicted environmental concentrations indicate that no significant risks to non-human organisms through atmospheric exposure to formaldehyde are expected. A low environmental risk to terrestrial organisms is also predicted due to likely low concentrations of formaldehyde in aquatic systems and soil.

5.1.1 Toxicity to aquatic organisms

Data exist on the acute toxicity to fish, invertebrates and algae. Table 5-1 below displays the results from the test showing the highest toxicity to aquatic organisms which were reported in the OECD SIDS report (2002). Also the results from the tests showing the highest toxicity and submitted during the REACH registration process are included in the table. Tests which are presented in the registration data but are also evaluated as “not reliable” or “not assignable” are however not included. Furthermore RIVM has prepared a report in 2002 presenting Environmental Risk Limits (ERL) for selected chemicals. In this report further aquatic toxicity data (acute and chronic) are reported for formaldehyde. No observable Effect Concentration (NOEC) values in the RIVM report are ranging from 0.14-19 mg/L (RIVM, 2002).

[4]OECD SIDS (Screening Information Data Sheet)

TABLE 5-1
AQUATIC TOXICITY OF FORMALDEHYDE (OECD SIDS, 2002, REACH REGISTRATION, 2013).

Test	Effect	Concentration [mg/L]	Reference
Acute toxicity to fish	LC_{50} (96h)	24.8 (freshwater) 6.7 (marine)	SIDS, 2002
Acute toxicity to fish *Morone saxatilis*	LC_{50} (96h)	6.7 (freshwater)	REACH Registration data, 2013
Chronic toxicity fish (*Oryzias latipes*)	NOEC (28d)	≥ 48	REACH Registration data, 2013
Acute toxicity invertebrates (*Daphnia pulex*)	EC_{50} (48h)	5.8	SIDS, 2002 REACH Registration data, 2013
Acute toxicity algae*	EC_{50} (24h) EC_{10} (24h)	14.7 3.6	SIDS, 2002
Acute toxicity algae *Desmodesmus subspicatus* (growth rate)	EC_{50} (72h)	4.9	REACH Registration data, 2013

*endpoint oxygen production and consumption.

The most sensitive organism in a valid acute aquatic toxicity test was *Daphnia pulex* with an EC_{50} (48h) of 5.8 mg/L. For the derivation of the $PNEC_{aqua}$ an assessment factor of 1000 is applied on this value resulting in a $PNEC_{aqua}$ of 5.8 µg/L (OECD SIDS, 2002).
In the RIVM report (2002) chronic NOEC values are available for freshwater bacteria, cyanobacteria, protozoan, alge and crustacean and a species sensitivity distribution method is applied resulting in a HC_5 of 0.18 mg/L, where HC_5 is the concentration hazardous to 95% of the population and protective of 5%. This value is used for deriving a Negligible Concentration (NC) = 0.0018 mg/L applying an assessment factor of 100 (NC = HC5 /100). The NC value is comparable to a Predicted No Effect Concentration (PNEC).
The REACH registration data report a $PNEC_{freshwater}$ and a $PNEC_{marin}$ = 0.47 mg/L, without stating the endpoint applied (REACH Registration data, 2013).

Toxicity to sediment living organisms
No information on the toxicity to sediment living organism is identified. The report by RIVM (2002) applies the equilibrium partitioning method to derive a $NC_{sediment}$ of 0.0016 mg/kg dw..
The REACH registration data report a $PNEC_{sediment}$ = 2.44 mg/kg sediment d.w. for both freshwater and marine sediment (partition coefficient method) (REACH registration data, 2013).

5.1.2 Toxicity to microorganisms
Three studies with microorganisms are reported. In a cell multiplication inhibition test with *Pseudomonas putida*, a 16h-EC_3 of 14 mg/L was found. For the protozoan species *Chilomonas paramaecium* and *Uronema parduzci,* toxic threshold values of 4.5 mg/L after 48 h and 6.5 mg/L after 20 h were determined. In an activated sludge respiration inhibition test a 3h-EC_{50} of 20.4 mg/l was found (OECD SIDS, 2002).
Sewage micro-organisms were inhibited at 30 mg/L in a Closed Bottle test suggesting that sewage treatment plant performance would only be impaired at relatively high concentrations of formaldehyde (Australian Government, 2006).
The REACH registration data report a $PNEC_{microorganism}$ = 0.19 mg/L (Applying an assessment factor of 100). It is assumed that a test according to the OECD Guideline 209 (Activated Sludge,

Respiration Inhibition Test) resulting in an EC50 (3h) = 19 mg/L has been applied in the derivation of the PNEC value (REACH registration data, 2013).

5.1.3 Toxicity to terrestrial organisms

No toxicity data which can be applied for the derivation of a PNEC for soil organisms is reported in the OECD SIDS (2002). The report by RIVM (2002) applies the equilibrium partitioning method to derive a NC_{soil} of 0.0016 mg/kg d.w..
The REACH registration data report a $PNEC_{soil}$ = 0.21 mg/kg soil d.w. which is also based on the partition coefficient method) (REACH registration data, 2013).
The formaldehyde report prepared by the Australian Government (2006) includes toxicity data on terrestrial organisms like bobwhite quail (exposure through feed, LD50 =790 mg/kg), different plants (Rapseed, LOEC = 14.9 ppb (fog)) and microscopic fungus (exposure through fog or gas) where 100 % mortality was observed after 24 hours exposure to 2 ppm (gas).

TABLE 5-2
TOXICITY OF FORMALDEHYDE ON TERRESTRIAL ORGANISMS (AUSTRALIAN GOVERNMENT, 2006)

Test	Effect	Concentration
Northern bobwhite quail *(Colinus virginianus)*	14-d LD50	LD50 = 790 mg/kg
Bean plant (*Phaseolus vulgaris*)	Imbalance in shoot and root growth after up to 4 weeks exposure	LOEC = 65 ppb (fog)
Rapeseed (brassica rapa)	Reduction in leaf area, leaf and steam dry weight, and flower and seedpod numbers	LOEC = 14.9 ppb (fog)
Lilium longiflorum	Reduction in pollen tube length after 5 hours	0.35 ppm (gas)
Microscopic fungus (*Scopulariopsis* and *Penicillum*)	100 % mortality in 24 h	2 ppm (gas)

The PNEC-values for the environmental compartments are summarised in Table 5-3 below together with the environmental quality standards for formaldehyde. The PNEC values reported are below the Danish quality criteria for the aquatic compartment of 9.2 µg/L

TABLE 5-3
PREDICTED NO EFFECT CONCENTRATIONS (PNEC) FOR FORMALDEHYDE

Compartment	PNEC	Source
Environmental quality standard	Environmental Quality Standards = 9.2 µg/L (fresh- and marine water) Short term release =46 µg/L	Danish executive order no. 1022 of 25/08/2010
Aquatic (freshwater and marine)	5.8 µg/L	OECD SIDS, 2002
Aquatic (freshwater and marine)	NC* = 1.8 µg/L	RIVM, 2002
Aquatic (freshwater and marine)	470 µg/L	REACH Registration data, 2013
Sediment (freshwater and marine)	2.44 mg/kg sediment d.w	REACH Registration data, 2013
Sediment (freshwater and marine)	NC* = 0.0016 mg/kg d.w.	RIVM, 2002
Microorganism	0.19 mg/L	REACH Registration data, 2013
Terrestrial	NC* = 0.0016 mg/kg d.w.	RIVM, 2002
Terrestrial	0.21 mg/kg soil d.w.	REACH Registration data, 2013

Negligible Concentration

5.2 Environmental fate

Transport and distribution modelling using Mackay Level I (BASF, 1995) indicates water to be the main target compartment for formaldehyde (99%) (OECD SIDS, 2002).

5.2.1 Environmental degradation

Formaldehyde is readily biodegradable according to OECD Guideline no 301D with a degradation of 90% after 28 days (Pass level for ready biodegradability = 60% after 28 days) (OECD SIDS, 2002; REACH Registration data, 2013).

5.2.2 Photodegradation

Formaldehyde is expected to be indirectly photodegraded by reaction with OH-radicals, with a half-life of 1.71 d.. Direct photolysis is also a relevant removal process for formaldehyde in air. A half-life of 4.1 hours was measured (OECD SIDS, 2002). According to REACH registration data a half-life of 1.7 d has been reported for direct hydrolysis (REACH Registration data, 2013).

5.2.3 Hydrolysis

Formaldehyde does not contain any hydrolysable groups, and hence hydrolysis will not be a degradation pathway.

5.2.4 Half-lifes reported for formaldehyde in the environment

Table 5-4 summarises the estimated half-lifes reported for formaldehyde. Half-lifes in soil are based on the estimated aqueous aerobic biodegradation half-lives.

TABLE 5-4
ESTIMATED HALF-LIFES FOR FORMALDEHYDE.;*ESTIMATED BASED ON HALF-LIFE IN WATER (AEROBE)

Compartment	T1/2
Surface water (aerobe) (aqueous anaerobe)	1-7 d 1-7 d
Ground water	2-14 d
Soil*	1-7 d
Air	4.1 h-1.71 d

5.2.5 PBT
Formaldehyde does not meet the screening criteria as persistent (P) or potentially very persistent (vP) because the substance is ready biodegradable. No results from bioaccumulation studies were identified during this project. However formaldehyde has a measured log P_{OW} of 0.35 at 25 °C. This is less than the screening criteria for bioaccumulation of 4.5. Therefore formaldehyde is not considered to bioaccumulate in aquatic organisms and does not meet the B or vB criterion. Based on the results from the toxicity studies (section 5.1.1) it is also concluded that the T criterion is not met (NOEC/EC10 < 0.01 mg/L (screening criterion: E(L)C50 ≤ 0.01mg/L))(ECHA, 2012).

5.2.6 Classification
As mentioned in section 2.1.1.1, there is a harmonised classification for formaldehyde. None of the classifications addresses the environment. The available data also supports the non-classification of formaldehyde for environmental effects.

5.3 Environmental exposure
5.3.1 Sources of release
Releases into the environment are likely to occur during production and processing as intermediate as well as from use of products containing the substance. For almost all sites there is no information available about releases into the waste water from production and processing (OECD SIDS, 2002). According to information in the OECD SIDS (2002) about 1,424 t were released into the environment from industrial sites in 1997 in Canada. From this release about 20 t/year were releases to surface waters by 4 sites. Industrial releases of formaldehyde reported for the US in 1999 are about 6,000 t/year to air and about 175 t/year to surface waters. From the direct use of the substance as e.g. biocide it can be assumed that a very high amount is released into the environment. With an amount of 75,000 to 90,000 t/year worldwide this is a significant pollution source. It can be estimated that formaldehyde contained in consumer products, like cleaning agents is released completely into the wastewater. In addition, reported use of formaldehyde in fish farming and in animal husbandry may lead to a significant environmental exposure (OECD SIDS, 2002). A Danish survey on the turnover of formalin in Danish fish farms estimated that up to 42 % of the applied formaldehyde can be released in the outlet from the fish farm after application. The exact percentage depends on the type of farm and recirculation of the water within the farms (DMU, 2008).

5.3.2 Predicted Environmental Concentration
The predicted environmental concentration (PEC) of formaldehyde was calculated for air and included in a report on formaldehyde presented by the Australian Government (2006). The

calculations were performed for various environmental compartments using modeling techniques. The modeling results are annual averages and maximum 24-hour averages for emission from various industries. Annual averages are relevant for long-term (chronic) exposure, whereas 24-hour averages are more representative of acute exposure. Results are presented in the table below (Australian Government, 2006). Results indicate that of the industries included in the modeling performed, the wood and papers industry is the largest source for formaldehyde emission with a maximum annual concentration of 16 ppb and a maximum 24-h concentration of 119 ppb.

TABLE 5.5
ANNUAL ESTIMATED AVERAGE AND MAXIMUM 24-H AVERAGE PREDICTED ENVIRONMENTAL CONCENTRATION (PEC) FOR POINT SOURCE EMISSIONS OF FORMALDEHYDE TO AIR (IN PPB) (BASED ON AUSPLUME MODELLING) (AUSTRALIAN GOVERNMENT, 2006).

Type of industry	Maximum Annual Average PEC		Maximum 24-hour average PEC	
	Average emitter ppm in air	Maximum emitter ppm in air	Average emitter ppm in air	Maximum emitter ppm in air
Mining	1.8	~1.8 (expected)	8.1	~8.1 (expected)
Wood and papers	4.8	16	36	119
Electricity supply	0.11	0.10	1.12	0.98
Materials manufacture	2.1	0.78	16	8.2
Petroleum	0.07	0.20	0.74	2.1
Chemical manufacture	0.05	0.57	0.41	4.4
Miscellaneous	0.14	2.0	1.2	17

5.3.3 Monitoring data

Ground water

Extensive monitoring of groundwater (from November 1991 to February 1992) from a Canadian site of production and use of formaldehyde included 10 samples in which formaldehyde concentrations were below the detection limit (50 µg/L) and 43 samples with concentrations ranging from 65 to 690,000 µg/L (mean of two duplicates). Data had been collected as part of a monitoring programme to delineate the boundaries of groundwater contamination at the facility and were used to design a groundwater containment and recovery system. Formaldehyde was not detected in samples taken from outside the contaminated zone.

Quarterly analyses of five monitoring wells on the property of a Canadian plant that produces Urea Formaldehyde (UF) resins were carried out during 1996–1997. Concentrations ranged from below the detection limit (50 µg/L) to 8,200 µg/L, with an overall median of 100 µg/L. Concentrations for different wells indicated little dispersion from wells close to the source of contamination.

Groundwater samples collected from wells downstream from six cemeteries in Ontario, Canada, contained concentrations of formaldehyde of 1–30 µg/L (detection limit not specified) (IPCS, 2002).

Atmospheric water
Monitoring of formaldehyde levels in water from rainwater tanks in suburban areas surrounding metal foundries has been performed in 1998. In total 26 samples were collected and analysed from several suburbs. Formaldehyde levels were found to range between 3 and 5.9 µg/L, which is below the level set out in the Australian Drinking Water Guidelines of 500 µg/L. In 2002, additional testing of rainwater found levels remained between < 3 and 6 µg/L (Australian Government, 2006).

Measured concentrations of formaldehyde in atmospheric water (rain, snow, fog) from various locations have been reported. In rain, formaldehyde concentrations ranged from 0.44 µg/L near Mexico City to 3,003 µg/L in Venezuela during vegetation burning-off season (IPCS, 2002). Concentrations in Venezuela during the non-burning season averaged 321 µg/L. In snow, concentrations of formaldehyde ranged from 18 to 901 µg/L in California, USA. A mean snow concentration of 4.9 µg/L is reported for Germany. In fog water, concentrations of 480–17,027 µg/L have been measured in the Po valley, Italy, with a mean of 3,904 µg/L season (IPCS, 2002).

Based on the relatively short half-lifes for formaldehyde in air and a degree of dilution of atmospheric water, which must be anticipated when entering aquatic ecosystems it is assumed that the concentration entering aquatic systems is lower. It is not known, however, if this dilution will be enough to reach a final concentration below the calculated $PNEC_{aquatic}$ and the NC.

Soil
Concentrations in soil were measured at manufacturing plants that use phenol/formaldehyde resins. At a plywood plant, six soil samples collected in 1991 contained formaldehyde concentrations of 73–80 mg/kg, with a mean of 76 mg/kg (detection limit not specified). At a fibreglass insulation plant, formaldehyde was not detected (detection limit 0.1 mg/kg) in soil samples collected in 1996 from six depths at four industrial areas on-site. Formaldehyde was also not detected in samples taken from a non-industrial site 120 km away from the plant (IPCS, 2002).

Sediment
No monitoring data available.

Sewage
The highest reported concentration from one of four plants reporting releases in 1997 was a 1-day mean of 325 µg/L, with a 4-day mean of 240 µg/L (IPCS, 2002). These concentrations are above the PNEC values reported in Table 5-3 for the aquatic environment.

Ambient air
The mean concentrations in air at various locations in Australia have been reported to be between 2-18 ppb. The higher concentration was measured in an industrial area in Adelaide with high traffic. Lower values where reported for low-traffic areas. The maximum atmospheric levels at an aluminium smelter was reported to be 5.1 and 7.18 ppb for background and event samples (samples taken when refinery odour was present throughout sampling), respectively. The average values for background and event sampling were 2.0 ppb (7 samples) and 2.3 ppb (6 samples), respectively (Australian Government, 2006).
Measurements conducted in Germany, and considered to be representative for the air in the rural areas of Central Europe, ranged from 0.1 to 4.5 µg/m³, with a mean value of about 1.5 µg/m³. Measurements in a high industrialized area with also heavy traffic conducted in Germany (1979 - 1984) gave annual mean values of 7 - 12 µg/m³. Additional measurements conducted in recent years (not specified in the OECD SIDS) in different locations indicate mean outdoor concentrations ranging from 2.5 µg/m³ to 15.7 µg/m³ (OECD SIDS, 2002).

5.4 Environmental impact

Water and sediment

Emissions of formaldehyde to water may be expected to occur via sewage treatment facilities during production of formaldehyde and formaldehyde products and during use of consumer products containing formaldehyde. Atmospheric formaldehyde may reach surface water when washed out of the atmosphere in rain. Due to its high biodegradability and low residence time, formaldehyde is not expected to reach significant levels in water (Australian Government, 2006). No Risk Characterisation Ratio (RCR[5]) has been calculated in the OECD SIDS Report (2002). RIVM also does not calculate a RCR for the aquatic compartment including sediment.
A PEC was calculated in the assessment performed by the Australian Government (2006). These calculations were based on a release of 1000 kg to water in 2001-2002. A daily effluent production of 4×10^8 L released to the sewer form a city with a population of 2 million people (each using 200 L of water per day) and a degradation of formaldehyde in the sewage treatment plant of 80%. The PEC would be further diluted in the receiving waters. They assume a 10-fold dilution in oceans (PEC = 0.14 µg/L) and no dilution in rivers. Emission levels reported for 2002-2003 were 200 times lower than in 2001-2002, this would be reflected in a 200-fold reduction of the PEC to 0.7 ng/L. Applying this value and the calculated $PNEC_{aqua}$ of 5.8 µg/L the risk characterisation ratio (RCR) can be calculated as the ratio of the PEC to the PNEC which (section 5.1.5) results in a RCR < 1, indicating that no risk to the water compartment is expected.

Terrestrial compartment

No RCR has been calculated for this compartment in the OECD SIDS (2002). The Log K_{ow} of 0.35 indicates that formaldehyde does not distribute to sludge if present in the sewage treatment plant. Transport to agricultural soil through the application of sludge is therefore unlikely.
However as monitoring data indicate that some local hot-spots may occur at production sites.

Waste water treatment plant

No information on the concentration of formaldehyde in the inlet to waste water treatment plants is available. Reported concentrations (4-day mean of 240 µg/L) in the outlet are, however, above the PNEC concentrations for microorganisms (Table 5-3) which results in a RCR > 1, indicating a risk to the waste water treatment plant. The data behind are, however more than 15 years old and it can be disputed if the measured values are representing the situation today.

Ambient air

The major environmental release of formaldehyde is to the atmosphere, where it breaks down in a short period of time. Because of its high water solubility, formaldehyde is efficiently transferred into clouds and rain, where it can react with aqueous hydroxyl radicals in the presence of oxygen to produce formic acid and hydroperoxide. The formic acid may then be removed in rainfall. Small amounts of formaldehyde may also be removed by dry deposition (Australian Government, 2006).

Secondary poisoning

No results from bioaccumulation studies have been identified within this project. The partition coefficient log P_{OW} is measured to 0.35 at 25°C which indicates that formaldehyde is not expected to bioaccumulate. Therefore no secondary poisoning is expected.

5.5 Summary and conclusions

Both acute and chronic toxicity data are available for fish invertebrate and algae. A Predicted No Effect Concentration $PNEC_{aqua}$ of 5.8 µg/L was calculated, based on acute data, in the OECD SIDS (they did not report any chronic toxicity data). In the RIVM report (2002) chronic NOEC values are

[5] The Risk Characterisation Ratio (RCR) is defined as the ration of the Predicted Environmental Concentration (PEC) to the Predicted No Effect Concentration (PNEC). An RCR > 1 indicates that a risk cannot be excluded whereas a RCR < 1 indicates that no risk is expected (ECHA, 2012).

available and a Negligible Concentration (NC) = 0.0018 mg/L is calculated. Both values are below the Danish quality criteria for the aquatic compartment of 9.2 μg/L
In the OECD SIDS report (2002) aquatic data were also applied for the calculation of a $NC_{sediment}$ of 0.0016 mg/kg dw. and this is also the method which is applied for the terrestrial compartment where a NC_{soil} of 0.0016 mg/kg dw. was reported. The report on formaldehyde prepared by the Australian Government (2006) however includes toxicity data on terrestrial organisms
For terrestrial organisms they conclude that formaldehyde is practically non-toxic to birds exposed to formaldehyde in food and that formaldehyde in air and fog water has potentially adverse effects on some plant species when exposed. No PNEC has been calculated for microorganisms. Sewage micro-organisms have been reported to be impaired at high concentrations (30 mg/L).

Formaldehyde does not meet the criteria's for Persistent, Bioaccumulative and Toxic (PBT). And there is no harmonised classification addressing the environment.

Releases into the environment are likely to occur during production and processing as intermediate as well as from use of products containing the substance. When released formaldehyde is ready biodegradable according to OECD Guideline no. 301 and can also be photodegraded in air either directly (half-life 4.1 hours)or indirectly by reaction with OH-radicals, with a half-life of 1.71 d. Half-lifes between 1-7 d and 2-14days are reported for surface- and ground water. The half-life for soil is between 1-7 days.
No monitoring data have been retrieved for the OECD SIDS report. The $PNEC_{aquatic}$ = 5.8 μg/L calculated in the OECD SIDS report and the (NC) = 0.0018 mg/L calculated in the RIVM report are below the concentrations reported for monitoring data from ground water, rain water, and atmospheric water presented in the IPCS report. It need be noted that the IPCS report refers to data that are more than 15 years old and that these observations have not been verified by more recent measurement. A degree of dilution of atmospheric water must be anticipated when entering aquatic ecosystems. It is not known if this dilution will be enough to reach a final concentration below the calculated $PNEC_{aquatic}$ and the NC. A PEC was calculated in the assessment performed by the Australian Government. Calculations were done for emission levels reported for 2001-2002 and 2002-2003 and resulted in a PEC of 0.14 μg/L and 0.7 ng/L for these two scenarios. Applying this value and the $PNEC_{aqua}$ of 5.8 μg/L results in a RCR < 1, indicating no risk to the water compartment.

Due to the lack of sufficient data for the soil and sediment compartment the equilibrium partitioning method was applied to derive a NC_{soil} and $NC_{sediment}$ both were = 0.0016 mg/kg dw. There is no monitoring data available for the concentration of formaldehyde in sediment. Soil concentrations are reported in the mg/kg range (at local production sites) and are therefore higher than the NC value. Here no risk can be excluded. However measurements at non-production sites indicate no risk. Formaldehyde is not anticipated to distribute to the sediment compartments based on the Log Kow of 0.35.

Concentrations in waste water reported in 2002 (4-day mean of 240 μg/L) are, however, above the PNEC concentrations for microorganisms (Table 5-3) which results in a RCR > 1, indicating that a risk to the waste water treatment plant. It need be noted that these data have not been confirmed by more recent measurements.

6. Human health effects and exposure

6.1 Human health hazard

The IARC monographs (2006, 2009), OECD SIDS (2002) and other reviews like the WHO (2010) evaluation and Nielsen et al (2013) presents a review of the available toxicological data covering all important endpoints including carcinogenicity. Therefore, data are compiled from these sources.

6.1.1 Toxicokinetics

In humans, as in other animals, formaldehyde is an essential metabolic intermediate in all cells. It is produced endogenously from the metabolism of amino acids, for example, of serine, glycine, methionine and choline, and xenobiotics (WHO, 2010). The endogenous turnover of formaldehyde was estimated to be approximately 0.61-0.91 mg/kg bw per minute and 878-1310 mg/kg bw per day assuming a half life of 1-1.5 min (EFSA, 2014). It is essential in the one-carbon pool, which is involved in the biosynthesis of nucleic acids and certain amino acids. Formate is incorporated in metabolic products or further oxidized to carbon dioxide. Additionally, it is excreted in the urine due to the high background formate excretion in the urine no increase is expected due to inhalation of formaldehyde. Inhalation of formaldehyde does not increase the concentration of formaldehyde in the blood (about 2–3 mg/L) (Nielsen et al., 2013).

No systemic absorption of formaldehyde has been reported in connection with oral, dermal and inhalational exposure (Nielsen et al, 2013). Orally exposed or inhaled formaldehyde is rapidly trapped in the mucous layer and on the surface tissue in the upper respiratory or gastrointestinal tract due to its high water solubility and reactivity. The biological half-life is extremely short at about 1 min. In rodents, absorption of inhaled formaldehyde occurs primarily in the nasal passages, while in humans this occurs also in the oral cavity, the trachea and bronchus.
Although formaldehyde or its metabolites can penetrate human skin, dermal absorption appears to be very slight (WHO, 2010).

Formaldehyde reacts rapidly at the site of first contact and is swiftly metabolised in humans by erythrocytes, which contain the enzymes formaldehyde dehydrogenase and aldehyde dehydrogenase. Formaldehyde reacts virtually instantaneously with primary and secondary amines, thiols, hydroxyls and amides to form methylol derivatives. Formaldehyde acts as an electrophile and can react with macromolecules such as DNA, RNA and protein to form reversible adducts or irreversible cross-links. Detoxification by formaldehyde dehydrogenase occurs subsequent to formation of a formaldehyde-glutathione conjugate. Formaldehyde and formate are incorporated in normal metabolic pathways or further oxidised to carbon dioxide. Much is eliminated in the expired air shortly after exposure. The other major route of elimination is excretion of formate in the urine (OECD SIDS, 2002, WHO, 2010).

6.1.2 Acute toxicity

Formaldehyde had acute effects in mammals: LD_{50} (rat, oral) 600 – 800 mg/kg bw., LC_{50} (rat, inhalation, 4 h) 578 mg/m^3 (480 ppm). The major acute effects are a result of the irritating properties of formaldehyde. After acute inhalation, irritation of the eyes, nose, throat, and lungs, as well as cellular changes, such as ciliar lesions and cellular swelling in the upper respiratory tract have been observed. In humans, no reports of deaths following acute inhalation exposure to formaldehyde were located. Serious ulceration of the gastrointestinal tract has been observed in humans after ingestion of formaldehyde (OECD SIDS, 2002).

These data are in accordance with the harmonised Acute Tox 3 classification.

6.1.3 Skin and eye irritation

In humans, transient and reversible sensory irritation of the eyes and respiratory tract has been observed in clinical studies and epidemiological surveys. Odour threshold for most people ranges between 0.5 and 1 ppm. In general, eye irritation, the most sensitive endpoint, is associated with airborne concentrations beginning in the range of 0.3 to 0.5 ppm. Eye irritation does not become significant until about 1 ppm, and rapidly subsides. Moderate to severe eye, nose and throat irritation occurs at 2 to 3 ppm. Under controlled exposure conditions, symptoms of irritation were noted by healthy individuals exposed to formaldehyde concentrations of 2–3 ppm during periods that varied between 40 minute and three hours (IARC, 2006). Sensory irritation has also been reported at lower exposure levels, but is then difficult to distinguish from background. Most studies show no effect on lung function in either asthmatics or non-asthmatics (OECD SIDS, 2002; IARC, 2006).

The eye irritation being the most sensitive parameter Lang et al. (2008) performed a study using subjective questionnaire ratings and objective methods. Twenty-one volunteers (11 m, 10 f) were examined over a 10 weeks period using a repetitive design. Each subject was exposed to 10 exposure conditions on 10 consecutive working days, each for 4 hours. Measurements were related to conjunctival redness, blinking frequency, nasal flow and resistance, pulmonary function and reaction times.
Subjective eye and olfactory symptoms were noted at concentrations as low as 0.3 ppm. Nasal irritation was reported at 0.5 ppm plus peaks of 1.0 ppm formaldehyde. The authors concluded that eye irritation was the most sensitive parameter recorded, and that the no-observed-adverse-effect (NOAEL) levels for subjective and objective eye irritation were 0.3 and 0.5 ppm, respectively (corresponding to 369 and 615 $\mu g/m^3$) .The authors concluded that the NOAEL for objective and subjective eye irritation was at 0.5 ppm formaldehyde in the case of a constant exposure, and at 0.3 ppm with peaks of 0.6 ppm in case of short-term exposures.

These data are in accordance with the harmonised classification as Skin Corr. 1B.

6.1.4 Skin sensitization

Formaldehyde was sensitising in the guinea pig maximisation test and the local lymph node assay with mice. On the other hand, specially designed studies (IgE tests, cytokine secretion profiles of lymph node cells) did not reveal evidence of respiratory sensitisation in mice (OECD SIDS, 2002). Induction of allergy in animal studies is seen at about 0.4 to 0.96% formaldehyde (Basketter *et al*, 2001; de Jong *et al*, 2005).

In humans, formaldehyde is a known cause of allergic contact dermatitis and, a form of eczema that affects the immune system and produces reactions characterized by rashes, blisters, and flaky, dry skin that can itch or burn (OECD SIDS, 2002).
The concentration for induction of allergy to formaldehyde is not known, but is believed to be lower than 5% (OECD SIDS, 2002). In some human individuals, contact dermatitis may occur at challenge concentrations at 30 ppm (OECD SIDS, 2002). Elicitation of allergy was observed in formaldehyde-sensitive persons in concentrations as low as 0.05% formaldehyde.
Some literature has estimated the number of people with allergic and irritant contact dermatitis caused by dermal exposure to formaldehyde. This literature focuses on subpopulations of patients—those with eczema—and therefore the results cannot be generalized to the rest of the population. For example, one study reported that 9.2% of patients suspected of having contact dermatitis tested positive to a diagnostic patch test that applied a 1% formaldehyde solution to the skin to test for any

dermal reaction. Other studies estimate that between 1.2% and 2.3% of people with eczema have dermatitis related to formaldehyde in their clothing. Allergic contact dermatitis may be underreported because medical practitioners might not distinguish it from cases of dermatitis with other causes, because of differences in how patch testing is conducted to determine dermatitis, and because some individuals may attempt to treat the condition themselves without seeking medical attention or are reluctant to make the number of visits to the doctor necessary to make a reliable diagnosis (US Government, 2010).

In Denmark the allergy clinics have reported the formaldehyde allergy incidents in 2012 to be around 1.2% in patients with already known allergy (Videncenter for allergi, 2012). In Denmark, Lundov *et al* (2010) looked into the prevalence of concomitant contact allergy to formaldehyde and formaldehyde-releasers in dermatitis patients, and to determine the sources of formaldehyde exposure based on personal and occupational products obtained from dermatitis patients. Patch test data from referred dermatitis patients with a positive patch test reaction to formaldehyde or formaldehyde-releasers were analysed. For the period 2000-2008, the formaldehyde content in products obtained from formaldehyde-allergic patients was analysed. The result of the investigation showed that patients allergic to a formaldehyde-releaser often had simultaneous contact allergy to formaldehyde. Other combinations were also prevalent. In patients who reacted to more than two formaldehyde-releasers, nearly all reacted simultaneously to formaldehyde. Seventy-five percent of the formaldehyde-allergic patients used a product that contained formaldehyde. The main source of formaldehyde exposure was cosmetics (78%). The authors concluded the concomitant contact allergy to formaldehyde and formaldehyde-releaser remains common. Furthermore, contact allergy to a formaldehyde-releaser was nearly always concomitant with another formaldehyde-releaser. Overall, formaldehyde was commonly found in personal products used by formaldehyde-allergic patients (Lundov *et al*, 2010).
In Finland, the Finnish Institute of Occupational Health investigated contact allergy for workers. They screened patch test files for allergic reactions to formaldehyde and 12 formaldehyde-releasing compounds. All patients with contact allergy to any of the substances were included, and their records were reviewed. Between January 2001 and May 2007, 81 patients with formaldehyde allergy and 18 with independent allergy to some formaldehyde releaser was patch tested. Of the formaldehyde allergies, 60 were new sensitizations, 25 of which were considered to be occupational. The most common source of occupational sensitization was metalworking fluids followed by creams and related products. Exposure to formaldehyde-releasing preservatives in liquid soaps and other rinse-off products was common in both occupational and non-occupational cases. Reactions to formaldehyde-releasing compounds were seen in 79% of the formaldehyde-allergic patients. The authors concluded that occupational formaldehyde allergy was common and occurred in metalworkers, hairdressers, masseurs, and workers using protective creams, detergents, and liquid soaps (Aallto-Korte *et al*, 2008).

These data are in accordance with the attributed harmonised classification as Skin Sens. 1.

6.1.4.1 Respiration sensitisation
Although some studies suggest that formaldehyde plays a role in airway sensitization, an association between formaldehyde and lung effects or sensitization in children have not been convincing owing to confounding factors in the studies, including exposure to traffic-related co-pollutants. Lung function remains unaltered in adults at exposures below 1 mg/m^3 formaldehyde (WHO, 2010).
Recent field studies don’t present a convincing association between formaldehyde exposure and asthma (Nielsen et al, 2013).

6.1.5 Repeated dose toxicity

Formaldehyde causes toxic effects in the tissues with direct contact after inhalation, oral or dermal exposure. The effects are characterised by local cytotoxic destruction. Toxic effects in the target tissues are dependent upon concentration rather than cumulative dose, and are highly non-linear.

Formaldehyde was administered daily in drinking water to Wistar rats (70/sex/dose) for up to 2years at mean doses of 0, 1.2, 15, or 82 mg/kg/day for males and 0, 1.8, 21, or 109 mg/kg/day for females (Iris, 2007). A NOAEL of 15 mg/kg bw/day were identified based on significant histopathological changes of the gastrointestinal tract. This effect of formaldehyde on the gastric mucosa was considered cytotoxic in nature (Iris, 2007).
An oral RfD (oral reference doses) for humans of 0.2 mg/kg bw/day was established by US-EPA (uncertainty factor of 100) on the basis of the above study (IRIS, 2007).
Additionally, WHO has established a Tolerable Daily Intake (TDI) of 0.15 mg/kg bw/day for drinking water (WHO, 2003).

Repeated exposure studies in mice were performed using dermal application, mostly in the context of skin initiation / promotion. None of these studies showed evidence of substance-specific 1 toxicity of formaldehyde (OECD SIDS, 2002).

According to Formacare[6] (2013), a DNEL (Derived no effect level) for workers of 0.5 mg/m^3 for long term inhalation exposure and 1 mg/m^3 for short term inhalation exposure was given in the formaldehyde REACH registration dossier composed by the formaldehyde consortium in 2010. These DNELs were based on several inhalation studies.

A maximum indoor air formaldehyde concentration of 100 µg/m^3 was established by WHO in 2010 based on NOELS for the eye irritation as a sensitive, and preventive, parameter for more severe effects of formaldehyde (WHO, 2010). The NOAEL for sensory irritation was 0.5 ppm (600 µg/m^3) and recently reconfirmed in hypo- and hypersensitive individuals (Nielsen et al, 2013). An assessment factor of five was used based on the steepness of the exposure–response relationship and the standard deviation of nasal pungency thresholds (Nielsen et al, 2013).

In conclusion, there is no evidence of systemic toxicity or of a systemic target organ. The high reactivity and the fast metabolic degradation of formaldehyde in biological environments prevent its systemic availability via physiological exposure routes. The effects are observed at the site of exposure with a NOAEL of 15 mg/kg bw/day.

6.1.6 Mutagenicity

Formaldehyde has shown evidence of mutagenicity in prokaryotic and eukaryotic cells *in vitro*. It has also been shown to be genotoxic in Drosophila melanogaster. Formaldehyde binds readily to proteins, RNA, and single-stranded DNA to induce DNA–protein cross-links and breaks in single-stranded DNA. It reacts readily with macromolecules in cells, mainly at the point of exposure.

In vivo, formaldehyde increases both DNA synthesis in rats and the number of micronuclei and nuclear anomalies in epithelial cells in rats. The overall evidence of available studies in laboratory animals supports the conclusion that the genotoxic effects after exposure via relevant routes are limited to those cells which are in direct contact with formaldehyde and no effects are observed in distant-site tissues. This is consistent with formaldehyde's high reactivity with many cellular nucleophiles and its rapid metabolic degradation (OECD SIDS, 2002, Nielsen et al, 2013).

[6] Formacare is the formaldehyde sector group of the European Chemical Industry Council (Cefic) representing key European producers of formaldehyde, aminoplast glues and polyols. http://www.formacare.org/

In conclusion, formaldehyde is genotoxic in multiple *in vitro* models and *in vivo* in exposed humans and laboratory animals, including formation of DPX, micronuclei, DNA monoadducts and DNA-DNA cross-links (Nielsen et al, 2013). Due to the induction of genotoxic effects *in vivo* on somatic cells at site of contact, supported by positive findings from mutagenicity and genotoxicity tests *in vitro*, a harmonised classification as Muta. 2 have been adopted by EU Member States in December 2013.

6.1.7 Reproductive toxicity

There are no indications of a specific toxicity of formaldehyde to foetal development and no effects on reproductive organs were observed by chronic oral administration of formaldehyde to male and female rats. Amounts of formaldehyde, which produce marked toxic effects at the portal of entry do not lead to an appreciable systemic dose and thus do not produce systemic toxicity (*cf.*6.1.5). Formaldehyde readily undergoes spontaneous reactions with cellular nucleophiles and is rapidly metabolised by various enzymes (*cf.*6.1.1). There is no human evidence of reproductive toxicity (OECD SIDS, 2002).

6.1.8 Carcinogenicity

Formaldehyde is highly cytotoxic and irritant and nasal tumours are observed only at doses producing chronic irritation as evidenced by the accompanying inflammatory, hyperplastic and metaplastic responses. Among species, the degree of sensitivity to nasal irritation is associated with the degree of sensitivity to nasal tumour induction. Localisation of damage to the nasal epithelium also corresponds with tumour site and distribution is attributable to regional dosimetry and/or local tissue susceptibility. Long-term exposure to 7.5 mg/m^3 formaldehyde and above caused squamous cell carcinoma of the nasal cavity of rats with a non-linear, biphasic concentration-response relationship having the break point at or above 2.5 mg/m^3.
Overall, there is sufficient evidence in experimental animals for the carcinogenicity of formaldehyde via inhalation.

In humans, ooccupational formaldehyde exposure has shown to cause cancer of the nasopharynx and leukemia in humans. Also, a positive association has been observed between exposure to formaldehyde and sinonasal cancer.
Over 25 cohort studies concerning professionals or industrial workers have examined the association between formaldehyde and cancer. Some have been conducted on workers exposed to formaldehyde in the chemical, garment, fibreglass, iron, woodworking, plastics and paper, pulp and plywood industries. Others are studies of professional groups (mainly health professionals, embalmers and funeral directors). Case–control studies have also been used to examine the association of formaldehyde with various cancers and, for rarer tumours such as sinonasal and nasopharyngeal cancer they have the potential to provide greater statistical power than can normally be achieved in cohort studies (SCOEL, 2008; WHO, 2010; RAC, 2012). Overall from these studies, there is consistent evidence that formaldehyde by inhalation causes cancer of the nasopharynx and leukemia. Also, a positive association has been observed between exposure via inhalation to formaldehyde and sinonasal cancer (IARC, 2009; RAC, 2012).
In humans, no excess nasopharyngeal cancer has been observed at mean exposure levels at or below 1.25 mg/m^3 and with peak exposures below 5 mg/m^3.
Exposure to formaldehyde is suspected to lead to lymphohaematopoetic malignancies. However, most long-term inhalation carcinogenicity studies in rats, mice and hamsters do not suggest induction of lymphohaematopoetic malignancies by formaldehyde at levels associated with nasal cancer. In humans, the overall conclusions from three meta-analyses, as well as a recent study in embalmers, suggest that formaldehyde may be causally associated with lymphohaematopoetic malignancies. A recent study in embalmers found evidence of myeloid leukaemia but no other haematopoietic malignancies; the 8-hour time weighted average formaldehyde intensity was 0.125-0.25 mg/m^3, the average formaldehyde intensity while embalming was about 1.9-2.25 mg/m^3, and

peak exposure was about 10-13 mg/m³. This suggests that an effect on bone marrow or blood progenitor cells is possible at high exposure concentrations. However, since exposure to formaldehyde concentrations up to 2.5 mg/m³ has negligible influence on the endogenous formaldehyde blood level, protection against nasal cancer should also protect against leukaemia.

In 2006, IARC changed the formaldehyde classification from Group 2A (probable human carcinogen) to Group 1 (carcinogenic to humans). This classification was based on "sufficient evidence of nasopharyngeal cancer in humans, strong but not sufficient evidence of leukemia in humans, and limited evidence of sinonasal cancer in humans." In 2009, IARC reaffirmed the Group 1 classification and also concluded that there was sufficient evidence of leukemia in humans.
In EU it was recently decided, in December 2013, to classify formaldehyde as a Carc 1B (H350) substance instead of the former classification as Carc 2 (H351).

Overall
Formaldehyde is mainly an irritant, and may cause sensitization and cancer (nasopharyngeal cancer, leukemia and sinonasal cancer).
The eye irritation being the most sensitive parameter a NOAEL for objective and subjective eye irritation was found at 0.5 ppm (corresponding to 615 µg/m³) formaldehyde in the case of a constant exposure, and at 0.3 ppm (corresponding to 369 µg/m³) with peaks of 0.6 ppm in case of short-term exposures. The onset of eye irritation is a very sensitive parameter that provides a safety margin to the onset of irritation-induced cytotoxicity and cell proliferation (SCOEL, 2008).
A maximum indoor air formaldehyde concentration of 100 µg/m³ was established by WHO in 2010 also based on NOELS for the eye irritation as a sensitive, and preventive, parameter for more severe effects of formaldehyde. With regard to the cancer potential of formaldehyde no excess of nasopharyngeal cancer has been observed at mean exposure levels at or below 1.25 mg/m³ and with peak exposures below 5 mg/m³ in humans (WHO, 2010).
A DNEL (Derived no effect level) for workers of 0.5 mg/m³ for long term inhalation exposure and 1 mg/m³ for short term inhalation exposure was given in the formaldehyde REACH registration dossier composed by the formaldehyde consortium in 2010 (ECHA, 2014).

6.2 Human exposure

Formaldehyde is found as a natural product in most living systems and in the environment. It occurs naturally in fruits and some foods, and it is formed endogenously in mammals, including humans, as a consequence of oxidative metabolism.
In addition to these natural sources, common non-occupational sources of exposure to formaldehyde include combustion processes, e.g. through emissions from motor vehicles, power plants, incinerators, refineries, and wood stoves. Formaldehyde may be released from particle boards and similar building materials, carpets, paints and varnishes, during cooking of some foods, and during its use as a disinfectant or as a preservative. It is also present in tobacco smoke (IARC, 2006).

6.2.1 Direct exposure

6.2.1.1 Consumers

For consumers a direct exposure to formaldehyde may occur during its use as a preservative in consumer products, such as cosmetics and household cleaning agents. Tobacco smoke as well as urea-formaldehyde foam insulation and formaldehyde-containing disinfectants are all important sources of formaldehyde exposure. Smoking 20 cigarettes per day e.g. corresponds to an intake of 1 mg formaldehyde/day via inhalation (OECD SIDS, 2002). Consumers are clearly exposed to formaldehyde. Pressed wood furniture is an example of article that may contain formaldehyde and which may be a source for exposure of consumers (IFC, 2013), and the use of engineered wood products in the furniture-making sector has grown substantially over the years. Currently, over 90 % of all furniture produced in the EU is made from wood-based panels, which in 2012 represented 14 million tonnes of wood panel furniture (ICF, 2013).

Formaldehyde is commonly used in several textile production processes; for example after treatment of substantive dyeing, hardening of casein fibres, as a wool protection agent, anti mould and above all as a cross linking agent in resin finishing. In 2007 the European Commission performed a survey on the release of formaldehyde from textiles (Piccinini et al, 2007). The focus was put on dermal exposure that can result from the direct contact of the skin with textile products. A total of 221 samples (t-shits, underwear, socks, pyjamas, trousers, dresses) were purchased in 21 out of 27 EU Member States of EU. With regard to the water extraction method, 11% of samples intended to come into contact with the skin exceeded the limit of 30 mg formaldehyde/kg textile established in the voluntary labelling scheme Ecolabel. About 3% also exceeded the limit of 75 mg/kg textile for adults considered by the Oeko-Tex Standard 100. 11% of garments for babies under the age of two showed a release of formaldehyde higher than 20 mg/kg texile. All textile categories were represented among the samples which released more than 30 mg/kg of formaldehyde, but shirts seem to be the category with the highest risk of exceeding the limit (Ecolabel limit) of 30 mg/kg textile. Piccinini et al (2007) calculated, based on their obtained data, a maximum dermal exposure of 4.5 mg/kg bw for a child and 1.7 mg/kg bw for an adult. Domestic washing effectively reduces the level of released formaldehyde .Also the US Government (2010) has performed a survey of the content of formaldehyde in textile. Their test results are similar to the result observed in Europe - that is, most items were found to meet the most stringent limits. Moreover, the studies they reviewed showed a decline in the formaldehyde levels in clothing since the 1980s. The decline is associated with the development and use of low-formaldehyde technologies (resins) in manufacturing clothing, which has been encouraged by such factors as the identification of formaldehyde as a probable human carcinogen via inhalation.

In cosmetic products, the total content of formaldehyde in the finished cosmetic product must not exceed 0.2% (SCCNFP, 2002). Cosmetics may contain formaldehyde, e.g. nail hardeners (Andersen *et al*, 2008), and a wide range of cosmetic products contain formaldehyde releasers as preservative, while the use of formaldehyde as a preservative in cosmetic products on the Danish market seems limited (Andersen *et al*, 2014 – unpublished data).

The general population may also be exposed during release from some building materials such as pressed wood products, insulation and carpets (see also chapter 6.2.3.5 about indirect exposure via indoor air).

6.2.2 Occupational exposure

Industrial workers who produce formaldehyde or formaldehyde-containing products, laboratory technicians, certain health care professionals, and mortuary employees may be exposed to higher levels of formaldehyde than the general public. Formaldehyde occurs in occupational environments mainly as a gas. Formaldehyde-containing particles can also be inhaled when paraformaldehyde or powdered resins are being used in the workplace. These resins can also be attached to carriers, such as wood dust. Exposure may also occur dermally when formalin solutions or liquid resins come into contact with skin.
Exposure measurements at workplace have been performed at different **production sites**:

Site 1 (1998 –2000; 8 h TWA, personal sampling; BASF AG) (OECD SIDS, 2002):

- Production (30 measurements): 0.32 mg/m³ (90-percentile)
- Processing (268 measurements): 0.19 mg/m³ (90-percentile)

Site 2 (1991 –1998; 8 h TWA, personal sampling; ISP GmbH) (OECD SIDS, 2002):

- Production and processing (117 measurements): <0.02 – 0.37 mg/m³

Site 3 (Methanova) (OECD SIDS, 2002):

- Production: 0.01– 0.08 mg/m³
- Processing: 0.02 – 0.25 mg/m³

Workplace measurements conducted in Helsinki, Finland indicated a mean exposure level of 15 µg/m³ (OECD SIDS, 2002).
In the IARC Monograph Volume 88 (IARC, 2006) data were reviewed and analysed from the CAREX (CARcinogen EXposure) database[7] on occupational exposure to formaldehyde by type of industry.
Based on these data it was observed that the highest continuous exposures (2–5 ppm; 2.5–6.1 mg/m³) were measured in the past during varnishing of furniture and wooden floors, in the finishing of textiles, in the garment industry, in the treatment of fur, and in certain jobs within manufactured board mills and foundries.
Short-term exposures to high levels (3 ppm and higher; ≥ 3.7 mg/m³) have been reported for embalmers, pathologists, and paper workers.
Lower concentrations have usually been encountered during the manufacture of man-made vitreous fibres, abrasives and rubber, and in formaldehyde-production industries.
A very wide range of exposure levels has been observed in the production of resins and plastic products. The developments of resins that release less formaldehyde and improved ventilation have resulted in lower exposure levels in many industrial settings in recent decades (IARC, 2006).

Workers in hair and nail salons may also be exposed to chemicals in cosmetic preparations they work with on a daily basis over long periods of time. Heat is often applied in hair salons by heating irons or hair dryers and this may increase the amount volatile vapours (ACCC, 2010).

In general, the working environmental legislation require that work is planned in a safely and healthy manner and that unnecessary exposure should be avoided. Preventive measures must be assessed in each individual case (e.g. process ventilation and spray booths). The individual evaluation of the exposure may trigger the requirement to use gloves and/or respiratory protection when working with products containing formaldehyde.

6.2.3 Indirect exposure

6.2.3.1 Air

Measurements conducted in Germany and considered to be representative for the ambient air in the rural areas of Central Europe ranged from 0.1 to 4.5 µg/m³, with a mean value of about 1.5 µg/m³. Measurements in a highly industrialised area with heavy traffic (automobile exhaust as a major source of formaldehyde in ambient air) conducted in Germany (1979 –1984) gave annual mean values of 7 – 12 µg/m³ (WHO IPCS, 1989). Additional measurements conducted in different locations indicate mean outdoor concentrations ranging from 2.5 µg/m³ to 15.7 µg/m³ (OECD SIDS, 2002).

6.2.3.2 Soil

Formaldehyde is not expected to adsorb to soil particles to a great degree and would be considered mobile in the soil, based on its estimated K_{oc} (Inchem, 2002).

6.2.3.3 Drinking water

Formaldehyde in drinking-water is formed mainly by the oxidation of natural organic (humic) matter during ozonation and chlorination. It also enters drinking-water via industrial effluents and leaching from polyacetal plastic fittings. Concentrations of up to 30 µg/litre have been found in ozonated drinking-water (WHO, 2003).

[7] an international information system on occupational exposure to known and suspected carcinogens based on data collected in the European Union (EU) from 1990 to 1993. The CAREX database provides selected exposure data and documented estimates of the number of exposed workers by country, carcinogen, and industry

6.2.3.4 Food

Formaldehyde occurs naturally in food and background levels vary widely. For example, formaldehyde measured in fish range between 6.4 and 293 mg/kg and in fruit and vegetables between 6 and 35 mg/kg (EFSA, 2014). The contribution of formaldehyde from food (meat and poultry, fish, milk and milk products, sugars and sweeteners, fruits and vegetables, coffee, and alcoholic beverages) have been assessed by EFSA not to exceed 100 mg/person, equivalent to 1.4 mg /kg bw/day for a 70 kg (EFSA 2014).
The indirect contribution of formaldehyde from additives (aspartame, alginates and carrageenan) are independently assessed by EFSA (EFSA, 2006 and EFSA, 2013) to be minimal in comparison with formaldehyde from food.
Migration of formaldehyde from food contact materials of melamine plastics to the food may contribute further to an exposure up to 0,25 mg/kg bw/day (the migration limit for formaldehyde from food contact materials is 15 mg/kg food; a 60 kg person eats daily 1 kg of wrapped food corresponding to additional maximum 0.25 mg/kg bw/day).

6.2.3.5 Indoor climate

Indoor air levels (non workplace), measured in various countries, ranged between <10 µg/m³ and a maximum of 5260 µg/m³. The highest levels were measured in trailers in Germany (WHO IPCS, 1989). The concentrations are mainly dependent on the age of the building, building materials, type of construction and ventilation (WHO IPCS, 1989). In more recent monitoring campaigns conducted in various countries (1992 –1998), mean indoor concentrations of formaldehyde in a range between 20.2 µg/m³ (greater Boston) and 68.5 µg/m³ (New Jersey) have been measured (OECD SIDS, 2002).
Marquart et al (2013) made an investigation in 2013 of available literature describing measurements of indoor formaldehyde concentrations in houses in Europe. They found, based on a data set of > 2500 measurements that the mean formaldehyde concentration turned out to be around 25 µg/m³. The reasonable worst case level as determined from all data is 85 µg/m³. Data shows, that measurements in new homes do show slightly elevated levels of formaldehyde.
Salthammer et al (2010) indicate that the average exposure level of the population to formaldehyde appears to lie between 20-40 µg/m³
In Denmark the formaldehyde concentrations were studied in 20 newly built houses in North Zealand between February and June 2007. Measurements of the formaldehyde concentration, temperature, humidity, CO2 and air exchange and registration of construction, the building area, dwelling area, inside area of the measuring room, ventilation type, and whether there were smoked in the home were performed. The measurements were carried out over a few hours in the smallest room in the house with closed windows and doors (Kolarik et al, 2008). Formaldehyde measurements showed a mean value of 50 µg/m³ (standard deviation 26 µg/m³) indicating a higher formaldehyde concentration in newly build houses in Denmark compared to the large amount of data seen analysed in the Marquart data set. The Danish results showed that the newest and the larges houses have a tendency to have the highest formaldehyde concentrations. There was no evidence of formaldehyde concentration and the size of the room, ventilation, temperature, humidity or smoke in homes. Two of the measurements obtained in the study exceeds WHO guidelines for the highest 30-minute mean concentration of 100 µg/m³ (Kolarik et al, 2008). One of the conclusions from the study was that there is a need to identify the main sources of formaldehyde in Danish homes. Both building materials and consumer products are suspected to be able to release formaldehyde (Kolarik et al, 2008).
Therefore another study was conducted in the period from 2008 to 2010 investigating the release of formaldehyde from different materials used as building materials (Logadóttir et al, 2010). The formaldehyde emission was determined from specimens prepared from purchased products and consumer products among the following possible formaldehyde sources: Wooden panels, insulation, carpets, textiles, paints and detergents. A total of 22 possible sources were tested. All samples tested met the requirements in the Building Code for wood-based panels for less than 124 µg/m³ in the chamber air during standardised testing. Medium density fiberboard (MDF) was

identified as the strongest formaldehyde sources but all 22 specimens complied with the limits set out in Denmark and the EU for formaldehyde emission of wood-based panels. The calculations in the Logadóttir (2010) study showed that the expected formaldehyde concentration in a small room is above 100 µg/m³ in indoor air if the room has paint on the walls and ceiling and wooden boards on the floor with formaldehyde donations. The concentration can be up to 6 times higher with materials on walls, floor and ceiling. However, this requires that the materials are not encapsulated or otherwise covered so that the formaldehyde emission is reduced in relation to the maximum allowable. This indicates that CE marking for construction products does not ensure that the formaldehyde concentration in buildings made of wood panels labelled comply with WHO's limit (Logadóttir et al, 2010).

Marquart et al (2013) also analysed emission rates of different product types. Emission rates showed a large range over the different product types and also within a product category. The testing method has a relatively large influence on the test result. The results in their analysis indicated that the main sources of formaldehyde emission are the uncoated materials and plywood, whereas products like paints, mineral wools and foams have lower emissions. In general, emissions decrease over time. However, as seen in the many measurements of indoor formaldehyde concentrations (Marquart et al, 2013; Kolarik et al, 2008) there is indications that the real indoor formaldehyde concentrations to be less than the theoretical potential based on emission from each formaldehyde source in the home.

Overall, indoor concentrations have been systematically monitored over the years and indoor air seems to be an important source for formaldehyde exposure to the general public. An evaluation of recent emission studies and indoor surveys has demonstrated that the situation has improved due to the progress made over recent decades regarding indoor products with reduced emissions.

6.3 Monitoring data

Formaldehyde is an essential metabolic intermediate in all cells. Inhalation of formaldehyde does not increase the concentration of formaldehyde in the blood (about 2–3 mg/L) (Nielsen et al, 2013). Thus, generating internal levels of formaldehyde for a specific formaldehyde exposure is not applicable.

6.4 Human health impact

6.4.1 Workers

An occupational 8-hour TWA exposure limit of 0.2 ppm and a short term (15-mintues value) STEL of 0.4 ppm was recommended by SCOEL in 2008. The Danish work authorities have established an 8-hour OEL of 0.3 ppm (0.37 mg/m³). These low OEL values are established as an expression of the effort to protect workers against formaldehyde.

According to the Danish working environment authority a number of diseases have been reported for formaldehyde exposure (table 6-1).

TABLE 6-1
DISEASES REPORTED TO THE DANISH WORKING ENVIRONMET AUTHORITY DUE TO FORMALDEHYDE EXPOSURE (DATA, 2013)

Total number of diseases with formaldehyde as (one of three) factor										
Diseases	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Skin disease	27	17	13	14	13	9	7	7	9	10
Cancer	1		3	2		1	1			
Respiratory disease	2	1	3	5	4	1	1	4	7	6

Total number of diseases with formaldehyde as (one of three) factor										
Diseases	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Mental disease									1	1
Nerv disease	1		1			2			1	1
Other diseases	4	4	1	2	1	13		1	7	5
total	**35**	**22**	**21**	**23**	**18**	**26**	**9**	**12**	**25**	**23**

The list of groups of diseases associated with formaldehyde exposure is not entirely surprising, skin diseases, respiratory diseases, cancer and other diseases (mixed symptoms such as headaches, etc.) – skin diseases being the most frequent overall. Given the mixture exposure it may of course also be other impacts that are decisive in the diagnosis declaration.
Office work (17% of total reported diseases), work at hospitals (12%) and unknown working places (22%) were reported to be the working environment areas with the most reported occupational diseases due to formaldehyde exposure; the exact source to the formaldehyde exposure is not known.
According to a report performed by Manen-Vernooij *et al.* (2013) measured data demonstrates safe use in the manufacture of formaldehyde and formaldehyde-based resins and other chemicals and in two major uses of the substance: production of wood based panels and in the tyre and rubber industries. However, in this study they evaluated the exposure to the DNEL values (0.5 mg/m^3 long-term, 1 mg /m^3 short-term) sat in the formaldehyde REACH dossier and did not compare the exposure to the OEL values (In Demark 0,3 ppm corresponding to 0.37 mg/m^3). Literature data and exposure modelling, supported by some measured data, also demonstrate safe use in industrial downstream uses of formaldehyde. In some cases, this (safe use) requires specific operational conditions and Risk Management Measures, e.g. reduction of duration of activities to below four hours/day or the use of respiratory protection. For professional uses, literature data and exposure modelling also demonstrate safe use; however, for some activities, highly stringent operational conditions and Risk Management Measures are required (Manen-Vernooij *et al.*, 2013).

Contact allergy to formaldehyde has been seen for workers (Aallto-Korte et al, 2008; Arrandale et al, 2012), and may be difficult to handle if a worker first has become allergic to formaldehyde as a very low concentration is needed for elicitation of allergy.

6.4.2 Consumers

Effects of formaldehyde in indoor air are generally expected to be limited to effects at the site of contact, specifically to irritation of the eyes and nasal and upper airways. Effects are due to direct reactions with formaldehyde itself and do not appear to require metabolism. The acute symptom of formaldehyde at indoor exposure concentrations is sensory irritation of the eyes and upper airways. Human exposure studies indicate that 615 µg/m^3 is the threshold for trigeminal stimulation of the eyes (e.g. increased blink frequency) and 369 µg/m^3 is the threshold for subjective sensory irritation (Lang *et al*, 2008; WHO, 2010). The indoor air risk assessment showed that the central tendency for formaldehyde indoor air concentration in Europe is around 25 µg/m^3 (Marquart e*t al.*, 2013). In new build homes or due to renovations/redecoration, the formaldehyde indoor air concentration can be higher than 25 µg/m^3, as e.g. seen in an investigation in Denmark in new houses, but still tends to be below threshold limit for eye effects, and lower than the WHO (2010) guideline for the highest 30-minute mean concentration of 100 µg/m^3 excluding some exceptions where higher values were observed (Marquart e*t al.*, 2013; Kolarik et al, 2008).

Overall, it can be concluded, based on the measured concentrations in real homes that exposure of the general population due to the use of wood-based panels/articles made with formaldehyde-based resins in Europe is below the WHO limit for indoor formaldehyde concentration of 100µg/m^3, which is evaluated as the safe indoor concentration protective of the general population against acute og chronic sensory irritation. Neither experimental nor epidemiological studies of adults and children have identified lung effects at formaldehyde exposure below 1 mg/m^3; this agrees with the high retention of formaldehyde in the nasal cavity. No evidence points to a major increase of formaldehyde induced airway susceptibility among children, elderly, and asthmatics (Wolkoff and Nielsen, 2010).

Furthermore, with regard to indoor air, there are initiatives which are currently in the pipeline which will act (eventually) to reduce indoor exposure to formaldehyde. Firstly, with the new classification of formaldehyde as Carc. 1B, restrictions on its use in certain consumer products (e.g. in toiletries and household products) may be triggered under the REACH regulation. These restrictions will act to reduce the sources of formaldehyde in the home contributing to cumulative exposure. The most important way to control the formaldehyde concentrations in the indoor air is the air exchange rate and the use of low-emitting materials and products (WHO, 2010)

More direct exposure to formaldehyde for the general population may also occur during handling of a wide range of consumer products including e.g. cosmetics, clothes and cleaning agents. Contact allergy seems to be the predominantly effect of this kind of consumer exposure. Studies indicates contact allergy to formaldehyde and formaldehyde releasers occurred on grounds of exposure to formaldehyde containing consumer products (Lundov *et al*, 2010, US Government, 2010). The amount of formaldehyde in cosmetics should maximum be 0.2% in the product. However, allergy to cosmetics containing this amount is still observed.

In some cases, allergic contact dermatitis (ACD) can be attributed to clothing treated with textile finish resins (TFRs), also named durable press resins or permanent press clothing resins. Under normal and foreseeable use, the majority of these resins can release formaldehyde. The frequency of ACD due to textile formaldehyde resins has been reported to be between 0.2% and 4.2% after 1990 (Piccinini et al, 2007).

Another exposure to formaldehyde is via food and indirect via food contact materials containing formaldehyde. The daily formaldehyde intake from diet and migrated formaldehyde may be 1.4 mg/kg bw/day plus an addition exposure of 0.25 mg/kg bw/day from migration of formaldehyde from food contact materials of melamine plastics to the food. The oral reference dose (RfD) (similar to a TDI) from the US-EPA at 0.2 mg/kg bw/day based on a study with rats exposed to formaldehyde via drinking water. Formaldehyde in food occurs both free and organically bound. The exposure available fraction of formaldehyde at equal concentrations will therefore be significantly less for food when compared to water, since it will be released more slowly and over a longer period.

In a "worst case scenario", the total exposure to formaldehyde from diet and migrated formaldehyde was overall 1.65 mg/kg bw/day (1.4 from food and 0.25 from food contact material) which is still at least 600 times lower than the endogenous turnover for formaldehyde. It is therefore considered that the existing migration limit for food contact materials of 15 mg/kg food does not constitute a significant fraction of the total exposure of formaldehyde from natural sources and therefore does not raise health concerns.

Overall, it is important to stress that there are concerns relating to the risks from formaldehyde on consumers, especially regarding the potential for contact allergy. The indoor air concentration in most houses seems to have a formaldehyde concentration at a level safe for the general population. However, higher concentrations is seen in new houses and may also be seen if new furniture's or other new material containing formaldehyde is introduced into an old house in a period where formaldehyde is evaporating from the products indicating that humans, and especially sensitive individuals, may be exposed to formaldehyde concentrations possibly giving a risk of health effects at certain periods. Allergy to formaldehyde in consumer products is regarded as a risk

6.5 Summary and conclusions

Formaldehyde is highly reactive, water soluble and rapidly metabolized. People may experience toxic, irritating and sensitizing effects at the site of contact.
Formaldehyde is a known skin- and eye-irritant, and causes irritation of the respiratory tract. Moderate to severe eye, nose and throat irritation occurs at 2 to 3 ppm. In humans, transient and reversible sensory irritation of the eyes and respiratory tract has been observed in clinical studies and epidemiological surveys. Formaldehyde is classified for its irritating potential.
A NOAEL for objective and subjective eye irritation was found at 0.5 ppm (corresponding to 615 $\mu g/m^3$) formaldehyde in the case of a constant exposure and at 0.3 ppm (corresponding to 369 $\mu g/m^3$) with peaks of 0.6 ppm in case of short-term exposures to humans.
Formaldehyde is also a sensitizer, and despite the concentration for induction of allergy to formaldehyde is not known it is believed to be lower than 5%.
There is no evidence of systemic toxicity or of a systemic target organ after prolonged exposure to formaldehyde. The high reactivity and the fast metabolic degradation of formaldehyde in biological environments prevent its systemic availability via physiological exposure routes. A NOAEL of 15 mg/kg bw/day was established bases on a 2-year study in rats exposed to formaldehyde via drinking water. Based on that study an oral reference dose of 0.2 mg/kg bw/day and a Tolerable Concentration (TC) of 0.15 mg/kg bw/day were established. A DNEL of 0.5 mg/m^3 for long term inhalation exposure and 1 mg/m^3 for short term inhalation exposure for workers was given in the formaldehyde REACH dossier.
Research studies of workers exposed to formaldehyde have found an association between formaldehyde exposure and several cancers, including nasopharyngeal cancer and leukemia.
In 2006, IARC changed the formaldehyde classification from Group 2A (probable human carcinogen) to Group 1 (carcinogenic to humans). This classification was based on "*sufficient evidence of nasopharyngeal cancer in humans, strong but not sufficient evidence of leukemia in humans, and limited evidence of sinonasal cancer in humans*" In 2009, IARC reaffirmed the Group 1 classification and also concluded that there was sufficient evidence of leukemia in humans. EU has recently also strengthened the classification of formaldehyde from Carc 2 to Carc 1b and Muta 2.
As the eye irritation is the most sensitive parameter the onset of eye irritation is believed to provide a safety margin to the onset of irritation-induced cytotoxicity and cell proliferation. A maximum indoor air formaldehyde concentration of 100 $\mu g/m^3$ was established by WHO in 2010 also based on NOELS for the eye irritation as a sensitive, and preventive, parameter for more severe effects of formaldehyde.

Based on the extensive use of formaldehyde in many different areas the exposure to the substance is complex. One of the main formaldehyde exposures for the general public is indoor air formaldehyde originating from different source like building materials such as pressed wood products, insulation and carpets. Large investigations of indoor air concentration in houses in Europe have shown that the average indoor concentration is about 20 – 40 $\mu g/m^3$. This concentration is regarded as safe as it is below the WHO limit of 100 $\mu g/m^3$. Although low average values, there are indications that still about 10 % of the homes exceed the limit value of 100 $\mu g/m^3$, which indicate concern for a rather high fraction of the population. Thus, higher concentrations may be measured in a period where formaldehyde is evaporating from new products, indicating that humans may be exposed to formaldehyde concentrations possibly giving a risk of health effects at certain periods. Some people are very sensitive to formaldehyde, whereas others have no reaction to the same level of exposure. Thus temporary higher indoor concentrations in periods could pose risk to especially sensitive people.

Another exposure to formaldehyde is via food and indirect via food contact materials containing formaldehyde. The natural content of formaldehyde in food is in a range of 1.6 mg/kg bw/day (1.4

from food and 0.25 from food contact material). This contribution to the formaldehyde exposure from food is evaluated to be safe as it is at least 600 times lower than the endogenous turnover of formaldehyde. Other exposures originate from consumer product like cosmetics, cleaning agents and textile, where the chance of allergy is the main risk.
Other exposures originate from consumer product like cosmetics and cleaning agents, and textile, where allergy is the main risk. Because of a low elicitation concentration the exposure to formaldehyde during use of consumer products the use may pose a risk for allergy to consumers.
For workers, exposure via inhalation is the most pronounced, but dermal exposure may also be relevant for few workplaces. Exposure to formaldehyde in the workplace may take place in many different industries because of the varied use of formaldehyde. Due to the severe health effects of formaldehyde, keeping the exposure level at a minimum in the working environment is regarded as critical. Investigations in different working environments indicates that the air concentration is decreasing and operational conditions and Risk Management Measures, e.g. reduction of duration of activities to below four hours/day or the use of respiratory protection, are being introduces to keep the formaldehyde exposure low. Furthermore, the very low OEL values established are an expression of the effort to protect workers against the substance.

7. Information on alternatives

It must be emphasised that in order to evaluate if a substance is a *suitable alternative* to another, several factors have to be investigated, and these factors have to be investigated on a case by case basis. This will include considerations of:

- Hazards and risks of possible alternatives:
  - does the alternatives lead to an overall reduced risk to humans and the environment
  - are there any implications in terms of increased energy consumption or resource issues related to the shift to the alternatives, e.g. increased CO2 emissions or potential depletion of non-renewable resources.
- Technical suitability:
  - are the alternatives just as effective as formaldehyde when it comes to their function as complex binders, do they do the job?
  - are the alternatives stable in the final product and during its application?
- Economic suitability:
  - are the identified alternatives economically suitable?

Further, the Danish Working Environment Authority have the AT guidance on"Product Selection for building painting", where the substitution requirement is central. The manual provides information on how to - in accordance with the requirement of substitution – based on product selection schemes, to choose the product with the lowest possible code number, which can cope with the paint job.

7.1 Identification of possible alternatives

An internet search was performed in order to retrieve information on possible alternatives to formaldehyde. Below substitutions examples are given for some specific uses of formaldehyde.

Carosafe

Carosafe is a preservative and holding solution for biological specimens. Carosafe® Concentrate contains 2-Amino-2-Ethyl-Propanediol (AEPD) (CAS: 115-70-8); Ethylene Glycol Phenyl Ether (CAS: 122-99-6) and Propylene Glycol (CAS: 57-55-6), the primary component being reported as propylene glycol. No information on the exact percentage of the single components was however retrieved (Carosafe MSDS, 2011).

Formalternate

Formalternate a holding solution for biological specimens is a proprietary mixture containing propylene glycol (57-55-6), ethylene glycol phenyl ether (122-99-6) and phenol (108-95-2). No information on the exact percentage of the single components was however retrieved (Formalternate MSDS, 2011).

The substances contained in the products above do not have environmental classifications but do have classifications regarding human health. However no classification as carcinogenic is included.

2-Amino-2-Ethyl-Propanediol (AEPD):
No harmonised classification is available for 2-Amino-2-Ethyl-Propanediol (AEPD) (CAS: 115-70-8). 401 notified classification reported by industry. The notified classifications, which do not include environmental classifications, are Acute Tox.4; H302 (Harmful if swallowed), Skin Irrit. 2; H315 (Causes skin irritation), Eye Irrit.2; H319 (Causes serious eye irritation) and STOT SE 3; H335 (may cause respiratory irritations).

Ethylene glycol phenyl ether
A harmonised classification is available for ethylene glycol phenyl ether (122-99-6), which does not include an environmental classification. The substance is classified as Acute Tox. 4; H302 (Harmful if swallowed) and Eye Irrit. 2; H319 8causes serious eye irritation). Ethylene glycol phenyl ether also needs to be labelled with the warning pictograms:


Exclamation mark

Propylene glycol
No harmonised classification is available for propylene glycol (CAS: 57-55-6). 4,005 notified classification reported by industry. Of these 3,968 do not classify propylene glycol. The notified classifications reported are Acute Tox.4; H302 (Harmful if swallowed), Skin Irrit. 2; H315 (Causes skin irritation), Eye Irrit.2; H319 (Causes serious eye irritation), Skin Sens. 1; H317 (may cause skin sensitisation), STOT SE 3; H335 (may cause respiratory irritations) and H336 (May cause drowsiness or dizziness), Aquatic Chronic 1; H410 (Very toxic to aquatic life with long lasting effects) and Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects).

Phenol
A harmonised classification is available for phenol (108-95-2), which does not include an environmental classification. The harmonised classification is Acute Tox.3; H301 (Toxic if swallowed); H311 (Toxic in contact with skin); H331 (Toxic if inhaled), Skin Corr. 1B; H314 (Causes severe skin burns and eye damage), Mut2; H341 (Suspected of causing genetic defects.) and STOT SE 2; H373 (May cause damage to organs through prolonged or repeated exposure.). Phenol also needs to be labelled with the warning pictograms:


Skull and crossbones


Corrosion


Health hazard

7.1.1 Alternative Resin Binders for Particleboard, Medium Density Fiberboard (MDF), and Wheatboard

Urea formaldehyde-based resins have been the standard binders used to glue the particles together in many composite wood products, including particleboard, wheatboard, and medium density fiberboard (MDF). In recent years, however, concerns have been rising about the risks of cancer and bronchial health impacts from formaldehyde, as UF resins are associated with the highest releases of formaldehyde when compared with other formaldehyde-based resins. Four major approaches to reduce the problem of exposure to formaldehyde from composite wood binders are:

1) Urea formaldehyde-based resins can be directly mixed with additives called scavengers, which bind with the urea formaldehyde to reduce emissions. Melamine and hexamine are the most common added scavengers.
2) Alternate formaldehyde resins, such as phenol formaldehyde, which cure at the factory during manufacture and hence have much lower formaldehyde emissions from the product in use than urea formaldehyde;
3) Alternate fossil fuel-based binders containing no added formaldehyde, such as methylene diphenyl diisocyanate (MDI). However, methylenedianiline an aniline building block of MDI has been classified as a probable human carcinogen (Group 2B) by IARC.
4) Alternate binders based on renewable resource materials, such as soy flour. These alternate binders are not expected to have health impacts as significant as the formaldehyde and MDI-based binders. Soy products can however cause allergic reactions in some people and contain plant estrogens.

(Global Health and Safety Initiative, 2008)

7.1.2 Food contact materials

No information on alternatives for formaldehyde in food contact materials of melamine (produced by resins containing residual amounts of formaldehyde), used for the handling and storage of food, has been identified in this project. As described in the section above regarding binders, a change in the way of processing and handling food may be a suitable "alternative". For instance kitchen tools, made of melamine are known to release melamine and formaldehyde when in contact with hot food or food with a low pH. Therefore suitable approaches in order to reduce exposure could be:

1. not use kitchen utensils, plates and bowls made of melamine to heat food (especially in the microwave oven.
2. use glass or porcelain in the microwave and when handling sour and hot foods.

Summary and conclusions

In developing any strategy for reducing the risks relating to a given substance, it is important to consider the availability of alternatives for the applications of concern, where this includes alternative substances, technologies and/or processes. Such considerations are important since any proposed risk management measures may initiate a shift to such alternatives.

Alternative preservatives and holding solutions for biological specimens, which were identified during an internet search, include substances such as 2-Amino-2-Ethyl-Propanediol (AEPD), ethylene glycol phenyl ether, propylene glycol and phenol. These substances do not have environmental classifications, except propylene glycol, but they do have classifications regarding human health. No classification as carcinogenic is included.

Major approaches to reduce the problem of exposure to formaldehyde from binders have been discussed. These approaches also include initiatives to reduce emissions of formaldehyde rather than a substitution with a substance of less concern.

- Alternate fossil fuel-based binders, containing no added formaldehyde, such as methylene diphenyl diisocyanate (MDI).
- Alternate binders based on renewable resource materials, such as soy flour, which is not expected to have health impact as significant as formaldehyde and MDI.

No information on alternatives for formaldehyde in kitchen tools, used for the handling and storage of food, has been identified in this project. A change in the way of processing and handling food may be a suitable "alternative".

Due to the large use of formaldehyde for many different purposes, it seems difficult to identify individual alternatives that generally can substitute formaldehyde. The substitution may have to be assessed case-by-case to suit the different application forms.

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Appendix 1 - Background information to chapter 2 on legal framework

The following annex provides some background information on subjects addressed in Chapter 3. The intention is that the reader less familiar with the legal context may read this concurrently with chapter 3.

EU and Danish legislation

Chemicals are regulated via EU and national legislations, the latter often being a national transposition of EU directives.

There are four main EU legal instruments:

- Regulations (DK: Forordninger) are binding in their entirety and directly applicable in all EU Member States.
- Directives (DK: Direktiver) are binding for the EU Member States as to the results to be achieved. Directives have to be transposed (DK: gennemført) into the national legal framework within a given timeframe. Directives leave margin for manoeuvering as to the form and means of implementation. However, there are great differences in the space for manoeuvering between directives. For example, several directives regulating chemicals previously were rather specific and often transposed more or less word-by-word into national legislation. Consequently and to further strengthen a level playing field within the internal market, the new chemicals policy (REACH) and the new legislation for classification and labelling (CLP) were implemented as Regulations. In Denmark, Directives are most frequently transposed as laws (DK: love) and statutory orders (DK: bekendtgørelser).
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The European Commission has the right and the duty to suggest new legislation in the form of regulations and directives. New or recast directives and regulations often have transitional periods for the various provisions set-out in the legal text. In the following, we will generally list the latest piece of EU legal text, even if the provisions identified are not yet fully implemented. On the other hand, we will include currently valid Danish legislation, e.g. the implementation of the cosmetics directive) even if this will be replaced with the new Cosmetic Regulation.

- Decisions are fully binding on those to whom they are addressed. Decisions are EU laws relating to specific cases. They can come from the EU Council (sometimes jointly with the European Parliament) or the European Commission. In relation to EU chemicals policy, decisions are e.g. used in relation to inclusion of substances in REACH Annex XVII (restrictions). This takes place via a so-called comitology procedure involving Member State representatives. Decisions are also used under the EU ecolabelling Regulation in relation to establishing ecolabel criteria for specific product groups.
- Recommendations and opinions are non-binding, declaratory instruments.

In conformity with the transposed EU directives, Danish legislation regulate to some extent chemicals via various general or sector specific legislation, most frequently via statutory orders (DK: bekendtgørelser).

Chemicals legislation

REACH and CLP

The REACH Regulation[8] and the CLP Regulation[9] are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP

[8] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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

provisions and give an overview of 'pipeline' procedures, i.e. procedures which may (or may not) result in an eventual inclusion under one of the REACH procedures.

(Pre-)Registration
All manufacturers and importers of chemical substance > 1 tonne/year have to register their chemicals with the European Chemicals Agency (ECHA). Pre-registered chemicals benefit from tonnage and property dependent staggered dead-lines:

- 30 November 2010: Registration of substances manufactured or imported at 1000 tonnes or more per year, carcinogenic, mutagenic or toxic to reproduction substances above 1 tonne per year, and substances dangerous to aquatic organisms or the environment above 100 tonnes per year.
- 31 May 2013: Registration of substances manufactured or imported at 100-1000 tonnes per year.
- 31 May 2018: Registration of substances manufactured or imported at 1-100 tonnes per year.

Evaluation
A selected number of registrations will be evaluated by ECHA and the EU Member States. Evaluation covers assessment of the compliance of individual dossiers (dossier evaluation) and substance evaluations involving information from all registrations of a given substance to see if further EU action is needed on that substance, for example as a restriction (substance evaluation).

Authorisation
Authorisation aims at substituting or limiting the manufacturing, import and use of substances of very high concern (SVHC). For substances included in REACH annex XIV, industry has to cease use of those substance within a given deadline (sunset date) or apply for authorisation for certain specified uses within an application date.

Restriction
If the authorities assess that that there is a risks to be addressed at the EU level, limitations of the manufacturing and use of a chemical substance (or substance group) may be implemented. Restrictions are listed in REACH annex XVII, which has also taken over the restrictions from the previous legislation (Directive 76/769/EEC).

Classification and Labelling
The CLP Regulation implements the United Nations Global Harmonised System (GHS) for classification and labelling of substances and mixtures of substances into EU legislation. It further specifies rules for packaging of chemicals.

Two classification and labelling provisions are:

1. **Harmonised classification and labelling** for a number of chemical substances. These classifications are agreed at the EU level and can be found in CLP Annex VI. In addition to newly agreed harmonised classifications, the annex has taken over the harmonised classifications in Annex I of the previous Dangerous Substances Directive (67/548/EEC); classifications which have been 'translated' according to the new classification rules.
2. **Classification and labelling inventory**. All manufacturers and importers of chemicals substances are obliged to classify and label their substances. If no harmonised classification is available, a self-classification shall be done based on available information according to the classification criteria in the CLP regulation. As a new requirement, these self-classifications should be notified to ECHA, which in turn publish the classification and labelling inventory based on all notifications received. There is no tonnage trigger for this obligation. For the purpose of this report, self-classifications are summarised in Appendix 2 to the main report.

Ongoing activities - pipeline
In addition to listing substance already addressed by the provisions of REACH (pre-registrations, registrations, substances included in various annexes of REACH and CLP, etc.), the ECHA web-site also provides the opportunity for searching for substances in the pipeline in relation to certain REACH and CLP provisions. These will be briefly summarised below:

Community Rolling Action Plan (CoRAP)
The EU member states have the right and duty to conduct REACH substance evaluations. In order to coordinate this work among Member States and inform the relevant stakeholders of upcoming substance evaluations, a Community Rolling Action Plan (CoRAP) is developed and published, indicating by who and when a given substance is expected to be evaluated.

Authorisation process; candidate list, Authorisation list, Annex XIV
Before a substance is included in REACH Annex XIV and thus being subject to Authorisation, it has to go through the following steps:

1. It has to be identified as a SVHC leading to inclusion in the candidate list[10]
2. It has to be prioritised and recommended for inclusion in ANNEX XIV (These can be found as Annex XIV recommendation lists on the ECHA web-site)
3. It has to be included in REACH Annex XIV following a comitology procedure decision (substances on Annex XIV appear on the Authorisation list on the ECHA web-site).

The candidate list (substances agreed to possess SVHC properties) and the Authorisation list are published on the ECHA web-site.

Registry of intentions
When EU Member States and ECHA (when required by the European Commission) prepare a proposal for:

- a harmonised classification and labelling,
- an identification of a substance as SVHC, or
- a restriction.
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This is done as a REACH Annex XV proposal.

The 'registry of intentions' gives an overview of intensions in relation to Annex XV dossiers divided into:
- current intentions for submitting an Annex XV dossier,
- dossiers submitted, and
- withdrawn intentions and withdrawn submissions
-

for the three types of Annex XV dossiers.

International agreements

OSPAR Convention
OSPAR is the mechanism by which fifteen Governments of the western coasts and catchments of Europe, together with the European Community, cooperate to protect the marine environment of the North-East Atlantic.

[10] It should be noted that the candidate list is also used in relation to articles imported to, produced in or distributed in the EU. Certain supply chain information is triggered if the articles contain more than 0.1% (w/w) (REACH Article 7.2 ff).

Work to implement the OSPAR Convention and its strategies is taken forward through the adoption of decisions, which are legally binding on the Contracting Parties, recommendations and other agreements. Decisions and recommendations set out actions to be taken by the Contracting Parties. These measures are complemented by other agreements setting out:

- issues of importance
- agreed programmes of monitoring, information collection or other work which the Contracting Parties commit to carry out.
- guidelines or guidance setting out the way that any programme or measure should be implemented
- actions to be taken by the OSPAR Commission on behalf of the Contracting Parties.

HELCOM - Helsinki Convention

The Helsinki Commission, or HELCOM, works to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental co-operation between Denmark, Estonia, the European Community, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden. HELCOM is the governing body of the "Convention on the Protection of the Marine Environment of the Baltic Sea Area" - more usually known as the Helsinki Convention.

In pursuing this objective and vision the countries have jointly pooled their efforts in HELCOM, which is works as:

- an environmental policy maker for the Baltic Sea area by developing common environmental objectives and actions;
- an environmental focal point providing information about (i) the state of/trends in the marine environment; (ii) the efficiency of measures to protect it and (iii) common initiatives and positions which can form the basis for decision-making in other international fora;
- a body for developing, according to the specific needs of the Baltic Sea, Recommendations of its own and Recommendations supplementary to measures imposed by other international organisations;
- a supervisory body dedicated to ensuring that HELCOM environmental standards are fully implemented by all parties throughout the Baltic Sea and its catchment area; and
- a co-ordinating body, ascertaining multilateral response in case of major maritime incidents.

Stockholm Convention on Persistent Organic Pollutants (POPs)

The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have adverse effects to human health or to the environment. The Convention is administered by the United Nations Environment Programme and is based in Geneva, Switzerland.

Rotterdam Convention

The objectives of the Rotterdam Convention are:

- to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm;
- to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.
- The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure. It built on the voluntary PIC procedure, initiated by UNEP and FAO in 1989 and ceased on 24 February 2006.

The Convention covers pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by Parties and which have been notified by Parties for inclusion in the PIC procedure. One notification from each of two specified regions triggers consideration of addition of a chemical to Annex III of the Convention. Severely hazardous pesticide formulations that present a risk under conditions of use in developing countries or countries with economies in transition may also be proposed for inclusion in Annex III.

Basel Convention

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted on 22 March 1989 by the Conference of Plenipotentiaries in Basel, Switzerland, in response to a public outcry following the discovery, in the 1980s, in Africa and other parts of the developing world of deposits of toxic wastes imported from abroad.

The overarching objective of the Basel Convention is to protect human health and the environment against the adverse effects of hazardous wastes. Its scope of application covers a wide range of wastes defined as “hazardous wastes” based on their origin and/or composition and their characteristics, as well as two types of wastes defined as “other wastes” - household waste and incinerator ash.

The provisions of the Convention center around the following principal aims:

- the reduction of hazardous waste generation and the promotion of environmentally sound management of hazardous wastes, wherever the place of disposal;
- the restriction of transboundary movements of hazardous wastes except where it is perceived to be in accordance with the principles of environmentally sound management; and
- a regulatory system applying to cases where transboundary movements are permissible.

Eco-labels

Eco-label schemes are voluntary schemes where industry can apply for the right to use the eco-label on their products if these fulfil the ecolabelling criteria for that type of product. An EU scheme (the flower) and various national/regional schemes exist. In this project we have focused on the three most common schemes encountered on Danish products.

EU flower

The EU ecolabelling Regulation lays out the general rules and conditions for the EU ecolabel; the flower. Criteria for new product groups are gradually added to the scheme via 'decisions'; e.g. the Commission Decision of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners.

Nordic Swan

The Nordic Swan is a cooperation between Denmark, Iceland, Norway, Sweden and Finland. The Nordic Ecolabelling Board consists of members from each national Ecolabelling Board and decides on Nordic criteria requirements for products and services. In Denmark, the practical implementation of the rules, applications and approval process related to the EU flower and Nordic Swan is hosted by Ecolabelling Denmark "Miljømærkning Danmark" (http://www.ecolabel.dk/). New criteria are applicable in Denmark when they are published on the Ecolabelling Denmark’s website (according to Statutory Order no. 447 of 23/04/2010).

Blue Angel (Blauer Engel)

The Blue Angel is a national German eco-label. More information can be found on: http://www.blauer-engel.de/en.

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