Analysis of the most appropriate risk management option (RMOA)

Substance Name: Formaldehyde

EC Number: 200-001-8

CAS Number: 50-00-0

Authority: France

Date: 06/2016

Cover Note

Formaldehyde was included in the list of substances included in the CoRAP (Community Rolling Action Plan) in 2013 on the grounds of human health concerns (CMR), worker exposure and wide dispersive use as well as high aggregated tonnage. The Substance Evaluation was jointly taken in charge by France and the Netherlands: the SEv performed by France addressed concerns for workers and was achieved in 2014 and the SEv performed by The Netherlands is still ongoing and focuses on consumers. The Conclusion Document will be published at the end of the whole process. The FR SEv concluded there is a concern for workers. Consistently with the conclusion of its SEv**, FR performed the present RMOA on the basis of the workers exposure to formaldehyde. This RMOA covers only industrial and professional uses of formaldehyde for which a risk for workers has been demonstrated or is anticipated.**

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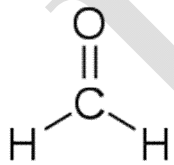
1 IDENTITY OF THE SUBSTANCE

Formaldehyde is a naturally-occurring chemical compound. It is composed of hydrogen, carbon and oxygen and is present in all organic forms of life, namely in plants, animals and humans. In the atmosphere, formaldehyde is in a colourless gaseous form and is generally broken down very quickly by sunlight. Formaldehyde is not stable and is used as an aqueous solution (formalin, consisting of 30-60% formaldehyde in water). Methanol may also be added to prevent polymerization.

Table 1. Substance identity

EC number:	**200-001-8**
EC name:	**formaldehyde**
CAS number (EC inventory):	**50-00-0**
CAS name:	**formaldehyde**
IUPAC name:	**formaldehyde**
Molecular formula:	**C H2 O**
Molecular weight range:	**30.0263**
Trade names	**Formaldehyde solution** **Formalin, formaldehyde, formalith, formol, formic aldehyde, methyl aldehyde, methylene oxide, methanal, oxomethane, oxymethylene, morbicid, paraform, methaldehyde** **Formaldehyde, gas** **Sadeform**

Structural formula:



Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

2.1 Completed or ongoing legislative processes

Formaldehyde is widely addressed in existing and forthcoming legislation, under EU regulation, national legislation, international agreements, etc.

The table below summarizes the completed or ongoing regulatory processes regarding formaldehyde. These processes are then detailed in section 2.2.

Table 2. Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA) other than this RMOA	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		x CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri-ction	☐ Annex XVII
Harmonised C&L	x Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	x Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive ; Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation; Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes/ EU legislation	x Other (see further details below in 2.2)	

2.2 Regulatory Context

The different pieces of legislation on formaldehyde are related to a large range of sectors e.g. industrial chemicals and chemical products, articles, biocides, cosmetics, toys, food, occupational environment, drinking water, environment, etc. This section provides an overview of the various RMOs that are currently in place, or are likely to be implemented, to control the emissions and exposure to formaldehyde.

2.2.1 EU General Regulation

2.2.1.1 REACH Regulation

Under REACH Regulation EC/1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals, formaldehyde is submitted to the

requirement of **Registration** of production, import and uses since it is a HPVC (high production volume chemical) with a tonnage band of 1,000,000 tonnes + per year. Formaldehyde has been registered under REACH with both full and intermediate dossiers:

- One joint submission with a full registration dossier;
- One individual submission with an intermediate registration dossier (on-site isolated intermediate).

Additionally, formaldehyde was included in the list of substances included in the CoRAP (Community Rolling Action Plan) in 2013 on the grounds of human health concerns (CMR), worker exposure and wide dispersive use as well as high aggregated tonnage. The **Substance Evaluation** was taken in charge jointly by France and the Netherlands as evaluating Member States: the SEv performed by France addressed concerns for workers exposure to formaldehyde and was achieved in 2014 and the SEv performed by The Netherlands is still ongoing and focuses on consumer exposure to formaldehyde. As already mentioned, the FR SEv is the starting point for this RMOA.

To date, formaldehyde is neither identified as a **SVHC** for authorisation nor restricted under **Annex XVII** of REACH Regulation (list of restrictions).

2.2.1.2 CLP Regulation

Formaldehyde is classified under Regulation EC/1272/2008 on classification, labelling and packaging of substances and mixtures at European level (CLP harmonized classification). As indicated below in section 3.1, formaldehyde is classified **Acute tox.3, H301; Acute tox. 3, H311; Skin Corr. 1B, H314; Skin Sens. 1, H317; Acute Tox. 3, H331; Mut. 2, H341; and recently reclassified from Carc. 2 to Carc. 1B, H350 (to be implemented in 2015)**. This recent reclassification Carc. 1B may lead to further regulation e.g. identification as a SVHC substance and possible inclusion on Annex XIV or lead to restrictions on consumer use of formaldehyde. CLP Regulation doesn't provide *per se* any exposure limit value nor require specific exposure control. However, it makes CMR substances eligible to the provisions of other legislation aiming at controlling exposure such as Directive 2004/37/EC and Directive 98/24/EC on the protection of workers from the risks related to exposure to carcinogens and chemicals at work. As a direct consequence of the reclassification as Carc. 1B, formaldehyde will be subject to control under the Carcinogens and Mutagens Directives (CMD) (see below for further details).

According to the CLP regulation, companies putting chemical substances or chemical mixtures on the EU market are obliged to notify the classification they apply for the substances to ECHA. There are around **3,800 notifications** available for formaldehyde on the CLP inventory database corresponding to 68 aggregated notifications[1].

[1] ECHA website consulted on December the 7th 2015: http://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/55163

At international level:

- formaldehyde was classified by the International Agency for Research on Cancer (IARC) in 2004 as carcinogenic to humans (group 1) and reaffirmed as such in 2009.
- in 2011, formaldehyde was classified by the US Department of Health and Human Services' National Toxicology Program (NTP) as a "known human carcinogen" (NTP, 2011).
- in 2012, Safe Work Australia updated the entry in HSIS () for formaldehyde to reflect recommended changes in classification with an update from carcinogen category 3 (limited evidence of a carcinogenic effect) to category 2 (may cause cancer by inhalation) (TNO/RPA, 2013).

2.2.1.3 EU RAR and Annex XV transitional report

No EU RAR (Risk Assessment Report) or Annex XV transitional report has been developed for formaldehyde.

2.2.2 EU sectorial regulations on substances and products (professionals and consumers)

For information, formaldehyde is widely covered by products consumers regulations. The sectorial regulations on substances and products addressing formaldehyde are indicated below while this uses are described in section 4.2.

2.2.3 EU Regulation addressing workers exposure

2.2.3.1 Chemical Agents Directive (CAD) and Carcinogens and Mutagens Directive (CMD)

The EU acquis principles of worker protection are laid out in the over-arching OSH 'Framework Directive', which establishes duties on employers and workers to identify and manage workplace risks – including by prevention.

Made under the Framework Directive, Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (Directive "CAD") and Directive 2004/37/EC on carcinogens or mutagens at work (Directive "CMD") aim at protecting workers from chemical risks at the workplace. They are written in a "goal setting" approach with general principles (see next, on the employers' obligations). They set minimum requirements to protect and prevent workers from health and safety risks which might arise from exposure to chemicals (for Directive 98/24/EC) and to carcinogens or mutagens specifically (for Directive 2004/37/EC). They may lay down limit values of exposure (namely Occupational Exposure Limits Values – OELs) and recommend the implementation of very similar risk management measures (RMMs) in order to control the risk at the workplace.

Another specification of CAD is the prohibition on the production, manufacture or use at work under Annex III of the CAD which specifies concentration limits above which certain chemical agents and activities involving chemical agents are

prohibited. Member States may permit derogations from these prohibitions in special circumstances. Currently, only 4 substances are on this list[2].

2.2.3.1.1 Directive CAD 98/24/EC

Directive CAD 98/24/EC sets indicative or binding occupational exposure limit values (IOELs or BOELs) as well as biological limit values (BLs) at Union level (biological limit values are always binding contrary to OELs). BOELs take account of socio-economic and technical feasibility factors as well as the factors considered when establishing IOELs. For any chemical agent for which a BOEL is established at EU level, Member States must establish a corresponding national BOEL which can be stricter, but cannot exceed the Union limit value. "Indicative" means that Member States are free to follow or not the proposed value when transposing it into national laws.

The legal status of IOELs derives from the CAD and are implemented through the IOELs Directives. Discussions regarding an IOEL for formaldehyde were first conducted by SCOEL (Scientific Committee on Occupational Exposure Limits) between 2005 and 2007; **in 2008, SCOEL recommended an 8-hr TWA OEL of 0.2 ppm or 0.2 mg/m^3 and a short term OEL (15 minutes value – STEL) of 0.4 ppm or 0.5 mg/m^3.** These values are indicative OELs. The same year, formaldehyde was included on a draft list of 20 substances to be included in the 3rd IOEL Directive (2009/161/EC) establishing a third list of IOELs in implementation of the CAD. Inclusion of formaldehyde in the 3rd IOEL Directive was aimed at aligning the OELs for formaldehyde throughout the EU. In spite of the Advisory Committee on Safety and Health at Work opinion, formaldehyde was not included in the published 3rd IOEL Directive (2009/161/EC). One reason put forward was that a human (rather than animal) study conducted by the European Panel Federation and Formacare was due for completion in 2011 (Hexion Specialty Chemicals, 2009). It is also known that the UK Health and Safety Executive proposed to remove formaldehyde from the 3rd IOEL Directive in 2008 following objections from the wood-based panels (WBP) industry (HSE, 2008). Finally, formaldehyde is not currently subject to an IOEL.

Employers' obligations

Employers must determine whether any hazardous chemical agents are present at the workplace and assess any risk to the safety and health arising from their presence taking into account any necessary information (hazard properties, exposure measurements, existing OELs or biological limit values, effectiveness of any preventive measure, etc.) and all uses including those expected with higher exposure such as maintenance. Risk assessment shall be documented in a suitable form according to national law and practice and kept up to date. In the case of activities involving exposure to several hazardous chemical agents, the overall risk must be assessed on the basis of risks presented by all chemical agents in combination.

Employers are required to ensure that the risk from hazardous chemical agents is eliminated or reduced to a minimum. To this purpose, substitution shall by preference be undertaken. When substitution is not possible, employers shall ensure that the risk is reduced to a minimum by the application of protection and prevention measures, including in order of priority:

[2] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01998L0024-20140325&from=EN

- design of appropriate work processes and engineering controls and use of adequate equipment and materials, so as to avoid or minimise the release of hazardous chemical agents,
- application of collective protective measures at the source of the risk, such as adequate ventilation and appropriate organizational measures,
- where exposure cannot be prevented by other means, application of individual protective measures including personal protective equipment.

Such measures shall be accompanied by health surveillance if it is appropriate to the nature of the risk. When an indicative or binding OEL value established on the territory of a Member State has been exceeded, the employer shall immediately take remediation by carrying out preventive and protective measures. Training of workers is also requested from employers.

Member States' obligations

For any chemical agent for which an indicative OEL value is established at Union level, Member States must establish a national OEL value (informal or binding depending on the willingness of the Member State) taking into account the Union limit value at the minimum requirement. Any chemical agent for which a binding OEL or biological limit value is established at Union level, Member States must establish a corresponding national BOEL or BL that does not exceed the Union limit value but can be stricter. Member States shall introduce arrangements for carrying out appropriate health surveillance of workers. Where a binding biological limit value has been set, health surveillance shall be a compulsory requirement for work with the hazardous chemical agent in question.

2.2.3.1.2 Directive CMD 2004/37/EC

Directive CMD 2004/37/EC is the codified version of former Directive 90/394/EEC on the Protection of Workers from Risks to Exposure to Carcinogens and Mutagens at Work. The Directive sets BOELs for substances which met the criteria as carcinogen or mutagen according to Annex I of the CLP. Contrary to Directive 98/24/EC, OELs are always binding. As soon as a chemical agent enters in the material scope of the CMD, it is not legally possible to establish an OEL for that agent on the basis of the CAD. For any carcinogen or mutagen for which a BOEL is established at European level, Member States must establish a corresponding national BOEL that does not exceed the Union limit value but can be stricter.
As a direct consequence of the recent classification as Carc. 1B, formaldehyde is subject to control under the CMD Directive, being part of the current consideration for BOELs among other 25 candidate substances (Wriedt, 2012). To date, **no BOELV for formaldehyde has been adopted at EU level**.

Employers and Member States obligations are similar to those required in Directive 98/24/EC.

The Directive also recommends substitution as a priority otherwise encourages to avoid exposure or to keep it as low as possible and below the binding limit that is set. Employers are required to "reduce the use of a carcinogen or mutagen […] in particular by replacing it, in so far as it is technically possible by a substance, preparation or process which, […] is not dangerous or is less dangerous to workers […]". "Workers exposure must be prevented when the results of the assessment reveal a risk to worker's health or safety". "Where it is not technically possible to replace the carcinogen or mutagen by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen or mutagen is, in so far as is technically possible, manufactured and used in a closed system".

"Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible".

At any time, the Commission can make a proposal for setting BOEL under CMD Directive especially when a limit value has already been recommended by the SCOEL.

BOELs are somehow different than workers DNELs as they are adjusted to the technical feasibility of European companies and Member States in order to ensure an harmonized implementation in Europe. Socio-economic aspects are taken into consideration whatever the status of the value is (especially for binding OEL). Setting an OEL in the existing legal framework is always a tripartite agreement with representatives of Employers, workers trade unions and Governments, that allow its social acceptance and thus facilitate its implementation.

2.2.3.1.3 OELs and formaldehyde: state of the art

National OELs in the EU

Although no BOELV for formaldehyde exists to date at EU level, a number of Member States have already set formal national OELs for formaldehyde. Since they are part of national legislation, these OELs may be different across European countries in relation to the legal or advisory framework which affects the way the limit is interpreted and applied. In addition, the legal duties imposed may vary.

As defined in Danish EPA survey (2013), an OEL 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. OEL values implemented in different European countries for formaldehyde emissions in air are presented in the table below.

Table 3. OELs for formaldehyde in place in European countries

Country	OEL (8h) (mg/m^3) reported in GESTIS database (consulted in January 2016)	OEL (short term) (mg/m^3) reported in GESTIS database (consulted in January 2016)
UK	2.5 (2 ppm)	2.5 (2 ppm)
Ireland	2.5 (2 ppm)	2.5 (2 ppm, 15 min)
Sweden	0.37 (=0.3 ppm)	0.74 (0.6 ppm, ceiling limit)
Hungary	0.6	0.6
France	0.5 ppm	1 ppm
Austria	0.6 (0.5 ppm)	0.6 (0.5 ppm)
Germany	0.37 (0.3 ppm)	0.74 (0.6 ppm, 15 min)
Poland	0.5	1
Latvia	0.5	
Switzerland	0.37 (0.3 ppm)	0.74 (0.6 ppm)
Spain		0.37 (0.3 ppm)
Finland	0.37 (0.3 ppm)	1.2 (1 ppm, ceiling)
Denmark	0.4 (0.3 ppm)	0.4 (0.3 ppm)

Belgium		0.38 (0.3 ppm)
The Netherlands	0.15	0.5

TWA: time-weighted average
STEL: short-term exposure limit

SCOEL IOEL recommendation under revision

As mentioned above, in 2008, SCOEL recommended an 8-hr TWA value of 0.2 ppm (or 0.2 mg/m^3) and a 15-min STEL of 0.4 ppm (or 0.5 mg/m^3).

In March 2015, SCOEL discussed about the possibility of revising its 2008 recommendation. In April 2015 then, SCOEL was formally requested by the European Commission to reconsider its 2008 recommendation on formaldehyde based on potentially new scientific data.

On the basis of the latest available scientific data the Commission services request to SCOEL in accordance with Commission Decision 2014/113/EU to:

a) Review all available and specifically the latest scientific data regarding formaldehyde.
b) Identify and describe formaldehyde such that Recommendation(s) for e specific chemical agent can be established.
c) Assess whether this is a hazardous chemical agent in accordance with Article 2 (b) of CAD and/or a carcinogen and/or mutagen in accordance with Article 2(a) and (b) of CMD.
d) Identify and describe all exposure routes of concern for workers.
e) By taking into account all available information, evaluate the health effects of formaldehyde and the level of occupational exposure and develop Recommendation(s) for OEL(s), biological limit value(s)/biological guidance values and appropriate notations and/or scientific Opinion(s) which shall be supported and explained in detail by information on the basic data, a description and explanation of the critical effects and the extrapolation techniques used and any data on possible risks to human health.
f) Assess the feasibility of monitoring exposure of the chemical agent concerned at any proposed OEL based on a description of possible approaches. This should include information on sampling techniques, sample preparation and measurement methods as well as the validity of the approaches.
g) Identify any lack of specific scientific information, which may be necessary for the evaluation of risks associated to health hazards of formaldehyde and inform the Commission services accordingly.

Late November 2015, SCOEL finally proposed an upward revision of its OEL at 0.3 ppm (long-term exposure) and 0.6 ppm (short-term exposure) and launched a public consultation[3] on this proposal until February 17th 2016:

[3] https://circabc.europa.eu/sd/a/d44aedf4-8e61-47b4-96c6-91a6ff3139f7/2015-11-16v11%20REC-125%20Formaldehyde%20stage%2040.20.pdf

8-hour TWA:	0.3 ppm (0.369 mg/m3)
STEL:	0.6 ppm (0.738 mg/m3)
BLV:	-
Additional categorisation:	SCOEL carcinogen group C (genotoxic carcinogen with a mode-of action based threshold)
Notation:	-

From DNELs to OELs

ECHA (2012) notes that when an EU IOEL exists, the registrant may, under certain conditions, use the IOEL in place of developing a DNEL. Where DNELs differ from OELs (especially those recommended by the SCOEL), this could potentially lead to short-term confusion if these diverging values are not substantiated by existing new data for example.

In any case, the Table 3 shows that different OELs are in place in European Countries.

2.2.3.2 Other workplace EU legislation

In addition to the OEL legislation, risk at workplace arising from exposure to hazardous substances may also be managed at European level by the following Directives related to the protection of occupational safety and health. They impose minimum standards for health and safety of workers and provide a framework of directions and safeguards to ensure that the occupational risk to health from hazardous substances is controlled. These Directives do not specifically address formaldehyde, but cover it indirectly regarding its classification as a hazardous substance. They are:

- ***Directive 89/656/EEC*** lays down minimum requirements for **personal protective equipment (PPE)** used by workers at work. PPEs must be provided by the employers and used by the workers when the risks cannot be avoided or sufficiently limited by technical means of collective protective equipment or procedures of work organization. Before choosing personal protective equipment, the employer is required to assess whether the PPE he intends to use satisfies the requirements of this Directive and Member States shall ensure that general rules are established for the use of PPE and/or covering cases and situations where the employer must provide such equipment.
- ***Directive 92/85/EC*** (**pregnant workers Directive**) introduces measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC); This type of workers is considered as more vulnerable therefore they are subject to particular treatment at the workplace e.g. when some types of activities may pose a specific risk of exposure to dangerous agents or work at night which might jeopardize their safety and health.
- ***Directive 94/33/EC*** (**young workers Directive**) lays down minimum requirements for the protection of young people at work. Member States shall take the necessary measures to prohibit work by children and shall ensure that the minimum working or employment age is not lower than the minimum age at which compulsory full-time schooling - as imposed by national law - ends or 15 years in any event. This Directive shall apply to

any person under 18 years of age having an employment contract or an employment relationship defined by the law in force in a Member State and/or governed by the law in force in a Member State. Exceptions can be adopted by Member States for occasional work or short-term work, involving domestic service in a private household or work regarded as not being harmful, damaging or dangerous to young people in a family undertaking.

Additionally to these pieces of legislation, ***Seveso III Directive 2012/18/EU*** on the control of major-accident hazards involving dangerous substances (ex-Directive 96/82/EC) addresses risks for workers as well as risks for the general population located around sensitive industrial sites. The Seveso III Directive aims to control major-accident hazards involving dangerous substances and lays down rules for the prevention of major accidents which might result from certain industrial activities and the limitation of their consequences for human health and the environment. It imposes requirements for industrial sites which use substances identified as dangerous such as formaldehyde. Under this Directive, formaldehyde (concentration ≥ 90%) is submitted to a lower-tier requirement for the sites using a minimal quantity of 5 tons and an upper-tier requirement for the sites using a minimal quantity of 50 tons (Annex I, part 2 of the Directive).

2.2.4 EU Regulation addressing emissions to environment

2.2.4.1 IED (ex-IPPC) Directive

EU legislation targeted on environment protection may also indirectly reduce occupational exposure to a limited extent. **Directive 96/61/EC concerning integrated pollution prevention and control (IPPC Directive)** is primarily focused on the reduction of impact from human activities to the environment. As such, its primary use is as a tool to ensure environmental protection and to reduce risks for humans indirectly exposed via the environment, rather than directly to ensure worker protection. Emission limit values to the environment are based on Best Available Techniques (BAT) that is published by the Commission as IPPC BAT Reference Documents (BREFs). BREFs and their BAT conclusions continue to serve as the reference at the EU level concerning the techniques to control/reduce environmental emissions and indirectly exposure at work.

The IPPC Directive (along with several other sectoral Directives such as the Volatile Organic Compounds – VOC – Directive 1999/13/EC) has been replaced on 7 January 2014 by **Directive 2010/75/EU on Industrial Emissions (IED)**, which maintains the same principles, while strengthening the requirements concerning the application of BAT. IED aims to limit emissions of VOCs in certain activities and installations (listed in Annex VII of the Directive) and to prevent or reduce the direct and indirect effects of emissions of VOCs on the environment and human health, by setting emission limits for such compounds and laying down operating conditions for installations using organic solvents. For example, Annex VII includes activities such as adhesive coating, coating activity, manufacturing of coating mixtures, varnishes, inks and adhesives, wood impregnation, wood and plastic lamination. Member States are required to take the necessary measures to ensure that all new installations comply with the provisions of the Directive. Table 5.5 provides limit values applicable to various industrial activities of relevance. Industrial operators concerned can conform to the specified emission limits in either of the following ways: i) by installing equipment to reduce emissions to comply with the emission limit values and the fugitive emission values, or total emission limit values; or ii) by introducing a reduction scheme (specially designed for a particular installation) to arrive at an emission level that is less than or equal to the target emission, in particular by

replacing conventional products which are high in solvents with low-solvent or solvent-free products (TNO/RPA, 2013).

Although this is not their primary purpose, the technologies defined in BREFs should also have an impact on the reduction of risks for workers, consumers and population in general by lowering exposure.

The BREFs applicable for/mentioning formaldehyde and developed under the IPPC Directive and the IED are[4]:

- The 2007 BREF on Surface Treatment Using Organic Solvents (including Wood and Wood Products Preservation with Chemicals): this BREF addresses installations for the surface treatment of substances, objects or products using organic solvents, in particular for dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning or impregnating
- The 2014 BREF on the production of Wood based-panels
- The 2007 BREF on the ceramics manufacturing industry: this BREF covers industrial installations for the manufacture of ceramic products by firing stoneware and porcelain
- The 2003 BREF on Common Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector: This BREF covers the entire chemical sector and provides information on aqueous and/or gaseous releases from chemical installations. Since there are numerous options for waste water and/or waste gas treatment in the chemical sector, this BREF is restricted to those techniques that are 'commonly' used or applicable. Another focus of this BREF is waste water and waste gas management as part of operational management
- The 2006 BREF on Food, Drink and Milk Industries: This BREF addresses activities for the treatments and processes intended for the manufacture of food products from animal raw materials (other than milk), vegetable raw materials and treatment and processing of milk
- The 2003 BREF for Intensive Rearing of Poultry and Pigs
- The 2011 BREF for Iron and Steel Production
- The 2006 BREF for Large Combustion Plants
- The 2007 BREF on the Manufacture of Large Volume Inorganic Chemicals: Ammonia, Acids and Fertilizers
- The 2003 BREF on Large Volume Organic Chemical Industry
- The 2011 BREF on the Manufacture of glass
- The 2006 BREF on Organic Fine Chemicals
- The 2001 BREF on Non Ferrous Metals Industries
- The 2007 BREF on polymers: this BREF focuses on the production of polymeric materials in plants on an industrial scale such as basic plastic materials (synthetic fibers and cellulose-based fibers), synthetic rubbers, hydrocarbons containing oxygen such as alcohols, aldehydes, ketones, carboxylic acids, esters, acetates, ethers, peroxides and epoxy resins
- The 2013 BREF on Production of Pulp, Paper and Board
- The 2013 BREF on Refining of Mineral Oil and Gas
- The 2005 BREF on Slaughterhouses and Animal By-products Industries
- The 2005 BREF on Smitheries and Foundries Industry
- The 2006 BREF on Surface Treatment of Metals and Plastics
- The 2013 BREF on Tanning of Hides and Skins
- The 2003 BREF on Textiles Industry
- The 2006 BREF on Waste Treatments Industries

[4] All these BREFs are available on http://eippcb.jrc.ec.europa.eu/reference/

Current BREFs' recommendations are normally implemented by Industry. Registration dossiers under REACH should reflect the on-sites situation.

It has to be noted that the IED Directive targets "the use of organic solvents". To this respect, the VOC-related aspects of IED Directive might not apply to some uses of formaldehyde, where formaldehyde is used as a resin and does not qualify under the definition of an organic solvent as defined in Article 3-46 of the Directive[5].

The impact of recent reclassification of formaldehyde as Carc. 1B on the IED should be minimal. The definition of BREFs is already a requirement for formaldehyde under its previous classification (Carc.2 H351). Therefore the reclassification is not expected to bring any substantial changes to the existing BREFs.

2.2.4.2 Environmental Quality standards

Directive 2008/105/EC on environmental quality standards in the field of water policy lays down environmental quality standards (EQS) for priority substances and certain other pollutants as provided for in Article 16 of Directive 2000/60/EC (Water Framework Directive), with the aim of achieving good surface water chemical status. The EU Member States shall apply the EQS laid down in Annex 1 for bodies of water.

To date, formaldehyde is not listed in Annex 1 of the EQS Directive and no European regulatory EQS exists for this substance. In 2011, INERIS made recommendations in the framework of the Water Framework Directive 2000/60/EC to establish NQE for formaldehyde. $NQE_{surface\ water}$=10µg/L; $NQE_{marine\ water}$=1µg/L)[6].

The EQS Directive and the WFD cover environmental compartments only. They are thus not further assessed then since they are out of the scope of this RMOA.

2.2.5 Regulation addressing waste management

Due to its CLP classification, formaldehyde-containing wastes fall under Waste Framework Directive. Additionnally, formaldehyde is covered by Basel Convention under item B3010 – Solid plastic wastes / cured waste resins or condensation products (including urea formaldehyde resins, phenol formaldehyde resins and melamine formaldehyde resins) and international Basel Convention while this uses are described in section 4.2. WFD Directive and Basel convention cover waste management only. They are thus not further assessed then since they are out of the scope of this RMOA. Indeed, it should be noted that exposure of workers during life cycle or recycled product containing formaldehyde are not covered by this RMOA as no data were available on that topic and it is judged highly unlikely that workers might be exposed at this stage of the life cycle (see 4.2.2.2 for further explanation).

[5] Article 3-46 states that : 'organic solvent' means any volatile organic compoundwhich is used for any of the following: (a) alone or in combination with other agents, and without undergoing a chemical change, to dissolve rawmaterials, products or waste materials; (b) as a cleaning agent to dissolve contaminants; (c) as a dissolver; (d) as a dispersion medium; (e) as a viscosity adjuster; (f) as a surface tension adjuster; (g) as a plasticiser; (h) as a preservative;

[6] http://www.ineris.fr/substances/fr/page/9

2.2.6 Targeted and prioritized Lists

formaldehyde is listed on the 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) is available for formaldehyde (OECD SIDS, 2002).

Formaldehyde is also included in the following lists:

- It is included as a substance in the SIN-list database developed by the Chemical Secretariat (ChemSec)[7]. The SIN-list includes substances which are identified by ChemSec as fulfilling the criteria for SVHC as defined in the REACH Regulation.
- It is included in the PRIO-list[8] developed by KEMI which is a web-based tool intended to be used to preventively reduce risks to human health and the environment from chemicals
- It was included on the LOUS list in 2009 by the Danish EPA based on its classification as Carc. 2 (H351) (now 1B) and because formaldehyde is applied on the Danish market in a quantity > 100 tonnes (Danish EPA, 2014)

Finally, formaldehyde has been recently prioritized by RIVM as a NERC priority 1 (new and emerging risk chemical) for workers in aluminium production (RIVM, 2015) on the basis of nose bleeding of workers after exposure to formaldehyde, also reported in BfR (2010), AFSSAPS (2010) and NIOSH HHE (2011).

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

The description of hazard information is based on the evaluation performed by France during substance evaluation process.

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

The harmonised classification of formaldehyde under CLP Regulation is summarized in the Table below. The classification of formaldehyde as Carc. 1B has entered into force on 1st January 2016. To date, no other proposal for CLH has been submitted.

Table 4. Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors
				Hazard Class and Category Code(s)	Hazard state-ment code(s)	
605-001-00-5	**formaldehyde … %**	200-001-8	50-00-0	**Acute Tox. 3 ***	**H301**	Eye Irrit. 2; H319: 5% ≤ C < 25% STOT SE 3; H335: C ≥ 5%
				Acute Tox. 3 *	**H311**	

[7] http://sinlist.chemsec.org/keywords/50-00-0 (search on september the 15th 2015)
[8] http://www2.kemi.se/templates/PRIOEngframes____4144.aspx

				Skin Corr. 1B	**H314**	Skin Irrit. 2; H315: 5% ≤ C < 25% *
				Skin Sens. 1	**H317**	
				Acute Tox. 3 *	**H331**	Skin Corr. 1B; H314: C ≥ 25%
				Muta. 2	**H341**	Skin Sens. 1; H317: C ≥ 0,2%
				Carc. 1B	**H350**	

Skull and crossbones Corrosion Health hazard

3.1.2 Self classification

The following hazard classes are notified among the aggregated self classifications in the C&L Inventory:

Eye Dam. 1	H318
Carc. 2	H351 (Inhalation)
Resp. Sens. 1	H334
STOT SE 3	H335 (Lungs)

3.1.3 CLP Notification Status

Table 5. CLP Notifications

	CLP Notifications[9]
Number of aggregated notifications	73
Total number of notifiers	About 3,800

3.2 Hazard information

This is a summary of the toxicological data taken from the FR SEv Report (2014).

Skin and eye irritation/corrosion

Aqueous solutions of formaldehyde like formalin (40%) induced skin corrosion in rabbits. Skin irritant effects are expected at concentrations > 3%. No studies according to current guidelines are available on eye irritation; however, formaldehyde has corrosive properties (no testing required). There is evidence that sensory eye irritation in humans due to exposure to gaseous formaldehyde is

[9] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed April 2016)

the most sensitive endpoint. From experimental studies with volunteers, it is concluded that the NOAEC for subjective and objective sensory eye irritation was 0.5 ppm in case of a constant exposure level and 0.3 ppm with peaks of 0.6 ppm.

Sensitisation

There is sufficient evidence for sensitizing properties of formaldehyde in the guinea pig maximisation test (GPMT), in the Buehler test in guinea pigs and in the mouse local lymph node assay (LLNA). Formaldehyde is also a dermal allergen in humans. Anaphylaxis has been documented in case reports. The threshold in sensitized humans under occluded test conditions was estimated to be 3 µg/cm². In non-sensitzised humans a threshold of 0.037% corresponding to 37 µg/cm² has been determined for induction of skin sensitization.

Repeated dose toxicity

In experimental studies, formaldehyde induces toxic effects only at the site of first contact after oral, dermal or inhalation exposure. General signs of toxicity occur secondary to these local lesions.

In chronic drinking water studies in rats, local effects in the forestomach and stomach were induced. For systemic effects the NOAEL is >= 82 mg/kg bw/day in males and 109 mg/kg bw/day in females.

Local effects in the upper respiratory tract were induced after repeated inhalation exposure in experimental animals. The most sensitive site in rodents and monkeys is the respiratory epithelium in the anterior part of the nasal cavity. At higher dose levels, the olfactory epithelium, larynx or trachea were also affected, especially in monkeys. Rats are more sensitive than mice or hamsters. The LOAEC is 2 ppm in rats (2.4 mg/m³), 3 ppm in monkeys and 6 ppm in mice. The overall NOAEC in experimental animals for local effects is 1 ppm (1.2 mg/m³). The NOAEC for systemic effects in long-term inhalation studies in rats and mice is 15 ppm.

Mutagenicity

In vivo, positive evidence in mutagenicity tests are available from induction of chromosomal aberrations in rats by inhalation at high dose and of micronuclei in rats in the GI tract by oral route.
These positive data are further supported by:
- *in vitro* positive results in numerous genotoxicity and mutagenicity tests,
- *in vivo* induction of DNA adducts and DNA protein cross-links at the site of contact,
- indications of consistent increases in micronuclei frequency in humans at the site of contact.

Carcinogenicity

No convincing evidence of a carcinogenic effect of formaldehyde via oral route is available.

By inhalation, the carcinogenicity of formaldehyde is well established in rats with the induction of tumours at the site of contact. The results from epidemiological studies show an increased risk of cancer: there is evidence from the NCI cohort and from several case-control studies that formaldehyde induce nasopharyngeal cancers. Based on experimental data, the biological plausibility of the induction of nasopharyngeal carcinomas in humans exposed to formaldehyde highly supports the epidemiological evidence. On this basis, RAC recommended to classify formaldehyde Carc. 1B – H350.

As additional details, in the EU, formaldehyde is one of the 10 carcinogenic substances to which the largest numbers of workers are currently exposed. Still, the incidence estimates of nasopharyngeal cancers in the EU-28 countries, as a result of past exposure to carcinogenic substances at work, is relatively low. The absolute incidence is comprised between 60 and 1,200 with a central estimate of 280, with a ten times higher rate in men, making occupational nasopharyngeal cancers incidence the 21st on 24 occupational cancers incidences (RIVM, 2016). Considering the mortality trends, significant declines in both genders were observed in some countries in Europe between 1970 and 2013 (Czech Republic, France, Germany, Malta, Nordic countries, Slovakia, Spain and Scotland, England and Wales in UK). Nevertheless, it is impossible to impute the part of formaldehyde exposure solely, as other factors trigger nasopharyngeal cancers such as wood dust.

The correlation between formaldehyde exposure and leukaemia, especially myeloid leukaemia, is still hypothetic. Carcinogenicity studies by inhalation did not highlight any significant increase of leukemia in treated animals. According to the current understanding, a risk for potential induction of haemopoietic cancers by formaldehyde may be regarded unlikely in humans at doses that do not saturate local detoxification at the site of first contact. This is supported by results from long-term studies in rats after inhalation exposure, which provide no firm indication that formaldehyde is able to induce neoplasms of the haemotopoeitic system in animals.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

Dissemination site accessed in December 2015.

4.1 Tonnage and registration status

Formaldehyde has been registered under REACH with both full and intermediate(on-site insolated) dossiers.

Formaldehyde has been registered with a high tonnage band (> 1,000,000 tpa). It is identified at European level as a HPVC (high production volume chemical).

Table 6. Tonnage and registration status

From ECHA dissemination site		
x Full registration(s) (Art. 10)	x Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
x 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential

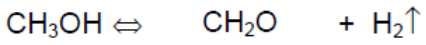
No data on import or export of formaldehyde was available at the time of the drafting fo this RMOA.

4.2 Overview of uses

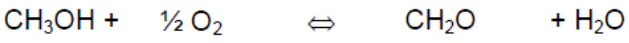
4.2.1 Manufacture of formaldehyde

Formaldehyde is technically produced as an aqueous solution by oxidative dehydrogenation of methanol with air via either a silver (for one half) or metal-oxide (the other half) catalyst process (Afsset, 2009; RPA/TNO, 2013):

- Partial conversion (via a silver catalyst heated from 600°C to 720°C):



- Total conversion (via a metal-oxide catalyst – iron, vanadium, molybdène) heated from 270°C to 380°C):



Formaldehyde production accounts for approximately 1/3 of global methanol demand.

In the EU, formaldehyde is usually manufactured, used and commercialized as an aqueous formaldehyde solution, known as **formol or formalin**, which usually does not contain more than 3% methanol or more than 10-15% depending on the source of information. Formaldehyde is commonly not produced in its pure form due to the fact that it is not stable in this form. Formal or Formalin is usually produced with 30% to 50% of formaldehyde. **Available data on the production and use of formaldehyde provided below mainly refer to a 37% formaldehyde solution (unless otherwise stated).**

Formaldehyde is also commercialized in a polymerized or solid form (Afsset, 2009):

- **paraformaldehyde** (polymer) in the form of powder or white crystals with a concentration of 90% to 93% of formaldehyde and up to 10% water;
- **trioxane** (trimer) in the form of solid crystal.

The manufacturing of formaldehyde such as described in the REACH registration dossier is presented in (confidential) Annexes A & B (use descriptors, related manufacturing processe and registered uses).

In 2010, 29 million tonnes of formalin (37% formaldehyde) were produced globally, of which Europe accounted for 23% (6.7 million tonnes) as the second largest producer after Asia (50%). The world production capacity of Formalin is 40 million tonnes per year of which Europe represents around 25% with a production capacity of 9.5 million tonnes per year (Merchant Research and consulting, 2012, quoted in RPA/TNO, 2013). In 2013, ICF reported an EU production of over 7 million tonnes of Formalin (ICF, 2013). In 2009, Formacare reported a production of formaldehyde of 3.6 million tonnes (100% formaldehyde) be it around 30% of global production. The Figure[10] below

[10] http://www.formacare.org/about-formaldehyde/eu-market/

presents the location of the 61 production sites of formaldehyde in the EU in 2015 (22 Member States in 28).

Figure 1: The EU production sites of Formalin in 2015

Within Europe, Germany is the biggest manufacturer of Formalin with a production of 2.2 million tonnes per year in 2010 which stands respectively for 33% of European production capacity and 7.5% of the global production capacity. Germany is followed by Italy, Spain, the Netherlands and the UK (Formacare, 2010; ICF, 2013).

Table 7. Main Manufacturers and production volumes of Formalin in Europe in 2013

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, Portugal	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
TOTAL	**5.7 million tonnes**

Source : Danish EPA, 2014 (information retrieved from www.export.by, 2013)

Table 8. Production capacity of Formalin in Europe in 2010

Country	Production volume (thousand tonnes)	Production capacity (thousand tonnes)
Austria	140	175
Belgium	232	290
Bulgaria	24	30
Denmark	92	115
Finland	128	160
France	44	54
Germany	1,716	2,145
Hungary	48	60
Ireland	64	80
Italy	736	919
Lithuania	86	107
Portugal	244	305
Spain	660	825
Sweden	432	540
The Netherlands	760	950
UK	372	465
TOTAL	**5.7 million tonnes***	**7.2 million tonnes***

Source : RPA/TNO, 2013
*sums not indicated in RPA/TNO, 2013

4.2.2 Uses of formaldehyde

Formaldehyde is a widespread use substance. It is produced for a very wide range of uses and applications from industrial synthesis of chemicals to general public applications.

At industrial and professional level, formaldehyde is used as :

- An intermediate in chemical synthesis, such as the synthesis of:
  - methylene dianiline (MDA)
  - diphenylmethane diisocyanate (MDI)
  - hexamethylenetetraamine (HTMA - hexamine)
  - trimethylol propane
  - neopentylglycol
  - pentarythritol (for the production of alkyd resins and neopolyol esthers)
  - butanediol (BDO)
  - acetylenic agents
- A starting material in the chemical industry for the production of:
  - condensed resins such as:
    - Urea-Formaldehyde (UF) resins

        - Melamine-Formaldehyde (MF) resins
        - Phenol-Formaldehyde (PF) resins
    - Polyacetal resins (polyoxymethylene – POM)
    - Paraformaldehyde (PFA), the smallest polyoxymethylene
    - Paper for graphism, hygienic, specific applications
    - Textile including printing inks, dyes and textile finishing products
- A reagent and bactericidal agent used in healthcare applications such as tissue preservation, embalming fluids in autopsy rooms and pathology departments, disinfectant in operating rooms, vaccines, animal medicines, etc.
- A preservative, biocidal and cleaning agent in food applications
- A biocidal in germicides, bactericides and fungicides as well as an ingredient in fertilizers in agriculture and non-agricultural sector

In consumers/general public applications, formaldehyde is used (Anses, 2011):

- As a preservative and biocidal agent in detergent, disinfectant and cleaning agent
- As a preservative in cosmetics
- In building and insulating material (such as UF or PF foam insulation)
- In wood-based panels
- As a binding agent in paints and lacquers
- As a binding agent in adhesives
- In human food (food additive and technological auxiliary)
- In vaccines and medicines

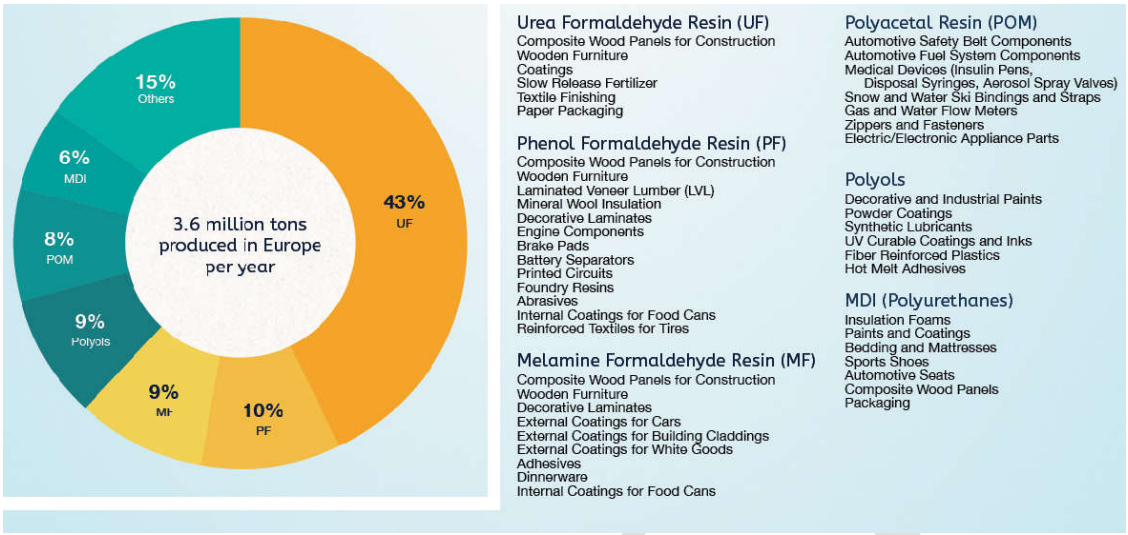
The ECHA dissemination website gives product categories and sectors of use of formaldehyde, summarized in the Table below:

Table 9. Product categories and sectors of use of formaldehyde (ECHA dissemination website)

Product categories	Adhesives and sealants, coating products, cosmetics and personal care products, washing & cleaning products, fuels, biocides, polishes and waxes, polymers, fillers, putties, plasters, modelling clay and inks and toners
Sectors of use	Formulation of mixtures and/or re-packaging and building & construction work. Manufacture of chemicals, plastic products, textile, leather or fur, pulp, paper and paper products, mineral products (e.g. plasters, cement) and rubber products

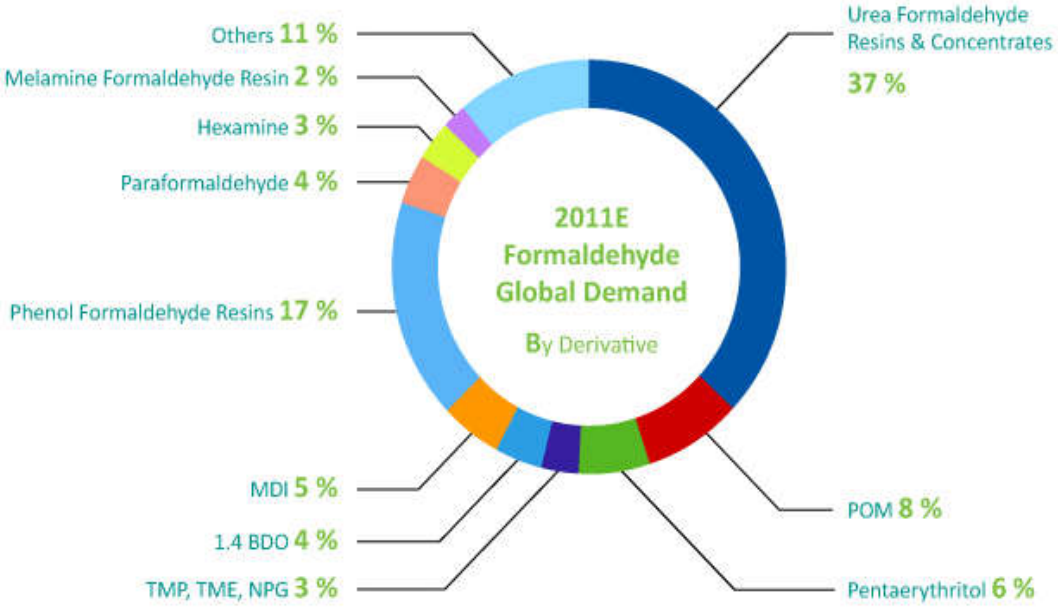
The EU vs. world consumptions of formaldehyde per use are represented in the figures below.

Figure 2. EU consumption of formaldehyde (100%) per use



Source: Formacare (june 2015)

Figure 3. World consumption of formaldehyde per use in 2011



Source: http://www.formacare.org/about-formaldehyde

The flow diagram below provides an overview of the uses and the supply chain for formaldehyde (inspired from ICF 2013, updated and completed).

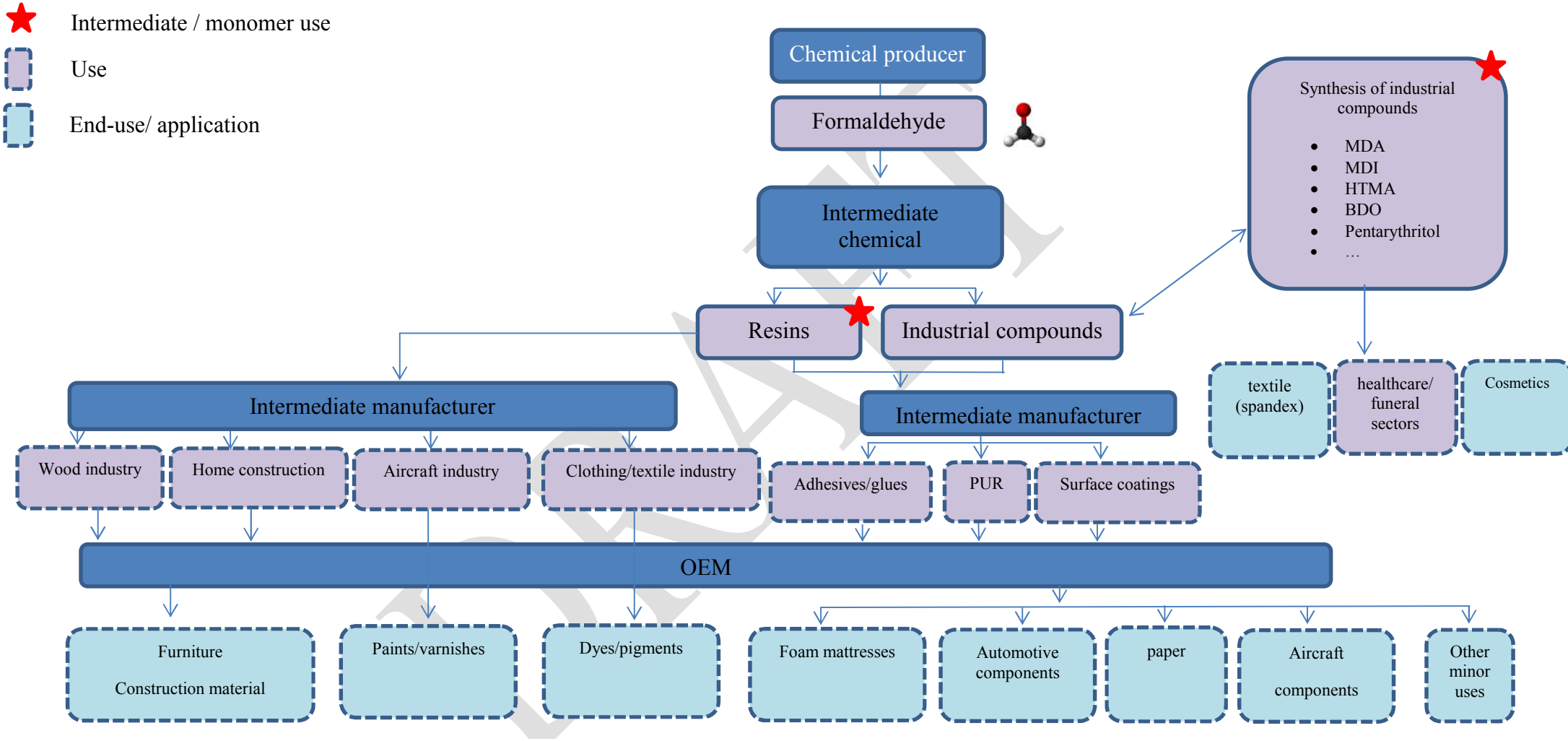


Figure 4. Overview of the uses of Formaldehyde and the corresponding supply chain

PUR: manufacturing of polyurethane (PUR) products

OEM: Original Equipment Manufacturer

4.2.2.1 Industrial and professional uses of formaldehyde

At industrial and professional level, formaldehyde is used as a biocidal, disinfectant, binding, fixing and redox agent.

In the REACH Registration dossier, the industrial and professional uses of formaldehyde are identified and described by the registrants such as presented in (confidential) Annex B.

4.2.2.1.1 Production of formaldehyde-based resins and their specific regulations

As depicted in the Figure 4 above, UF, MF and PF resins are the 3 major commercially-used resins formulated with formaldehyde and the primary use of formaldehyde. **They accounted for about 56% of world consumption** for formaldehyde in 2011 (Formacare, XX) and for 63% of world consumption in 2013 (ICF, 2013). They are "thermosetting adhesives" and are cured through the application of heat and generally with the addition of an acid catalyst, which enhances the polymerization (Formacare, 2007).

Urea-formaldehyde (UF) resins

UF resins are the over-all main use of formaldehyde accounting for about **50% of EU formaldehyde consumption**. The UF resins are primarily used as binders (adhesives) in non-structural wood-based panels (WBP). 80% of the UF resins that are manufactured in the EU are currently used to make building materials such as particle board, PW (plywood), MDF (medium-density fiberboard) and components of melamine-phenolic resins for production of laminated flooring board.

Regarding paper manufacturing, formaldehyde is used to manufacture different types of paper, such as graphic paper (printing paper), hygienic paper (absorbing paper), packaging paper and kraft paper as well as special paper applications requiring security features (passports, bank notes, etc.) (Afsset, 2009).

The table below summarizes the product applications of UF resins

Table 10. Major product applications for UF resins

Category	Material	Applications
Construction Materials and Home Improvement	Composite panels (particleboard, medium density fiberboard)	Cabinets, furniture, flooring, countertops, decorative molding
	Plywood	Furniture, interior finishing
	Fiberglass insulation	Architectural insulation
	Surface coatings (alkyd-urea finishes)	Kitchen cabinets, furniture, lacquers
	Wood Adhesive	Countertops (laminating adhesive)
Molding Compounds	Molded plastic products	Electrical switches, circuit breakers, stove hardware, buttons, housings
Paper Treatment	Coatings, wet strength resins	Coated paper, paper towel, tissue
Textiles	Textile treatment	Finishing compound
Other	Foundry binder, slow release fertilizers	

Source : Formacare, 2007

The European sector of UF resins is flourishing and standed for 11,600 jobs in 2004 with a sales generation of €1.7 bn and a value of raw materials purchased and utilities of €1.1 bn (Formacare, 2007). 55% of UF resin production is done by a few captive integrated producers and the remaining 45% of the market is served by a few non-integrated producers (EU+Norway) (Formacare 2007).

Melamine-formaldehyde (MF) resins

MF resins account for about 10% of EU formaldehyde consumption and are used predominantly as paper impregnating resins for surfacing of panels.

The European sector of MF resins standed for 3,300 jobs in 2004 with a sales generation of €975m and a value of raw materials purchased and utilities of €430m (Formacare, 2007). The supply is provided by many manufacturers among which a few big chemical groups and many other companies which produce MF for captive requirements. Captive consumption amount to approximately 30% of total production.

The table below summarizes the product applications of MF resins

Table 11. Major product applications for MF resins

Category	Material	Applications
Construction Materials and Home Improvement	Paper impregnation and lamination	Countertops, cabinets, furniture, flooring, wall covering, sheathing, automobile interiors
	Wood adhesive	Curved plywood, truck and train car beds, marine grade plywood, interior structural panels
	Ceiling tiles	Ceiling tiles
Surface Coatings	Alkyd, acrylic	Automobile, metal containers and furniture, coil coating
Molding Compounds	Molded plastic products	Dinnerware, knobs, handles, buttons, circuit breakers
Other	Tire cord adhesive, tanning agent, cross-linking agent, water treatment resin, textile finishing agent, coated paper	

Source : Formacare, 2007

Phenolic formaldehyde (PF) resins

PF resins account for about 12% of formaldehyde European consumption. The first trade name for PF was 'Bakelite' invented in 1909. There are two types of PF resins: resols and novolacs. Resols (no cross-linking agent needed) provide hardness and dimensional stability, heat moisture and chemical resistance whereas novolacs (cross linked with HTMA) provide less brittleness and more impact resistance. Equally water-resistant as UF and MF, PF resins are mainly used for insulation binding, wood product applications and paper impregnation.

- 30% of PF resin is demanded for insulation binding. It is one of the main material used to bind fiberglass threads into fiberglass insulation in construction industry
- 30% of PF resin is demanded for wood products applications as a durable binder and adhesive in structural wood panels (20%) and impregnated

paper such as high pressure laminates (10%). High pressure laminates are made of an MF-impregnated decorative sheet coated by several PF(resols)-impregnated paper. The laminated sheet/paper produced is adhered to a substrate material, usually particleboard or plywood and is used for counter-tops, furniture tops, cabinet and drawer faces, wall cladding, automobile interiors, laminated flooring and wall coverings. Additionally to The high thermal stability and fire-resistant properties of PF resins are particularly well-suited to a wide spectrum of uses in the automotive (brake linings, friction material, foundry resins) and electro-industry (printed circuit boards and insulators) (Formacare, 2007).

The European sector of PF resins supported 1,725 jobs in 2004 with a sales generation of €650m and a value of raw materials purchased and utilities of €285m (Formacare, 2007). The market is structured with a few big producers who account for a substantial proportion of the PF resins manufactured and some smaller regional and/or captive suppliers (forest products sector) and a number of producers of specialty phenolics for industrial (non-wood) applications.

The table below gives an overview of the product applications of PF resins.

Table 12. Major product applications for PF resins

Market	Material	Applications
Construction Materials & Home Improvement	Structural panels	Cabinets, furniture, flooring countertops, decorative molding
	Hardboard, molded wood, particleboard	Tabletops, furniture, paneling, door material, flooring, window assemblies
	Fiberglass insulation	Architectural insulation, pipe insulation
Automotive	Decorative laminates	Countertops, cabinets, furniture, flooring, wall covering, sheathing, automobile interiors
	Molding compounds	Under-the-hood components (engine, transmission, brakes)
	Friction materials	Brakes, clutches, automatic transmissions
	Foundry resins	Cast metal parts
Industrial	PF Saturated paper or cloth	Gears, bearings, rings, valves, printed circuits
	Coated and bonded abrasives	Grinding wheels, sand-paper
	Sheet molding, phenolic composites	Train and aircraft interiors, automotive
Coatings	Protective coatings	Food containers, drum linings, storage tanks
Other	Rubber processing chemicals, oil field, phenolic foams	

Source : Formacare, 2007

Polyacetals resins (POM)

Additionally to UF, MF and PF resins, formaldehyde is also used in the production of polyacetal resins.

POM also known as acetal polymers or polyoxymethylene are thermoplastics, they are inherently self-lubricating and are particularly suited to a wide range of applications such as replacing metal parts in many sectors. For example, POM are used in the manufacture of gears, bearings and housings. Gears account for the largest segment across all markets in automobile and industrial products but also in consumer articles and appliances, such as cameras, DVD players and printers. **The demand for polyacetals in Europe is growing and accounts for about 8% of formaldehyde consumption**.

The table below gives an overview of the product applications of POM resins.

Table 13. Major product applications for POM resins

Industrial Applications	
Gears, cams, bearings, levers, pulleys, sprockets, bushings, valves	Gas meters & water flow meters
Chemical mixing screws	Pump impellers
Conveyor systems	Police nightsticks
Fan and blower blades	Pumps and beverage valves
Farm machinery	Sausage presses
Food and dairy machinery	Scaffolding hardware
Automotive Applications	
Automatic transmission parts	Gear selector for automatic gearbox
Car heater plates	Locks, hooks, fasteners, clips, mirror housings
Carburetor floats	Seatbelt systems
Control switches & instrument knobs	Steering column shear pin parts
Door handles, door catches and window cranks	Suspension links
Door module	Tire valve stems
Electrical switch parts	Trunk release levers
Exterior and interior trim	Window transport mechanisms
Fan parts and car ventilation grille	Windscreen washer nozzles
Fuel systems components	Light sockets
Consumer Articles	
Aerosol spray valves	Roller-skate brake supports
Can opener drive train	Mixers and blenders
Cannula disposal unit for dental practices	Pen components
Cell phone cover	Marine fittings, fishing reels
Disposable lighters, lighter bodies	Scrubbing discs on power rug cleaners
Disposable syringes	Sliding mast for windsurfers; parts for surfboards, sailboats, and sailboards
Electric toothbrushes	Snow and water ski bindings and straps
Garage door opener components	Temperature control timer gears
Gears in watches	Utensils and bowls
Gun components and accessories	Zippers
Hospital bed (height adjustment mechanism)	
Plumbing & Irrigation	
Agricultural irrigation systems, turf maintenance sprinkler systems	Garden hose nozzles
Ballcocks, taps, pipe couplings, valve mechanisms	Showerheads
Faucets	Water softener components
Appliances & Power Tools	
Clothes washers and dryers	Kitchen appliances
Dishwashers	Laser welding
Fans and vacuum cleaners	Paint sprayer parts
Garden chemical sprays and tools	Powered craft tools
Electrical & Electronic	
Business machines	Keyboard push buttons
Coil forms	Laser printer (gear trains)
Computer printers and plotters	Precision instruments
Electromechanical counter frames	Relay components, buttons, knobs
Internal ratchets and other moving parts	Switches
Other	
Artificial heart valves	Neck and foot prostheses
Pacemakers	

Source : Formacare, 2007

The European sector of POM resins supported 900 jobs in 2004 with a sales generation of €515m and a value of raw materials purchased and utilities of €225m (Formacare, 2007).

Regulation to be applied on these resin uses:

EC Wood-based panels Regulation

- *Construction Products Regulation (CPR)*

The Construction Products Directive (CPD) 89/106/EEC was introduced in 1988 (modified by Directive 93/68/EEC) with the aim of removing the technical barriers to trade in construction products in Member States of the EU. The CPD introduced harmonized technical specifications and the mandatory CE marking of construction products in most Member States of the EU in order to show compliance with the Directive. In 2011, the Construction Products Regulation (CPR) 305/2011/EU was introduced, repealing the CPD and making the CE marking of construction products mandatory to all EU Member States from July the 1st 2013 for the marketplacing of construction products. The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition. This includes the emissions of dangerous substances.

Regarding formaldehyde, for wood-based panels (WBP) to receive the required CE mark they must comply with harmonized standard EN 13986. This standard sets the minimum safety requirements which allow WBP to be placed on the market in any Member State and provides mechanisms by which specific products such as plywood, flaxboard, particleboard, MDF, OSB, CBPB (cement bounded particle board) and fibreboard are able to satisfy the CPD (TNO/RPA, 2013).

The CPR aims preliminary to protect general population but it also specifies that it *"should not affect the right of Member States to specify the requirements they deem necessary to ensure the protection of health, the environment and workers when using construction products".* Moreover, it is indicated that *"by 25 April 2014, the Commission shall assess the specific need for information on the content of hazardous substances in construction products and consider the possible extension of the information obligation provided for in Article 6(5) to other substances, and shall report thereon to the European Parliament and to the Council. In its assessment, the Commission shall take into account, inter alia, the need to ensure a high level of protection of the health and safety of workers using construction products and of users of construction works, including with regard to recycling and/or reuse requirements of parts or materials".*

- *European Standards for emissions from Wood-based panels*

As reminded in TNO/RPA 2013 report, one of the initial steps taken to reduce formaldehyde emissions was to standardize the emissions from WBP into classes. Depending on the standard and country of manufacture, WBP are likely to fall under emission classifications E3, E2, and E1 – with E3 being the emission class with the highest emissions and E1 the lowest (Wood Solutions, nd).

In 2004, the Harmonized European Standard EN 13986 established Emission Classes E1 and E2 for use in construction. These standards basically require testing to be done on formaldehyde containing wood products used in construction, with Annex B of EN 13986 establishing two classes of WBP, E1 and E2, based on formaldehyde emissions (E1≤8mg/100g dry board; E2>8-≤30mg/100g dry board). When formaldehyde-containing materials (such as resins) have been added to the WBP as part of the production process, the product is required to be tested and classified into one of the two classes, either

E1 or E2. Standard EN 13986 was revised in 2015 and was replaced by Standard EN 13986+A1[11].

EN Standard 717:1:2004 (confirmed 2014) also adressed wood-based panels and formaldehyde release (Determination of formaldehyde release - Part 1: formaldehyde emission by the chamber method). This standard gives a climate chamber method for determining formaldehyde emission from panels in a steady concentration under well-defined conditions. EN 717-1 for plywood, OSB and LVL provides formaldehyde emission classification and release values used for initial type testing according to E1 and E2 classes.

The table below summarizes the board classes and corresponding limit values set up by EN 717.

Table 14. board classes and corresponding limit values set up by EN 717

Test Method	Board Class	Limit Value
EN 717-1 EN 120	E1 particleboard, MDF and OSB	≤ 0.1ppm ≤ 8mg/100g
EN 717-1 EN 717-2	E1 plywood	≤ 0.1ppm ≤ 3.5 mg/(h m²)
EN 717-1 EN 120	E2 Particleboard, MDF, OSB	> 0.1ppm > 8 - ≤ 30 mg/100g
EN 717-1 EN 717-2	E2 Plywood	> 0.1ppm > 3.5 - ≤ 8.0 mg/(h m²)

E1 is the dominant emission class in Europe and is a legal requirement for some European countries. E1-rated boards release less formaldehyde and, as such, are less likely to result in any danger, irritation or inflammation of the eyes, nose and mouth mucous membranes. WBP of the E2 emission class release more formaldehyde compared with E1 boards and are legally permitted in most countries in Europe, however they are widely recommended for use only in outdoor applications.

As reported in TNO/RPA 2013 report, there is existing legislation in various Member State which place restrictions (based on releases of formaldehyde) on the type of WBP which may be placed on these national markets. Generally speaking, these restrictions restrict the production and import of E2 WBP and only E1 WBP (or better) is allowed to be placed on the market in these countries.

TNO/RPA 2013 report indicates that since 2006, the members of European Panel Federation (EPF) agreed to only produce E1 boards and that compliance should be monitored through a system of internal and external checks (Chimar Hellas, 2008). All European manufacturers can meet this standard with some developing products with lower formaldehyde emissions (e.g. boards with half the emission levels of E1 boards) (EC, 2010). At the same time, the members firmed up the E1 limit values for on-going production monitoring. The E1 level is currently valid and has been adopted, more by trade than by regulation, by a lot of other European countries.

Following further studies and work into formaldehyde emissions from WBP, EPF introduced the 'E1plus' class in 2011. 'E1plus' imposes significantly lower

[11] http://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:59825,6094&cs=18933C568445E8B2AE24B40EFE93D8AFD

emission levels for WBP than existing European standards. 'E1plus' requires formaldehyde release of 0.08mg/m³ (corresponding to 0.065 ppm concentration in relevant emission test) for wood based materials used in construction, using the chamber method EN 717-1. It has also been suggested that tightening national and European regulations on indoor air emissions may require emission levels at the E1plus level (Haas Group, nd).

The 'E1plus' class can be achieved for the following products (when unfaced, coated, overlaid or veneered): particleboard, OSB, MDF, flaxboards, plywood, LVL, solid wood panels, fibreboards and cement bonded particleboards.

This voluntary agreement aims to protect consumers as well as professionals.

These regulations cover consumer products. They are thus not further assessed then since consumers products are out of the scope of this RMOA.

4.2.2.1.2 Intermediate in the production or synthesis of industrial chemicals and plastics

Formaldehyde is used as a starting material in chemical synthesis, such as the synthesis of diphenylmethane diisocyanate (MDI), butanediol (BDO) or polyols hexamethylenetetraamine (HTMA - hexamine) (for the most important ones in volume), and as an intermediate in the production of Paraformaldehyde (PFA).

MDI - diphenylmethane diisocyanate

MDI accounts for about 6% of formaldehyde EU consumption. The market for MDI is a rapidly-growing formaldehyde derivative market. MDI is one of the isocyanate family of chemicals that includes diisocyanates and polyisocyanates, a group of low molecular weight aromatic and aliphatic compounds containing functional isocyanate groups. MDI constitutes an important material for the manufacturing of polyurethane (PUR) products which are widely used in the footwear, household appliance, construction, automotive and furniture manufacturing industries. The PUr are produced in a variety of forms: rigid and flexible foams and used in binders, coatings, adhesives, sealants and elastomers. Rigid PUR foams account for 56% of all MDI consumption, mainly used in construction applications as insulation (Formacare, 2007):

The European sector of MDI supported 5,200 jobs in 2004 with a sales generation of €2.6 bn and a value of raw materials purchased and utilities of €1.15 bn (Formacare, 2007). The EU market for MDI is oligopolistic and MDI manufacturers are mostly located in Germany, Berlgium and the Netherlands.

The table below gives an overview of the product applications of MDI.

Table 15. Major product applications for MDI

Rigid Foams	Flexible Foams
Insulation	Furniture
Roofing	Office chairs
Windows/doors	Stadium/arena seats
Metal panels	Automotive
Appliance insulation	Headrests
Freezers	Fenders
Refrigerators	Interior parts/panels
Air conditioners/water heaters	Exterior trim
Flotation devices	Packing/packaging
Surface Coatings	Carpet underlays
Paints	Bedding/mattresses
Concrete flooring	**Polyurethane Elastomers**
Adhesives & Sealants	**Cast Elastomers**
Used in bonding and insulation	Gaskets
Automotive interiors	Shoe soles
Textile laminates	Tires
Indoor/outdoor athletic surfaces	**Microcellular Products**
Binders	Auto panels/interior parts
Binds wood chips into wood products	Bumpers
Adhere rubber chips/flakes to surfaces	Spoilers
PU Fibers	**Thermoplastic Elastomers**
Sportswear	Flexible tubing, hose
Spandex	Film

Source : Formacare, 2007

1,4-Butanediol – BDO

BDO is another industrial chemical that is currently manufactured using formaldehyde. **It accounts for about 4% of formaldehyde consumption.** 70% of current BDO production in the EU and Norway is based on formaldehyde (30% is based on propylene oxide/allyl alcohol or n-butane) through the Reppe process, based on the reaction of acetylene with formaldehyde (Formacare, 2007). 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. 71% of BDO consumption is used as an intermediate in the production of tetrahydrofuran (THF) and polybutylene terephthalate resins (PBT) (Formacare, 2007).

The European sector of BDO supported 650 jobs in 2004 with a sales generation of €450m and a value of raw materials purchased and utilities of €200m (Formacare, 2007). The market is structured around a couple of big manufacturers in Europe.

The table below gives an overview of the product applications of BDO.

Table 16. Major product applications for BDO

Automotive	**Adhesives**
Metal/mechanical parts in engines	Coating for magnetic tape
Car Bumpers	Polyvinyl cements & coatings
Applications	**Consumer**
Cosmetics	Skate wheels
Hair sprays	Belts
Germicides	Rollers
Appliances	Buttons
Plumbing equipment (pipe fittings)	Zippers
Furniture	Printing Inks
Hardware fixtures	**Fibers & Solvents**
Electronics	Spandex
Connectors	Oil lube extraction
Insulators	Electronic appliances
Relays	Paint strippers

Source : Formacare, 2007

Pentarythritol (penta)

Pentarythritol is an alcohol produced from formaldehyde and acetaldehyde and is mainly used in the EU for the production of alkyd resins and neopolyol esters. **Penta accounts for about 3% of formaldehyde EU consumption and 6% of global consumption** (Formacare, 2007).

The European sector of Penta supported 300 jobs in 2004 with a sales generation of €145m and a value of raw materials purchased and utilities of €65m (Formacare, 2007). The market is structured around a few manufacturers in Europe, mostly located in Germany, Sweden and Spain.

The table below gives an overview of the product applications of Penta.

Table 17. Major product applications for Pentarythritol

Alkyd Coating Resins
Architectural Coatings: Exterior and interior enamels, flat house paints, flat wall paints, semi-gloss and gloss paints
Product Finishes –OEM: Automotive and transportation, machinery and equipment, metal furniture and fixtures, wood furniture
Special-Purpose Coatings: Aerosols, automotive refinishing, industrial maintenance coatings, marine, traffic paints, and printing inks
Neopolyol Esters (NPEs)
Synthetic lubricants: Aviation turbine oils (military and civilian jet aircraft), gasoline and diesel engine cars and trucks, refrigerator oils, two-cycle engines, plasticizers, synthetic waxes
Rosin and Tall Oil Esters
Adhesives, caulking compounds, flooring materials, inks, surface coatings, varnishes
Pentaerythritol tetranitrate (PETN)
Detonating cord, detonators, military uses, priming compositions, sheet and plastic explosives
Other
Medication for angina, antioxidant for olefins, flame retardant paints, radiation curing

Source : Formacare, 2007

HTMA - Hexamine

HTMA (CAS No 100-97-0) is a crystalline, solid material, which is produced starting from formaldehyde and Ammonia. It accounts for about **3% of formaldehyde global consumption** (Formacare, 2007). Hexamine is used as a curing agent, a rubber accelerator and in the production of explosives.

Though small in terms of volume, HMTA used as a formaldehyde donor is important. Despite the performance of the products based on HMTA, sales of HMTA amounts to less than €10 million in Europe. The European sector of HTMA is hold by a few manufacturers, mostly located in Germany, the Netherlands and Italy.

Paraformaldehyde - PFA

Paraformaldehyde is the smallest polyoxymethylene (POM) also derived from formaldehyde. PFA is mainly used as a fungicide and/or disinfectant. In 2012, nearly 128,000 tonnes of paraformaldehyde were produced in the EU[12]. It accounts for about **4% of formaldehyde global consumption** (Formacare, 2007).

4.2.2.1.3 Health care applications

Manufacture of Vaccines

Formaldehyde is used as a strong antimicrobial agent in most inactivated vaccines (flu, cholera, hepatitis A), toxoid vaccines (diphtheria, tetanus) and component vaccines (Formacare, 2007). It is an ingredient of the manufacture of 45 vaccines and its concentration is limited to 0.2g/l (Afsset, 2009).

[12] Eurostat, Prodcom 24146160, database consulted on July the 16th 2015.

Table 18. Examples of vaccines containing formaldehyde

Company	Vaccine	Type
Aventis Pasteur	Hexavac®	6-valent DTPa HepB IPV Hib combined vaccines (diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliomyelitis and Haemophilus influenzae type b conjugate vaccine)
Aventis Pasteur	PEDIACEL®	Diphtheria, tetanus, five component acellular pertussis, inactivated poliomyelitis and Haemophilus influenzae type b conjugate vaccine
SBL Vaccin AB	IPV	Diphtheria, tetanus, acellular pertussis vaccine
SBL Vaccin AB	Dukoral™	Cholera vaccine
Chiron Corporation, Aventis Pasteur	Fluad®	Influenza virus vaccine
Sanofi Pasteur MSD	Procomvax®	Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) vaccine
GlaxoSmithKline	Tritanrix HepB®	Diphtheria, tetanus, pertussis and hepatitis B vaccine
GlaxoSmithKline	Fluarix®	Influenza vaccine
GlaxoSmithKline	TWINRIX®	Hepatitis A, hepatitis B
GlaxoSmithKline	Infanrix HeXa®	6-valent DTPa HepB IPV Hib combined vaccines
GlaxoSmithKline	HAVRIX	Hepatitis A
GlaxoSmithKline	Priorix®	Measles, mumps, and rubella vaccine

Source : Formacare, 2007

Manufacture of gelatin capsules

Formaldehyde is used to crosslink gelatin to produce enteric capsules or hard capsules that contain and deliver drugs. The enteric coating slows the dissolution of the capsule and promotes maximum absorption of its contents. Examples of drugs that use such capsules are Prosec®, Nexium®, Prevacid®, and Zelnorm®. Hard and soft gelatin capsules market in Europe was reported to be well over €2.5 billion (Formacare, 2007).

Laboratory usage

In laboratories:

- Formaldehyde is used as a tissue preservative (fixative) or organic chemical reagent. The most widely used fixatives in diagnostic histology and anatomopathology laboratories are formalin-based. Most of the time, it is used at a concentration of 10%.
- According to the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices, specimen receptacles are considered to be *in vitro* diagnostic medical devices. They are specifically intended for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination, whether vacuum-type or not.

Formaldehyde in solution, when contained in these specimen receptacles, is thus considered as an *in vitro* diagnostic medical device.

- Formaldehyde is also employed in electrophoresis. This technique is largely used in proteomics (study of proteins) and genomics (study of DNA and RNA) in life science and pharmaceutical researches (Formacare, 2007).

- Formaldehyde is also used for air decontamination in rooms and surfaces by fumigation for example. This use falls under the Biocidal Products Regulation whereby formaldehyde is regulated as TP 2 (Disinfectants and algaecides not intended for direct application to humans or animals).

In control laboratories: Formaldehyde is used as a reactant agent in controls laboratories (control of raw materials and finished products such as revelation and identification tests for the detection of aldehydes and phenolic cores, coloured reactions as well as microbiological control) (Afsset, 2009).

Embalming

Despite formaldehyde was not covered by the French SEv Report for this use, formaldehyde is the most widely used substance in thanatopraxy sector. It is registered in PT22 under the Biocidal Products Regulation (Embalming or taxidermist fluids).
Formaldehyde is used to delay the process of natural decomposition of bodies by the injection of formaldehyde-based solutions. It is used as a preservative, bactericidal and dehydrating agent for this purpose (Afsset, 2009).

Healthcare sector

Formaldehyde is used as a biocidal and cleaning agent in hospitals (disinfection of surfaces, medical devices, linen) in the form of diluted formaldehyde (Bouin' fluid or B5) as well as in dental surgery (preparation of dental mastics, disinfection of sterilization autoclaves) (Afsset, 2009). It is a broad spectrum disinfectant and is active against bacteria, fungi and many viruses and spores. It is used to disinfect surfaces in a 0.5 – 5% solution. Its mechanism of action is based on protein denaturation (Kayser et al., 2001; subsport, 2013).

The EC Biocidal Products Regulation (BPR) n°528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products aims to protect professional users and general population from the use of hazardous substances such as formaldehyde. Under this Regulation, formaldehyde is part of the list of active substances to be evaluated for several products type (PT) : PT2 (Disinfectants and algaecides not intended for direct application to humans or animals), PT3 (Veterinary hygiene) and PT22 (Embalming or taxidermist fluids). These PT are further developed below when the workers exposure is addressed. The German Competent Authority evaluated formaldehyde for PT2 and PT3 in 2012 and their conclusions were made available in August 2013 (Germany recommends an approval of formaldehyde in these products). After the public consultations and European discussion, the European Commission should adopt a decision by 2016. In December 2015, the BPC concluded the formaldehyde in PT3 may be approved. Regarding the use of formaldehyde in PT22, Germany's evaluation is still underway and the Commission Decision is expected for 2023.

- The Commission Decision of 28 July 2008 concerns the non-inclusion of formaldehyde for PT 11, 12, 13.
- The Commission Decision of 8 November 2010 indicated that formaldehyde shall not be included for the PT 4 and 6.
- The Commission Decision of of 1 July 2011 concerns the non-inclusion of formaldehyde for PT 1, 5, 9, 23.

- The Commission Decision of 25 April 2013 concerns the non-inclusion of formaldehyde for PT 20.
- The Opinion of the Biocidal Products Committee (BPC) for PT 3 has been published the 10th December 2015. The overall conclusion of the BPC is that the formaldehyde in PT 3 may be approved.
- Formaldehyde-releasers are registered under PT 6 (Preservatives for products during storage) and PT13 (Working or cutting fluid preservatives). PT6 corresponds to the products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life and the products used as preservatives for the storage or use of rodenticide, insecticide or other baits. PT13 includes the products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.

As indicated above, formaldehyde-releasers are also registered under PT6 (Preservatives for products during storage) and PT13 (Working or cutting fluid preservatives). The PTs not mentioned indicate that no uses are identified.

Medicines

Medicines and medical-related applications are regulated by EU Regulation 726/2004 for the authorisation and supervision of medicinal products for human and veterinary use and related regulations such as Directive 2001/82/EC (on the Community code relating to veterinary medicinal products), Directive 2001/83/EC (on the Community code relating to medicinal products for human use), Directives 90/385/EEC (relating to active implantable medical devices), 93/42/EEC (concerning medical devices) or 98/79/EC (on *in vitro* diagnostic medical devices). These regulations are coordinated under the auspices of EMEA (European Medicines Agency).

In animals, formaldehyde is used to treat externally fishes against bacterias, to clean and disinfect ovines and bovines hoofs and umbilical cords, to manufacture animal vaccines (up to a concentration of 0.5 mg/ml), to clean surfaces, etc. (Afsset, 2009).

4.2.2.1.4 Food applications

In human food, formaldehyde is used as a technological auxiliary for its biocidal property in the manufacture of sugar (saccharose extraction from beetroots), as a preservative agent for the production of food additives or as food additive itself, as a cleaning agent for surfaces, as a synthetic reactive substance for the food contact materials, as an ingredient for specific MF resin in the water treatment, as a formulation agent in glues and adhesives for plastic pipes in contact with drinking water.

In animal food, formaldehyde is used in the form of formol (aqueous solution) as a preservative agent for silages, to tan proteins for certain animal food, as a preservative agent in milk for piglets, as a fumigating bactericidal agent to fight against e.g. salmonella (Afsset, 2009).

Human food

Formaldehyde is regulated under EU Regulation n° 231/2012/EC laying down specifications for food additives listed in Annexes II and III to Regulation (EC) n° 1333/2008 of the European Parliament and of the Council:

- Formaldehyde is used for its biocidal property as a technological auxiliary in the production and conservation of alginates (linear polymers). Under this Regulation, formaldehyde-containing alginates are authorised with a maximal concentration of formaldehyde residues of 50mg/kg in food

additives (E400 alginic acid, E 401 Sodium alginate, E 402 potassium alginate, E 403 ammonium alginate, E 404 calcium alginate, E 405 propane-1,2-diol alginate).
- Formaldehyde is limited in the food additives E 200 (Sorbic acid), E 202 (Potassium sorbate), E 203 (Calcium sorbate) and E 280 (Propionic acid) to a maximum of 0.1 % of the food additive.
- Formaldehyde is limited as non-intentional impurity in E 407 (Carrageenan)and E 407a (Processsed euchema seaweed) to not more than 5 mg substance per kg food additive.

Formaldehyde is also regulated under EC Regulation 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.

Animal food

Formaldehyde is regulated under EU Regulation 1831/2003 on additives for use in animal nutrition as preservative for pigs feeding stuffs (Commission Directive of 8 July 1985).

EC Food contact materials Regulation
Formaldehyde is regulated under Regulation 1935/2004 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.

4.2.2.1.5 Fertilizers

Formaldehyde is used in the manufacture of CRFs (controlled release fertilizers). The CRFs release their nutrients at a specific rate over a period of time, providing a constant source of nutrients to plants, soils and turf. The main form of formaldehyde used in CRFs is **urea-formaldehyde reactions products** (Formacare, 2007; Afsset 2009). The manufacture of urea-formaldehyde CRFs include is mainly operated by a few leading producers in Europe. Twenty-two percent of the end markets for CRFs are agricultural markets (strawberries, vegetable crops, citrus, melons and fruit trees) and 78% are non-agricultural markets (28% professional horticulture; 28% landscaping; 22% consumers) (Formacare, 2007).

4.2.2.1.6 Phytopharmaceutical products

In phytopharmaceutical products, formaldehyde is used for its biocidal and preservative properties, to sterilize and clean soils, hothouses and all kind of materials for storage, transport, crop, livestock farming. The end-use sectors are miscellaneous: horticulture, pisciculture, ovine and bovine livestock farming, etc.

4.2.2.1.7 Other industrial and professional uses

Formaldehyde is also used (Formacare, 2007; Afsset, 2009):

- To treat nuclear wastes (2,300 tonnes in 2005 in France);
- As an intermediate in photography industry for emulsions coatings (gelatin hardener/binder).
- In mechanic and metallurgy industry as an anti-corrosion agent or in precious metals recycling, enamels manufacturing or silver galvanization
- In the production of chelating agents such as aminopolycarboxylic acids and sodium salt. Chelating agents are used in a wide range of

sectors and applications : they can be used to help control undesirable metal ions as iron, copper, calcium, lead, and magnesium in solution ; in paper and pulp manufacturing (the 1st end-use market for chelating agents) to prevent decomposition of sodium hydrosulfite and hydrogen peroxide, improve bleachability and increase brightness ; to control water hardness and scale control in water boilers, evaporators, and heat exchangers; in agricultural and photographic applications or in food to preserve color, flavor or stability. Different types of aminopolycarboxylic acids account for chelating agents produced in the European Union : Ethylenediaminetetraacetic acid (EDTA) is the primary chelating agent used, accounting for almost half of aminopolycarboxylic chelating agent consumption in the European Union and Norway; Diethylenetriaminepentaacetic acid (DTPA), hydoxyethylethylenediaminetriacetic acid (HEDTA), nitrilotriacetic acid (NTA), methylglycinediacetic acid (MGDA), 1,3 propylenediamine tetra acetic acid (PDTA), di(hydroxyethyl)glycine (DHEG), ethanoldiglycinate (EDG), and glutamic acid – N,Ndiacetic acid (GLDA), are also produced.

- To produce Trimethylolpropane (TMP): it is a trifunctional alcohol and one of the first polyalcohols to be used in the resin producing industry. It is used in industrial stoving, baking alkyds or saturated polyesters, in PUR sytems for coatings and foams and in radiation-cured acrylates in the printing, coating and electronics industries. The main end-use markets for TMP are coating resins (61%), neopolyol esters for lubricants (28%), multifunctional acrylates/methacrylates (6%), trimethylolpropane allyl ethers (3%).
- To produce pyridines: pyridines are synthetically produced by reacting acetaldehyde and ammonia, with or without formaldehyde. They are used to formulate pyridine (41%), beta-picoline (15%), alpha-picoline (3%) and gamma-picoline (0.2%). 41% of pyridines are not lmade from formaldehyde (Formacare, 2007). Pyridines are used, among others, in the manufacture of agricultural chemicals, solvents, latexes, feed supplements for poultry, dairy cattlen swine and pet food, cosmetics, personal care products

4.2.2.2 Waste management

4.2.2.2.1 *Waste from manufacture and use of formaldehyde*

According to OECD SIDS (2002), Releases into the environment are likely to occur during production and processing as intermediate as well as from use of products containing formaldehyde. Depending on industrial sites, emissions of formaldehyde in wastewater vary from none to thousands tons per year.

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

As indicated in Danish 2014 Survey, 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. Many of these products are released directly into wastewater streams during their use. 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 (Danish EPA, 2014).

Water is considered to be the main target compartment for formaldehyde (99%) (OECD SIDS, 2002).

4.2.2.2.2 Recycling

Chemical recycling is not applicable to formaldehyde due to its high reactivity.

These waste management uses are not further assessed since it is highly unlikely that workers might be exposed at this stage of the life cycle. These uses are thus considered as being out of the scope of this RMOA.

4.2.2.3 Summary and conclusion on uses of formaldehyde

Formaldehyde is a HPV chemical. More than 1,000,000 tpa has been registered under REACH. The European Union is the second largest producer of formaldehyde after Asia which has approximately 50% of global capacity. Within Europe, Germany is the biggest manufacturer of formaldehyde.

At industrial and professional level, formaldehyde is mainly used in chemical synthesis of many chemicals and agents and in the production of resins in the chemical industry mostly for wood, paper and textile processing industries. **It has to be noted that Industry (TNO/RPA, 2013) and the Danish EPA (2014) consider formaldehyde is used as an intermediate in these two major uses. The question of the intermediate status of formaldehyde is a critical issue which is developed further under section 6.**

5 RISK CHARACTERISATION

5.1 DNELs for short-term and long-term exposures

In its 2014 REACH Substance Evaluation, FR-MSCA concluded that the long-term DNEL by inhalation should be based on the study by Lang *et al.* (2008) using a NOAEL of 0.3 ppm and an assessment factor of 3 (AF of 3 and not 5 as recommended in ECHA R8 Guidance considering only local effects). This resulted in a DNEL for long-term exposure of 0.1 ppm (0.2 ppm for short-term exposure).

Late 2015, the Scientific Committee on Occupationnal Exposure Levels (SCOEL) proposed for public consultation until the 17th of February, 2016, new OELs for formaldehyde based on 2 key-studies (Lang *et al.* (2008) and Mueller *et al.* (2013)): 0.3 ppm for long-term exposure and 0.6 ppm for short-term exposure. As Anses proposed OELs in 2008 of 0.2 ppm for long-term exposure and 0.4 ppm for short-term exposure, Anses opened a discussion about DNEL/OEL for formaldehyde in order to aligne both sets of values. An *ad-hoc* expertise group was set up between December 2015 and February 2016 in order to propose harmonized inhalation occupational values for formaldehyde (see table Table **19**). The final Anses DNELs and OELs are described in sections 5.1.1 and 5.1.2.

The Registrant updated the CSR in December 2015, proposing new DNELs to be considered for risk characterization: 0.3 ppm for long-term exposure and 0.6 ppm for short-term exposure, based on the 2 key-studies (Lang *et al.* (2008) and Mueller *et al.* (2013)) with an AF of 1. The long-term DNEL is supported by mathematical risk extrapolations from experimental animals to humans.

Nevertheless, the justification provided by the Registrant remains unclear and would need to be clarified as the NOAEC are different from the Registrant final DNELs.

Table 19. DNELs and OELs considered in the scope of this RMOA

	Long-term	Short-term	AF	Starting point
ANSES 2008	0.2 ppm	0.4 ppm	1.5	Lang 2008
CSR 2013 (registration dossier)	0.4 ppm	0.8 ppm	1	Mueller 2013
FR 2014 SEv	0.1 ppm	0.2 ppm	3	Lang 2008
SCOEL 2015	0.3 ppm	0.6 ppm	1	Lang 2008 Mueller 2013
CSR 2015 (registration dossier)	0.3 ppm	0.6 ppm	1	Lang 2008 Mueller 2013
ANSES 2016	**0.3 ppm**	**0.6 ppm**	**1**	**Lang 2008 Mueller 2013**

5.1.1 Anses worker local long-term DNEL for inhalation route

The carcinogenic mode of action of formaldehyde relies on a serie of key events above a threshold. In animals, nasal tumours are only observed at doses producing chronic irritation as evidenced by the accompanying inflammatory, hyperplastic and metaplastic responses. *In vitro*, formaldehyde is a genotoxic agent for high doses only. Epidemiological data shows formaldehyde genotoxicity is observed at the site of contact. A consistent database provides evidence that the mechanism of induction of local tumours is driven by regenerative proliferation that may secondarily amplify the high-dose genotoxic effects of formaldehyde. Prevention of irritant effects of formaldehyde is considered protective of its carcinogenic effects. The dose-response relation for tumour incidence is essentially dependent on cell proliferation which is not observed at the low dose range. For formaldehyde, the practical threshold for cytotoxicity is considered to be protective for its genotoxic and carcinogenic effects.

Sensory irritation occurs at lower concentrations than cytotoxic irritation. The mode of action relies on the stimulation of trigeminal nerves leading to clinical observations such as eye or nose irritation. Thus, sensory irritation observed in humans is considered to provide a sufficient margin of safety regarding intraspecific variability for the onset of irritation-induced cytotoxicity and cell proliferation inducing carcinogenicity in humans after long-term inhalation exposure (see below).

The most relevant controlled studies of Lang *et al.* (2008) and Mueller *et al.* (2013) took into consideration objective signs of sensory irritation (eye blinking rate, nasal resistance and flow), influence of personality factors and confounding by odor (Lang study). According to the identification of objective signs of ocular and nasal sensory irritation, which are the most precursor effects, the NOAEC is set at 0.3 ppm and is chosen for the derivation of long-term DNEL. No AF is applied as epidemiological data show that formaldehyde vulnerable occupational subpopulation were already considered in the Lang and Mueller studies. Besides, sensory irritation is a precursor key event providing a margin of safety for the onset of more severe irritative effects of formaldehyde.

The Worker long-term DNEL for inhalation is 0.3 ppm (0.37 mg/m^3).

A limit of 0.3 ppm would prevent sensory irritation in occupationally exposed individuals but will not protect from 'nuisance' at the workplace cause by

subjective symptoms of irritation and odor" since data from Lang *et al.* (2008) and Mueller *et al.* (2013) support the occurrence of subjective annoyance at equivalent concentrations.

5.1.2 Anses worker local short-term DNEL for inhalation route

Results issued from human studies indicates that eye irritation is the most sensitive effect induced by an acute exposure to formaldehyde. It occurs at concentrations below concentrations inducing respiratory irritation. Eye irritation is therefore the most sensitive endpoint retained as the critical effect for DNEL derivation by inhalation.

Lang and Mueller studies design comprise exposition to formaldehyde during 4 hours with a serie of peaks of exposure, considered as realistic exposure conditions at work. Objective tests for eye irritation were implemented measuring eye blinking rate or conjunctival redness. The NOAEC for eye irritation was thus set at 0.6 ppm. No assessment factor was applied for the same reason as mentioned above.

The Worker short-term DNEL for inhalation is 0.6 ppm (0.74 mg/m^3).

5.2 Summary of the risk characterisation

Considering these short-term and long-term DNELs, the Risk Characterisation Ratios (RCRs) have been calculated based on exposure data from the 2014 SEv Report (2013 registrant CSR) and by the French Colchic database (see chapter 5.2.2).

The table below provides the list of the uses at risk (RCRs > 1). The details of the calculated RCRs and the specific tasks/steps considered at risk are presented in confidential Annex C.

Table 20. Occupationnal sectors at potential risk (exposure data from 2013 registrant CSR and French Colchic database)

Identified uses of formaldehyde from Registrant	***Corresponded uses as described in section 4.2.2***
Manufacturing of formaldehyde and Resins	Formaldehyde manufacturing Production of resins
Resin / chemicals manufacturing	Production of resins Synthesis of chemicals
Panel production (wood panels – paper impregnation, lamination, maintenance and cleaning)	Production of wood-based panels
Fertilizer granules production	CPRs (controlled release fertilizers)
Industrial production of foams, bonded particulates, bonded fibers/mats and paper	Use of UF and PF resins in foams MDI in foams Paper production Wood-based panels Textiles dyes and finishing
Impregnation of Leather and Textile	Textiles dyes and finishing
Professional use: production of foams	Insulating and binding material (foams)
Professional use: resins in wood applications	Resins in wood-based panels
Identified uses of formaldehyde from Colchic	***Corresponded uses as described in section 4.2.2***
Building industry and civil engineering	Construction/Insulating/binding material Wood-based panels
Chemicals, rubber and plastic industries	Other industrial uses
Wood, paper, furniture, textile, clothes, leather,	Wood-based panels

Identified uses of formaldehyde from Registrant	*Corresponded uses as described in section 4.2.2*
hides and earthenware	Paper production
Public health services Private health services	Anatomo-pathology Anatomo-pathology + biological laboratories Laboratories/hospitals/healthcare structures

5.2.1 Analysis of Registrant's data

Registrants' assessment for occupational inhalation risks is based on:

- 2013 CSR: monitoring data gathered from downstream users, a literature analysis, supplemented by model estimates for situations with insufficient useful user and literature data with ECETOC TRA version 3.0 in a first tier and refined with ART when necessary[13]. The Registrant defined a short-term DNEL of 0.8 ppm and a long-term DNEL of 0.4 ppm. **Considering the herein proposed DNELs (see chapter 5.1), some occupational sectors are at risk as showed in the table below**;

- 2015 SCR update: only modelling data using EasyTRA 4.0.0. The registrant considered that the previous data gathered in the 2013 CSR support the model estimations in the CSR. Risk characterisation was undergone with new DNELs : 0.6 ppm for short term exposure, 0.3 ppm for long term exposure. Based on these new DNELs, all RCRs are below 1. **Nevertheless, risk characterisation based exclusively on modelling data is not sufficient enough, considering all the uncertainties related to model estimations and choices of modelling parameters. In particular, corrective factors were applied for protective equipment reducing final exposure estimations. All relevant datasets on formaldehyde exposure should be taken into account for risk characterisation, including modelling and monitoring data, especially for long-term exposure as formaldehyde is a carcinogenic compound. For these reasons, 2015 CSR exposure data are considered insufficient for workers risk characterization.**

Table 21. Sectors at risk depending on monitored or modelled formaldehyde concentrations for short and long term exposures, from 2013 Registrant CSR

Long-term exposure	**DNEL 0.3 ppm**
Monitoring data from downstream users (90th Percentile, personal)	Manufacturing of formaldehyde and Resins (during transfer of formaldehyde and Resins) Resin / chemicals manufacturing (during control of the Resin / chemicals manufacturing process) Panel production (during paper impregnation of wood based panels and maintenance in the wood panel industry)

[13] ECETOC TRA 3.0, personal long-term, 75th Percentile. Except for Formalin (60% formaldehyde): ART 1.0, 75th Percentile.

Modelling data (75th Percentile)	Production of fertilizer granules (PROC 8b) Industrial production of foams, bonded particulate, bonded fibers/mats, paper and impregnation of leather and textile (PROC 3,4,7,8a,8b,9,10,13) Professional production of foams and use of resins in wood applications (PROC 10,23,25)
Short-term exposure	**DNEL 0.6 ppm**
Monitoring data from downstream users (90th Percentile, personal)	Panel production (during paper impregnation of wood based panels and maintenance in the wood panel industry)
Modelling data (75th Percentile)	Industrial production of foams, bonded particulate, bonded fibers/mats, paper and impregnation of leather and textile (PROC 1,2,5,6,14) Professional production of foams and use of resins in wood applications (PROC 10)

5.2.2 Additional data: extraction from the French COLCHIC database

COLCHIC is a French database collecting occupational exposure measurements carried out by the chemical laboratory services of CARSAT (Health insurance) and the INRS institute. These measures are not undertaken for regulatory control but for the purpose of prevention. They are implemented by safety engineers and controllers but can also be requested by occupational physicians or companies directorates. These measurements cannot be generalized to all situations found in the workplace and are not representative of one specific occupational sector. They can however give an overview of ocupationnal exposure in SMEs (which is not probably the case of data provided by Industry in the framework of Substance Evaluation).

In particular, measurements gathered in the Colchic database are undertaken without any respiratory protective equipment. No exposure reducing factor is applied (whether nominal nore assigned). Measurements are not adjusted on the time of occupational exposure but correspond to the concentrations measured during the sampling time. A statistical exploitation is proposed depending on the number (n) of measures for one occupational sector/task : probabilistic approach if n>20, mean and standard deviation if 10<n<19, no data if n<9.

The use of the database and the statistical analysis for formaldehyde exposures were done by INRS on two periods of time : 2000-2006 and 2007-2013 estimating the impact of a French decree of 13th of July, 2006 adding processes emitting formaldehyde to the list of substances, preparations and carcinogenic processes from the 1st of January, 2007. An analysis by sectors, activities and tasks was provided, showing numerous specific sectors at risk, not cited in the registration dossier. The following table gives an overview of sectors for which COLCHIC collected formaldehyde concentrations (90th percentile) above DNELs (see detailed information in Annex C).

Table 22. Occupationnal sectors at potential risk (exposure data from French Colchic database for the period 2007-2013)

Long-term exposure	**DNEL 0.3 ppm**

Activity sector at risk (as cited in COLCHIC)	Building industry and civil engineering Chemicals, rubber and plastic industries Wood, paper, furniture, textile, clothes, leather and hide and earthenware Public health services Private health services
Short-term exposure	**DNEL 0.6 ppm**
Activity sector at risk (as cited in COLCHIC)	Public health services Private health services

1) Building industry and civil engineering

The global exposure value has decreased from 1.54 for the 2000-2006 period to 0.48 mg/m^3 for the 2007-2013 period.

For specific tasks, exposure values remain so high for the 2007-2013 period that additional RMM would be necessary:

- Roofing with all materials (except plumbing). 90th percentile exposure value = 0.75 mg/m^3
- Joinery (manufacture and installation) including or not the structural wood: 90th percentile exposure value = 0.42 mg/m^3

2) Chemicals, rubber and plastic industries

The global exposure value has decreased from 0.27 for the 2000-2006 period to 0.15 mg/m^3 for the 2007-2013 period.

Exposure values remain high for specific tasks for the 2007-2013 period:

- Production of base-products for pharmacy, alkaloids, glycosides and derivatives, algae extracts: 90th percentile exposure value = 0.55 mg/m^3
- Casting machine operations and controls: 90th percentile exposure value = 0.66 mg/m^3

3) Wood, paper, furniture, textile, clothes, leather and hide and earthenware

The global exposure value has decreased from 0.48 for the 2000-2006 period to 0.4 mg/m^3 for the 2007-2013 period.

Exposure values remain high for specific tasks for the 2007-2013 period:

- Wood based panel production (chopped, ground, defibrillated wood): 90th percentile exposure value = 0.42 mg/m^3
- Production of wooden frame pieces, grinding and shaping including brush woods: 90th percentile exposure value = 0.73 mg/m^3
- Machining, assembling, welding, bonding, assembly lines: 90th percentile exposure value = 0.47 mg/m^3
- Serial production of building carpentry: 90th percentile exposure value = 0.47 mg/m^3
- Impregnated, tar, coated and painted paper production: 90th percentile exposure value = 0.69 mg/m^3

4) Public health services

Based on the Colchic data registered during 2000-2006 or 2007-2013, the global exposure value has decreased from 0.67 to 0.33 mg/m^3.

Concerning specific tasks, some have such a value that additional RMM would be necessary:

- 751AE (2007-2013) in hospital authority: Anatomopathological examinations (lamella preparation, tissue binding…): 90th percentile exposure value = 0.47 mg/m^3

5) Private health services

Based on the Colchic data registered during 2000-2006 or 2007-2013, the global exposure value has decreased from 1.19 to 0.65 mg/m^3, which is still far above the DNEL of 0.3 ppm derived for long-term exposure.

Concerning specific tasks some have such a value that additional RMM would be necessary and useful:

- Medical analysis outside hospital services: 90th percentile exposure value = 0.92 mg/m^3
- Biological laboratories: 90th percentile exposure value = 1.07 mg/m^3
- Anatomo-pathology: 90th percentile exposure value = 0.64 mg/m^3

In October 2015, the French Ministry of Labour published a French occupational exposure survey, focusing on formaldehyde: were registered 153,600 workers in 2003 *vs* 122,500 in 2010 (i.e. a decrease of 20%). Exposure measures implemented on sites showed that formaldehyde exposures were mainly short term and of weak intensity. Collective protective equipment has raised of 32% in the wood industry (general ventilation) whereas health services sectors have implemented personal protective equipment.

5.2.3 Additional data on thanatopraxy sector

In 2009, Anses demonstrated high levels of short-term formaldehyde exposure in thanatopraxy, based on published literature as this professional sector is not considered by the French Colchic database. Published studies showed mean short-term formaldehyde levels from 0.11 to 17 ppm, measured during the preparation of formaldehyde solution before embalming. Compared to the Anses short-term DNEL of 0.6 ppm, this sector seems clearly a professional sector at risk.

5.3 Information on alternatives

Given that this RMOA only covers industrial and professional uses of formaldehyde (consistently with the scope of the Substance Evaluation carried out by FR MSCA), the information on alternatives provided hereafter only refers to these uses. Moreover, the alternatives assessment has been performed only for the uses for which a risk for workers has been demonstrated in the FR SEv Report, such as reminded in section 4.3 above), would this use be covered by REACH or not. In other words, this RMOA provides information on the capability of other regulation to regulate, would they take into account the alternatives propose thereafter.

The analysis of alternatives is based on public available litterature, including reports from industry. Annex D gives information on hazard (classifications when available) of alternatives relies on information gathered from ECHA website and public scientific litterature.

5.3.1 Alternatives to formaldehyde-based resins (UF, MF, PF, POM)

5.3.1.1 Substitutes to UF resins

The information collected on the alternatives identified for UF resins in the available literature allows getting some indication about their availability and their hazards as well as their technical and economic feasibility. However, the information is scarce and some degree of uncertainty remains. In particular, very

little information on indirect substitutes could be collected. The table below summarizes the assessment carried out on the (direct and indirect) alternatives identified for UF resins, based on the available information. More details on the substitution cost for UF resins are provided in section 5.2. below.

Table 23. Summary of the alternatives assessment identified for UF resins

Alternative	End-use market	Availability	Technical feasibility	Economic feasibility
PU adhesives (pMDI)	Particleboard and MDF	-	+ (but high tackiness, sticky and hydrophilic nature)	- (3 times higher market price)
Soybean adhesives	Particleboard and MDF	++	(+)	(+) (low cost but to be improved)
	plywood		(+)	
Blood adhesive	Particleboard and MDF	- (limited feedstock)	+ (but objectionable workplace conditions due to odor and vermin)	+ (low cost)
Casein adhesive	MDF and particleboard	- (limited feedstock)	(+) (too long cure time)	+ (cost competitive)
Lignocellulosic residue extracted from wood	MDF and particleboard	(+) (uncertain)	+ (but not as durable as synthetic resin-based adhesives)	
Tannins	MDF and particleboard and plywood	-	- (inconstant reactivity)	- (more expensive)
Lignin adhesives	Plywood	+	+	+
EPI	Particleboard and MDF		(+) (high tackiness)	- (higher cost 20%-30% and additional process steps)
	plywood		+	
PU dispersions	MDF and particleboard		+ (but longer cure time)	- (higher cost)
VAE (EVA and PVA)	MDF and particleboard		- (poorer performance, tendency to creep, higher viscosity)	- (new capital investments needed, higher cost)
	Plywood (PVA)		- (limited stand time, poorer performance)	
Epoxy	MDF and particleboard		- (longer cure time)	- (higher cost, more equipment needed)
	Molding compounds (Electrical)			
	Surface coating (machinery and metal applications)			
Thermoplastic polymers (ABS or polypropylene)	Molding compounds (electrical and non-electrical)		+	- (ABS: higher costs)
Polyester thermosets	Molding compounds (Electrical)		+	+
Silicones	Molding compounds (Electrical)			
Alkyds, acrylics, and polyesters coatings	Surface coating		+ (except acrylics for wood)	- (acrylics: costly)
PAE resins	Paper treatment		+	
Chitosan	Textile finishing			
Dimethyl urea glyoxal				
Polyvinyl-pyrrolidone				
Polymaleic acid				

Additionally, a summary of the main characteristics of each of the alternatives to formaldehyde resins in wood products is provided in Annex D, taken from TNO/RPA 2013 report.

5.3.1.2 Substitutes to MF resins

The information collected on the alternatives identified for MF resins in the available literature allows getting some indication about their availability and their

hazards as well as their technical and economic feasibility. However, the information is very scarce and a high degree of uncertainty remains. The table below summarizes the assessment carried out on the (direct and indirect) alternatives identified for MF resins, based on the available information. More details on the substitution cost for MF resins are provided in section 5.2. below.

Table 24. Summary of the alternatives assessment identified for MF resins

Alternative	End-use market	Availability	Technical feasibility	Economic feasibility
Polyester	Laminates paper (HPL)			
	Surface coatings			
epoxy	Laminates paper (HPL)		(-) lower aesthetics attributes	- (higher cost)
	Surface coatings			
	Specialty wood applications			
acrylic	Surface coatings			
	Laminates paper (HPL)		- (less durable)	
EPI	Specialty wood applications			
PU	Specialty wood applications			
PVA	Specialty wood applications			
ABS	Molding compounds (non-electrical)			- (higher cost)
Polyester thermosets	Molding compounds (electrical)			

Additionally, a summary of the main characteristics of each of the alternatives to formaldehyde resins in wood products is provided in Annex D, taken from TNO/RPA 2013 report.

5.3.1.3 Substitutes to PF resins

Like for other formaldehyde-based resins, there are both direct and indirect substitutes available for most, if not all PF-based applications. As might be expected, the more "commodity-like" the application, the narrower the range of direct substitute materials since higher priced substitutes (on a price/functionality basis) become less attractive. In addition, in the more commodity-like applications, the higher the market share held by the low-cost application technology tends to be.

The table below shows the direct and indirect alternatives identified. As indicated, the choice of the alternative depends on the application and the end-use market for PF resins.

Table 25. Substitutes for Phenol Formaldehyde

End-use Market	Substitute binder or resin	Substitute end-use material
Plywood, LVL	Blood, soy, EPI, PU	Alternatives to wood frame housing (concrete, steel frame, insulating concrete form)
Insulation binder	Polyacrylic acid	
Paper impregnation	Epoxy, silicone, polyester	HPL: Corian®, granite LPL: vinyl film, decorative foils, low basis weight paper
Molding compounds	Consumer and appliance applications: thermoplastics, polyester bulk molding compounds	Automotive – metal
Friction materials		Carbon fiber
Coated and bonded abrasives	Coated: animal glue, epoxy Bonded: ceramic, shellac, rubber	
Foundry	Furan, silicates, isocyanates, acrylic	Die casting
Specialty wood adhesives	Epoxy, EPI	Solid or laminated wood, steel, concrete

Source : Formacare, 2007

The information collected on the alternatives identified for PF resins in the available literature allows getting some indication about their feasibility. However, the information is scarce and some degree of uncertainty remains. The table below summarizes the assessment carried out on the (direct and indirect) alternatives identified for PF resins, based on the available information. More details on the substitution cost for PF resins are provided in section 5.2. below.

Table 26. Summary of the alternatives assessment identified for PF resins

Alternative	End-use market	Availability	Technical feasibility	Economic feasibility
Polyacrylic acid	Insulation binder	+	+	- (2 to 3 times more costly; additional maintenance costs due to corrosive nature)
pMDI	Wood products (plywood)	-	-- (thus not used)	- (higher cost)
MF	Wood products (plywood)	+	+	- (twice higher cost)
Resorcinol Formaldehyde (RF)	Wood products (plywood)		+	- (higher cost)
Blood albumin adhesives	Wood products (plywood)	- (limited feedstock)	+	
Casein adhesives	Wood products (plywood)	- (limited feedstock)	+	+
Soybean adhesives	Wood products (panel board)	+ (modified soybean adhesives under development)	- (lower in strength and less moisture tolerant; modified soybean – to be commercialized - would be feasible)	- (modified soybean – to be commercialized - would be feasible)
Lignin adhesives	Wood products	+	+	+
EPI	Wood products	+	++	- (higher cost)
	Specialty wood products			
PU dispersions	Wood products	+	+ +	- (higher cost, mainly niche applications)

VAE	Wood products		- (for exterior grade applications)	
polyester	Lamination		+	- (higher cost, not used)
Epoxy	Lamination	+	+	- (higher cost, not used)
	Coated abrasives		+	
	Specialty wood products			
Vinyl ester	Lamination		+	- (higher cost, not used)
Engineering thermoplastics (polyamide, ABS, PC, etc.)	Molding compounds (industrial applications)		- (inferior physical properties)	- (twice higher cost)
BMC	Molding compounds (industrial and home applications)		+ (for some applications)	- (higher cost in many cases)
polybutylene terephthalate, PET and glass-reinforced thermoplastic polyester	Molding compounds (home applications)			
Ceramic, shellac, rubber	Bonded abrasives		(+) (lower productivity)	
Animal hide glues (collagen)	Coated abrasives		- (for most applications)	
Furan, silicates, isocyanates, acrylic	Foundry			

5.3.1.4 Substitutes to POM resins

Due to its superior properties, including high stiffness and strength, low coefficient of friction and good lubricity, and good solvent resistance, polyacetal has become commercially important and is used widely in industrial, transportation, agricultural, construction, and consumer markets.

The table below shows the direct and indirect alternatives identified for POM resins. The choice of the alternative depends on the application and the end-use market for POM resins.

Table 27. Substitutes for POM resins

End-Market Market	Thermoplastic Engineering Resins Substitute	Metal Substitutes
Industrial	Nylon, polyester	Brass, steel, die-cast zinc
Automotive	Nylon, polyester	Steel, die-cast zinc
Consumer articles	ABS, nylon, polystyrene	-
Plumbing and irrigation	-	Brass
Appliances and tools	-	Brass, steel, die-cast zinc
Electrical and electronic	ABS, nylon, polystyrene	-
Other	Polycarbonates, polyolefins	-

Source : Formacare, 2007

The information collected on the alternatives identified for POM resins in the available literature allows getting some indication about their feasibility. However, the information is scarce and some degree of uncertainty remains. The table below summarizes the assessment carried out on the (direct and indirect) alternatives identified for POM resins, based on the available information. More details on the substitution cost for POM resins are provided in section 5.2. below.

Table 28. Summary of the alternatives assessment identified for POM resins

Alternative	End-use market	Availability	Technical feasibility	Economic feasibility
Nylons	automotive	+	+	- (higher cost)
	Industrial applications		+ (- for bearings: low coefficient of friction and greater lubricity; for food and dairy machinery: less hydrolysis resistant)	
	Consumer articles		+	+ (cheaper for some applications such as videocassette, audiocassette and reel hubs)
Polystyrene	Consumer articles	+	+	+ (cheaper for some applications such as videocassette, audiocassette and reel hubs)
ABS	Consumer articles	+	+	+ (cheaper for some applications such as videocassette, audiocassette and reel hubs)
Polyesters (PET)	Automotive	+	+ (higher heat distortion temperature)	+ (lower cost per kg)
	Industrial applications		(-?) (lower stiffness and chemical resistance) (- for food and dairy machinery: less hydrolysis resistant)	
Polycarbonates (PC)	Medical uses	+	(-?) (lower stiffness and chemical resistance)	+ (lower cost per kg)
polyolefins	Medical uses	+		

5.3.2 Alternatives to formaldehyde in chemical synthesis industry

5.3.2.1 Substitutes to the synthesis of MDI

MDI is the most important diisocyanate in commercial use. Its precursor, diamino diphenyl methane, is produced by the reaction of aniline with formaldehyde. Polymeric MDI can then be purified to form pure MDI.

The table below shows the direct and indirect alternatives identified for MDI. The choice of the alternative depends on the application and the end-use market for MDI.

Table 29. Substitutes for MDI

End-Use Market	Polyurethane Substitutes	Thermoplastic Substitutes	Others
Rigid Foam	TDI, other aromatic isocyanates	EPS, EPP, expanded PVC, polycarbonate structural foam	Fiberglass
Binders	TDI, other aromatic isocyanates	-	Latexes
Flexible Foam	TDI, other aromatic isocyanates	EPS, EPP, EPE, expanded PVC, polycarbonate structural foam	SB/SBR and other elastomers
Adhesives & Sealants	TDI, other isocyanates	-	SB/SBR and other latexes
Polyurethane Elastomers	TDI, other isocyanates	EPP/EPE	SB/SBR and other latexes
Coatings	TDI, other isocyanates	-	Various other latexes

Source : Formacare, 2007

The information collected on the alternatives identified for MDI and on formaldehyde-free route to MDI in the available literature allows getting some indication about their availability and feasibility. However, the information is scarce and some degree of uncertainty remains. The table below summarizes the assessment carried out on the (direct and indirect) alternatives identified for MDI, based on the available information. More details on the substitution cost for MDI resins are provided in section 5.2. below.

Table 30. Summary of the alternatives assessment identified for MDI

Alternative	End-use market	Availability	Technical feasibility	Economic feasibility
TDI, other aromatic isocyanates	Rigid foams (for pour-in-place applications and construction applications with low cure times)	+	+	- (TDI is less expensive than MDI but significant performance losses, aliphatic iscocyanates are more costly)
	Flexible foams		++ (TDI: excellent compression properties)	
TDI, other isocyanates	CASE		+	- (Significant higher cost - mainly niche applications)

5.3.2.2 Substitutes to the synthesis of BDO

The information collected on the alternative processes identified for BDO in the available literature allows getting some indication about their availability and feasibility. However, the information is scarce and some degree of uncertainty remains. The table below summarizes the assessment carried out on the alternatives identified for BDO, based on the available information. More details on the substitution cost for BDO resins are provided in section 5.2. below.

Table 31. Summary of the alternatives assessment identified for BDO

Alternative	Availability	Hazards/ Classification	Technical feasibility	Economic feasibility
propylene oxide, allyl alcohol, n-butane	+ (feedstock access)	Propylene oxide (CAS 75-56-9): Harmonised classification H224-H302-H312-H315-H319-H332-H335-H340-H350	+	(+) (additional capital investments)

5.3.2.3 Substitutes to the synthesis of Penta

Penta is a neopentyl polyhydric alcohol produced from formaldehyde and acetaldehyde.
The table below shows the alternatives identified for Penta. The choice of the alternative depends on the application and the end-use market for Penta.

Table 32. Substitutes for Penta

End-Use Market	Substitutes
Alkyd Resins	Glycerin or other polyol-based alkyds, latex, waterborne coating systems, epoxy, urethane, vinyl
Neopolyol esters (NPEs) for lubricants	Dibasic acid esters, diesters, mineral oils, alkylbenzenes, polyalkene glycol, polyvinyl ethers
Rosin and tall oil esters	Hydrocarbon resins
PETN (Explosives)	TNT, RDX

Source : Formacare, 2007

The information collected on the alternatives identified for Penta in the available literature allows getting some indication about their availability and feasibility. However, the information is scarce and some degree of uncertainty remains. The table below summarizes the assessment carried out on the alternatives identified for Penta, based on the available information. More details on the substitution cost for Penta are provided in section 5.2. below.

Table 33. Summary of the alternatives assessment identified for Penta

Alternative	End-use market	Availability	Technical feasibility	Economic feasibility
Glycerin (or other polyol-based alkyds)	Alkyd coating resins	+	- (less performance in durability, drying, heat stability, etc.)	+ (lower cost, decreasing price)
Waterborne coating systems	Alkyd coating resins (architecture: waterborne acrylics)	+		
	Alkyd coating resins (products finishes: waterborne systems, powder coating, high-solid polyesters)	+		
latexes	Alkyd coating resins (special-purpose coatings and surface coatings)	+	+ (easier to clean and use than oil based paints)	
Epoxies				
Urethanes				
Polyester and vinyl-based systems	Alkyd coating resins (surface)	+		
diesters or dibasic acid esters	NPEs (lubricants in aircraft engines)		- (less efficient, lower performance, less stable, etc.)	- (redesign cost of the engine, cost for testing and certification)
mineral oils, alkylbenzenes, NPE lubricants, polyalkene glycols, modified polyalkylene glycols and polyvinyl ethers	NPEs (lubricants in refrigeration)		+ (depending of the refrigeration systems)	
Hydrocarbon resins	Rosin and tall oil esters			
TNT	PETN (explosives)		- (not in the booster applications)	
RDX				

5.3.2.4 Substitutes to the synthesis of HTMA

Hexamethylenetetramine (HMTA) is a versatile chemical intermediate that can be used as an ammonia or formaldehyde donor. HMTA is a specialty chemical produced from formaldehyde and ammonia.

The information collected on the alternatives identified for HTMA in the available literature allows getting some indication about their availability and feasibility.

However, the information is scarce and some degree of uncertainty remains. The table below summarizes the assessment carried out on the alternatives identified for HTMA, based on the available information. More details on the substitution cost for Penta are provided in section 5.2. below.

Table 34. Summary of the alternatives assessment identified for HTMA

Alternative	End-use market	Availability	Technical feasibility	Economic feasibility
Regular epoxies	Novolac-based epoxy resins		(-) (less chemical and temperature resistant)	
imidazolidinyl urea (Germall®), diazolidinyl urea (Germall II®), DMDM hydantoin (Glydant®), bromonitropropane diol (Bronopol™), and tris (hydroxymethyl) nitromethane (Tris Nitro®)	Preservative (cosmetics, creams, personal care products)	++		
Methylparaben, ethylparaben, propylparaben, butylparaben, benzylparaben				
Methylchloroisothiazolinone/Methylisothiazolinone Methylisothiazolinone Methyldibromoglutaronitrile/phenoxyethanol Sorbic acid				
HMM	Rubber applications			

5.3.2.5 Substitutes to the production of ParaFormaldehyde (PFA)

No information could be collected for the production of PFA.

5.3.2.6 Substitutes to Formaldehyde in fertilizers

Formaldehyde is used in the manufacture of Controlled release fertilizers.

The presence of nitrogen, phosphorous, and potassium in fertilizers provide increased growth rates and greening to the plants upon which they are applied. Fertilizers are classified as fast-release or controlled-release. Fast-release fertilizers release their nutrients all at once. In comparison, controlled release fertilizers (CRFs) release their nutrients at a specific rate over a period of time, providing a more constant source of nutrients to plants, soils, and turf.

From an economic viewpoint, CRFs are usually more costly than its competing fertilizers.

The main form of Formaldehyde used in CRFs is urea-formaldehyde reactions products (Formacare, 2007; Afsset 2009). CRFs containing Formaldehyde include UF concentrates, ureaform, methylene ureas (MU), methylene diurea/dimethylene triurea (MDU/DMTU), UF solutions, urea-triazone solutions, and other slowly soluble fertilizers such as spikes, stakes, tablets and briquettes. Ureaform is the oldest type of UF fertilizer product and continues to be used in blended fertilizers. It is a granular substance produced by reacting urea and Formaldehyde. Ureaform is composed largely of higher molecular weight UF polymers.

Regarding substitution, the rate of release of the nutrient materials may be controlled in a variety of ways, including encapsulating them within polymer matrices. Incorporating them directly within soluble matrices based on

Formaldehyde and urea is usually the most cost effective approach. Manufactured UF products compete with other CRFs, with lower-cost soluble fertilizers and with processed **natural organic fertilizers such as processed sludge and fish and bone meal**. In non-agricultural markets, UF products compete based on advantages in labor cost savings and increased convenience. In agricultural markets, CRFs are not widely used due to their higher costs. However, because of increasing environmental concerns about nitrate pollution caused by leaching and run-off of nitrogen fertilizers, the slow release and non-leaching properties of controlled-release nitrogen sources have become more important product selection criteria.

Among the manufactured slow and controlled-release fertilizers, urea-formaldehyde based products still have the largest market share. Urea-formaldehyde competes with **urea-isobutyraldehyde (IBDU)** and **urea-crotonaldehyde (CDU)** as the two other nitrogen reaction products designed for professional turf and landscaping. Coated or encapsulated CRFs such as **sulfur-coated fertilizers (SCU)** are another type of controlled release fertilizer that competes with the UF-based products. These are conventional soluble fertilizer materials with rapidly available nutrients which are given a protective coating to control the water penetration and nutrient release. The greatest increase in consumption in recent years for CRFs has been with the **polymer-coated fertilizer types**. Another alternative to urea-formaldehyde CRFs is **fast-release fertilizer (FRF)**. While fast-release fertilizers are less expensive than CRFs, they have many disadvantages in many non-farm applications. The nitrogen in the fast-release fertilizers is exhausted quickly, and the application can be washed away. They need to be applied more than once, making it easy to apply in excess and thereby damaging plants and turf.

The information collected on the alternatives identified for the use of Formaldehyde in fertilizers in the available literature allows getting some indication about their feasibility. However, the information is very scarce and a high degree of uncertainty remains. The table below summarizes the assessment carried out on these alternatives, based on the available information.

Table 35. Summary of the alternatives assessment identified for the use of Formaldehyde in fertilizers

Alternative	End-use market	Availability	Technical feasibility	Economic feasibility
natural organic fertilizers (processed sludge, fish and bone meal)	Agricultural and non-agricultural		+ (increased convenience)	+ (lower cost)
IBDU	Non-agricultural (professional turf and landscaping)		+	
CDU			+	
SCU	Not specified		+	- (twice more costly)
FRF	Not specified		- (many disadvantages)	+ (cheaper)

5.3.3 Alternatives to formaldehyde in other industrial or professional uses

5.3.3.1 Substitutes to formaldehyde in healthcare applications

5.3.3.1.1 Laboratory/hospitals/healthcare structures

- The use of formaldehyde in **Histology and anatomopathology**: the most widely used fixatives in are formalin-based. No information was collected from industry on potential substitutes in this sector. It has to be noted that this use corresponds to the use "health services" described in section 4.3 above for which a RCR>1 has been demonstrated. However, literature provides valuable information. Many potential alternatives are identified and assessed in the literature against performance criteria such as the morphologic quality of the slide in optical microscopia, the quality and quantity of DNA and RNA extracted, etc. Among them, 6 are more largely and deeply studied. These alternatives are:

    - **Paxgene®**: mixture of methanol and acetic acid, of soluble organic compounds and of different alcohols including ethanol as a stabilising agent (Belloni, 2013)
    - **Finefix®**: concentrated formaldehyde-free aqueous solution, used once diluted with ethanol (Aydin, 2013)
    - **Histochoice®**: mixture of glyoxal, sodium choride, butanedial and zinc sulfate (Titford, 2005). One reported experience of substitution with glyoxal by a French laboratory shows that substitution is possible, requiring the modification of incubation times but no further equipment cost or training cost were needed. The purchasing price of glyoxal was higher than the price of formaldehyde but was quickly amortized. The laboratory stopped however the substitution process in 2015 because its partners (oncology centers and other hospitals) were reluctant to use other fixatives than formaldehyde (ANSES – to be published).
    - **RCL2®**: solution of acetic acid, ethanol and carbohydrates (Zanini, 2012). One reported experience of substitution with RCL2 in France shows that the reliability of RCL2 is insufficient, the results were considered too variable. Moreover, again, the laboratory indicated that international standards in this sector are all based on formaldehyde and it is thus very difficult to deviate from it in practice (ANSES – to be published).

  Subsport (2013) report also mentions **ethanol-glycerin fixation with thymol conservation, Shellack resin in ethanol**, **Fixall-his (Ethanol, acetic acid, propan-2-ol)** and **1-Methyl-3-octyloxymethylimidazolium tetrafluoroborate** as alternatives nut no assessment is made.

  As indirect non chemical substitutes, Subsport (2013) quotes tissues **freazing**, **freaze drying** and **cryosubstitution** (with no further assessment).

  In conclusion, the whole scientific corpus on these substitutes seems to agree that these alternatives are only feasible under very specific conditions of use and are not compatible with other ones. This heavily limits their feasibility for any possible situation. Moreover, given that the international standards are all based on formaldehyde, the medical structures and intitutions practices are dependent on one another and

none is willing to switch. The analysis of literature shows that there does not exist for now any universal substitute for the use of formaldehyde in histology and anatomopathology.

- **Electropheresis**: Electrophoresis is a standard "workhorse" procedure in life science research. In this process, tissue samples are usually fixed with formaldehyde and electrophoresed through a denaturing gel (e.g. formaldehyde-agarose gels, polyacrylamide-urea gels). Agarose electrophoresis of RNA requires the inclusion of denaturing agents in the gel. Of the variety of denaturants which can be used for RNA analysis, all are toxic or noxious to some extent. **Methylmercuric hydroxide (MMH)** reacts reversibly with amino groups on RNA and is a very effective denaturant. However, its toxicity and high volatility make its use inconvenient and hazardous. Formaldehyde also denatures RNA but is safer than MMH. Formaldehyde agarose gels provide a denaturing environment that allows more accurate size determinations and efficient binding to membrane supports (Formacare, 2007).

- **Cleaning agents:** a high hygienic standard is required in several facilities such as: hospitals, laboratories, sanitary facilities, etc. Cleaning has a dual function: surface cleanliness, and infection prevention and control. This requires intensive and frequent cleaning with a wide range of products including disinfectants. Subsport (2013) report lists without priority chemical and non chemical alternatives to formaldehyde as a cleaning agent. The chemical alternatives are **glutaraldehyde, hydrogen peroxid, ortho-phthalaldehyde, peracetic acid, chlorine dioxide and quaternary ammonium compounds (benzalkonium chloride).** The non chemical alternatives are **microfiber mopping, the use of cleaning machines that require minimal chemicals**, substitution through **organisational measures** (cleaning areas depending on the level of disinfection required from an infection prevention and control perspective) or substitution through **design** (selection of flooring material that reduces the need of cleaning with disinfectants) (Subsport, 2013). It has to be noted that Subsport mentions these non-chemical alternatives but does not consider them as suitable.

Table 35 further below summarizes the assessment carried out on the alternatives identified for the use of formaldehyde in healthcare applications, including the use in laboratories and hospitals.

5.3.3.1.2 Embalming

formaldehyde is the most widely used substance in embalming (registered in PT22 under the Biocidal Products Regulation: Embalming or taxidermist fluids).

As reported in Formacare (2007), concern for mortuary workers' exposures to formaldehyde has prompted research into alternative embalming chemicals. **Ethyl alcohol/polyethylene glycol, glutaraldehyde, and phenoxyethanol** are reported to be alternatives to formaldehyde but may possess other worker health and safety concerns.

Other sources in the public literature as well as the Biocidal Products Regulation itself provide valuable information about alternatives identified in this sector.

The BPR identifies 7 active subtances as potential alternatives to formaldehyde in PT22:

- 2 alternative active substances are approved under the BPR: **iodine** and **poly(vinylpyrrolidone)-iodine**. These are used as embalming fluids with a iodin concentration between 0.29% and 1.54% w/w.
- the other 5 active substances are **bronopol** and alkyl chlorides (currently under evaluation under the BPR by Spain and Italy; decision expected for 2022): **Quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides** (CAS 85409-22-9), **C12-14-alkyl[(ethylphenyl)methyl]dimethyl, chlorides** (CAS 85409-23-0), **benzyl-C12-18-alkyldimethyl, chlorides** (CAS 68391-01-5) and **benzyl-C12-16-alkyldimethyl, chlorides** (CAS 68424-85-1).

Additionally, the **4 ionic compounds of the above-mentioned quaternary ammonium** are active substances and are identified as potential substitutes to formaldehyde (ANSES, 2015). However, these substances are listed on Part 2 of Annex II of the BPR and are thus subject to notifications by industry. In case no notification is made by October 2015, they will be subject to a non-approval decision (at the beginning of January 2016 there are still under review by Italia according to ECHA website).

Finally, a literature review allowed getting information on other potential alternatives to formaldehyde in thanatopraxy sector (ANSES, 2015):

- **aldehydes**: **glyoxal and trichloroacetaldehyde.** Glyoxal is concentrated at only 4% w/w but seems to be a satisfactory preservative. This substance is not approved under PT22 in the BPR due to its hazardous properties (Muta 2; H341 under CLP Regulation). Trichloroacetaldehyde (also called "Winckler solution") used to be used already in the past in thanatopraxy. Its toxicologic profile is however not known.
- **Mixture of Glycerin-ethanol and thymol**: the mixture of glycerin and ethanol are the fixative agent and the thymol plays the role of preservative. It has been developed in Germany with the goal of substituting formaldehyde in thanatopraxy, histology and anatomopathology sectors (Hammer et al. 2012). Its toxicity for human health is low and it shows good technical properties (similar efficiency and higher capacity than formaldehyde to preserve tissues and skin coloration). Nevertheless, the mixture is very costly and little available.
- **Metal salts: zinc chloride and aluminium sulphate**. Zinc chloride is used on its own as preservative and fixative in tissues at a concentration up to 41% w/w. Like formaldehyde, it gives a unfavourable greyish color to the tissue after injection as well as some rigidity (Dessart et al 2006). To avoid these disadvatanges, it is advised to complete its action with humectant, tensioactive and coloring agents. It is often used as an additive in conservative aldehydes- or alcohol-based solutions. Zinc chloride shows adverse cutaneous effects. Aluminium Sulphate is used as a conservative agent in thanatopraxy and could stand for an alternative to formaldehyde.
- **1,1-diethoxyethane** is the main conservative agent used in thanatopraxy. It is formulated between 30% and 33% in an embalming solution and associated with tanins up to 7%-9% and potassium carbonate (Afsset, 2009).
- **Acids**: acids are also used as conservatives of corpses such as **ascorbic acid, citric acid, sodium carbonate and sodium bisulfide** similarly formulated with concentration ranging from 10% to 40%. Satisfactory results have been reported in the conservation of animal tissues (Dessart et al 2006).
- **Acetones**: **Dihydroxyacetone (DHA compounds) and dialkylketone peroxyde**. DHA compounds are patented in the USA for its tanning action on skin. However, its formulation cost if very high (Dessart et al 2006). Dialkylketone peroxide-based products are conservation fluids

concentrated between 5% and 24% w/w. These products are considered efficient, non toxic and non irritative. However, they have not been approved under BRP due to their explosive properties (ANSES, 2015).

- **Ethanol, peracetic acid and propolis alcoholate** are active substances contained in products used in thanatopraxy and are being approved by Health Ministry in France. However, for the time being, these substances are not listed in the examination work program of biocidal existing active substances (ANSES, 2015).

Subsport (2013) also reports **Propan-2-OL** as a chemical alternative for embalming sector. However, it is known to be highly inflammable.

Indirect non chemical substitutes to formaldehyde in thanatopraxy are also reported such as **carbonic ice** and **refrigerating equipments** (ANSES, 2015). Carbonic ice is the most used traditional technique in tissues conservation and is recommended particularly in medical treatments at home. Ice is placed on different parts of the corps which instanteously freeze (-96°C). Application must be repeated very 24 to 36 hours (Venter et al 2013). Refrigerating equipments such as beds are used in specialized institutions (like death chambers) in order to preserve the corpses in good conditions until funeral takes place.

Table 35 further below summarizes the assessment carried out on the alternatives identified for the use of formaldehyde in healthcare applications, including embalming.

5.3.3.1.3 Conclusion on the alternatives identified for the use of formaldehyde in healthcare applications

Considering art. 2(5a) of REACh, authorisation (title VII) shall not apply to the substance used in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC. However, the substitutes presented below should be considered for restriction if a risk is identified for these uses.

The information collected on the alternatives identified for the use of formaldehyde in healthcare applications in the available literature allows getting some indication about their availability and feasibility. The information is scarce and some degree of uncertainty remains. The table below summarizes the assessment carried out on these alternatives, based on the available information.

Table 36. Summary of the alternatives assessment identified for the use of formaldehyde in healthcare applications

Alternative	End-use market	Availability	Technical feasibility	Economic feasibility
Glutaraldehyde	Production of vaccines (inactivate toxins in acellular pertussis) Embalming/ thanatopraxy Cleaning agent	+		
Betapropiolactone	Production of vaccines (inactivate rabies virus)	+		
Application of heat	Production of vaccines	+	- (applied on inactivate virus, risk of ineffectiveness)	

Fish gelatin	Production of gelatin capsules			
Starch				
Paxgene®	Histology and anatomopathology (fixative)	+	- (all: feasible only under very specific non-universal conditions, not compatible with international standards) - (RCL2: too variable results, based on French experience)	+ (glyoxal, based on French experience)
Finefix®		+		
Histochoice®		+		
RCL2®		+		
Ethanol-glycerin fixation with thymol conservation				
Shellack resin in ethanol				
Fixall-his				
1-Methyl-3-octyloxymethylimidazolium tetrafluoroborate				
MMH	Denaturant for electrophoresis		+ (very effective but high volatility)	
Hydrogen peroxid	Cleaning agent			
Ortho-phthalaldehyde				
Chlorine dioxide				
Benzalkonium chloride				
Ethyl alcohol/ Polyethylene glycol	Embalming/ Thanatopraxy (+ cleaning for peracetic acid)			
Phenoxyethanol				
Iodine				
Poly(vinylpyrrolidone)-iodine				
Bronopol				
ADBAC C12-C18				
ADBAC/BKC C12-C16				
ADBAC C12-C14				
ADEBAC C12-C14				
4 ionic compounds of the above-mentioned quaternary ammonium compounds				
Ethanol			+ (being approved in France)	
Peracetic acid			+ (being approved in France)	
Propolis alcoholate			+ (being approved in France)	
glyoxal			+ (good technical properties)	
trichloroacetaldehyde			+	
Glycerin-ethanol+thymol		-	+	- (very costly)
Zinc chloride			+ (but additional agents needed)	
Aluminium sulphate				
1,1-diethoxyethane		+	+	
Acids (ascorbic acid, citric acid, sodium carbonate and sodium bisulfide)			+	
DHA compounds			+ (skin tanning)	- (very high cost)
Dialkylketone peroxyde			+	
Propan-2-ol				

5.3.3.2 Substitutes to formaldehyde in food applications

Considering art. 2(5b) of REACH, authorisation (title VII) shall not apply to the substance used in food or feedingstuffs in accordance with Regulation (EC) No 178/2002. However, the substitutes presented below should be considered for restriction in food application if a risk is identified for these uses.

5.3.3.2.1 Human food

In human food, formaldehyde is used as a technological auxiliary for its biocidal property in the manufacture of sugar (saccharose extraction from beetroots), as a preservative agent for the production of food additives or as food additive itself, as a cleaning agent for surfaces, as a synthetic reactive substance for the food contact materials (coatings), as an ingredient for specific MF resin in the water treatment, as a formulation agent in glues and adhesives for plastic pipes in contact with drinking water.

- **Manufacture of sugar**

Formaldehyde is used for its biocidal property as a technological auxiliary. As such, technological auxiliaries are not consumed as food ingredients. They are intentionally used during the treatment and transformation processes of raw materials, food materials and ingredients for a targeted purpose. In those circumstances, formaldehyde-based solution (Formalin) has been globally used in the manufacture of sugar for its bacteriostatic property for more than 100 years. No particular elimination process of formaldehyde is carried out during the sugar manufacturing but formaldehyde is not present in the final product other than in traces. It degrades almost totally during the lime process (ANSES – to be published).

At French level, the **extract of hop in aqueous solution** containing about 10% of beta acids is authorised in the manufacture of sugar as technological auxiliary with bacteriostatic property (French Arrêté 19 October 2006, Annex 1A) with a maximum dose of 50mg/kg of beetroots and may be used as a substitute for formaldehyde (ANSES – to be published). Moreover, in 2000 and 2002, an authorisation dossier was submitted by sugar industry to Afssa (now ANSES) in France on a paracetic acid-based biocidal solution (composed of paracetic acid, acetic acid, hydrogen peroxide and co-formulants), claimed to be a possible substitute to formaldehyde. In 2002, Afssa published a supportive opinion on the use of this **paracetic acid solution**, as technological auxiliary in sugar industry. In 2005, the authorisation request was resubmitted with nex industrial tests and Afssa concluded that the use of such a solution was safe for consumers at a maximal dose of 17g/tonne of beetroot but still requested additional information on the tests carried out (ANSES – to be published). Since then, no further information has been submitted by industry to Afssa/ANSES to finalize their authorisation request. In conclusion, the use of paracetic acid solution seems to be technically feasible and safe, even though the efficiency couldn't be quantified and demonstrated. The economic considerations related to this solution have not been assessed either.

No further information could be collected on the alternatives of formaldehyde in sugar manufacturing. Research is still ongoing at ANSES on this issue.

- **Human food additives**

Formaldehyde is also used for its biocidal property as a technological auxiliary in the production and conservation of alginates (linear polymers). As indicated above, alginates are food additives authorised by EU Regulation n° 231/2012/EC (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).

This Regulation allows a maximal concentration of formaldehyde residues of 50mg/kg in food additives.

Formaldehyde is used in the production of alginates because it allows avoiding microorganisms proliferation and microbiological alteration of marine seaweeds used as raw materials and stored during crop season, from mid-may to mid-september (EFSA, 2006). The technical properties of formaldehyde particularly efficient for this use are the following : its pH is relatively neutral, it is on ionic and not volatil and stable over long periods.

The neutral biocidal chemicals such as **Ozone** and **hydrogen peroxide** might be used in replacement of formaldehyde. However, their volatility and their short half-life (oxydisation and chemical instability) are strong disadvantages for the storage of alginates at medium-term. The use of **quaternary ammonium** may also be a possible alternative. To date, 2 quaternary ammonium compounds are authorised under Biocidal Products Regulation n°528/2012 in Europe as pesticides and biocides: the DDAC (didecyldimethylammonium chloride) and the BAC (benzalkonium chloride). They are both submitted to Maximum Residue Limits (MRL) under former Biocidal Regulation n°396/2005 and will be submitted to MRLs under Biocidal Regulation n°528/2012, after EFSA has delivered its opinion. Discussion for possible solutions for food industry is thus still open (Holah et al., 2014). Marginally, Moen et al. (1999) studied the use of **dry salting** of Ascophyllum nodesum seaweeds in replacement of formaldehyde. The salted seaweeds are proved to be able to be conserved at least during 46 days.

No further information could be collected on the alternatives of formaldehyde in additives.

No information could be collected on the alternatives to formaldehyde in the other uses in human food.

5.3.3.2.2 Animal food

In animal food, formaldehyde is used in the form of formol (aqueous solution) as a preservative agent for silages, to tan proteins for certain animal food (suh as oil cattle cakes), as a preservative agent in milk for piglets, as a fumigating bactericidal agent to fight against e.g. salmonella (Afsset, 2009).

- **Tanning of oil cattle cake**

The oil cakes used to feed cattles are treated and tanned with formaldehyde in order to protect them against microbial proliferation. This use is authorised at EU level under Regulation n°68/2013/EC (Catalogue of feed materials) under classification 56 ("rumen protection"). To date, there seems to be no suitable alternative which shows as much efficiency as formaldehyde to treat animal food materials rich in proteins. During the last past years, Industry has attempted to substitute formaldehyde with tanning agents such as **vegetal tannins** (such as sweet chestnut tannin) and **essential oils** but the results were not satisfactory (ANSES – to be published).

- **Silage preservation**

Formaldehyde is use for the preservation of silages for all types of animals. This use is authorised by Regulation (EC) No 1831/2003 on additives for use in animal nutrition, and listed in the 2005 Register of Feed Additives under Categorie 1 - Groupe k (silage additives). Formaldehyde allows lowering the pH of grass of the silages to approximately 4.5 and its use is recommended by EFSA in order to judge about the efficiency of other additives used in silages (EFSA, 2014).

In general, the efficiency of the susbtitutes to formaldehyde in silages preservation depends on the silage composition itself. Some formol-based compounds are also sometimes used in combination of other partially neutralised acids in the form of salts such as nitrates or sulfates. These are **bacteriostatic preservatives**. **Microbiological preservatives** have been used as substitutes to formaldehyde. Many of them are already used on the market and show similar preservation quality as formaldehyde but restricted conditions of use are required (Andrieu et al. 1998, ANSES – to be published). Finally, the technique of **balage** operated under specific conditions of ventilation, air temperature and favourable climate conditions may stand for a substitute to formaldehyde and chemical preservation of silages. In that case, the use of preservatives is not really useful to improve again the preservation quality. For meteorological reasons, this technique is limited and couldn't totally replace the use of silages preservative.

- **Preservation of milk for piglets**

Formaldehyde is used in milk for piglets up to 600mg/kg of skimmed milk for its antimicrobial property. Bovin milk is used to feed piglets during weaning. Other preservation techniques exist to conserve unpasteurised milk such as **lactoperoxydase system** (LP), the use of **chemicals** or the acidification of milk with **lactic ferments**. LP is an enzyme naturally present in milk, shows bacteriostatic properties and allows milk preservation also at air temperature for a couple of hours (OMS, 2006). There is no adverse public health effects reported for the autorized doses. However, the limit of LP system is that LP has to be activated just after the milking. As an example of chemicals used for this use as an alternative to formaldehyde, one can find **hydrogen peroxide**. Compared to LP, it has to be used in higher doses. Its use is prohibited in the USA due to its mutagen effects on human health. It is authorised in Europe as an technological auxiliary for decontamination in association with acetic acid and peracetic acid. Moreover, FAO specifies that the use of peroxide in milk disaggregates proteins and lowers the levels of Vitamine A and carotenoids (OMS, 2006; ANSES – to be published). Other preservative and acidification agents which are authorised in Europe have been studied for milk preservation such as acetic acid (E260), adipic acid (E355), benzoic acid citric acid (E330) or lactic acid (E270) (Chase, 2011; ANSES – to be published) but their efficiency compared to formaldehyde has not been tested. Finally, old studies showed that preservation of milk could be done through the addition of **lactobacillus** in the form of acid milk or yogurt (McKenzie and Lambert, 1955; Février et al., 1979).

- **Bactericidal agent to fight against e.g. salmonella**

ANSES (2014) reports shows that assicated with methanol at doses between 200 and 1000 mg/kg, formaldehyde is efficient to limit the food contamination by e.g. salmonella. However, some studies demonstrate that formaldehyde might also hide the presence of salmonella in food and others show that when formaldehyde concentration exceed 600 mg/kg in food, some zootechnical properties might be altered. Substitutes to formaldehyde for this use are organic acids and essential oils. **Organic acids** possess bactericidal properties on salmonella during the manufacturing of food for cattle but the demonstration of their efficiency has not been performed. As to **essential oils**, they are potentially attractive due to their properties shown in human food. However, no study has been carried out so far in order to prove their efficiency in animal food.

5.3.3.2.3 Conclusion on the alternatives identified for the use of Formaldehyde in food applications

The information collected on the alternatives identified for the use of formaldehyde in food applications in the available literature allows getting some indication about their feasibility. However, the information is very scarce and a

high degree of uncertainty remains. The table below summarizes the assessment carried out on these alternatives, based on the available information.

Table 37. Summary of the alternatives assessment identified for the use of formaldehyde in food applications

Alternative	End-use market	Availability	Technical feasibility	Economic feasibility
extract of hop in aqueous solution	Human food – sugar manufacturing		+ (?)	
paracetic acid solution	Human food – sugar manufacturing		+ (?)	?
Ozone	Human food additives		- (volatility and short half-life)	
Hydrogen peroxide			- (volatility and short half-life)	
Quaternary ammonium			+ (?)	
dry salting			+ (more than 46 days?)	
Vegetal tannins	Animal food – Tanning of oil cattle cakes		-	
Essential oils	Animal food – Tanning of oil cattle cakes +bactericidal agent		-	
Microbiological preservatives	Animal food – silage conservation			
lactoperoxydase system	Animal food – milk for piglets		+ (but time constraint)	
hydrogen peroxide			+ (but shortcommings on vit. A and carotenoids)	
lactobacillus			+?	
Organic acids	Animal food – bactericidal agent		+?	

5.3.3.3 Substitutes to formaldehyde in other industrial and professional uses

As presented in section 4.2.2 above, formaldehyde is also used in other minor professional and industrial uses such as the use in nuclear wastes treatment, the use in photography industry, in mechanic and metallurgy industry, the production of chelating agents, the production of TMP and of pyridines.

Some of these uses have been addressed already within this section such as the use of formaldehyde in metallurgy (metal containers, metal furniture and enamels under "MF resins" section and metal molds and foundry under "PF resins" section), the use of formaldehyde in phytopharmaceutical products as a biocidal and preservative agent (under the "cleaning agent" section), or the use of

formaldehyde in photography industry under "chelating agents" section just below. However, no information could be collected on the alternatives to formaldehyde for the remaining "other" industrial and professional uses listed in section 4.2.2 such as the treatment of nuclear wastes, the applications in photography industry, precious metal recycling or silver galvanization.

5.3.3.3.1 Production of chelating agents

formaldehyde is used in the production of chelating agents such as aminopolycarboxylic acids and sodium salt.

Chelating agents are compounds whose molecules can form several bonds, usually in ring structures, to metal ions. They remove metal ions by sequestration or through metal buffering and solubilization. Chelating agents can be used to help control such undesirable metal ions as iron, copper, calcium, lead, and magnesium in solution.

Aminopolycarboxylic acids have many properties that make them desirable in a wide variety of applications. Chelating agents can be synthesized and are stable at high temperatures, are inert to most chemicals, can be used over a wide pH range, are insoluble in organic solvents, and have a low toxicity. Chelating agents boost performance of many end-use applications: they prevent discoloration and rancidity, improve rinsability of soaps and detergents, improve bleachability of pulp, control water hardness, and preserve color and flavor of foods, beverages, and pharmaceuticals.

As mentioned above, different types of aminopolycarboxylic acids account for chelating agents produced in the European Union: Ethylenediaminetetraacetic acid (EDTA), Diethylenetriaminepentaacetic acid (DTPA), hydoxyethylethylenediaminetriacetic acid (HEDTA), nitrilotriacetic acid (NTA), methylglycinediacetic acid (MGDA), 1,3 propylenediamine tetra acetic acid (PDTA), di(hydroxyethyl)glycine (DHEG), ethanoldiglycinate (EDG), and glutamic acid – N,Ndiacetic acid (GLDA).

As reported in Formacare (2007), **hydroxycarboxylic acids (gluconic acid), polyphosphates and organophosphonate-based chelating agents** are the primary substitutes for the aminopolycarboxylic chelating agents. The choice of the preferred chelating agent depends on pH range and temperature of the system, the metal ions to be sequestered, the presence of other interfering materials, and on biodegradability. While most chelating agents cannot be used interchangeably and do not compete with each other, some products of the major chelating groups can be interchangeable for others. Usually, there is significant loss of utility for imperfect substitutes for chelates. It would also be possible to produce some formaldehyde-based chelating agents using alternative, **formaldehyde-free chemistries**. For example, EDTA can be synthesized by the reaction of EDA and chloracetic acid. However, this route involves the use of more costly starting materials and the product price would have to increase still more to justify investments in the new plant and equipment required.

The information collected on the alternatives identified for the use of formaldehyde in the production of chelating agents in the available literature allows getting some indication about their feasibility. However, the information is very scarce and a high degree of uncertainty remains. The table below summarizes the assessment carried out on these alternatives, based on the available information.

Table 38. Summary of the alternatives assessment identified for the use of formaldehyde in the production of chelating agents

Alternative	Availability	Technical feasibility	Economic feasibility
hydroxycarboxylic acids (gluconic acid)		+ (?) (loss of utility)	
polyphosphates		+ (?) (loss of utility)	
organophosphonates		+ (?) (loss of utility)	
Formaldehyde-free synthetized EDTA			- (higher cost)

5.3.3.3.2 Production of TMP

Formaldehyde is used to produce Trimethylolpropane (TMP). TMP is a neopentyl polyhydric alcohol produced from formaldehyde and nbutyraldehyde.

Formacare (2007) reports that the primary product applications of TMP are coating resins for surface coatings, neopolyol esters (NPEs) for lubricants, multifunctional acrylates/methacrylates for radiation-curable coatings, polyether polyols for urethanes, surface treatment of pigments (TiO2) and isocyanate adducts for PUR. Coating applications are the largest use of TMP.

TMP-based NPEs are primarily used as lubricants in aviation and automotive applications and metal working. Less expensive NPEs used in fire-resistant hydraulic fluids face competition and potential substitution by phosphate esters.

In the European Union and Norway, TMP-based multifunctional monomer coatings such as TMP acrylates and methacrylates are used as in radiation-curable coatings, printing inks, and adhesives (Formacare, 2007).

As reported in Formacare (2007), radiation-curable coatings are used in both wood and plastic for finishes on flooring. Both wood and resilient vinyl flooring benefit from the hard and durable qualities of the surface coatings. Product enhancements of the TMP-based surface coatings continue to result in increased demand of the coatings for wood and vinyl flooring. **Phosphate esters** are the largest competitor of TMP-based fire-resistant hydraulic fluids. While phosphate esters are intrinsically more fire resistant, TMP-based hydraulic fluids can be enhanced by using additives to make them more fire resistant. Since these materials can be used almost interchangeably, the TMP-based fire-resistant hydraulic fluids will continue to replace phosphate esters at minimal cost.

Polyether polyols for urethanes are manufactured with a hydrogen-containing initiator, such as water, glycols, and polyols including TMP. TMP-based polyether polyols for urethanes can be substituted by **polyether polyols made from some other initiator**. However, the functionality of the polyether polyol depends on the functionality of the initiator used. The non-TMP initiators would not produce polyether polyols with the same properties and would not be perfect substitutes since loss of utility would result from their use. Not all polyester and alkyd coating resins or NPEs are produced using TMP. **Other neopentyl polyhydric alcohols** also produce these resins and lubricants, but they are also

manufactured by the reaction of formaldehyde with another aldehyde and so would not be available to substitute for TMP.

The information collected on the alternatives identified for the use of formaldehyde in the production of TMP in the available literature allows getting some indication about their feasibility. However, the information is very scarce and a high degree of uncertainty remains. The table below summarizes the assessment carried out on these alternatives, based on the available information.

Table 39. Summary of the alternatives assessment identified for the use of formaldehyde in the production of TMP

Alternative	Availability	Technical feasibility	Economic feasibility
Phosphate esters		+ (but less fire-resistant)	- (more costly – how far?)
polyether polyols made from non-TMP initiators		+ or – (depending on the initiators)	
Non-TMP neopentyl polyhydric alcohols		+	

5.3.3.3.3 Production of pyridines

Formaldehyde is used to produce pyridines: pyridines are synthetically produced by reacting acetaldehyde and ammonia, with or without formaldehyde and are used, among others, in the manufacture of agricultural chemicals, solvents, latexes, feed supplements for poultry, dairy cattlen swine and pet food, cosmetics, personal care products.

As reported in Formacare (2007), synthetic processes account for most European production of pyridines. Pyridines from other sources are a poor substitute for synthetically produced pyridines since they are more costly, can be of variable composition, and can only supply a small fraction of demand. Pyridines are not present in raw coal, but are synthesized during the coking process without the use of formaldehyde. The amount of pyridine bases isolated from coking operations is very small, amounting to about 0.04-0.12 kg per metric ton of coke. The most likely approach to substitute for formaldehyde-based synthetic pyridines is to employ alternate chemistries for their synthesis. **Chemistries based on acetone and acrylonitrile, or on acrolein, acetaldehyde or propionaldehyde and ammonia** are possible, but it is not clear whether they can be effective in producing all the isomers and derivatives currently available. An alternate route to beta-picoline is the **conversion of 1,5- diaminopentanes** to pyridines. This is accomplished by hydrogentating 2-methylglutaronitrile, cyclizing to methylpiperidine, and then dehydrogenating to beta-picoline.

The information collected on the alternatives identified for the use of formaldehyde in the production of pyridines in the available literature allows getting some indication about their feasibility. However, the information is very scarce and a high degree of uncertainty remains. The table below summarizes the assessment carried out on these alternatives, based on the available information.

Table 40. Summary of the alternatives assessment identified for the use of formaldehyde in the production of pyridines

Alternative	Availability	Technical feasibility	Economic feasibility
synthesis based on acetone and acrylonitrile, or on acrolein, acetaldehyde or propionaldehyde and ammonia	?	+?	+ (more costly)
conversion of 1,5-diaminopentanes (alternative route to beta-picoline)			

6 JUSTIFICATION FOR THE RISK MANAGEMENT OPTION

6.1 Need for (further) risk management

As already mentioned, the CSR carried out by the registrants was firstly based on DNELs of 0.4 ppm for long-term and 0.8 ppm for short-term exposure, with exposure data either measured or modelled with RMMs that have been fitted to be below these DNELs. These exposure data were taken from the RMOA carried out by TNO and RPA in 2013. In 2015, the updated CSR mentioned new DNELs of 0.3 and 0.6 ppm respectively for long and short-term exposures, using solely modelling data.

Following the recent Anses discussion about worker DNELs/OELs for formaldehyde, final DNELs were adopted for long-term exposure (0.3 ppm) and short-term exposure (0.6 ppm) in the framework of this RMOA. **Considering these values, the previous set of exposure data provided by the Registrant in its 2013 CSR and the exposure data gathered from the French Colchic database (for the period 2007-2013), Anses identified a number of uses for which risks arise for workers as shown in the section 5.2 and Annex C.**

As a result, the expected target of a potential RMO for formaldehyde would be at least both the formal setting of appropriate DNELs for short and long-term exposures (0.3 and 0.6 ppm respectively) and the control of the on-site occupational exposures to formaldehyde below these exposure limits. **The respect of such limits is defined herein as the risk reduction strategy (RRS) to be achieved**. This may require one or a combination of the following solutions: collective protective equipments, personal protective equipments, changes in the processes, closed systems and automation, substitution of the substance within the same/similar process, alternative process, stop of use, etc.

This RRS has been implemented in France since the 1st of January, 2007, by a French decree of 13 July 2006 adding processes emitting formaldehyde to the list of substances, preparations and carcinogenic processes. If substitution is not technically possible, exposures should be reduced as low as possible, aiming at respecting current regulatory French OELs (0.5 ppm for long-term and 1 ppm for short-term exposures) (cf. section 5.2.2). According to the French Colchic database measures, formaldehyde exposures decreased between the 2000-2006 period and the 2007-2013 period following the implementation of this decree. If the Colchic exposure values are compared to the proposed Anses DNELs (0.3 and 0.6 ppm respectively), as it was done in section 5.2.2, the number of

occupational sectors at risk decreased from 24 to 17 for long-term exposures between 2000-2006 and 2007-2013, with a fall of more than 50% of formaldehyde exposures in numerous occupational sectors identified by Colchic database. This analysis underline the efficiency of the implementation of this French decree, showing that the control of the on-site occupational exposure to formaldehyde below exposure limits is relevant as a risk reduction strategy.

Therefore, several RMOs are identified in the following section aiming at assessing their potential effectiveness and appropriateness in implementing such EU wide setting and control.

6.2 Identification and assessment of RMOs

6.2.1 List of identified eligible RMOs

This section explores the potential of REACH and non-REACH RMOs able to manage the occupational health risks arising from the manufacture and uses of formaldehyde. As already said, the target is the control of the exposure below the set DNELs. Therefore each RMO is assessed in this perspective.

As presented above (section 2), several pieces of European legislation already exist which aim at avoiding, controlling and/or reducing emissions on formaldehyde and exposure of workers. No voluntarily concerted commitment from Industry has been identified so far except the initiative on formaldehyde emissions from WBP in order to protect consumers and professionals presented in section 4.2.2.1.1.

The table below summarizes the RMOs identified as regards their consistency in addressing the EU-wide occupational risks related to formaldehyde accordingly to the RRS. Most of these RMOs have been presented above in section 2 since they already regulate formaldehyde. The underlined RMOs are considered as eligible and are then further assessed in the following section. The other ones are discarded.

Table 41. The Risk Management Options identified to address the risks

Type of Regulation		**Piece of legislation**
Non-REACH regulations	EU general legislations on hazardous chemicals	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP regulation)
	EU workplace legislation	Directive 98/24/EC - Chemical Agents at work Directive (CAD) / OELs Directive 2004/37/EC on Carcinogens and Mutagens at work (CMD) / OELs
		Directive 2001/58/EC and EC Regulation 2015/830 on Safety Data Sheets
		Directive 89/656/EEC on the use of personal protective equipment
		Directive 92/85/EC (pregnant workers Directive)
		Directive 94/33/EC (young workers Directive) on the protection of young

Type of Regulation		Piece of legislation
		people at work
		Seveso III Directive 2012/18/EU
		Biocidal Products Regulation 528/2012/EU
	EU legislation on environment protection and/or covering human health safety through environmental exposure	IED Directive 2010/75/EC (ex-IPPC)
	Sectorial regulation – wood based panels	Construction Products Regulation (CPR) 305/2011/EU – CE Marking / HES EN 13986-A1
REACH regulation	REACH restriction	REACH - Annex XVII - ECHA reference agency
	REACH SVHC identification /Authorisation	REACH - Annex XIV - ECHA reference agency

6.2.2 Assessment of the identified eligible RMOs

In the following, are assessed the RMOs considered as appropriate to address the occupational risks, comparing the non-REACH and REACH regulations. As a summary, Figure 5 below provides an overview of the possible RMOs to be recommended for all the uses for which a risk has been demonstrated.

6.2.2.1 Non-REACH legislation – OSH Regulations (CAD and CMD Directives)

6.2.2.1.1 Discussion on Directive CAD 98/24/EC and Directive CMD 2004/37/EC

In the perspective of addressing the risks demonstrated for workers exposed to formaldehyde, setting Binding OELs within the framework of the CMD would be in practice an option that would allow a harmonized measure within the EU and would oblige Industry to comply with the requirements and to prevent workers exposure.

Limit values set by CMD are binding and shall be transposed in national laws by each Member States either with the same or with more restrictive values. This ensures harmonised implementation within Member States without imbalance both for Industry's competition and workers protection.

Formaldehyde is now eligible to be covered by CMD due to its classification as Carc. 1B. An update of Directive 2004/37/EC is thus expected. An additional 2-years period (maximum) for transposition in national laws by Member States and enforcement by companies is expected. Depending on the Commission's priorities and bodies involved in binding OEL development, an effective date for a limit value to be enforced by Member States is difficult to anticipate.

However, if formaldehyde misses the next update of CMD, no indication for another update is yet available and it is not known if the Directive will be updated on a frequent basis or not. The recent experience shows that ten years may be needed to update the Directive, partly explained by extended discussions

between stakeholders on the addition of new limit values, especially in a context where REACH Regulation adds legal requirements on Industry on same issues (occupational health and safety, substances of very high concern, etc.). **A long timeframe of 10 years could be expected to update the Directive**, as the review of both CMD and CAD Directives has also been launched for discussion.

Regarding CAD/CMD, except for few BOELs e.g. for lead and lead compounds, only IOELs are currently set. Therefore a **binding value for formaldehyde is not expected easily achievable**, considering in particular the difficulty to take into account socio-economic data in order to set a binding value. If IOELs are set for formaldehyde, Member States would then be free to set more restrictive national BOELs, missing the opportunity to harmonise these values within Europe. As a reminder in Europe:

- There is no BOELV set at EU level.
- There are currently different national level of OELs implemented in EU countries.
- SCOEL has recently proposed an upward revision of its OELs at 0.3 ppm for long-term exposure and 0.6 ppm for short-term exposure. SCOEL's final conclusion may be expected by spring/summer 2016.
- In their updated 2015 registration dossier, Industry of formaldehyde used a long-term DNEL of 0.3 ppm and a short-term DNEL of 0.6 ppm.
- Anses has recently finallised an harmonization of OELs/worker DNELs proposing a long-term DNEL of 0.3 ppm and a short-term DNEL of 0.6 ppm.

As stated in both CAD and CMD, priority should be given to avoid exposure but drivers for substitution are weak (not mandatory for CAD and to be undertaken 'if technically possible' for CMD). These directives may be seen as providing **low incentives to substitution.** The choice of the best option is left to each company, justifying if/why substitution is not feasible. It may however be anticipated that companies would rather implement more stringent on-site RMMs. Moreover, considering section 5.3 and economic considerations in Annex E, substitutability of formaldehyde and the related costs varies a lot among the sectors. This process is not EU harmonized but usually Member States (at least in France) require one control per year in each concerned company with retaliation measures.

Based on the French experience (French decree of 13 July 2006 adding processes emitting formaldehyde to the list of substances, preparations and carcinogenic processes), it is expected that despite the classification as Carc. 1B, Industry would preferably adapt the processes or work stations and/or improve collective protective equipments (e.g. better local exhausted ventilation) and personal protective equipments with adequate filtering before going to closed systems and automation - if it is technically possible. It should however be recognized that these measures are efficient in reducing the overall exposure and consequently the overall risk as shown by the COLCHIC data. Indeed, after this French decree, exposures led to a drop of formaldehyde levels.

6.2.2.1.2 Impacts of setting EU harmonized BOELs for formaldehyde

As already mentioned, OELs are set by competent national authorities or other relevant national institutions as limits for concentrations of hazardous compounds in workplace air. There are different OELs across Member States, mainly due to divergences in assessment approaches of the risks of the chemical. There are also divergences in the nature of OELs between Member States where it varies between obligation, indication and recommendation. As both industry and enforcement authorities require clear and sound limit values for reliable testing and stable emission requirements, these limit values would benefit from harmonisation across the EU-27. However, in Table 3 above in section 2.2.3.1.3,

most of limit values set nationally in EU Member States are set around 0.5 ppm. As a consequence, setting BOELs below proposed DNELs would impact most of EU Member States.

Costs of harmonised OELs have been estimated by industry (TNO/RPA 2013, see details in Annex E). An analysis of costs has been made for complying with long-term OEL of 0.4, 0.3 and 0.2 ppm. While exposures in most industries can be maintained below 0.4 ppm with feasible conditions and risk management measures, additional improvements are needed for several industries, leading to costs. This is specifically the case for the wood-based panel industry, that will be faced with the largest cost per unit (production line) as well as the largest total cost per sector.

Overall, setting BOELs within the framework of CMD would be in principle an option to address the risks for workers demonstrated herein depending on the value of these BOELs. Given the recent SCOEL and national proposals for formaldehyde OELs (France and Germany), a European discussion on harmonisation of OELs may be expected.

6.2.2.1.3 Conclusion on Directive CAD 98/24/EC and Directive CMD 2004/37/EC

Since specifically designed for risk management of chemicals at the workplace, both CAD and CMD appear in principle relevant for implementing European OELs for formaldehyde. Setting BOELs rather than IOELs is seen by Anses as a relatively more efficient tool in order to allow stricter OELs across the EU and to oblige Industry to comply with these requirements. Indeed, IOELs are not considered foreseeable to rely on a shared agreement between all Member States for transposing these values with a binding status. Moreover, as formaldehyde complies with the CMD considering its carcinogenic harmonized classification, Directive CMD 2004/37/EC is considered better suited than Directive 98/24/EC to achieve the RRS defined herein.

As for all regulatory approaches, the efficiency of the measure would rely on the efficiency of the enforcement bodies of each Member States and the harmonization of the national penalty measures.

In conclusion, Directive 2004/37/EC on Carcinogens and Mutagens at work is considered consistent with the objective of the RRS stated above. Indeed, it would, depending on the value agreed on, generally decrease the accepted exposure level at the EU level. Stricter measures could be decided later on if needed, based on results from on site surveys and national controls. The uses of formaldehyde that would fall under the scope of this Directive are represented in the Figure 5 further below. Nevertheless, setting BOELs shows shortcomings:

- **First of all, the pressure for substitution is not so evident in practice and Directive 2004/37/EC may be seen as a less efficient measure for this specific purpose compared to alternative RMOs.**
- **Secondly, it is possible that formaldehyde could finally not be included in the next Directive 2004/37/EC update. Other RMOs should then be investigated as the authorisation procedure of REACH.**

6.2.2.2 REACH Regulation - SVHC Identification

Based on the SVHC (Substance of Very High Concern) Roadmap Relevance Assessment Support Tool provided to Member States by ECHA in 2013, **formaldehyde meets the SVHC Roadmap 2020 criteria**.

Table 42. SVHC Roadmap 2020 criteria

	Yes	No
a) Art 57 criteria fulfilled?	x	
b) Registrations in accordance with Article 10?	x	
c) Registrations include uses within scope of authorisation?	x	
d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution?	x	

According to Article 57 of REACH Regulation (Substances to be included in Annex XIV), formaldehyde would be eligible to SVHC identification in pursuance with articles 57 a) and b) since formaldehyde is classified Carc. 1B and Muta 2 (meeting criterion a) of the SVHC Roadmap).

Formaldehyde has been registered as a full registration dossier (joint submission) under REACH accordingly to Article 10 of REACH Regulation (meeting criterion b) of the SVHC Roadmap). Regarding the uses falling under the scope of authorisation (criterion c) of the SVHC Roadmap), this question raised the potential intermediate status of formaldehyde in particular for formaldehyde-based resins manufacture, leading to exemption of authorisation for these uses.

6.2.2.2.1 Discussion about the intermediate status of formaldehyde

The discussion about the intermediate status of formaldehyde for some uses is important since it determines the impact of RMOs to address the risks demonstrated herein for these uses.

→ REACH and ECHA guidances' interpretation

REACH legal text provides the following definitions for "intermediates".

Article 3-15: Intermediate means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis"):

> *(a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;*
>
> **REACH Regulation does not apply to non-isolated intermediates in pursuance with Article 2-1 c.**
>
> *(b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the*

intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

On-site isolated intermediates are exempted from the Authorisation procedure (Article 2-8 b)). This is also reminded in the ECHA 2010 Guidance on intermediates[14] (p.32). Moreover, there is no possibility of adding a new entry in Annex XVII (Restrictions) or amending it for a substance used as an on-site isolated intermediate (article 68-1; p5 of 2010 ECHA Guidance). In other words, on-site isolated intermediates are also exempted from the Restriction procedure, except for intermediates already restricted on Annex XVII of REACH (article 37).

(c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.

Transported isolated intermediates are exempted from Authorisation procedure (Article 2-8 b)) but not from the Restriction procedure.

Intermediates registered under REACH are subjected to specific information requirements as far as their registration is concerned in pursuance with articles 17 and 18 of REACH. However, these specific requirements do not change anything about their intermediate status.

In case formaldehyde is used in the purpose of producing an article, it cannot be considered as an intermediate even though there is a chemical reaction. It is not however the case for the production of resins or the synthesis of other chemicals.

→ Industry's viewpoint

In the industry TN/RPA report, formaldehyde is claimed to be mostly used as an "intermediate": in the production of resins and in the synthesis of chemicals (TNO/RPA, 2013). These uses stand for more than 80% of total EU (and global) use of formaldehyde. Moreover, as presented above, formaldehyde has been registered as a full registration dossier (joint submission) and only one individual submission registered formaldehyde as an on-site isolated intermediate.
The full registration dossier provides the comment that the formaldehyde is used "as a monomer in a polymer[15]"."Monomers" are defined under REACH in Article 36 and cannot benefit from registration as intermediate, such as detailed in articles 17 and 18 of REACH and shall be registered with a full dossier. **As a consequence, if formaldehyde is actually used as an (intermediate) monomer for some uses (such as the production of resins and the**

[14] https://echa.europa.eu/documents/10162/13632/intermediates_en.pdf
[15] Polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a "monomer unit" means the reacted form of a monomer substance in a polymer.

chemical synthesis), this status is thus consistent with a full registration dossier.

→ Legal status of the formaldehyde-based resins (UF, MF, PF, POM)

The resins produced from formaldehyde are in principle substances in the sense of REACH (article 3-1)[16]. They are:

- either polymer substances such as defined in Article 3-5,
- or non-polymer substances.

As substances, these resins are in principle subjected to registration under REACH except if they are polymer substances which are exempted from registration (as well as evaluation) procedures (article 2-9) but not exempted from restriction nor authorisation as such.
To date, UF, MF and PF-resins have been pre-registered under REACH but have not been registered so far. Given the high tonnages of these resins, it is unlikely they will be registered by the third flow of registrations, from 2018 for substances between 1 and 100 tpa. If they have not been registered so far, they might be polymers in the sense of REACH and thus exempted from registration.

6.2.2.2.2 Conclusion about the intermediate status of formaldehyde

Formaldehyde seems to be used as a monomer intermediate in the purposes of formaldehyde-based resins production or chemical synthesis since there is transformation of formaldehyde in another substance. The fact that the resins would be polymers or non-polymers does not have any impact on the intermediate status of formaldehyde.

Consistently with this interpretation, the intermediate status of formaldehyde for these uses would affect the eligible RMOs. Indeed, **for the uses of formaldehyde as intermediate, no option under REACH could be possibly proposed except if there is evidence that formaldehyde would be an isolated transported intermediate (e.g. if the manufacture of formaldehyde takes place in another site than the production of resins or the chemical synthesis and is then transported to another site for these purposes). In that case, and in that case only, a restriction under REACH could be possible.**

However, for the non-intermediate uses, others RMOs under REACH are possible to address the risks demonstrated herein.

In order to determine with certainty the legal intermediate status of formaldehyde, a formal request to the Registrant could be sent according to Article 36(1) of REACH regulation. This article requires each manufacturer or importer to assemble and keep available "all the information he requires to carry out his duties under this Regulation" and to make such information available without delay upon request.

[16] Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

6.2.2.2.3 Conclusion about the possible identification of formaldehyde as a SVHC

The intermediate uses of formaldehyde cannot exempt it from SVHC identification. In case the intermediate status of formaldehyde would be confirmed for resin production and chemical synthesis, formaldehyde could thus still be identified as a SVHC. Indeed, formaldehyde meets all the criteria of the SVHC Roadmap 2020.

This identification would send a strong signal about its hazardous nature and would trigger the obligations related to the substances formally identified as such. Companies would need to comply with the requirements (in REACH Article 7 and 33) to provide extended Safety Data Sheets (eSDS), including hazard information, risk management measures and exposure scenarios to producers and importers and to communicate information on safe use to customers and consumers for substances in articles.

Concerning the status of resins as "substances", they could be eligible to the authorisation route since they are not considered as intermediates themselves. It would require to identify them as SVHC based on their classification. However, to current Anses knowledge, none of these resins are registered nor classified under CLP. Similarly, they could be the object of restriction if they are registered and if such uses demonstrate a risk for workers. These considerations could be considered in a specific separate RMOA.

6.2.2.3 REACH Regulation - Authorisation procedure

The Authorisation procedure is intended to ensure the risks from SVHC are properly controlled and these substances are progressively replaced by less hazardous or safe substances. The authorisation does not distinguish uses: all uses of a substance submitted to authorisation under REACH are covered by the authorisation obligation, except the substance's manufacturing, the uses considered as intermediates and in case there are grounds for specific exemptions (e.g. substance only used in scientific research and development "product and process orientated research and development" - PPORD).
A prerequisite for a substance to be included on the Annex XIV of REACH is to be identified as a SVHC. Once listed on the Annex XIV, its continued use, beyond an agreed sunset date, will only be allowed if an authorisation for a specific use has been applied for, has been scrutinized by the ECHA committees and finally granted by the European Commission, or if the use is exempted from authorisation requirements.
The prioritisation for inclusion in Annex XIV from the candidate list should not be risk-based but mainly hazard-based (triggered by SVHC identification). Priority is driven by several criteria that are set by Article 58 of REACH and implemented by ECHA following a methodology that has been agreed by the Member States Committee (MSC).

As formaldehyde can be identified SVHC and put on the candidate list, the prioritisation of formaldehyde and the proportionality of authorisation route to address its related risks could be questioned because of its potential – still under discussion - intermediate uses. Indeed, the wide dispersive use of formaldehyde and its high tonnage would make formaldehyde a good candidate for Annex XIV inclusion according to Art. 58.3. However, if it is accepted that resins are substances *per se*, the tonnage and wide dispersive uses would drop dramatically for formaldehyde, rendering its priorisation doubtfull. In case the intermediate status of these uses would not finally be demonstrated, formaldehyde could be prioritized for an inclusion in Annex XIV. Its capacity to be substituted would also be considered by the European authorities before this inclusion.

The issue around the intermediate status of formaldehyde for producing resins is a key parameter on the choice of the most appropriate option to be conducted.

The threshold dose-response relation of formaldehyde means that authorisation could be granted either via the adequate control route or the socio-economic analysis (SEA) route. In the first case, authorisation may be granted if the risk is considered as adequately controlled and if no safer alternatives are available. These considerations are subjected to the expertise of RAC (Risk Assessment Committee) to assist the European Commission in its decision-making process. In the second case, although the risk might not be adequately controlled, authorisation may be granted if the applicant demonstrates that there are no suitable alternatives and the socio-economic benefits from the continued use of the substance outweigh the risks to human health. These considerations are subjected to SEAC (Socio-Econmic Analysis Committee). It is not yet possible to anticipate which route would be preferably chosen by the applicants as regards the uses of formaldehyde considering the complexity and the number of uses reported.

Generally speaking, the authorisation process shows some advantages over the restriction process (described further below):

- Except when the socio-economic route is chosen by the applicant, an authorisation is granted only when the risk is clearly controlled. The appropriateness of the proposed RMMs is evaluated and some additional or alternative conditions to the granting may be imposed; the applicant should address use and supply chain specific RMMs which would be assessed too.
- In principle, the application for authorisation would require a better documented and clearer risk assessment of the use applied for, since the applicant has an incentive to demonstrate that the risk is adequately controlled.
- Given the complexity of the processes at stake, the applicants may have the highest capacity to obtain and share the information needed to build a robust analysis of exposures as well as alternatives.
- The total substitution of the hazardous substance of concern remains the final goal of the process. Since getting an authorisation is expensive and always temporary, authorisation is a relevant tool for substitution and therefore a helpful mechanism to ensure workers protection.
- The authorisation process keeps the burden of proof to the applicants, which reduces the workload of the authorities and ECHA, but increases the applicants' costs.

However, the authorisation process may have some limits:

- Authorisation might not be considered as proportionate if only one or some uses are actually at risk.
- The data provided by the applicants in an application for authorisation might be difficult to challenge by ECHA Committees and the Commission. Whatever the route ("controlled risk" or "socio-economic") chosen by the applicant is, it might be difficult to verify the robustness of industry data. The public consultation foreseen by the procedure aims specifically at recuding this asymmetry in giving the opportunity to stakeholders (NGOs, competitors, civil society, public institutions) to provide additional or challenging information about the case.
- The timescale might be long between the decision from a dossier submitter to propose an Annex XV SVHC identification, the Commission decision to include the substance in Annex XIV and the sunset date from which the non-use is effective. Meanwhile, risk remains.

- **The substance manufacturing is not part of the scope of the authorisation in pursuance of article 60-2 of REACH. Therefore any occupational risk arising from manufacturing cannot be covered by the authorisation route. This is the case of formaldehyde.**
- **The intermediate uses are exempted from authorisation requirements. Therefore any occupational risk arising from intermediate uses cannot be covered by the authorisation route. It seems to be the case of formaldehyde for the production of resins and chemical synthesis.**
- Authorisation is unlikely to be effective as the risk from imported articles is not covered by this route.
- The authorisation route stands for a significant financial and regulatory burden for Industry and no information is at hand to date to anticipate any particular reaction or strategy from them in case formaldehyde would be listed on Annex XIV. Whether they would substitute or apply for an authorisation or even delocate outside the EU is uncertain.
- **The final goal of authorisation is substitution. However, the substitutability of formaldehyde varies a lot among its different and numerous uses. Moreover, as presented above in section 5.3, the level of information about alternatives to formaldehyde greatly differs from one use to another.**

Consistently with the interpretation of the intermediate status of formaldehyde for the production of resins and for the synthesis of chemicals, only the other uses of formaldehyde could be then covered by REACH authorisation (Figure 5). For intermediate uses of formaldehyde, the CMD Directive and the establishement of appropriate BOELs would be the sole suitable RMO to address occupational risks.

6.2.2.4 REACH Regulation - Restriction

According to REACH regulation, "when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Union-wide basis, Annex XVII shall be amended (...) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles (…)" (article 68-1).
A restriction proposal under REACH has to meet the REACH Annex XV requirements aiming at tackling a risk by reducing the exposure to the hazardous substance down to a safe level, otherwise at removing it. For this purpose, a restriction proposal may have several forms such as e.g. limiting the concentration or the migration of a substance in one specific article to protect consumers and users; or, more specifically in the case of workers protection, it may also consist in limiting the exposure from the devices handled and/or occurring during the processing operations. The proposed exposure limits may be so low that the restriction might be equivalent to a total ban of the use of the substance. In those cases, the existence of available and suitable alternatives is crucial.
The Annex XV restriction proposals are the remit of the MS competent authorities and ECHA.

A REACH restriction shows several advantages over the REACH authorisation procedure in particular:

- It can be targeted and tailored for one specific use at risk instead of restricting the substance as a whole.
- It may be coupled with derogations to take into account some particular situations of market actors or uses.
- This is a rather fast process to reduce the risks.

- It may cover EU imports of articles containing hazardous substances (SVHC or others) which are not addressed by the authorisation route.
- **It may cover the manufacture of the substance, which is not the case of REACH authorisation. To this respect, a restriction under REACH for the risk demonstrated for workers during the manufacture of formaldehyde process may be an interesting RMO.**
- Its possible scope is less constrainted by exemptions.

Submitting a REACH restriction to address a particular risk requires the following preliminary conditions:

- First of all, the dossier submitter has to be sure that the substance of concern and the risks targeted can be legally addressed under the REACH restriction procedure. In those circumstances, REACH restrictions may cover a wide range of situations. The only exception concerns non-isolated or on-site isolated intermediate. **In case of formaldehyde, if its intermediate status for the uses in the production of resins and in synthesis of chemicals is confirmed, these uses would not be covered by a restriction such as indicated above in pursuance with Article 67 of REACH except if formaldehyde is proved to be an isolated transported intermediate. In that case, and in that case only, a restriction under REACH could be possible.** Another option would be to restrict the use of the formaldehyde-based resins, if polymers can be subject to restriction. However, data showing that the risk identified is due to these resins would not be available as they are not subject to registration. Therefore, the feasibility of this option depends on the level of data necessary to demonstrate a risk.
- Then, the scope of the restriction has to be defined very precisely, including the substance as well as the definitions of the working conditions/workstation targeted. This requirement is important to ensure the effectiveness, the enforceability and the monitorability of the restriction but also its consistency with other existing pieces of legislations which may cover the same or close field. This capacity highly depends on the quality of the information provided in the registration dossiers.
- Last, an "unacceptable" risk has to be demonstrated. This "unacceptability" is not strictly defined in the REACH technical guidances or the legal text but it implies that the argumentation has to be scientifically-based and the risk robustly demonstrated, such as described in the Guidance on Annex XV Restrictions. The proposal submitted by the Member State (or ECHA) has thus to include a hazard and exposure assessment as well as a risk characterisation. Although a certain level of uncertainty might remain (if highlighted and treated) in the demonstration, the analysis has to be as precise as possible and supported by evidences. To that respect, depending on the quality of the information provided in the registration dossier, this capacity may be hindered or made easier. Regarding specifically the 2015 registration dossier for formaldehyde, exposure assessments are solely based on modelling data. These data are questionable regarding their relevance and robustness.

In terms of timing, a REACH restriction proposal is procedurally scheduled to be elaborated within 12 months by the dossier submitter, from the official date of intention (announced on the ECHA Register of Intention). Then, the proposal is scrutinized in RAC and SEAC within at least 12 extra months, depending on different factors and steps (success or not during the conformity check step and consistency between RAC and SEAC opinions). Finally, the European Commission has to take its decision within 3 months. As a whole, the REACH restriction procedure takes at least 27 months to be finally adopted. Taking also into account the transitional period (usually 12-36 months) proposed by the dossier submitter

to allow the industry to comply with the new restriction, this timescale may be actually even longer.

In summary, the ability of REACH restriction to be a suitable RMO to address the risks demonstrated for the uses of formaldehyde depends on several factors among which the intermediate status of these uses. In case its intermediate status for the production of resins and synthesis of chemicals is confirmed, these uses could not be covered by a restriction except if formaldehyde is proved to be an isolated transported intermediate. But no information is available on this respect to date. In that case, the CMD Directive and the establishement of appropriate BOELs would be the sole suitable RMO to address these risks. Only the other uses of formaldehyde could be then covered by REACH restriction (Figure 5).

A REACH restriction could take different forms to limit the workers exposure:

- Option 1: a restriction with broad scope proposing a mandatory appropriate DNEL and subsequently a binding OEL. In this matter, there is ongoing discussion about the borders between OSH vs REACH Regulations. The relevancy of REACH Restriction to propose "BOELs" as a RMO is being questionned.
- Option 2: targeted restrictions on specific uses for which the risk can be demonstrated in line with the expectations and requirements of RAC and for which the data are available and robust.
- Option 3: a restriction on the use of formaldehdye-based resins for wood panels manufacturing. This option is however discarded at this stage as formaldehyde-based resins are not registered, as Industry consider resins as polymers, exempted from registration and their compositions are not known.

Industry provided valuable information on impacts of the non-use in case of a restriction of formaldehyde under Annex XVII and estimated substitution costs in case of replacement of formaldehyde as a consequence of a restriction. Only the magnitude of the impacts might change according to the scope of the restriction and the targeted uses.

6.2.2.5 Sectorial regulations

6.2.2.5.1 EU Biocidal Products Regulation (BPR)

The risk characterization showed that a risk has been demonstrated for the use of formaldehyde as **biocidal agent in embalming sector covered by the PT22 category (Embalming and taxidermist fluids)**. As indicated in paragraph 5.2.3, a foresseable risk exists for short-term formaldehyde exposure. Substitutes are registered as PT22 and are currently being assessed according to the BPR (cf. paragraph 5.3.3.1.2).
This RMO is the best fitted, targeted and appropriate one to address the risks demonstrated, although restriction within REACH is legally possible. As a consequence, regulators are invited to take into account this consideration.

6.2.2.5.2 EU Construction Products Regulation (CPR)

Wood-based panels production is one major sector of use of formaldehyde and this sectorial regulation could naturally stand for a suitable RMO to address the risk demonstrated for this use. However, the emissions classes E1 and E2 defined by the harmonized standard EN 13986-A1 concern the wood-based panel as a finished and ready to be used product by professionals and consumers.

This Regulation does not directly address the risks for workers who manufacture the wood-based panels event though there is an obvious correlation between the level of emission of formaldehyde in the finished panels and the quantity of formaldehyde or formaldehyde-based material used to produce them. Nevertheless, limiting the emissions from finished panels does not necessarily prevent workers exposure during the manufacturing process. At least, the risk demonstrated above for the manufacture of wood-based panels is the evidence that this limitation is not sufficient to minimize workers exposure.

In order to prevent risks for workers, a possible RMO could be to amend the CPR reducing the standardized emissions classes of finished wood-panels. Still remain the question about the link between formaldehyde emissions from finished panels and the quantity of formaldehyde used to produce them. Other RMOs, such as developed in paragraph 6.2.2.1, may have a broader impact including all the uses of wood-based panels and are considered as more appropriate.

6.2.3 Discarded RMOs

The following RMOs are not considered appropriate to achieve the RRS. They are thus discarded and not assessed further.

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

As mentioned in paragraph 2.2.1.2, no additional Harmonised Classification is foreseen. No limit exposure values will be directly implemented to manage the risks via inhalation exposure at the workplace.
Therefore the CLP regulation is not fitted for the purpose of the control of inhalation exposure at the workplace for formaldehyde.

EU workplace legislation other than CAD and CMD

As presented in section 2.2.3.2, risk at workplace may also be managed by the following Directives 89/656/EEC, 92/85/EC and 94/33/EC. These Directives do not specifically address formaldehyde, but cover it indirectly regarding to its classification as hazardous & carcinogen substance.
Directive 92/85/EC and Directive 94/33/EC are not considered fitted to the RRS since the risks concern all workers populations and not only the particular vulnerable ones (pregnant or young workers). Directive 89/656/EEC is not considered sufficient as it only lays down minimum requirements for personal protective equipment used by workers at work.
These RMOs play an important role in protecting workers but are not considered fitted to achieve the minimization of formaldehyde exposure such as targeted above.

EU legislation targeted on environment protection (IED Directive 2010/75/EC, ex-IPPC)

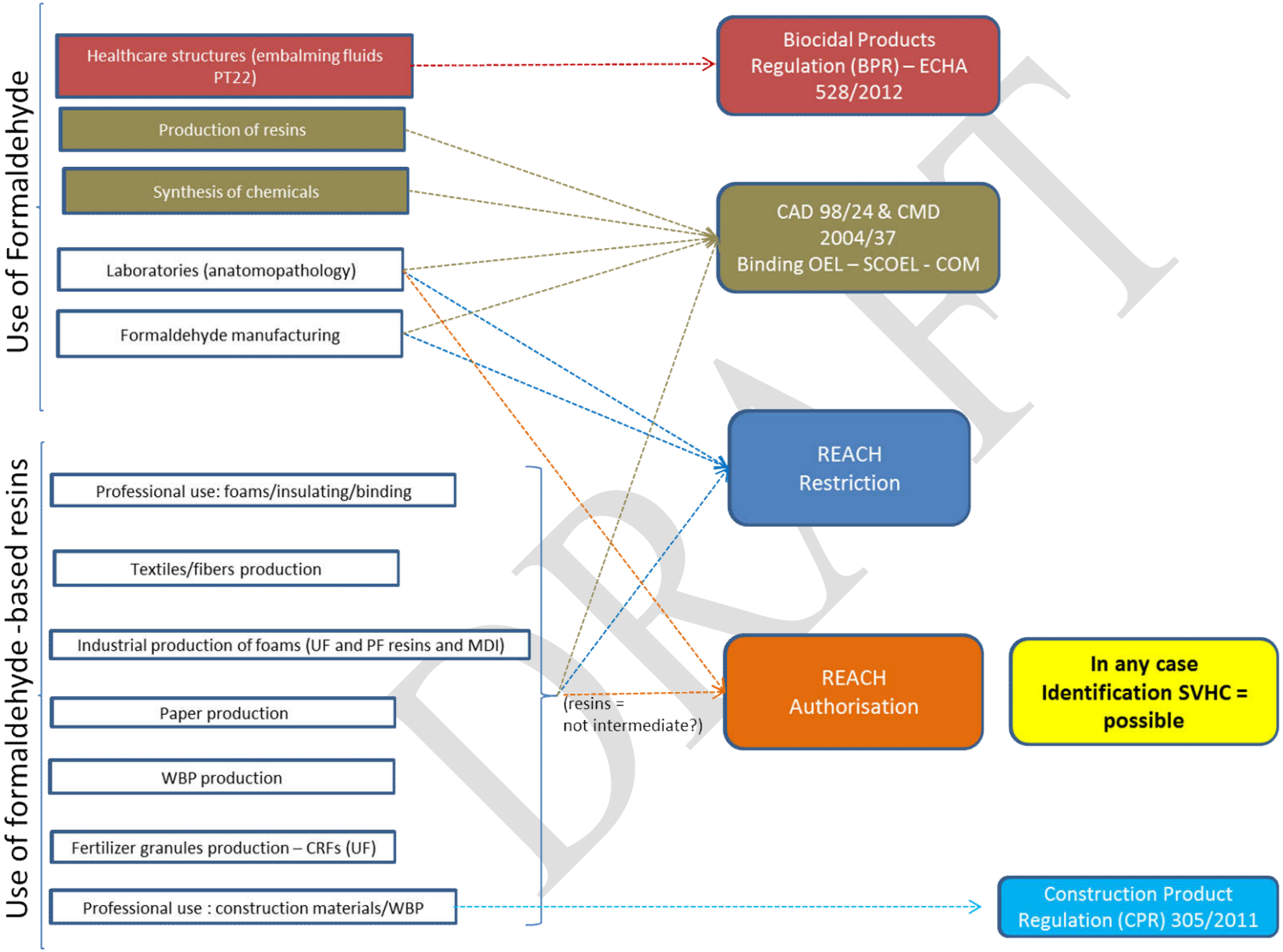
The IED may also indirectly reduce occupational exposure to a limited extent. As presented in section 2.2.4.1, IED is primarily focused on the reduction of impact from human activities to the environment, through the setting of emission limit values based on BREFs. The BREFs addressing formaldehyde provide recommendations which are not binding but voluntarily implemented by industries (registration dossiers under REACH should reflect to this respect the on sites situation). Moreover, as mentioned in section 2 and as indicated in the TNP/RPA 2013 report, the VOC-related aspects of this Directive does not apply to formaldehyde in wood-based panels. This limits its scope and appropriateness to

address the risks identified. Moreover, as a Directive, its harmonized implementation in all EU countries is not mandatory. The Directive might be transposed in different terms within each EU Member State (implementating e.g. different emission limit values).
The current BREFs and the IED are not sufficient to fit with the occupational risk reduction strategy for formaldehyde.

Seveso III Directive 2012/18/EU

Seveso III directive is not fitted to achieve the risk reduction strategy for formaldehyde.

Figure 5. Overview of the possible RMOs to be recommended for each use identified at risk



6.3 Conclusions on the most appropriate risk management options

Formaldehyde is a high tonnage and wide-dispersive compound with numerous occupational uses where risks need to be managed. The conclusion of this analysis depends on key questions that still need to be clarified:

- The (isolated transported) intermediate status of formaldehyde for formaldehyde-based resin manufacture and chemical synthesis;
- The value of the (B)OELs after stakeholders consultation and the date of application.

In case formaldehyde is confirmed by Industry as an intermediate in the production of resins and the synthesis of chemicals:

- such uses would be excluded from authorisation,
- these uses will not be subject to a restriction except if formaldehyde is proved to be an isolated transported intermediate (no information is available yet on this respect).

For these uses, **the workplace legislation such as defined by CMD Directive and the establishment of appropriate BOELs would be the sole suitable RMO** to address these occupational risks.

A complementary option is the identification of formaldehyde as a SVHC as it meets all the criteria of the SVHC Roadmap 2020 (in particular its classification as Carc. 1B). It would send a strong signal about its hazardous nature and would trigger the obligations related to the substances formally identified as such.

Concerning the other uses of formaldehyde that are not intermediates and that are not covered by sectorial regulations, the authorisation procedure under REACH would promote effectively the substitution of formaldehyde for these uses. Sectorial Biocidal Regulation seems also well suited to address the potential risks in embalming fluids. The non-intermediate uses eligible to a REACH restriction could be in principle limited (use in laboratories and in anamatopathology, formaldehyde manufacturing).

In case Industry does not provide sufficient justification on the on-site isolated intermediate status of formaldehyde in the production of resins and the synthesis of chemicals:

- a REACH restriction could be feasible and could take different forms to limit the workers exposure, as explained in paragraph 6.2.2.4;
- **authorisation would cover uses with the highest occupational risks** except for the manufacture of the substance. The final goal of authorisation is substitution. However, the substitutability of formaldehyde varies a lot among its different and numerous uses.

The Table below summarizes the RMOs comparison, subject to further discussion depending on the justification provided by Industry concerning the intermediate status of formaldehyde.

Table 43. Comparative assessment of the selected RMOs for workers

	Workplace EU legislation (CMD) / EU BOELs	Candidate List	Authorisation under REACH	Restriction under REACH
Intermediate use covered ?	Yes	Yes (indirectly)	No	No except isolated transported intermediate
Time period to achieve the objective	Short-medium term (to be confirmed)	Short term	Medium-long term (5 to 10 years)	Short-medium term
Consistency towards the Risk Reduction Strategy (RRS)[(1)]	Well fitted	Low	Well fitted (except for intermediate uses)	Possibly fitted
Ability to achieve the RRS[(1)]	Possibly but highly dependent on the BOELs finally adopted by COM (uncertain)	Indirectly	Yes (except for intermediate uses)	Yes but depending on the scope and the form of the proposal (would OEL be accepted as a possible restriction proposal? overlapping with the workplace legislation)
Proportionality towards the RRS[(1)]	Proportionate	Proportionate	High numbers of authorisations might be granted due to numerous uses identified. Proportionnality will depend on intermediate status of FA: limited uses with identified risks if intermediate status confirmed. If Industry does not provide sufficient justification on the intermediate status, uses with identified risks will be covered by authorisation	Possibly proportionate but will greatly depend on the scope
Clarity of the obligations imposed on the operators	Clear regarding the BOELs objective (RMM left to the operators; obligation of results)	Clear	Clear (substitution/socio-economic route/adequate control route)	Depending on the conditions and scope
Balance of the costs compared to the benefits of the reduced risks	Possibly moderate (highly dependent on the adopted by COM)	Low	Possibly high (uncertainties due to unchallenged economic data provided by industry)	Possibly moderate (depending on the conditions and scope and economic data provided by industry however not challenged)

	Workplace EU legislation (CMD) / EU BOELs	Candidate List	Authorisation under REACH	Restriction under REACH
Technical feasibility for the operators	Expected more or less easily feasible (highly dependent on the sectors and on the BOEL finally adopted by COM)	/	Substitution: varies among sectors Application for an authorisation: feasible but costly for industry	Depending on the conditions and scope (not yet identified)
Acceptability for the operators	Expected well accepted (depending on the BOELV finally adopted by COM)	/	Expected not accepted	Expected accepted for certain uses
Technical feasibility for the MSCA	Feasible France: example of efficiency of French decree since 1/1/2007	Feasible	Feasible	Might be difficult (definition of scope and demonstration of unacceptable risk) + many uses
Overall relevancy on a short term	Significant	Yes	Significant for the uses in the scope of authorisation Dependent on the intermediate status of the major uses	Yes but limited to very few uses

(1): the RRS (Risk Reduction Strategy) is herein defined as the setting of BOELs at 0.3/0.6 ppm and exposure below these BOELs at the workplace.

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