Analysis of the most appropriate risk management option for formaldehyde

A joint report by:

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0. EXECUTIVE SUMMARY

0.1 Background to Study

Formaldehyde (CAS number: 50-00-0) has come under particular scrutiny from European regulators, Member State authorities and scientific bodies.

In February 2012, the first Community Rolling Action Plan (CoRAP) was published and listed formaldehyde as one of 90 substances to be subject to the Substance Evaluation Procedure under the REACH Regulation (EC) No 1907/2006. The CoRAP list contains substances for which there is a suspicion that their manufacture and/or use could pose risks to human health or the environment. Substance evaluation is the process under REACH that allows for clarification of such risks to decide if further risk management is necessary. Formaldehyde's addition to the list was a joint action by France and the Netherlands and the initial grounds for concern have been documented as "*human health/CMR properties; exposure/wide dispersive use, workers exposure, high aggregated tonnage*". In the update of the CoRAP of March 2013, it is stated: "The first draft decisions for the substances listed in 2013 need to be submitted to ECHA by 19 March 2014. ECHA will forward any draft decisions to the registrants for comments without undue delay. Draft decisions will also be reviewed by the other Member States and ECHA."

Based on the above, Formacare has contracted TNO Triskelion and Risk & Policy Analysts Limited (RPA) to carry out an "*analysis of the most appropriate risk management option for formaldehyde*" in accordance with the risk management option (RMOs) guidelines as defined by the European Institutions for such analyses. Taking this into account, this study is expected to – amongst other things:

- analyse the manufacture and use of formaldehyde in Europe, including use in downstream applications;
- establish where risks exist relating to formaldehyde in both the workplace and consumer products;
- specify processes or products responsible for those risks;
- evaluate substitution options;
- evaluate other RMOs; and
- propose the most appropriate RMO(s).

The data generated under the present study is intended to inform the work of the authorities within the Substance Evaluation Procedure. If, after review of the available and new risk assessment data, the evaluating Member State(s) consider that the use of a substance poses a risk, they may then proceed with follow-up actions to address the concern, which may include (ECHA, nd3):

- a proposal for harmonised classification and labelling;
- a proposal to identify the substance as a substance of very high concern (SVHC) and subsequently a need for authorisation;
- a proposal to restrict the substance;
- actions outside the scope of REACH such as a proposal for EU-wide occupational exposure limits, national measures or voluntary industry actions.; and

0.2 Summary of Risk Assessment

0.2.1 Worker Risk Assessment

The exposure of workers via inhalation in the manufacture and use of formaldehyde in Europe (including downstream applications) was analysed based, as far as possible, on user measured data. In the absence of sufficient useful user measured data, literature data and exposure modelling were used. Measured data demonstrates safe use in the manufacture of formaldehyde and formaldehyde-based resins and other chemicals and in two major uses of the substance: production of wood based panels and in the tyre and rubber industries. Literature data and exposure modelling, supported by some measured data, also demonstrate safe use in industrial downstream uses of formaldehyde. In some cases, this (safe use) requires specific operational conditions (OCs) and Risk Management Measures (RMMs), e.g. reduction of duration of activities to below four hours/day or the use of respiratory protection. For professional uses, literature data and exposure modelling also demonstrate safe use; however, for some activities, highly stringent OCs and RMMs are required. For a detailed description, the reader is referred to the separate worker risk assessment report (Manen-Vernooij *et al.*, 2013).

0.2.2 Consumer (Indoor Air) Assessment

The indoor air risk assessment showed that the central tendency for formaldehyde indoor air concentration in Europe is around 0.025 mg/m^3, considerably below the DNEL of 0.1 mg/m^3. In new build homes or due to renovations/redecoration, the formaldehyde indoor air concentration can be higher than 0.025 mg/m^3, but still tends to be below the DNEL.

Emission rates of wood based panels (WBP) vary according to the type of material used (e.g. plywood, particleboard, MDF), whether it is coated or uncoated and the type of test method employed. A reasonable worst-case exposure scenario of a wardrobe in a European reference room with both ceiling and floor made of WBP and conforming to the European E1 emission standard resulted in a maximum formaldehyde concentration of 0.09 mg/m^3, which is marginally below the DNEL of 0.1 mg/m^3. Calculations further show that with (largely coated) material conforming to the E1 standard and loading of a room up to 2 m^2 emitting area per m^3 room volume, the formaldehyde concentrations stay below 0.1 mg/m^3.

Overall, it can be concluded, based on the measured concentrations in real homes and the calculated exposure scenarios based on emission data, that exposure of the general population due to the use of WBP/articles made with formaldehyde-based resins in Europe is below the DNEL and, is therefore, safe (Marquart *et al.*, 2013).

0.2.3 Need for RMOs

According to the ECHA restrictions guidance (ECHA, 2007), RMOs refer to possible changes to legislation or other requirements on industry to control "risks" accordingly; they may also cover the use of economic instruments and industry's voluntary commitments. Effectively, RMOs are strictly required to control risks, where these have been identified. At present, risks have not been identified for the manufacture and use of formaldehyde and for consumers. However, it is the case that, there may be a need to address "concerns" relating to a substance, where these are identified and could include situations in which:

- there are concerns regarding the safety of consumers and citizens (e.g. a precautionary approach is required);
- the proper implementation and enforcement of OCs and RMMs may be uncertain (e.g. where downstream users cannot/are not complying with OCs/RMMs in eSDS);
- there is an emergence of new data on effects (human health or environmental), or a re-interpretation of existing data or identification of 'new' risks of concern; and/or
- the risk characterisation results are not accepted by the authorities; etc.

For formaldehyde, it is the case that there are concerns amongst regulators which need to be investigated and addressed, where necessary, as evidenced by the various on-going regulatory initiatives (e.g. the on-going reclassification of formaldehyde as a Cat 1B carcinogen as recommended by the RAC). With these in mind, the aim of a systematic analysis of RMOs is to facilitate the identification and choice of the most appropriate measure (or combination of measures) for addressing these concerns, where necessary.

In undertaking an assessment of RMOs, it is noted that '*wide dispersive use*' was identified as one of the initial grounds for concern under the Evaluation procedure, where this selection criterion is explained as being characterised by "*the use(s) of a substance on its own, in a preparation or in an article that may result in not insignificant releases and exposure to a considerable part of the population (workers, consumers, general public) and/or the environment*". Effectively, it takes into account instances where a substance is incorporated into mixtures or articles used by the public and the potential size of the exposed population (ECHA, 2011). Considering that the primary use of formaldehyde and formaldehyde-based resins is in the manufacture of glues and resins, which are in turn used in the production of wood based panels (WBP), it was considered that an assessment of RMOs should focus on the use of formaldehyde in WBP and the potential to manage any concerns arising.

0.3 Assessment of Alternatives

Formaldehyde-based resins are used in binding mechanically cut particles to WBP and most WBP for interior use are bonded using urea-formaldehyde (UF)-based resins. Possible alternative adhesives identified can be grouped into:

- alternative formaldehyde-based adhesives (e.g. MF, MUF, PF, PRF-based resins, etc.);
- isocyanate-based adhesives (e.g. p-MDI and emulsion polymer isocyanates);
- polyurethane-based adhesives;
- epoxy-based adhesives;
- polyvinyl and ethylene vinyl acetate adhesives; and
- bio-based adhesives (e.g. protein glues, lignin, tannins, etc.).

These alternatives were assessed for technical feasibility, economic feasibility and environmental/health impacts (i.e. risk reduction capacity). Two key conclusions have been drawn based on the analysis:

- Firstly, none of the potential alternatives is currently suitable across all grades of WBP. There are some, apparently technically feasible, alternatives to high-emitting UF resins in specific applications and the WBP industry already uses these alternatives, although not on a universal/harmonised basis. .

- Secondly, these alternatives do result in a different set of risks, which appear to be currently manageable because of the relatively 'small-scale' extent of use. There are also trade-offs associated with switching to any alternative on a large-scale basis. These trade-offs include deciding between:

  - **Safety for consumers versus risks to workers and society:** p-MDI, for example, has relevant hazard properties, different to formaldehyde, but results in no formaldehyde releases in the home. Formaldehyde is also used in the production of p-MDI, and as such, an increase in demand for p-MDI would necessitate an increase in use of formaldehyde in the workplace.
  - **Safety of the final substance *versus* risks from building blocks of concern**: While use of p-MDI reduces formaldehyde in the home, MDA used in production of p-MDI is a substance of very high concern (SVHC) for its potential CMR properties.
  - **Additional health benefits *versus* additional costs associated with switching**: In this context, it is recognised that there are approaches which can be used to reduce releases of formaldehyde from WBP (including use of low-emitting UF resins and production of WBP to a higher European standard, i.e. E1plus) which would result in significant health benefits and lower costs to industry compared with the uncertain health benefits and high costs associated with a complete switch to non-formaldehyde-based resins. Also, while p-MDI is (currently) the most technically suitable non-formaldehyde based alternative, a wholesale switch to p-MDI could result in a cost increase of up to 600%, depending on how this switch is implemented. This would impact on the ability of consumers to purchase these WBP and the economy more broadly.
  - **Technical feasibility *versus* potential future availability**: Resorcinol and p-MDI are both technically suitable, but there are not enough supplies of these to support a complete move away from formaldehyde-based resins. There may also be (unintended) impacts for instance on food supply and availability associated with the use of bio-based alternatives (including supply issues for blood).

Overall, taking into account the information on alternatives, it is clear that the most appropriate RMO must focus on the key concern which is releases of formaldehyde from WBP, rather than on focusing solely on switching away from formaldehyde-based resins as a family. The analysis of alternatives indicates that there are other formaldehyde-based resins (PF, MF, MUF, RF, and PRF) which release little to no formaldehyde from the cured product and, as such, can be considered as substitutes for high-emitting UF resins for specific uses. The use of these resins effectively reduce, if not eliminate (to background levels), releases of formaldehyde from the specific WBP and avoid adverse effects on the health of consumers. Some companies are currently able to reduce releases of formaldehyde based on years of R&D and investment and such information/know-how is commercially confidential. Getting access to such information/know-how will also require substantial investments for other companies.

0.4 Possible Risk Management Options (RMOs)

0.4.1 RMOs considered

With the above in mind, three scenarios have been considered, with each scenario composed of a number of RMOs and RMMs for workers and consumers, as follows:

- **Scenario 1** is the **Baseline Scenario** and anticipates that no further risk management action is required beyond those existing at present.
- **Scenario 2** is a **Risk-based Scenario** which considers the most appropriate RMO based on the risk assessment. The focus is on the implementation of a harmonised occupational exposure limit (OEL) at the EU level and on the restriction of the emission of formaldehyde from articles. This Scenario also describes the effect of the on-going reclassification of formaldehyde.
- **Scenario 3** is the **Authorisation Scenario** and considers a situation where formaldehyde is subject to the Authorisation Procedure under REACH.

These Scenarios are discussed in detail below.

0.4.2 Scenario 1 - Baseline

This is the baseline scenario and anticipates that no further regulatory action is taken relating to formaldehyde. It assumes full compliance with the current legal requirements under REACH (and other relevant legislation); in particular, the requirement to ensure the safe use of the substance for each exposed population during all the lifecycle stages of the substance, including the waste stage and the article service life, where applicable.

Workers

It is important to bear in mind that, currently, all exposure scenarios have been calculated to be safe using monitoring data and models. The risk assessment/CSR also indicates that adequate control of the risks to workers is possible under specific OCs and applying specific RMMs. However, it is recognised that there are some concerns, which need to be taken into account, in particular:

- on-going regulatory interest in formaldehyde evidenced by the number of on-going regulatory initiatives by different authorities (i.e. review of the CSR under the Evaluation procedure, consideration of OELs by DG EMPL/SCOEL and various initiatives by WHO and the EC);
- the on-going reclassification of formaldehyde regarding carcinogenicity. In this context, it is important to ensure that formaldehyde is used in ways that lead to the minimisation of significant adverse effects on human health; and
- differences in the risk management approaches and/or risk communication which currently exist (especially as regards OELs across Member States).

The implications of these on-going activities and differences in approaches are discussed and taken into account in Scenario 2.

Consumers

For consumers/EU citizens, based on the measured concentrations in real homes and the worst-case exposure scenarios, the risk assessment undertaken for this study concludes that the exposure of the general population due to the use of WBP made with formaldehyde based resins in Europe is below the DNEL and, as such, there is no unacceptable risk to consumers. This finding is particularly applicable where WBP conforming to the European E1 emission standard and proposed E1-plus standard are used in the home.

Taking into account the regulatory interest of authorities, it is important that industry implements the operational conditions and RMMs shown to lead to safe use and that specific actions are taken to increase the certainty on the absence of adverse effects on human health, where possible, even if these measures are precautionary by nature based on the results of the risk assessment.

0.4.3 Scenario 2 – Risk-based

Workers - OEL

Currently, OELs are set by competent national authorities or other relevant national institutions as limits for concentrations of hazardous compounds in workplace air. Currently, there are varying OELs across Member States, mainly due to divergences in approaches taken for the assessment of the actual risks of the chemical. As both industry and enforcement authorities require clear and sound limit values for reliable and consistent risk management, these limit values would benefit from harmonisation across the EU-28.

Most appropriate RMO 1: Based on the analysis undertaken, the most appropriate RMO is that **a harmonised OEL of 0.4 ppm be implemented at the EU level as soon as possible**. This will help ensure an appropriate level of protection for EU workers, avoid confusion for employees and employers in ensuring such protection, minimise the potential for unfair competition between economic operators on the EU market and enhance the harmonisation of the internal market. In practice, workers in 13 MS with higher OELs would be impacted by the introduction of such an OEL, where this provides more clarity regarding risk communication and ensures adequate control of the risks in the workplace.

This recommendation can be carried out within the existing legal framework and would require amendments to existing legal requirements and more effective enforcement of existing controls. The OEL can be either indicative (under Chemical Agents Directive) or, if formaldehyde is reclassified, binding (under the Carcinogens and Mutagens Directive).

In this context, it is noted that during negotiations for the 3rd IOELV Directive, it was proposed that formaldehyde be removed from the 3rd IOELV Directive and a binding limit taking into account socio-economic factors be introduced in due course – an IOELV of 0.3ppm was indicated as having merit according to studies undertaken by the UK HSE (UK HSE, 2008).

In the development of this scenario, the option of a lower OEL of 0.3 ppm or 0.2 ppm is also considered. A number of MS currently have national OELs which have been set at 0.3 ppm.

While it is clearly the case that an OEL of 0.3 ppm is technically feasible for some companies and such an approach could provide a higher level of protection for workers, this RMO is not proposed as the most appropriate RMO – at the present time – on the basis that the present DNEL, with which the exposure levels have been compared, is considered to be a scientifically derived safe value that is supported by a lot of data and that there is therefore no need to set an OEL at a lower level. Furthermore, there will be substantial additional costs for OELs below 0.4 ppm.

Workers – reclassification

In October 2011, a dossier prepared by the French Competent Authority was published on the ECHA website concerning the reclassification of formaldehyde as a Carcinogenic Cat 1A and Mutagenic Cat 2 substance (ANSES, 2011). In December 2012, the European Chemical Agency (ECHA) announced the adoption of a scientific opinion of the Risk Assessment Committee (RAC) proposing that formaldehyde be classified as Carcinogen Category 1B and germ cell Mutagen Category 2 under the CLP Regulation. In reaching their opinion, the RAC considered that the science relating to human exposure could not support classification as a Carcinogenic Cat 1A substance, opting instead for the lower category 1B (presumed human carcinogen) which is based on nasopharyngeal cancer (an extremely rare cancer in Europe). This proposal will be considered by the Commission and EU Member States and a new classification for formaldehyde could be adopted by 2015.

If formaldehyde is reclassified as a Carcinogen Cat 1B and Mutagen Cat 2 substance, RMMs need to be put in place.

If this proceeds, industry will be required to implement various RMMs and these will act to further control the releases/exposure to formaldehyde in the workplace. In particular, formaldehyde will be subject to control under the **Carcinogens and Mutagens Directive (CMD)**. The CMD aims at the protection of workers from risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens at work. Based on a determination and assessment of risks by the employer, it provides a step-by-step approach for risk control, ranging from replacement of the substance to measures that limit the quantities of a carcinogen at the workplace and keeping as low as possible the number of workers exposed or likely to be exposed. Further requirements are the use of existing appropriate procedures for the measurement of carcinogens and the application of suitable working procedures and methods. Provisions are made for employers to ensure that workers receive sufficient information and appropriate training as well as for Member States who shall establish arrangements for carrying out relevant health surveillance of workers. Furthermore, the possibility to set OEL values is laid down in the Directive. New harmonised classification and labelling will also be introduced under the **CLP Regulation** and registrants would be required to **update their registration dossiers**, including CSRs. The protection of young people and pregnant workers will also be required under specific EU legislation.

Consumers

The Construction Products Regulation (CPR) (305/2011/EU) requires that all construction products bear the CE marking before being placed legally on the European market. For WBP to receive the CE mark, they must comply with the Harmonised European Standard *EN*

13986, which sets the minimum safety requirements for WBP. Annex B of EN 13986 establishes two classes of WBP, E1 and E2, based on formaldehyde emissions. 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.

Scenario 2 considers introducing EU-wide restrictions on WBP with formaldehyde emissions equal to or higher than E1 emission levels (defined as a concentration of 0.1 ppm in the relevant emission test). The advantages of such a restriction are as follows:

- it is **targeted at a route of exposure of concern** (i.e. WBP and imports of high-formaldehyde releasing WBP) and the relevant actors in the supply chain;
- it is **consistent with existing legal requirements**, especially as it takes forward existing national restrictions and harmonised standards already established under the CPR;
- it will **apply to all EU manufacturers and importers of WBP**, rather than being limited to signatories to the industry voluntary agreement and/or countries where there are national restrictions in place;
- it will help **ensure that the EU market does not become a new market for sales of high formaldehyde-releasing wood based products**, which would have been sent to the USA prior to the introduction of the *Formaldehyde Standards for Composite Wood Products Act* (signed into law in the US in July 2010) (note that E1 WBP can be up to double the price of E2 WBP);
- the vast majority of EU companies are able to and currently manufacture WBP which comply with the proposed restrictions and, as such, **it is feasible and practical**; and
- there would be **a further reduction in consumer exposure to formaldehyde** as a result of implementing restrictions which do ensure that E2 WBP are not placed on the EU market.

Most appropriate RMO 2: Taking the above into account, the most appropriate RMO would be **to introduce restrictions under the REACH Regulation on WBP with formaldehyde emissions higher than E1 emission levels** (0.1 ppm concentration in the relevant emission test) in order to ensure an adequate level of protection for EU citizens, avoid unfair competition on the EU market and enhance the harmonisation of the internal market. It is also recommended that adequate monitoring programmes are put in place to ensure compliance of imported WBPs with this restriction. This recommendation takes into account the findings of the risk assessment which shows that adequate control of the risks to EU citizens is possible when using E1 WBP.

Over the last few years, there has been a lot of scientific and technical work which has gone into updating the Harmonised Standard EN 13986 under Mandate M/113, as amended, given to CEN by the European Commission and the European Free Trade Association. Of key relevance, is the proposed inclusion of a new formaldehyde class in Annex B known as E1plus (in addition to E1 or E2). This European Standard is not intended to be applicable to WBP for use in non-construction applications.

This Scenario therefore also considers a situation where EU wide restrictions are introduced under the REACH Regulation on WBP with formaldehyde emissions equal to or higher than

the E1plus standard (defined as a concentration of 0.065 ppm in the relevant emission test). In this context, it is noted that a new law (the *Formaldehyde Standards for Composite Wood Products Act*) was introduced in the US in July 2010, which sets emission standards for composite wood products and will apply on a national scale from January 2013

While it is clearly the case that the E1plus standards are technically feasible for some WBP and such an approach could provide a higher level of protection for consumers, this restriction is not proposed as the most appropriate RMO under this Scenario – at the present time - for the following reasons:

- **Disproportionate Impacts**: there will be significant costs for certain stakeholders as a result of a restriction. In addition, it cannot be stated with certainty that there will not be disproportionate impacts on specific countries, companies or SMEs as a result of restrictions. There is indeed the possibility for certain companies to gain a competitive advantage over others; however, the extent and implications of this advantage are not clear at this time.

- **Cost-Benefit Comparison**: Considering that the E1 standard does not result in unacceptable risks to citizens, it cannot be stated with certainty that the benefits associated with introducing the E1plus standard outweigh the costs which will be incurred by industry and EU citizens (e.g. through higher WBP prices). In this regard, it is worth noting that the benefits associated with the US regulations were higher than those that would apply under an EU restriction (the US industry voluntary standard was 0.30 ppm, while the EU voluntary standard is 0.1 ppm (test method EN120)).[1] It is possible that given time (see next point) the costs will reduce which will allow for a more favourable balance between costs and benefits.

- **Lead-in Time**: There will be a need to have sufficient lead-in time for EU companies to adapt their production processes (and for some to develop new resin technologies and formulations) in order to comply with the restrictions. For instance, companies in the US had between four and six years to prepare for the CARB Phase II standards; despite this, there was still a need last year to extend the deadlines for compliance.

- **Need for Derogations**: Finally, there are important differences between the EU and US WBP markets (e.g. market size, the nature of WBP used, the amount of WBP used in a typical home, regulatory history, etc.) which must be taken into account in considering the costs of restrictions. Furthermore, there may be a need to consider specific derogations for specific WBP and/or different limits for different WBP, taking into account technical issues, including the availability and feasibility of alternatives.

[1] Prior to the CARB Standards, furniture manufactured in North America generally conformed to the American National Standard for Particleboard (ANSI A208.1), which is the North American industry *voluntary* standard, for formaldehyde emission levels (0.30 ppm for particleboards in the relevant emission test). Furniture manufactured in Europe conforms to the European E1 standard (0.1 ppm for particleboards in the relevant emission test).

Most appropriate RMO 3: With the above in mind, the most appropriate RMO is that **the E1plus standard is introduced as an industry self-regulatory initiative**. With a view to minimising the likelihood of adverse effects from formaldehyde and encouraging research into alternative substances and technologies, companies should manufacture WBP with formaldehyde emissions equal to or lower than E1plus emission levels (0.065 ppm in the relevant emission test), in cases where this is technically suitable, economically feasible and does not result in higher risks to workers' health. Appropriate monitoring and (annual) reporting mechanisms must also be documented and established to report on the extent to which the E1plus standard is being taken up.

Consumers - reclassification

If formaldehyde is classified as Carcinogen Category 1B, a 'fast-track' restriction on consumer use of formaldehyde as a substance, in mixtures, or in articles can be triggered by a proposal by the Commission in accordance to Article 68(2) of REACH: "For a substance on its own, in a mixture or in an article which meets the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply." Note also that under the Biocidal Products Directive (98/8/EC), CMR substances are also not authorised for marketing to, or use by the general public.

0.4.4 Scenario 3 – Authorisation

Scenario 3 considers the possibility to address the risks relating to formaldehyde using the Authorisation procedure under REACH. Some potential drawbacks associated with the approach are set out below.

- **Lack of effectiveness in targeting imports of WBPs**: The authorisation process only addresses the placing on the market of substances and their mixtures - it does not affect the import of articles containing substances subject to authorisation. In practice, this will mean that (without restrictions) importers will continue to be able to place WBPs on the EU market which do not comply with the authorisation requirements. Considering that some of the imported WBP are likely to be E2 WBP or worse, this means that authorisation is likely to be ineffective in targeting the source of WBPs of concern.

- **Potential unintended impacts on market for imports**: As a general rule, the less formaldehyde released by WBP, the more expensive the price of the WBP. In general, high-formaldehyde emitting WBPs (i.e. E2 and worse) tend to be significantly cheaper than the lower (or zero)-formaldehyde emitting WBPs. With this in mind, it is reasonable to anticipate that the market for imported, cheaper, high-formaldehyde emitting WBPs could grow in the short-term, thereby, putting consumers at increased risk. It is also important to bear in mind that, as the CARB Phase 2 restrictions start to be implemented in the US, importers to the US will seek alternative markets for their products and their E2 WBP could end up in the EU, especially if there is a market access and a price advantage for the importers.

- **Potential impacts on economic leakage and loss of competitiveness for EU manufacturers**: This study estimates that there is a €10/m³ price advantage for imported E2 WBP, compared with E1 WBP. It also estimated that EU WBP manufacturers suffer a loss of around €7 million per year due to a lack of competitive advantage against imported E2 WBP. This economic leakage or loss will continue into the future. Assuming that authorisation is granted for only E1plus WBP, this means that the price advantage for importers importing E2 WBP, compared with E1plus WBP, would increase significantly beyond €10/m³ and the overall loss to EU WBP manufacturers would increase significantly. In this context, it is important to note that there is currently a legal case in the US involving the US plywood industry which filed an unfair trade petition with the US Department of Commerce and the US International Trade Commission regarding the alleged dumping of unfair and subsidised Chinese hardwood plywood imports onto the US market. The US industry claims that the imported products have an unfair competitive advantage over US manufactured plywood with Chinese plywood being sold up to 50% cheaper than plywood manufactured in the USA. It is also claimed that Chinese producers sell their products at less than one-third of their fair value.

- **Effectiveness (Intermediates)**: Intermediate uses are also excluded from the Authorisation regime (this is important since formaldehyde is mainly used as an intermediate for production of urea-formaldehyde resins which are then used in WBP). On the other hand, restrictions could be based on existing harmonised or industry standards and linked to the Construction Products Regulation, and as such, are practical and understandable and importantly take into account the characteristics of the sector.

- **Challenges relating to monitoring and enforcement**: It is known that the incorporation of an Annex XIV substance into an article is a use which is subject to the authorisation requirement. However, for formaldehyde, two main problems arise: firstly, formaldehyde is used in resin form (mostly as UF resin) and is not incorporated directly into the WBP – the resin is incorporated directly into an article; and secondly, once incorporated into the WBP, there is no easy way of differentiating (especially for imports) between UF resins, MUF resins, PF resins and ultra-low UF resins. Each of these different types of resins results in different levels of releases of formaldehyde, with PF resins in particular releasing very little formaldehyde.

- **Speed of risk reduction**: Authorisation is also likely to entail significant costs to companies/industry, it can be a much more protracted process than a restriction (if the preparation of the Authorisation applications is taken into consideration) and, at the earliest, any positive effects for consumers could not be felt for at least five years (2018 onwards).

- **Cumulative impact of other legal requirements**: Finally, it is important to bear in mind that, if reclassification proceeds, the use of formaldehyde may already be subject to strict control through the CMD and the VOC Directive. These legislations require substitution where technically possible and there is some concern that the significant costs (particularly the administrative burden associated with preparing applications) which will be incurred by employers if the authorisation provisions are put in place may not be justified by the additional health benefits which would accrue, taking into

account the RMMs which would be put in place to comply with these legislation as well as restrictions or OELs (under Scenario 2).

Having considered the RMOs available for dealing with concerns relating to formaldehyde, it is concluded, inter alia, that targeted restrictions are a more appropriate RMO for dealing with concerns relating to WBP, taking into account the challenges highlighted above, in particular, due to the issue of imports.

0.4.5 Dealing with Residual Risks or Concerns

Workers

As noted in Section 1.2, the risk assessment currently concludes that risks are adequately controlled when specific operational conditions (OCs) and risk management measure (RMMs) are applied. Despite this, there is a distinct possibility that the industry will be required to invest significantly to further reduce emissions/exposure to formaldehyde due to:

- **the probability that formaldehyde may be reclassified as a Cat 1B carcinogen and Cat 2 mutagen**. If this happens, it is likely that a series of further controls and RMMs will be introduced (in order to comply with the CMD and other legislation) that will impact upon the emissions/exposure of workers and consumers to formaldehyde (and therefore, risks);

- **the introduction and implementation of a harmonised OEL** of 0.4 ppm (or potentially lower) across the EU. This will require significant investment in abatement equipment, as well as, other organisational measures so as to reduce emissions/exposure of workers to formaldehyde to comply with these limits;

- **a possible revision of the CSR and ES**. For instance, to reflect any updates to the worker risk assessment and indoor air assessment as a result of the Substance Evaluation procedure. Such a revision may also result in more stringent measures being put in place to protect workers.

Taking these into account, it is important to stress that, where there are concerns relating to the risks from formaldehyde from other industrial sectors, **further sampling, monitoring and analysis should be undertaken by industry** to confirm and characterise any risk from formaldehyde in such processes at specific industrial sites, taking into account the likely consequences of the measures put in place by industry to comply with the CMD and a harmonised OEL. This approach would help to clarify, inter alia, the actual residual risk which is applicable and ensure that proportionate measures are put in place, where risks are found.

Consumers

With regard to indoor air, it is important to bear in mind that, there are other initiatives which are currently in the pipeline which will also act (eventually) to reduce indoor exposure to formaldehyde. Firstly, assuming formaldehyde is reclassified, restrictions on its use in certain consumer products (e.g. in toiletries and household products) will be automatically

triggered under the REACH Regulation. These restrictions will act to reduce the sources of formaldehyde in the home contributing to cumulative exposure. It is also expected that the E1plus standard will be implemented as soon as possible as a voluntary agreement and this will also act to reduce releases of formaldehyde from WBP. Also, of particular relevance are the World Health Organisation (WHO) indoor air guidelines and initiatives relating to indoor material labelling schemes.

In 2010, formaldehyde was included in the WHO first **indoor air quality guidelines** on indoor chemicals. These guidelines are targeted at public health professionals and authorities involved in the design and use of buildings, indoor materials and products and are also considered to provide a scientific basis for legally enforceable standards for preventing the health risks of environmental exposures (WHO, 2010). It is understood that these guidelines are currently feeding into various on-going initiatives involving the EC.

In 2010, the process of developing and implementing a framework for the harmonisation of **indoor material labelling schemes** in Europe was also significantly advanced following an initiative co-ordinated by the EC's Joint Research Centre and supported by DG ENTR, DG SANCO, DG ENV and DG ENER (JRC, 2010). In 2012, the European Collaborative Action (ECA) Group established a working group of 27 European experts to oversee the development and introduction of an EU harmonised indoor products labelling scheme (ECA, 2012). The European Commission is also exploring whether there are specific needs for information on the content of dangerous substances in construction products within the context of the **Construction Products Regulation** (DG ENTR, 2012). The Commission also notes that it will be particularly important to take into account REACH-generated data, and DNELs in particular, in developing EU lowest concentration of interest (LCI) values in the context of the Commission's EU-LCI harmonised framework for construction products (EC, 2013).

Taking these into account, it is important to stress that, where there are still concerns relating to the risks from formaldehyde on consumers, the potential impacts of these measures in the pipeline (in particular, the labelling proposals) should be considered before further RMOs are put in place. This approach would help to ensure that proportionate and effective measures are put in place.

ACRONYMS

BOELV	Binding Occupational Emission Limit Value
CAD	Chemical Agents Directive
CBPB	Cement Bonded Particle Board
CLP	Classification, Labelling and Packaging
CMD	Carcinogens and Mutagens Directive
CMR	Carcinogenic, Mutagenic and Reprotoxic
CoRAP	Community Rolling Action Plan
CSA/CSR	Chemical Safety Assessment/Chemical Safety Report
DNEL	Derived No Effect Level
DPD	Dangerous Preparations Directive (1999/45/EC)
DSD	Dangerous Substances Directive (67/548/EEC)
ELR(s)	Existing Legal Requirement(s)
ELV	Emission Limit Value
ES	Exposure Scenario
GHS	Globally Harmonised System (of Classification and Labelling)
IOELV	Indicative Occupational Emission Limit Value
MEL	Maximum Exposure Limit
MF	Melamine Formaldehyde
MUF	Melamine Urea Formaldehyde
MUPF	Melamine Urea Phenol Formaldehyde
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (of Australia)
OC(s)	Operational Condition(s)
OEL	Occupational Exposure Limit
OSB	Oriented Strand Board
PF	Phenol Formaldehyde
p-MDI	Polymeric Diphenylmethane Diisocyanate
PRF	Phenol Resorcinol Formaldehyde
PPE	Personal Protective Equipment
PWD	Pregnant Workers Directive
RAC	Risk Assessment Committee (of ECHA)
RCR	Risk Characterisation Ratio
REACH	REACH Regulation (EC) No 1907/2006

RF	Resorcinol Formaldehyde
RMM(s)	Risk Management Measure(s)
RMO(s)	Risk Management Option(s)
SDS	Safety Data Sheet
SEA	Socio Economic Assessment
STEL	Short Term Exposure Limit
TWA	Time Weighted Average
UF	Urea Formaldehyde
VA	Voluntary Agreement
VOC	Volatile Organic Compounds
WBP	Wood-based panels
WPIF	Wood Panels Industry Federation
YWD	Young Workers Directive

1. PROPOSAL FOR ADDRESSING RISKS FROM FORMALDEHYDE

1.1 Background to Study

Formaldehyde (CAS number: 50-00-0) has come under particular scrutiny from European regulators, Member State authorities and scientific bodies.

In February 2012, the draft Community Rolling Action Plan (CoRAP) was published and listed formaldehyde as one of 90 substances to be subject to the **Substance Evaluation procedure** under the REACH Regulation (EC) No 1907/2006. The CoRAP list contains substances for which there is a suspicion that their manufacture and/or use could pose risks to human health or the environment; substance evaluation is the process under REACH that allows for clarification of such risks to decide if further risk management is necessary. Formaldehyde's addition to the list was a joint action by France and the Netherlands and the initial grounds for concern have been documented as "*Human health/CMR; Exposure/Wide dispersive use, workers exposure, high aggregated tonnage*". The first draft decisions for the substances listed in 2013 (which includes formaldehyde) are likely to be submitted to ECHA by February 2014, after which ECHA will forward any draft decisions to the registrants for comments.

Formacare has contracted TNO Triskelion and Risk & Policy Analysts Limited (RPA) to carry out an "*analysis of the most appropriate risk management option for formaldehyde*" in accordance with the risk management options guidelines as defined by the European Institutions for such analyses. Taking this into account, this study is expected to – amongst other things:

- analyse the manufacture and use of formaldehyde in Europe, including use in downstream applications;
- establish where risks exist relating to formaldehyde in both the workplace and consumer products;
- specify processes or products responsible for those risks;
- evaluate substitution options;
- evaluate other risk management options; and
- propose the most appropriate risk management option(s).

1.2 Structure of this Report

This Final Report complements the risk assessment report and is arranged accordingly as follows:

- Section 2 provides background information on the **manufacture and use of formaldehyde** in the EU (the baseline);
- Section 3 provides an overview of the **summary results of a new risk assessment relating to consumers/indoor air and the revision of the risk assessment for workers** based on measured data;

- Section 4 outlines the existing information on possible **alternatives** to formaldehyde in its use in WBP;
- Section 5 discusses **existing legal requirements** on releases of and exposure to formaldehyde **and potential risk management options**;
- Section 6 describes a range of **potential risk management options** and how they could apply to those uses of formaldehyde of concern;
- Section 7 presents the **qualitative assessment** of the further risk management options against the standard decision criteria of effectiveness, practicality, and monitorability;
- Section 8 provides the **summary assessment of the proposed risk management option(s) and scenarios**;
- Section 9 sets out the **most appropriate risk management options**;
- Section 10 provides a **list of sources for the information in the report**.

2. MANUFACTURE AND USE OF FORMALDEHYDE

2.1 Formaldehyde

2.1.1 Manufacturing Process

Formaldehyde is a naturally occurring substance in the environment. It is formed during the oxidation of hydrocarbons in the troposphere and is an intermediary in the methane cycle (WHO, 2001). At an industrial scale, formaldehyde is manufactured by catalytic oxidation of methanol via either a silver or metal-oxide catalyst process. Formaldehyde production accounts for approximately one third of global methanol demand. Production capacity is split almost equally between production which uses the silver catalyst process and that which uses oxide manufacturing processes.

The silver catalyst process is conducted in one of two ways:

1. Partial oxidation and de-hydrogenation with air in the presence of silver crystals, steam and excess methanol at 680-720°C and at atmospheric pressure (also called the BASF process; methanol conversion, 97-98%); and
2. Partial oxidation and dehydrogenation with air in the presence of crystalline silver or silver gauze, steam and excess methanol at 600-650°C (primary conversion of methanol, 77-87%); the conversion is completed by distilling the product and recycling the unreacted methanol.

In the metal oxide process, methanol is oxidized with excess air in the presence of a modified iron-molybdenum-vanadium oxide catalyst at 250-400°C and atmospheric pressure (methanol conversion, 98-99%) (IARC, 2006).

Figure 2-1 below presents an illustrative summary of the formaldehyde manufacturing process; it also highlights the inputs and outputs from the production of formaldehyde.

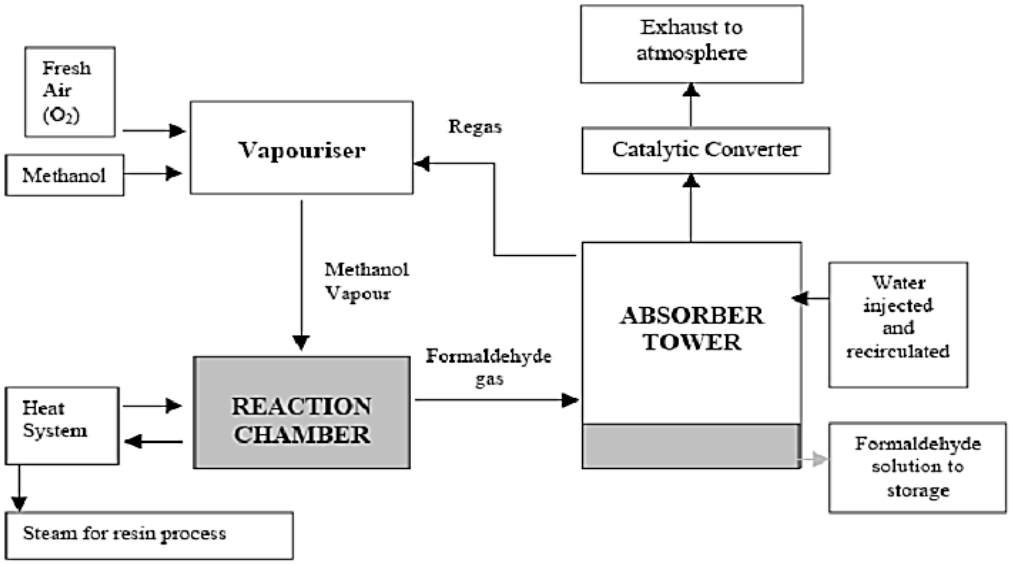


Figure 2-1: Formaldehyde Manufacturing Process
Source: Merchant Research & Consulting (2012)

2.1.2 Production and Capacity

In 2006, production of pure formaldehyde in Europe was over 3 million tonnes (Formacare, 2006); in 2010, this had decreased to around 2.3 million tonnes (Formacare, 2010).

In the EU, formaldehyde is manufactured and used as an aqueous formaldehyde solution, known as formalin, which usually does not contain more than 3% methanol. Formaldehyde is not commonly purchased in its pure form due to the fact that it is not stable in this form. Available data on the production and use of formaldehyde therefore refer to a 37% formaldehyde solution.

In 2010, 29 million tonnes of 37% formaldehyde were produced globally, of which Europe accounted for 23% (6.7 million tonnes) (Merchant Research and Consulting, 2012). The European Union is the second largest producer of formaldehyde after Asia. The total global capacity for the production of 37% formaldehyde is estimated to be 40 million tonnes per year. Europe is estimated to have the second largest formaldehyde production capacity, behind Asia which has approximately 50% of global capacity. It is estimated that Europe has the capacity to produce 9.5 million tonnes of 37% formaldehyde per year, which equates to around 25% of global production capacity (Merchant Research and Consulting, 2012). Within Europe, Germany has the highest formaldehyde manufacturing capacity with 2.2 million tonnes per year which is approximately 5% of global production capacity and 23% of European production capacity (Merchant Research and Consulting, 2012). Table 2.1 presents the production volumes for formaldehyde by EU countries.

Table 2.1: EU 37% Formaldehyde Production & Capacity

Country	Production 2010 (tonnes)	Capacity (tonnes/year)
Germany	1,716,000	2,145,000
Netherlands	760,000	950,000
Italy	736,000	919,000
Spain	660,000	825,000
Sweden	432,000	540,000
United Kingdom	372,000	465,000
Portugal	244,000	305,000
Belgium	232,000	290,000
Austria	140,000	175,000
Finland	128,000	160,000
Denmark	92,000	115,000
Lithuania	86,000	107,000
Ireland	64,000	80,000
Hungary	48,000	60,000
France	44,000	54,000
Bulgaria	24,000	30,000

Source: Merchant Research and Consulting (2012)

2.1.3 Uses of Formaldehyde

Formaldehyde is a basic chemical building block and as a result is used in many processes and applications. The uses and applications of formaldehyde include (Formacare, 2010b):

- the production of formaldehyde-based resins, through the combination of formaldehyde with other substances, which are used in construction and furniture applications;
- an intermediate in the production of chemicals many of which are used in the manufacture of paints and coatings; and
- as a biocidal product used in various products (including healthcare applications) due to its antibacterial properties, as well as in some paints and other products as a preservative.

Figure **2-2** below illustrates the estimated global demand for formaldehyde by derivative in 2009. Based on the data presented, more than half of the formaldehyde produced annually on a global scale is used in the manufacture of formaldehyde-based resins.

Figure 2-2 also clearly shows that UF resins and concentrates are the largest consumer of formaldehyde on a global scale; consuming significantly more formaldehyde than any other derivative.

Figure 2-2: Global Formaldehyde Demand (by derivative)
Source: Formacare (2010b)

Formaldehyde and its derivatives are used in a vast range of applications and are used equally in products that are used in industrial settings and by the general public. Table 2.2 summarises the products in which formaldehyde is present and emphasises those which are used in industrial settings and those accessible by the general public.

Table 2.2: Uses of Formaldehyde and Formaldehyde Derivatives	
Industrial/Occupational Uses	**General Public**
Starting material in chemical synthesis	Detergents
Intermediate in chemical industry for production of resins for wood, paper and textile industries	Disinfectants
	Preservatives in cosmetics
Reagent used for tissue preservation	Cleaning agents
Embalming fluid	Building and insulating material
Disinfectant in operating rooms	Paints and lacquers
	Adhesives
Source: ANSES (2011)	

2.2 Formaldehyde-based Resins

The primary use of formaldehyde-based resins is in the manufacture of wood based panels (WBP). They are used to bond the wood particles together so they can be pressed to the board shape. They are also commonly used as adhesives in the lamination lines; being used to affix the impregnated paper to the raw board to produce a laminated board.

Around 15 million tonnes of formaldehyde-based resins (in liquid form) are used in the manufacture of WBP on an annual basis globally. As shown in Figure 2-3 below, although UF resins are the most commonly used resin in the wood industry (accounting for 61% of the market by volume according to 2001 data), they are of lower value than the other formaldehyde-based resins (33% of the value of the market) - emphasising the low cost and high availability of UF resins.

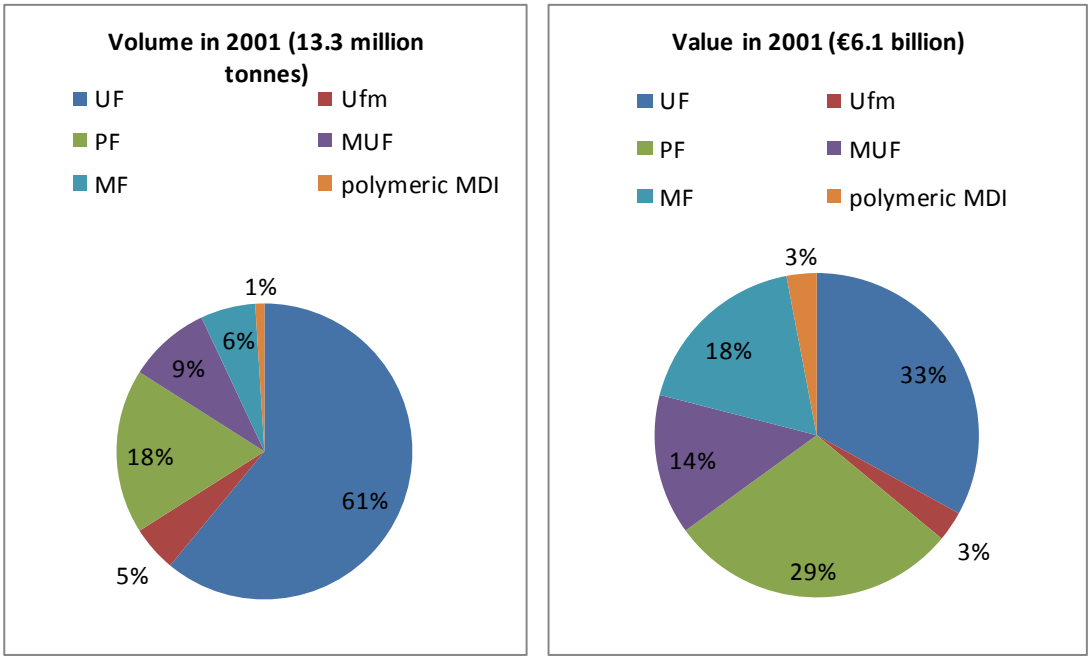


Figure 2-3: Volume and Value of the Global Wood Adhesive Resin Market (2001)
Source: Westermeyer (2002), cited in Athanassiadou (2008)

Of the 6 million tonnes of formaldehyde-based resins used in the production of WBP in Europe, UF resins account for 80%, MUF/MUPF resins account for 10% and PF resins account for 5% (Athanassiadou, 2008). Table 2.3 below sets out the demand for formaldehyde-based resins by WBP in Europe (as reported in 2005) (including Russia). The data may have changed to some degree but the Table does serve to illustrate that the particleboard industry uses more formaldehyde-based resins compared to other types of WBP and consistent with the fact that particleboard is manufactured in Europe in far greater quantities than other WBP.

Table 2.3: Demand for Adhesives from WBP (Europe, incl. Russia)	
Type of WBP	**Formaldehyde Condensation Resins (tonnes)**
Particleboard	3,550,000
MDF and HDF	1,350,000
OSB	150,000
Total	**5,050,000**
Source: Lukkaroinen and Dunky (2005)	

2.3 Wood Based Panels

2.3.1 Background

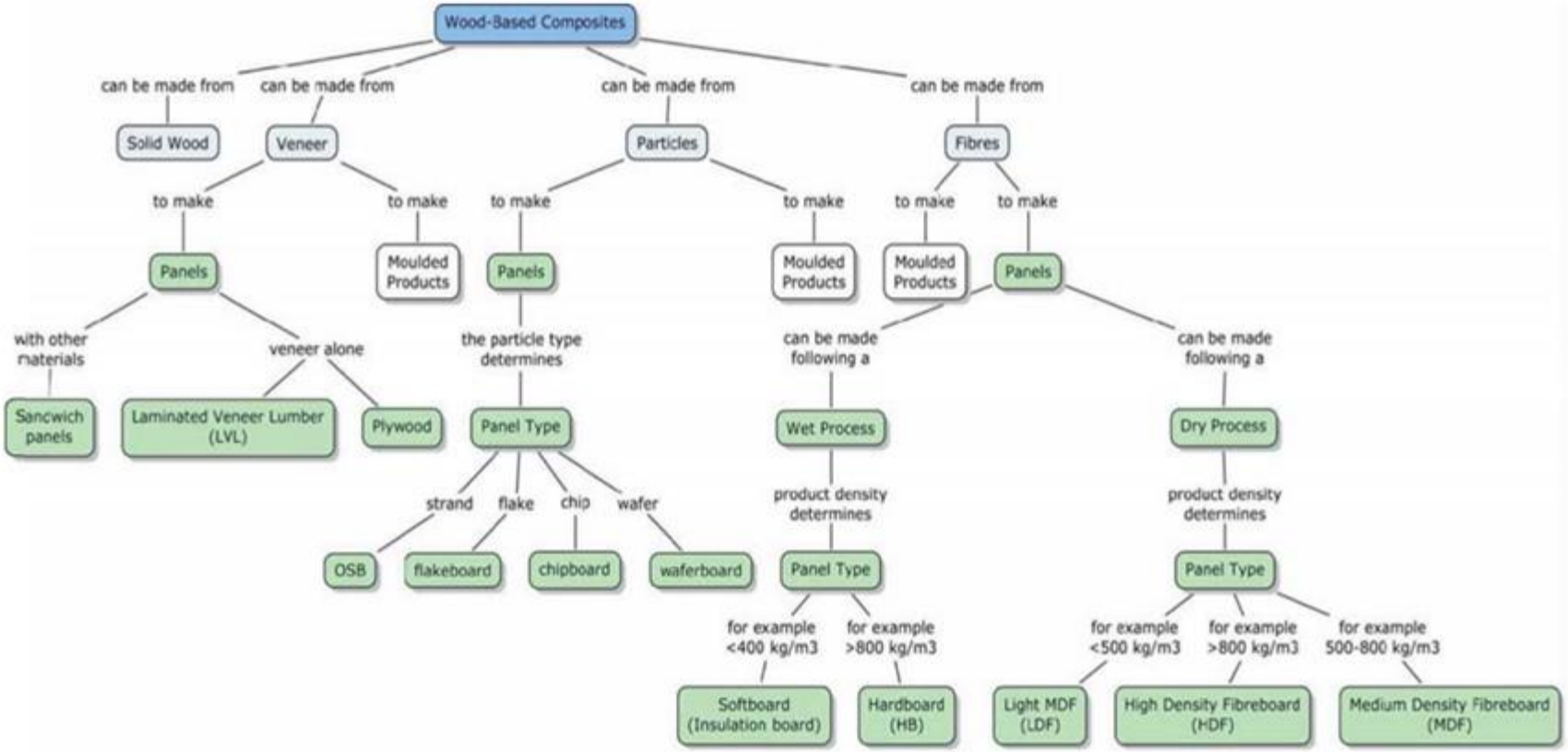
Wood based panels (WBP) are a general term used to describe sheet materials in which wood is the dominant component in the form of strips, veneers, particles, strands or fibres, and the wood parts have been bonded together with adhesives and pressed to form a panel. Typically, WBP are made of laminated wood, wood particles, wood flakes or wood fibres and are engineered to precise design specifications and to meet national and/or international standards (WPIF, 2008; Winandy and Skog, 2007). The performance of WBP can be tailored to the end use application of the product by varying the physical configuration of the wood material, adjusting the density of the composites, varying the resin type and amount, and incorporating additives to increase or improve particular performance characteristics.

WBP are generally categorised into the following categories (WPIF, 2008):

- particleboard (also known as chipboard) (see Section 2.4);
- fibreboard (see Section 2.5); and
- plywood (see Section 2.6).

Figure 2-4 overleaf illustrates the different types of WBP which can be manufactured, highlighting how the type of wood, the manufacturing process and other factors influence the final end product.

Figure 2-4: Summary of Types of WBP (Thoemen et al, 2010)



2.3.2 Production of WBP

The European woodworking industry is worth an estimated €230 billion to the EU economy and the manufacture of WBP is indicated to account for 9% of this value (Pinto, 2011).

The EU manufactures an estimated 60 million m³ of WBP per year which includes the manufacture of veneer sheets, plywood, particleboard and fibreboard. The production of WBP (in m³) by type of WBP is presented in Table 2.4.

Table 2.4: EU-27 Total Production of WBP (2011)	
Type of WBP	**Production (m³)**
Veneer Sheets	1,513,370
Plywood	3,639,200
Particleboard (including OSB)	36,152,190
Fibreboard	15,682,730
Total	57,910,330
Source: Eurostat (2011)	

Particleboard is the most highly manufactured WBP in Europe accounting for over 60% of the total WBP manufactured. When compared with the manufacture of particleboard, the EU manufactures all other types of WBP in significantly lower quantities; this is illustrated in Figure 2-5 below. From Figure 2-5 it is clear to see the domination of European WBP production by particleboard and the fact that the remaining 40% of WBP manufacture is divided between several types of WBP.

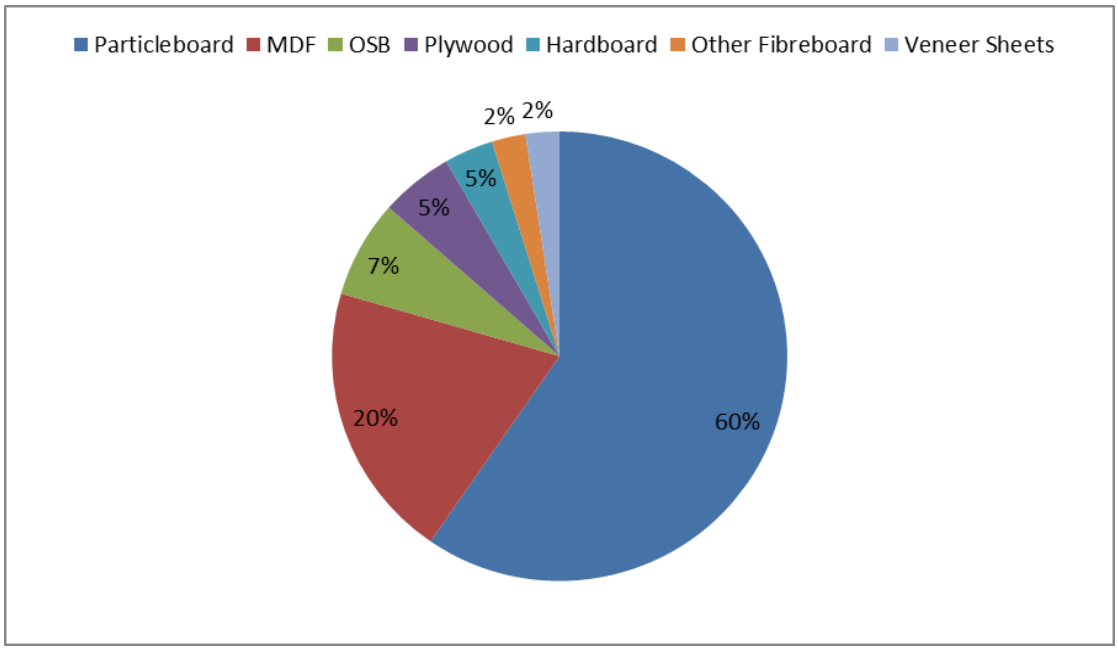


Figure 2-5: EU-27 Production of WBP
Source: Eurostat (2011)

2.3.3 Manufacturers of WBP

Within the EU, there are hundreds of producers of WBP, with these ranging from SMEs with one plant to large, multinational companies with tens of plants and thousands of employees. Table 2.5 below lists the largest WBP manufacturers in Europe currently and also includes the production level of each company. Not all WBP manufacturers conduct the same manufacturing activities. Some WBP manufacturers in Europe are active across the WBP supply chain; manufacturing formaldehyde, formaldehyde-based resins, raw WBP and finished WBP (e.g. value added WBP such as laminated boards). Others are active only in a part of the production process for example they only manufacture the raw board and purchase all raw materials such as formaldehyde and formaldehyde-based resins.

Table 2.5: Manufacturers of Wood Based Panels in Europe (in thousands of metres³)

Company	**Production (m³)**
Kronospan	14,370,000
Sonae Indústria	6,040,000
Egger	5,630,000
Swiss Krono Group	5,262,000
Pfleiderer	4,350,000
Kastamonu Entegre	3,064,000*
Finsa/Utisa	2,970,000
Mauro Saviola	1,800,000
Fantoni	1,700,000
Unilin	1,650,000
Frati	1,550,000
Norbord	1,370,000
Triax	1,000,000
Interbon	980,000
Constantia Iso	900,000
Swedwood	640,000

Source: Sonae Industria (2012)
* PB Romania (450.000m³) which has not started yet

2.3.4 Imports of WBP

In addition to the domestic manufacture and consumption of WBP, the EU also imports and exports WBP. Table 2.6 overleaf provides a breakdown of the imports of WBP from extra EU countries by type of WBP and by EU MS. Overall, around 8 million m³ of WBP are imported into the EU each year, equivalent to around 14% of EU manufactured WBP. Plywood is imported from extra EU countries in the largest quantities and it accounted for over 55% of all extra EU imports of WBP in 2011. Particleboard, fibreboard and veneer sheets account for significantly lower proportions of imports from extra EU countries; accounting for 16.3%, 14.7% and 13.5% of extra EU imports respectively in 2011.

Table 2.6: Imports of WBP to the EU-27 from Extra-EU Countries (in m³)								
	Plywood	**Particleboard (including OSB)**	OSB	**Fibreboard (including hardboard and MDF)**	Hardboard	MDF	Other Fibreboard	**Veneer Sheets**
Belgium	**504,000**	**2,250**	570	**50,450**	44,870	5,170	410	**25,900**
Bulgaria	**27,770**	**24,640**	4,630	**18,870**	1,850	16,810	220	**12,940**
Czech Republic	**16,670**	**25,690**	1,080	**3,670**	1,720	1,100	860	**31,750**
Cyprus	**6,220**	**5,350**	5,170	**940**	170	0	770	**220**
Denmark	**181,100**	**3,530**	1,330	**24,140**	220	18,470	5,450	**6,290**
Germany	**722,730**	**227,880**	1,810	**226,680**	8,260	116,600	101,820	**59,160**
Estonia	**65,340**	**1,560**	160	**39,910**	37,600	2,250	0	**2,210**
Ireland	**43,020**	**2,080**	0	**4,010**	1,250	2,770	0	**790**
Greece	**314,990**	**29,500**	18,840	**4,260**	80	2,950	1,230	**581,080**
Spain	**31,540**	**2,660**	130	**14,840**	2,090	10,280	2,470	**50,880**
France	**101,640**	**34,380**	4,680	**57,990**	7,420	17,780	32,800	**84,110**
Italy	**264,000**	**37,000**	16,000	**56,000**	2,000	30,000	24,000	**100,000**
Latvia	**44,330**	**530**	180	**1,290**	1,060	220	10	**560**
Lithuania	**28,480**	**820**	20	**3,180**	490	2,650	40	**6,880**
Luxembourg	**180**	**0**	0	**0**	0	0	0	**0**
Hungary	**19,160**	**9,830**	0	**3,980**	2,540	1,420	10	**3,790**
Malta	**3,170**	**290**	10	**820**	200	620	0	**30**
Netherlands	**620,400**	**633,400**	46,700	**399,500**	42,600	286,700	70,200	**26,300**
Austria	**15,790**	**3,230**	120	**5,910**	2,970	1,020	1,930	**11,290**
Poland	**118,050**	**82,930**	180	**4,110**	1,060	2,790	260	**14,100**
Portugal	**26,510**	**490**	370	**6,550**	40	6,470	30	**7,250**
Romania	**23,700**	**38,240**	10,810	**91,890**	38,820	23,080	29,990	**8,350**

Table 2.6: Imports of WBP to the EU-27 from Extra-EU Countries (in m³)								
	Plywood	**Particleboard (including OSB)**	OSB	**Fibreboard (including hardboard and MDF)**	Hardboard	MDF	Other Fibreboard	**Veneer Sheets**
Slovenia	**5,640**	**22,700**	0	**850**	320	110	420	**5,660**
Slovakia	**9,830**	**15,190**	15,130	**2,650**	840	930	880	**10,940**
Finland	**95,400**	**550**	0	**16,080**	4,420	4,420	7,240	**7,970**
Sweden	**83,330**	**81,310**	900	**56,070**	7,700	23,940	24,430	**1,970**
United Kingdom	**1,019,920**	**5,000**	1,620	**67,440**	4,700	54,740	8,000	**5,460**
Total Imports	**4,392,910**	**1,291,030**	130,440	**1,162,080**	215,290	633,290	313,470	**1,065,880**
Source: Eurostat (2011)								

2.4 Particleboard

2.4.1 Overview

Particleboard (also known as chipboard) is an umbrella term for WBP that are made from wood particles and includes flake board, wafer board and OSB. The type of wood particle used in manufacture (e.g. flakes, wafers, strands) defines the type of particleboard product produced (Thoeman et al, 2010). While synthetic resin adhesives are typically used in the manufacture of particleboards, cement-bonded particleboards are also manufactured (WPIF, 2008).

Particleboard is generally composed of three layers, however one, five and multi-layer particleboards are also possible. The outer layers are referred to as the surface or face layers and the inner layer as the core. Typically, particles are longer in the core and shorter, thinner and smaller on the surface layers. A smooth surface is achieved in particleboard by increasing the panel density on the surface layers (using smaller wood particles and a higher quantity of resin binders) (Youngquist, 1999; Defra, 2006; WPIF, 2008).

Different grades of particleboard are available for different environmental conditions and different levels of loading, ranging from domestic to industrial usage including usage for platforms and raised access floors. Particleboards manufactured in Europe and used in construction must also comply with European standard EN 312, which defines seven grades of particleboard (WPIF, 2008).

2.4.2 Production

Particleboard is the most heavily produced WBP in Europe, with EU production of around 36 million m^3 being around double that of fibreboard (Eurostat, 2011). It is estimated that particleboard accounts for 60% of all WBP produced in Europe (Pinto, 2011). In 2011, raw particleboard accounted for 41% of production in 2011 and the remaining 59% was split between melamine-faced (84%) and other (16%) particleboard such as fire resistant and moisture resistant panels (EPF, 2012).

Germany is the largest producer of particleboard in Europe, followed by Poland, France, Italy and the UK. These five countries account for approximately 60% of the total EU-27 particleboard production (based on data from Eurostat). The two principal drivers of the particleboard industry are the furniture industry and the construction sector. In 2011, 52% of particleboard was sold directly to the industry for further processing, 41% was sold through trade channels and 7% was sold to DIY stores (EPF, 2012).

In 2011, 28 million m^3 of particleboard was consumed in the EU, with the largest market for particleboard being Germany with apparent consumption of 6.2 million m^3 in 2011. Poland and Italy are also large markets for particleboard consuming 3.5 million m^3 and 3 million m^3 respectively in 2011 (EPF, 2012).

2.4.3 Resins Used in Manufacture of Particleboard

The typical constituents of a particleboard are of the order (by mass) of (WPIF, 2008):

- 83-88% wood chips;
- 6-8% formaldehyde-based resin or 2-3% p-MDI;
- 5-7% water; and
- 1-2% paraffin wax solids.

UF, MUF, PF and p-MDI can be used in particleboards. Typically more resin is used in the surface layers of particleboards than the core layers and the type of resin used to bind the wood particles depends upon the end use and intended grade of the particleboard (WPIF, 2008). For economic production of particleboards, the adhesive must also cure in the press very quickly (within one and five minutes) and must have a pot life in excess of 20-30 minutes to ensure that the adhesive does not cure before entering the press (Thoemen et al, 2010). With regard to specific resins:

- the most common resin employed in particleboards is UF resins, accounting for 90% of the resins used in the manufacture of particleboard on a global scale (Saffari, 2011). In Europe, 60% of the UF resin consumed in Europe is used in the production of particleboard (Mamiński and Parzuchowski, 2006). Particleboard manufactured using UF resins are only suitable for use in interior applications and dry conditions;
- particleboard produced using MUF has improved moisture resistance and is suitable for exterior and semi-exterior applications (Frihart, 2005);
- particleboard produced using PF is suitable for exterior applications due to the superior water resistant properties provided by PF resins (Pizzi, 2003);and
- p-MDI is used in the manufacture of OSB.

Table 2.7 provides general information on the addition levels of different resins for particleboard (excluding OSB) however it is important to note that the figures provided may vary in some cases.

Table 2.7: Typical Resin Addition Levels for Particleboards

Resin	Addition Levels	Surface Layer	Core Layer
UF	4%-10%	8% - 14%	4%-8%
PF	6%-8%	8%-12%	6%-9%
MDI	2%-6%	6%-8%	2%-4%
Source: Thoemen et al (2010)			

2.4.4 Oriented Strand Board

Overview

OSB differs from other types of particleboard because the strands are orientated in one direction rather than being randomly assembled. Generally, the strands are oriented in the outer layers of the board, however, sometimes all three layers are orientated. OSB lacks the

smoothness of particleboard and it is used due to its high mechanical performance rather than its appearance (WPIF, 2008). Four grades of OSB have been defined under standard EN 300. These four standards define the grade of OSB based on mechanical performance and relative resistance to moisture.

OSB also possesses many of the characteristics of plywood but is a cheaper alternative. As a result, OSB has been used as a replacement for plywood in a number of areas including walls and roof sheathing and flooring underlayment.

Production

OSB is produced on a far smaller scale in the EU than particleboard. According to data from Eurostat, 4.2 million m^3 of OSB was produced in Europe in 2011. Production of OSB by members of the EPF was estimated at 3.6 million m^3 in 2011 (EPF Annual Report, 2011-2012) and Germany is the largest manufacturer of OSB in the EU-27 followed by the Czech Republic and Poland.

Resins used in the manufacture of OSB

The resins most often used in the manufacture of OSB are PF, MUF and isocyanates (MDI or p-MDI) (WPIF, 2008). A combination of resins is often used when manufacturing OSB; p-MDI is often used in the core and MUF or PF used in the surface layers of the panel. The resin addition levels for OSB are PF 6% - 8% and MDI 2% - 6% (Thoemen et al, 2010). This combination has the advantage of reducing press cycles whilst providing a bright appearance to the surface of the panel (EPF, nd). Furthermore, as the fines are removed from the wood, less resin is required in the manufacture of OSB compared to other particleboards (Industrieverband Klebstoffe, 2009).

2.5 Fibreboard

2.5.1 Overview

Fibreboard is made from compressed wood or non-wood ligno-cellulosic fibres. Fibreboards can be classified as either dry process or wet process fibreboards based on the manufacturing process used. The principal difference between wet process and dry process fibreboard is that fibreboard manufactured using the wet process typically does not use large amounts of synthetic resins, the wood fibres are bonded together using their own adhesive properties (lignin) with only a small quantity of synthetic resin added to particular products (UK Government, nd). Fibreboards manufactured using the dry process however use synthetic resins as the binding agent.

Wet Process Fibreboard

Fibreboard manufactured using the wet process include **hardboard, mediumboard and softboard**.

- **Hardboard** is used in the manufacture of drawer bottoms, unit backs, door facings, caravan interiors floor coverings, shop-fitting and display work. Standard hardboard is not recommended for exterior use or use in areas subject to direct wetting or high levels

of humidity. Enhanced performance hardboards are available which have higher strength properties and resistance to abrasion which are suitable for exterior applications (WPIF, 2008). Hardboard is made of wood fibres that are pressed into a dense sheet while applying heat. Natural resins hold the sheet together without glue. Relatively small amounts of formaldehyde-based resins are added along with other chemicals to improve its strength and moisture resistance.

- Low density **mediumboards** are used as pin boards, components of partitioning systems, in shop-fitting and display applications. High density mediumboard can be used as wall and ceiling lining boards and as sheathing material in timber frame construction. The use of high density mediumboard is limited (WPIF, 2008).
- **Softboards** can be used for interior applications such as in pin boards, underlay materials, insulation, and in the house building industry as softboard has excellent weather shield and wind-protection capabilities (Industry Europe, nd).

European Standard EN 622 defines standards for wet process fibreboards. The grades of fibreboard are defined based on ambient climatic conditions and the level of loading expected (WPIF, 2008).

Synthetic resins are not typically required for fibreboard that is manufactured using the wet process. Resins may be added to impart or improve specific properties such as resistance to abrasion and moisture and to increase strength and durability (Composite Panel Association, 2012). PF resin is at times used in the production of wet process fibreboards such as hardboard (González-García et al, 2011). Overall, wood fibreboard manufactured using the wet process releases very low levels of formaldehyde.

Due to the low productivity of the wet process and the waste water generated during the production of this product, fiberboard produced by the wet process is available in marginal quantities, only.

Dry Process Fibreboard

The most common form of dry process fibreboard is MDF which is a generic name for any dry process fibreboard that also includes HDF and LDF. MDF is stronger and denser than particleboard and uses smaller particles than those used in particleboard. MDF has more uniform density throughout the board than particleboard and has smooth, tight edges (DEFRA, 2006). It is also extremely versatile and can be machined and finished to a high standard.

European standard EN 316 provides the definition for MDF. MDF manufactured in Europe for use in construction must be specified in accordance with European standards, specifically EN 622 part 1 (general requirements for all fibreboards) and EN 622 part 5 (requirements for dry process boards (MDF)).

2.5.2 Production of Fibreboard

In 2011, over 15 million m^3 of fibreboard was produced in the EU. Of this, 5.5 million m^3 was hardboard and other types of fibreboard. MDF accounted for 65% of fibreboard produced in the EU in 2011 and according to Eurostat (2011), an estimated 10.2 million m^3 of MDF was

produced in Europe in 2011. Poland is the largest manufacturer of MDF, followed in second place by Germany and Spain, Italy and France completing the top 5 producers. Production of MDF by the top 5 countries accounted for 61% of total European production in 2011.
Data from the EPF puts production of MDF in Europe at a higher level in 2011 than Eurostat. Based on data from EPF members, the production of MDF in Europe was 11.7 million m^3 in 2011. Furthermore, EPF data shows that the majority of MDF panels produced in 2011 were raw boards (56%) while melamine faced boards accounted for 32% and the remaining 12% had a different covering (EPF, 2012).

2.5.3 Resins Used in the Manufacture of Fibreboard

UF resins are the most commonly used adhesive in the manufacture of MDF; 30% of UF resins consumed in Europe are used in the manufacture of MDF (Mamiński and Parzuchowski, 2006). However MUF, phenolic resins and p-MDI may also be used depending on the grade of the board and its intended end use (HSE, nd). While UF resins are used for MDF that will be used in interior applications under dry conditions, MUF is used for exterior grade MDF as it has high water and weather resistance. PF resins are also used for exterior grade MDF as a result of its superior water resistance. MDF is composed of around 10% resin, contains a higher resin-to-wood ratio than any other UF pressed wood product and is recognised as being the highest formaldehyde-emitting pressed wood product (Greenspec, 2012; EPA, 2012). Table 2.8 shows resin addition levels in MDF.

Table 2.8: Resin addition levels of MDF

Resin	Addition levels	Comments
UF	8%-14%	In blow-line resin application
UF	6%-10%	Resin application to dry fibres
MUF	8%-12%	For HDF as flooring quality
MDI	~4%-10%	-

Source: Thoemen et al (2010)

2.6 Plywood

2.6.1 Overview

There are two types of plywood: veneer plywood and core plywood (WPIF, 2008):

- Veneer plywood is the official term for what is commonly referred to simply as plywood. It is an assembly of layers (veneers) glued together in which all of the plies are made of veneers orientated with their plane parallel to the surface of the panel.
- Core plywood has a central core of wood strips (or other materials) which are placed edge to edge and sandwiched between veneers of wood.

Plywood is produced in accordance with European Standards:

- European Standard EN 314 describes the bond performance of plywood (e.g. dry interior use, high humidity use, exterior use);
- European Standard EN 635 classifies the surface appearance of plywood; and

- European standard EN 636 defines the durability of plywood (e.g. structural or general).

2.6.2 Production of Plywood

Based on data from Eurostat, around 3.7 million m³ of plywood were produced in the EU in 2011. Finland is by far the largest producer of plywood, accounting for around 1 million m³ of plywood in 2011, followed by Poland at around 400,000 m^3.

2.6.3 Resins Used in Manufacture of Plywood

The resins most commonly used in the manufacture of plywood are (TRADA, 2003):

- **UF resins** - boards made with this type of glue are suitable for interior use. Some boards may also be suitable for use in humid environments but not for use in exterior situations;
- **PF resins** - boards made with this type of glue are suitable for use in humid or in exterior situations. The durability of the veneer species should also be taken into account when selecting plywood for such uses; and
- **MUF resins** - are used in some types of plywood. Bonds tend to be intermediate in resistance to moisture and weather. However, some reputable manufacturers make exterior or even marine plywood with melamine-based adhesives.

3. INFORMATION ON HAZARD AND RISK

3.1 Worker Risk Assessment

Based on the study of measured data, literature and model estimates, it is concluded that it is possible to keep exposure levels below 0.4 ppm with generally feasible conditions and risk management measures. More detail is presented in Manen-Vernooij *et al.* (2013).

3.2 Consumer (Indoor Air) Assessment

Based on the study of literature on indoor air concentrations, emissions from articles and emission criteria, it is concluded that the central tendency of indoor air concentrations of formaldehyde is considerably below the DNEL of 0.1 mg/m^3 and also the reasonable worst case estimate is below this value (Marquart *et al.,* 2013).

3.3 Need for RMOs

According to the ECHA restrictions guidance (ECHA, 2007), RMOs refer to possible changes to legislation or other requirements on industry to control **"risks"** accordingly; they may also cover the use of economic instruments and industry's voluntary commitments. Effectively, RMOs are strictly required to control risks, where these have been identified. At present, risks have not been identified for the manufacture and use of formaldehyde and for consumers. However, it is the case that, there may be a need to address "**concerns**" relating to a substance, where these are identified and could include situations in which:

- there are concerns regarding the safety of consumers and citizens (e.g. a precautionary approach is required);
- the proper implementation and enforcement of OCs and RMMs may be uncertain (e.g. where downstream users cannot/are not complying with OCs/RMMs in eSDS);
- there is an emergence of new data on effects (human health or environmental), or a re-interpretation of existing data or identification of 'new' risks of concern; and/or
- the risk characterisation results are not accepted by the authorities; etc.

For formaldehyde, it is the case that there are concerns amongst regulators which need to be investigated and addressed, where necessary, as evidenced by the various on-going regulatory initiatives. With these in mind, the aim of a systematic analysis of RMOs is to facilitate the identification and choice of the most appropriate measure (or combination of measures) for addressing these concerns, where necessary.

In undertaking an assessment of RMOs, it is noted that '*wide dispersive use*' was identified as one of the initial grounds for concern under the Evaluation procedure, where this selection criterion is explained as being characterised by "*the use(s) of a substance on its own, in a preparation or in an article that may result in not insignificant releases and exposure to a considerable part of the population (workers, consumers, general public) and/or the environment*". Effectively, it takes into account instances where a substance is incorporated into mixtures or articles used by the public and the potential size of the exposed population (ECHA, 2011). Considering that the primary use of formaldehyde and formaldehyde-based resins is in the manufacture of glues and resins, which are in turn used

in the production of wood based panels (WBP), it was considered that an assessment of RMOs should focus on the use of formaldehyde in WBP and the potential to manage any concerns arising.

4. ALTERNATIVES IN WBP PRODUCTION

4.1 Introduction

In developing any strategy for reducing the risks relating to a given substance, it is important to consider the availability of alternatives for the applications of concern, where this includes alternative substances, technologies and/or processes. Such considerations are important since any proposed risk management measures (RMMs) may instigate a shift to such alternatives. Also, the feasibility of alternatives is an important aspect to be considered in determining the most appropriate RMO and, in particular, in developing any restriction proposal. The sections below provide an overview of possible alternatives to formaldehyde that could be used as an adhesive/binder in WBP. Note that this assessment does not cover potential alternative products (for example gypsum board, cement bonded particleboard, metal etc.), but focusses on substitute adhesives.

Table 4.1: below sets out the various wood adhesives that are currently available, grouped according to structural integrity and suitable service environment. These adhesives are discussed in detail in the sections below, categorised under: alternative formaldehyde adhesives (Section 4.2) and non-formaldehyde-based adhesives (section 4.3). In this regard, it is important to note that the term "non-formaldehyde-based" adhesives is used loosely here as some of these alternatives are manufactured using formaldehyde or use formaldehyde as a cross linker for improved technical performance.

Table 4.1: Wood Adhesives Based on Expected Structural Performance at Varying Levels of Environmental Exposure

Structural Integrity	Service Environment	Adhesive Type
Structural	Fully exterior (withstands long-term water soaking and drying)	Phenol formaldehyde
		Resorcinol formaldehyde
		Phenol-resorcinol formaldehyde
		Emulsion polymer/isocyanate
		Melamine formaldehyde
	Limited exterior (withstands short-term water soaking)	Melamine-urea formaldehyde
		Isocyanate
		Epoxy
	Interior (withstands short-term high humidity)	Urea-formaldehyde
		Casein
Semi-structural	Limited exterior	Cross-linked polyvinyl acetate
		Polyurethane
Non-structural	Interior	Polyvinyl acetate
		Animal
		Soybean
		Elastomeric construction
		Elastomeric contact
		Hot-melt
		Starch
Source: Vick (1999)		

4.2 Alternative Formaldehyde-based Adhesives

4.2.1 Overview - Alternatives to UF Adhesives

Urea formaldehyde (UF) resins are the most commonly used formaldehyde-based resins in the manufacture of WBP. They are very economical and fast curing but are not suitable for damp conditions and, as such, are typically used for panels intended for non-structural use such as particleboard and hardwood plywood. UF adhesives are also non-staining and therefore do not blemish the high quality expensive face veneers used for hardwood panels for interior finish applications. Because the formaldehyde component of UF adhesives is not completely chemically fixed by the urea, some formaldehyde is free to dissipate and, as such, UF resins are associated with the highest releases of formaldehyde when compared with other formaldehyde-based resins (IARC, 2006).

There are, however, other formaldehyde-based resins (PF, MF, MUF, RF, and PRF) which release little to no formaldehyde from the cured product and, as such, can be considered a substitute for UF resins. The sections below consider these formaldehyde-based resins.

4.2.2 Phenol Formaldehyde (PF) Adhesives

Overview

Phenol formaldehyde is a thermoset polymer which is manufactured by condensation of formaldehyde and phenol (American Chemistry Council, 2011) and can be used to manufacture various products including plywood, particleboard, MDF, HDF and OSB.

Technical Feasibility

In terms of technical properties, PF adhesives are highly durable and stable, have high wet and dry strength, offer excellent resistance to water and damp conditions and have excellent hardness and abrasion resistance. PF adhesives are also more resistant than the wood itself to high and low temperatures and chemicals, and is also unaffected by mould or fungus (BRE, 2007).

Process wise, PF adhesives require high temperature curing (which takes twice as long as UF), have long press times and have a dark glue line (Dunky, 2003). Various types of extenders (e.g. walnut shell flour, Douglas fir bark flour, etc.) may also be required to moderate the cost of PF glues, control penetration into the wood fibre, and moderate strength properties to suit the materials being bonded (CWC, nd).

PF resins are more likely to be used in WBP that are intended for applications that require durability under adverse conditions; hence, they are typically used in water and weather resistant boards and are suitable for use in exterior and structural grade boards (e.g. particleboard grades P3, P5, P7 and OSB). Overall, PF adhesives can meet the bonding needs for most wood applications if cost and heat curing times are not an issue (Frihart, 2005). Table 4.2 below summarises the principal technical properties of PF resins and compares these against UF resins.

Table 4.2: Properties of UF and PF Resins		
Attribute	**Phenol-Formaldehyde Resin**	**Urea Formaldehyde Resin**
Appearance	Red brown	Milky cloudy
Solid Content	45-60%	68 ± 1%
pH-value (20°C)	12	7.5-9.5
Density (20°C)	1.2 g/cm³	1.29-1.31 g/cm³
Viscosity at filling in factory (20°C)	400-600 mPa s	300-500 mPa s
Hardening temperature	130°C	104°C
Required hardener addition	Only in middle layer	Yes
Storage time	3-12 weeks	4-6.5 weeks
Price (kg dry) (in 2006)	€1.20	€0.40
Source: Kloeser et al (2007)		

Economic Feasibility

PF resins are significantly more expensive than UF resins (double to triple the price of UF resins), although they are cheaper than MF, MUF and PRF resins. In addition to the higher unit price of PF, production capacity is lower when using PF and it is necessary to use PF in larger quantities than UF resins in order to achieve the same mechanical properties (Rescoll, 2009). Despite this, PF resins are considered to be cost-effective where water resistance is a key requirement (Frihart, 2005).

Environmental and Health Concerns

PF adhesives emit very small amounts of formaldehyde (less than other formaldehyde-based resins) due to the fact that formaldehyde is efficiently consumed in the curing reaction and the cross-linking is more stable. Completely cross-linked PF is inert and non-toxic and, as a result, the health risks to end-users (consumers) are minimal.

However, it is possible that workers in the wood panel industry may be exposed to PF resins that are not completely cross-linked. PF resins may cause contact and allergic dermatitis, conjunctivitis, respiratory sensitisation, and contact dermatitis.

Workers may also be exposed to both phenol and formaldehyde in the uncured form. The 1st IOELV Directive established an 8 hour TWA for phenol (2ppm) and, in addition, a skin notation was also assigned to phenol (HSE, ndb). However SCOEL reviewed the IOELV for phenol due to new scientific data and recommended the establishment of a STEL to complement the existing 8 hour TWA IOELV. The 3rd IOELV Directive established a STEL of 4ppm in addition to the 8-hour TWA value of 2ppm (EU, 2009). Under the CLP Regulation, phenol is classified as Muta 2, Acute Tox, 3, STOT RE 2 and Skin Corr. 1B.

Overall, while the use of PF resins reduces the risk to consumers, it is not certain that this is the case for workers and even communities located around phenol production and/or storage facilities (when compared to urea).

4.2.3 Resorcinol Formaldehyde (RF)/Phenol-Resorcinol Formaldehyde (PRF) Adhesives

Technical Feasibility

In terms of technical properties, RF and PRF adhesives are curable at room temperature, very reactive, form highly durable bonds and are resistant to bond failure and degradation (Frihart, 2005). They also have high wet and dry strength, and are very resistant to heat and damp conditions. PRF resins also offer heat resistance meaning they are suitable for use in exterior, humid and interior conditions and very few adhesives are able to match the durability of RF in waterproof assemblies. RF and PRF are suitable for use in structural and fully exterior service environments, meaning they are technically suitable for use in a wide range of WBP (Funch, 2002; Extance, 2009). The dark colour of both RF and PRF is, however, considered a disadvantage.

Process wise, RF and PRFs have the same basic properties as the PF adhesives; except that they are more reactive than PF adhesives and, as such, curing is faster and takes place at room temperature and below. The room temperature cure results in a lengthy assembly time; basically, if the cure were rapid at room temperature, then there would not be enough time to mix the components, spread them on the wood, and press the wood pieces together prior to adhesive curing. The slow cure results in a longer clamping time before the adhesive has sufficient strength to allow handling of the wood pieces. Thus, a room temperature cure is desirable, to avoid heating large laminated pieces, but suffers from the long clamping times (Frihart, 2005).

Economic Feasibility

RF resins are significantly more expensive than UF resins (around four times the price of UF resins) due to the high cost of resorcinol. By reducing the resorcinol content and adding phenol (to produce PRF) the cost of the resin is reduced without losing the room temperature curing properties. In general, RF and PRF are not widely used in the production of WBP (due to cost) and have instead been used primarily as assembly glues in a few specialist applications.

Despite the high cost of resorcinol and the low uptake in the wood industry, wood adhesives currently consume an estimated 25% of global resorcinol supply (Extance, 2009; CWC, nd). Information on the quantity of resorcinol manufactured today is not publicly available; in 2004, global production of resorcinol was 48,000 tonnes (Extance, 2009) and unsubstantiated sources suggest that global resorcinol production capacity today is less than 100,000 tonnes per year. Taking into account the amount of UF resins required to meet the needs of the WBP industry, it is highly unlikely that there will be sufficient RF resins to meet the needs of the WBP industry in the short-term.

Environmental and Health Concerns

RF and PRF do not emit substantial amounts of formaldehyde. In RF and PRF, the polymers do not chemically break down in service and, as a result, no detectable formaldehyde is released and consumers are not at risk from significant formaldehyde emissions from the finished product (Frihart and Hunt, 2010).

However, workers involved in WBP manufacturing may be exposed to uncured RF and PRF adhesives and due to the (combined) toxicity of formaldehyde, resorcinol and phenol and the risk of absorption through the skin, contact with the resin in the uncured form is to be avoided (Huntsman, 2009).

Resorcinol was included on the **Community Rolling Action Plan (CoRAP)** which was published on 29 February 2012. The CoRAP contains substances for which there is a suspicion that their manufacture and/or use could pose risks to human health or the environment and substance evaluation is the process under REACH that allows for clarification of such risks. Resorcinol is one of the substances to be evaluated in 2014 by the Finnish authorities. The initial grounds for concern relate to suspicions of resorcinol as an endocrine disruptor, exposure and wide dispersive use.

Resorcinol is also toxic to aquatic organisms and has been assigned the following hazard statements under the CLP regulation (1272/2008) '*Aquatic acute 1 H400: very toxic to aquatic life*'.

4.2.4 Melamine Formaldehyde (MF) Adhesives and Melamine Urea Adhesives (MUF)

Technical Feasibility

MF resins are formed from a chemical combination of melamine and formaldehyde. MF and MUF resins are commonly used in the manufacture of exterior and semi-exterior WBP and in the preparation and bonding of both low and high pressure paper laminates and overlays (Pizzi, 2003).

In terms of technical properties, MF adhesives are water borne, fast curing, have excellent hardness and abrasion resistance, good dimensional stability, a clear glue line, good water resistance and excellent heat, chemical and flame resistance. MF resins are similar to UF resins in terms of processing and applications, however MF resins offer significantly more moisture resistance and are harder and stronger than UF resins (Britannica, 2012). MF resins are distinguished from UF resins because of their high level of wet resistance and, as a result, MF resins are suitable for use in structural and fully exterior applications.

MUF adhesives exhibit similar characteristics to UF adhesives but with increased moisture resistance. The melamine content is adjusted based on the required moisture resistance: the higher the content of melamine, the higher the stability of the hardened resin towards the influence of humidity and water (hydrolysis resistance). MUF resins do not exhibit precisely the same characteristics as MF resins and in particular, MUF resins are suitable for use in structural applications but only in limited exterior applications. MUF resins are suitable for a wide range of WBP but importantly are not suitable for all exterior applications. Table 4.3 below summarises the principal properties of MUF.

In the production of WBP, MF and MUF resins are most commonly employed in the lamination lines due to the strength that they impart to the surface, however in such boards it is likely that UF has been used in the production of the raw board. The similarities between MF, MUF and UF mean that the existing plant and equipment used in the manufacture and use of UF can be easily adapted to be suitable for the use of MF and MUF.

Table 4.3: Summary of the Properties of MUF	
Property	**MUF**
Price	Medium to High
Necessary hardening temperature	Medium
Press time	Medium
Susceptibility against wood species	Medium
Efficiency	Medium to High
Manipulation	Easy
Resistance against hydrolysis	Medium to High
Use in humid conditions	Partly Yes
Formaldehyde emission	E1; (lower possible)
Source: Lukkaroinen and Dunky (2005)	

Economic Feasibility

MF resins are significantly more expensive than UF resins (around three times the price of UF resins) due to the high cost of melamine which is around three times more expensive than urea (Rescoll, 2009). MUF adhesives are cheaper than MF resins and are considered a good compromise between the high performance of MF adhesives and the low cost of UF adhesives (Frihart, 2005).

Environmental and Health Concerns

MF adhesives do emit formaldehyde; however, this is in significantly lower amounts compared to UF resins (but in higher quantities than PF). The lower levels of formaldehyde released from the cured product means the risk to consumers is low. Melamine may, however, be hazardous in case of skin contact, eye contact, ingestion and/or inhalation (Science Lab, 2012).

Other

It is important to note that the resin industry has invested significantly in research into ultra-low emitting UF resins. These resins combine the emission advantages of the formaldehyde free resins with the performance advantages of the high molar ratio resins. Such resins give boards with low formaldehyde emission with the addition of formaldehyde catchers or scavengers.

4.3 Non-Formaldehyde-based Adhesives

4.3.1 Isocyanates in Wood Adhesives

Polymeric Diphenylmethane Diisocyanate (p-MDI)

Technical Feasibility

p-MDI is a highly durable adhesive that is already used in the WBP industry in the manufacture of OSB and to a lesser extent in the manufacture of particleboard. Using p-MDI as a resin in the production of WBP offers several benefits including (Connor, 2001):

- the possibility of use with wood which has a higher moisture content because water is needed to form the polyurea that acts as the polymeric adhesive material;
- cure at a lower temperature;
- a smaller dosage of p-MDI is required (on a weight basis) to form a bonded material with acceptable properties; and
- there are no formaldehyde emissions.

In addition, p-MDI has a fast reaction rate, is efficient to use and is able to adhere to difficult to bond surfaces. It is able to form strong, durable and water resistant bonds, even with high moisture content wood (Frihart, 2005; Dunky, 2003) and has higher moisture tolerance than the formaldehyde-based resins. p-MDI is suitable for use in structural applications and in limited exterior uses and, as such, for many WBP, p-MDI is the only practical alternative and the closest substitute for UF resins. However, p-MDI does present some performance challenges (e.g. it has greater creep) and manufacturing challenges (e.g. it sticks to metals such as the press platens and for successful use a release agent is needed) (American Chemistry Council, 2011). Table 4.4 below summarises the main characteristics of p-MDI and also offers a comparison with the characteristics of the main formaldehyde-based resins UF, MUF and PF.

Table 4.4: Characteristics of UF, MUF, PF and p-MDI

Property	UF	MUF	PF	p-MDI
Price	Low	Medium to High	Medium	High
Necessary hardening temperature	Low	Medium	High	Low
Press time	Short	Medium	Medium to Long	Medium
Susceptibility against wood species	High	Medium	Low	Low
Efficiency	Low	Medium to High	Medium to High	High
Manipulation	Easy	Easy	Easy	Difficult
Resistance against hydrolysis	No	Medium to High	High	High
Use in humid conditions	No	Partly Yes	Yes	Yes
Formaldehyde emission	E1	E1; (lower possible)	More or less no emission	No (only from wood)

Source: Lukkaroinen and Dunky (2005)

p-MDI offers many attractive characteristics for use in WBP. However, the majority of European plants are not built to operate with p-MDI on a large scale. The production processes for p-MDI are quite different from those for formaldehyde-based resins and it is indicated that for p-MDI to be used more extensively in the WBP industry, a higher level of technology is required (Rescoll, 2009). Plant alterations will only be possible at some plants producing WBP and only at significant cost to the manufacturers.

It is also necessary to consider the legal requirements governing the use of p-MDI and any changes that will be required from switching from the use of formaldehyde-based resins to the isocyanate p-MDI. The majority of existing WBP installations do not have a permit to use p-MDI and, in some EU countries, it has been indicated that the use of p-MDI for industrial production is restricted to certain locations. The building and permitting process for a p-MDI plant is very complex and is only feasible on a secluded chemical industrial park (where production of phosgene can take place safely).

Economic Feasibility

By weight, p-MDI is four times more expensive than amino-plastic resins (e.g. UF) and two times more expensive than phenolic resins (e.g. PF) (Hervillard et al, 2007). Rescoll (2009) estimates that p-MDI costs approximately €1,400/tonne while UF resins cost €350/tonne. More recent estimates estimate the cost at of p-MDI at €1,600 – €1,800 per tonne. It is, however, important to note that the p-MDI used in WBP is one of the poorer quality-grades; high quality p-MDI is used in other industry sectors and in applications with higher technical requirements (e.g. in the automotive industry) costs over €3,500 per tonne.

However to achieve the same board mechanical properties as UF resins, a smaller dosage of p-MDI resin is required (Papadapoulous, 2006). For example, in order to produce 3 mm sheets of MDF, approximately 11% UF resin is required while only 3% p-MDI is required to achieve a higher performing board in terms of swell resistance and internal bond (Panels & Furniture Asia, 2009). To produce more robust 12 mm MDF boards approximately 10.5% MUF (containing 4% melamine) would be used, only 3% MDI is required to produce panels with similar internal bond but improved swell resistance (Panels & Furniture Asia, 2009). Hence, although p-MDI costs more than other resins (on a weight by weight basis), it has increased in popularity due to its rapid cure and ability to work at lower application rates (Frihart, 2005).

Process wise, p-MDI offers the potential for lower production costs as it has faster production rates and lower press temperatures. p-MDI also has the potential for increased mill productivity and savings in drying, blending and pressing. However, a major issue with p-MDI when considering economic feasibility is the limited supply and availability of the substance. It is widely acknowledged that there is insufficient capacity currently for p-MDI to meet the needs of the WBP industry and no additional capacity is expected to be created globally until 2020. The fact that p-MDI will require different plant, processes and technology (which may not be in the public domain) (EC, 2000) will result in costs for manufacturers, which will in turn, impact on the economic viability of p-MDI as an alternative to formaldehyde-based resins.

Environmental and Health Concerns

Although formaldehyde is used in the production of p-MDI, p-MDI is promoted as a formaldehyde-free (or no added formaldehyde 'NAF') resin as properly cured p-MDI adhesives are not considered hazardous in bonded wood products (Vick, 1999). As a result, p-MDI based panels are automatically classified to E1 standard (following EN 13986) without testing, and can also be classified under the Japanese F**** classification, the most stringent formaldehyde emissions classification worldwide (EC, 2010). The final bonded product does not contain any risk of formaldehyde emissions because of the reaction of the isocyanate groups (Frihart, 2005). Therefore, any health risks from p-MDI fall primarily on workers as risk of exposure occurs during the manufacture and use of the resin itself.

IARC classifies p-MDI as a group 3 substance: 'not classifiable as to its human carcinogenicity'. However, IARC does consider MDA (an aniline building block of p-MDI) as a probable human carcinogen although aniline itself is not considered a human carcinogen (Global Health & Safety Initiative, 2008). Studies have suggested that benzene (used in the production of MDI and p-MDI) may be linked to leukaemia, multiple myeloma, prostate cancer and non-Hodgkins lymphoma (Global Health & Safety Initiative, 2008). There are currently marketing and use restrictions on MDI-containing consumer products under REACH. As of December 2010, all consumer products manufactured and imported into the EU containing concentrations of 0.1% or more MDI must include specific types of protective gloves and specific warnings and use instructions (EPA, 2011).

The toxicity of isocyanates is also a major disadvantage of p-MDI. Exposure to isocyanates is a leading cause of occupational asthma worldwide. Particular worries also surround the issue of workers health as uncured p-MDI resin can result in the chemical sensitisation of persons exposed to it; special precautionary protective measures are therefore required (Stark et al, 2010). Workers manufacturing the p-MDI resin, and those manufacturing WBP which use p-MDI resin as a bonding agent, are thought to be at risk from exposure. The hazards associated with isocyanates/p-MDI and the extra costs associated with maintaining safe working operations in plants is one of the key reasons for the limited the use of p-MDI to date (Frihart, 2005). In October 2012, ANSES, (the French Agency for Food, Environmental and Occupational Health and Safety) issued a call for contributions from stakeholders of MDI for information which may be useful in its OEL recommendations (European Agency for Safety and Health at Work, 2012).

Emulsion Polymer Isocyanates (EPI)

Emulsion Polymer Isocyanate (EPI) adhesives are another potential formaldehyde-free or no added formaldehyde substitute for formaldehyde-based resins. EPI adhesive systems are typically water-emulsion adhesives with an isocyanate cross-linker which have been used in the manufacture of many wood related applications including parquet, window frames, furniture parts, plywood, finger joints and load-bearing constructions such as glulam beams and I-beams (Grøstad and Pedersen, 2010). EPI has also been used in the production of particleboard.

Technical Feasibility

The precise technical characteristics of EPI adhesive systems depend upon the specific formulation used however they are generally known to form fairly durable bonds and give good water resistance (Frihart, 2005). EPI adhesives also have fast setting speeds, can be cold cured, have a light glue line, have low creep of the glue line and have high moisture resistance (Grøstad and Pedersen, 2010). EPI also has good heat resistance (McCloskey, 2009). Studies have indicated that the strength and durability of EPI systems can reach the same levels as PRF resins (Forest & Wood Products Australia, 2010). EPI adhesive systems are suitable for use in structural applications and fully exterior environments meaning they are suitable for use in a wide range of WBP. However, due to limitations in production processes, it is argued that EPI adhesive systems are not suitable for use in OSB or particleboard. However, another source states that in Japan and other Asian countries EPI adhesives have been used in the production of particleboards. The advantage of using EPI is the ability to use different wood materials, high moisture content wood and lower pressing temperatures (Grøstad and Pedersen, 2010).

EPI adhesives are typically two component adhesives which have to be mixed prior to use. They also have a relatively short pot life and are required to be applied mechanically (Industrieverband Klebstoffe, 2004). EPI adhesive systems also have a relatively short assembly time and stick to metals therefore release agents or treatment of the press platen is required. EPI adhesive systems are also difficult to handle and apply. EPI adhesive systems will require additional equipment in order to be used in the manufacture of WBP.

Economic Feasibility

The high cost of EPI is prohibitive to its use in the manufacture of WBP. As a substitute for formaldehyde-based resins, increased costs also stem from the additional process steps and equipment which are necessary for mixing and metering EPI and also managing the high tackiness of EPI. Costs will be incurred in buying new or additional equipment, although for many applications, the same production equipment and adhesive application equipment may be used for EPI adhesives as for traditional adhesive systems.

Environmental and Health Concerns

The precise health concerns of the EPI adhesive system will depend on the components used. EPI adhesive systems are two-component systems that are based on a reaction of a mixture of:

- a water based emulsion polymer, for example PVA, EVA, SB or acrylic; and
- an isocyanate hardener/cross linker, for example MDI, HDI or p-MDI.

EPI adhesives are formaldehyde free and no formaldehyde is emitted from the cured product. When EPI is properly hardened, it is inert and physiologically safe (Industrieverband Klebstoffe, 2007) therefore the risk of exposure falls on workers involved in manufacturing and using EPI resins.

EPI may cause irritation to the skin, eyes and respiratory system and allergic skin reactions may occur after repeated contact (Industrieverband Klebstoffe, 2007). The health risks

associated with isocyanates also apply to EPI which use isocyanates as a cross-linker. Isocyanates are powerful irritants to the mucous membranes of the eyes and gastrointestinal and respiratory tracts and can sensitise workers making them subject to severe asthma if exposed again (Centers for Disease Control and Prevention, 2012).

EPI adhesives are considered to be environmentally friendly due to the absence of volatile hazardous chemicals. They are also non-biodegradable and in the hardened state will remain in the environment (abiotic or biological degradation will be very slow). EPI is not classified as toxic to the environment and does not result in bioaccumulation (Industrieverband Klebstoffe, 2007).

4.3.2 Polyurethanes

Technical Feasibility

Polyurethane chemistry is versatile and, as such, adhesives displaying a wide variety of chemical and physical properties can be manufactured (IPIRTI, 2012). Polyurethane adhesives provide strong bonding in a variety of applications (IPIRTI, 2012) and are suitable for semi-structural, limited exterior applications (see Table 4.1).

Polyurethane resins have high dry and wet strength and are resistant to water and damp atmospheres (Connor, 2001). They also have: excellent adhesion to most substrates, flexibility, low temperature performance, high cohesive strength and cure speeds that can be tailored to the manufacturer's needs (Lay and Cranley, 2003). They are known as being particularly durable and reliable and they can be tailor made to fit the application for which they are required (Desai et al, 2003). Polyurethane resins also cure well at room temperature (Frihart and Hunt, 2010).

On the down side, polyurethane glues can be difficult to work with as they stick to a variety of substrates, stain easily and require a stronger solvent than water to clean up (Fine Woodworking, 2007).

Economic Feasibility

Pure polyurethane systems are costly and costs can be increased due to the requirement of release agents (as polyurethanes stick to the press platens) and the removal of any bad quality top layers of the end product (as a result of sticking). The high cost of polyurethanes may be prohibitive to their use in the manufacture of WBP.

Environmental and Health Concerns

Concerns regarding the health hazards of polyurethane resins typically centre on occupational exposure (for polyurethanes which contain isocyanates) as cured polyurethane products are considered inert and non-toxic.

With regards workforce exposure, polyurethanes can cause harm when inhaled and can be irritating to the eyes, respiratory system and skin. Polyurethanes may cause sensitization through inhalation and skin contact. Isocyanates are the leading cause of work induced asthma and studies have shown that isocyanate-induced asthma occurs in between 5% and

25% of workers in polyurethane production plants (Global Health & Safety Initiative, 2008). There is limited evidence of a carcinogenic effect of polyurethanes, and they are classified as an IARC group 3 substance – *unclassifiable as to carcinogenicity in humans*.

4.3.3 Epoxy Adhesives

Epoxy resins are not commonly used in wood bonding or wood working applications due to high material costs; however, they have been successfully used in some more specialist or niche applications where other adhesives have failed. Epoxy resins have been used in laminating veneer and lumber in cold-moulded wood boat hulls, assembly of wood components in aircraft, lamination of architectural railings and posts, repair of laminated wood beams and architectural building components, and laminating sports equipment (Connor, 2001).

Technical Feasibility

Epoxy resins offer good environmental resistance and the ability to bond with a variety of substrates (Frihart, 2005). When compared with other wood adhesives, epoxy resins cure at ambient temperatures, have good gap filling ability, have high wet and dry strength, are versatile and are water and damp resistant (Frihart, 2005). Epoxy resins also create very strong bonds which can be as strong as the wood itself (Vick et al, 1995). With regards curing, epoxy resins have negligible shrinkage during cure (as a consequence, the parts do not need to be in intimate contact) and they do not require pressure to effect a cure (SP Gurit, 2002). As a result of these features epoxy resins are effective for bonding less well prepared surfaces (SP Gurit 2002). Epoxy resins also have excellent chemical resistance and versatility (Goulding, 2003).

Epoxy resins do not result in durable bonds to wood under all conditions; in some cases their durability is limited. In particular, there is disagreement regarding the durability of epoxy bonds in wet conditions and as a result most standards limit epoxies for load bearing applications (Frihart, 2005). Epoxy resins are suitable for use in structural applications but can only be used in limited exterior environments. In addition, epoxy resins do not have particularly good UV resistance. Due to the high viscosity of epoxy resins, it requires a post-cure to obtain the ultimate mechanical properties; this makes epoxy resins particularly difficult to use (ACMA, nd).

To use epoxy resins in the manufacture of WBP, additional equipment in the form of metering and mixing equipment will be required. The formulation of epoxy adhesives into a serviceable adhesive binding system requires a highly specialized technology (Bhatnagar, 1996). In addition, there are concerns over the technical feasibility of epoxy resins for some end uses. In particular, the use of epoxy resins in laminates, for example, is likely to result in final product aesthetics which are inferior to the industry requirements.

In summary, epoxy resins offer potentially high performance but also require longer cure time as well as special equipment (American Chemistry Council, 2011). Table 4.5 below provides a comparison of the principal properties of epoxy resins with the formaldehyde-based resins RF and UF.

Table 4.5: Comparison of Properties of Epoxy Adhesives with RF and UF used in Wood Construction			
Property/Criterion	**Adhesive Type**		
	Epoxy	**RF**	**UF**
Bond Strength	Excellent	Excellent	Good
Resistance to Moisture and Weathering	Excellent	Very Good	Poor
Gap Filling	Excellent	Poor	Poor
Toughness (resistance to cracking with ageing)	Good (ideal for high stressed joints)	Poor (brittle)	Poor (brittle)
Curing Temperature	5-30°C – but ideally 15°C+	Min 15°C	Min 10°C
Bonding Dissimilar Materials (e.g. wood to metal)	Excellent	Special primer required for good bond	Poor
Gluing Difficult Timbers	Forms excellent bonds	Curing temperature of 40^{o}C required	Not recommended
Source: SP Gurit (2002)			

Economic Feasibility

Epoxy resins are not commonly used in wood bonding or wood-working as they are too expensive and are considerably more expensive than formaldehyde-based resins such as UF and PF. Also, while compared with other resins such as PVA and p-MDI, epoxy resins are typically used at greater weights per bonded surface (Frihart, 2005b).

In addition to their high material cost, epoxy resins are not technically suitable for the existing plant and equipment and require metering and mixing equipment which increases the cost of substitution (Global Insight, 2007). Furthermore, it is argued that the formulation of epoxy adhesives into a serviceable adhesive binding system requires highly specialised technology.

Environmental and Health Concerns

Occupational exposure is most significant when discussing the health risks of epoxy resins as cured epoxy resins are inert. Cured epoxy resins (a fully hardened combination of the epoxy resin system chemicals) should also be non-irritating and non-sensitising.

The most common epoxy resins are produced from a reaction between epichlorohydrin and bisphenol-A. Epichlorohydrin is classified by the EU as a category 2 carcinogenic substance – *substances which should be regarded as if they are carcinogenic to humans*. Bisphenol-A is a known endocrine disruptor; a chemical which interferes with hormone systems in animals and humans and can cause health effects such as cancerous tumours, birth defects and learning difficulties. Bisphenol-A can induce allergic contact dermatitis and is a weakly estrogenic monomer (European Agency for Safety and Health at Work, 2009). Epoxy resins (those based on bisphenol-A) are not considered to be carcinogenic by IARC.

Epoxy resins are skin sensitisers which cause sensitization of the hands, arms, face and throat (photosensitisation has also been noted). Some components of epoxy resins may also cause irritation of the eyes, respiratory tract, contact uriticaria, rhinitis and asthma (European Agency for Safety and Health at Work, 2009).

Epoxy resins are considered to be toxic to the aquatic environment and may cause long term effects in the aquatic environment.

4.3.4 Polyvinyl and Ethylene-Vinyl Acetate Adhesives (PVA and EVA)

PVA is a popular adhesive in furniture manufacturing and assembly and in carpentry, because it is relatively inexpensive (Connor, 2001). PVA adhesives are thermoplastic and so they soften when exposed to heat (above room temperature) or lasting mechanical stress, and solidify when cooling to room temperature. EVA is similar in many ways to PVA however it is arguably of higher quality.

Technical Feasibility

PVA adhesives typically have good dry strength, are ready to use, have a short setting time (at room temperature, under pressure), long pot life and create flexible and invisible joints (Connor, 2001). Set PVA resins are light in colour and are often transparent (Connor, 2001).

However, PVA adhesives are limited by their poor performance under moderately high temperatures (over 50^{o}C), and in moist and humid conditions. They also have a tendency to creep under load (Global Insight, 2007). The thermoplastic nature of PVA is a severe limitation as the adhesive softens when exposed to heat and solidifies when cooling to room temperature. Consequently, PVA does not form a chemical bond and the bond formed is reversible. This is not suitable for the manufacture of WBP. PVA also has a limited stand time and will begin to cure as soon as it is applied which limits the time available to set up the panel prior to pressing. PVA can be combined with cross-linking agents and catalysts to increase durability and low moisture resistance however this often makes the resin more toxic and more expensive. They are not generally suitable for use in their basic unmodified state as they form very brittle films and have limited adhesion capabilities.

EVA copolymers are used in hot melt adhesives (10-40% vinyl acetate) and emulsions (more than 40% vinyl acetate). EVA has high initial adhesive strength, high wet tack, good creep resistance, good alkali resistance, and good thickening response and operation safety. However, because they are not cured, they will lose much of their strength at high moisture levels.

Economic Feasibility

Weight for weight, PVA adhesives are more expensive than UF adhesives. However they appear to be generally considered to be 'cost effective 'or 'moderately' priced. PVA is, however, not a realistic alternative for UF resins as it is indicated to be around five times more expensive than PF/PRF resins (EEC, 2000).

PVA can be easily produced in small plants (unlike EVA). However, the resins cannot be produced at plants designed for formaldehyde-based resins (EC, 2000). Furthermore, PVA

has higher viscosity than water-based adhesives which would require manufacturers to make capital investments before using PVA in panel production (Global Insight, 2007).

Environmental and Health Concerns

PVA and EVA are 'environmentally friendly', have low emissions and do not pose health risks. PVA itself is not considered hazardous, however, it contains trace amounts of its precursor, vinyl acetate which is toxic, may be a carcinogen (t3db, nd) and may have other health effects.

4.3.5 Bio-based Adhesives

Protein Glues

Background

Proteins are well suited to making wood adhesives and were widely and successfully used as wood adhesives in the past in the production of WBP. However, since the 1970s protein glues have been widely replaced by synthetic adhesives. Protein glues can be both plant (e.g. soybean, plant oil) and animal based (e.g. blood, casein).

Technical Feasibility

The durability of unmodified, uncross-linked protein adhesives is a problem and they do not have any resistance to water or mould (Lambuth, 2003). When used alone, **soy** based adhesives are not water resistant, have moderate to low strength and do not have sufficient dry strength for WBP. **Casein** has high dry strength but moderate resistance to water, damp atmospheres and intermediate temperatures. Casein does have superior moisture resistance when compared to other animal and plant protein adhesives (BRE, 2007) and does not soften at high temperatures. However casein easily stains timber with high tannin contents and is susceptible to moulds and fungal attack. Casein, like many of the protein adhesives, provides good fire resistance and is therefore suitable for use in fire doors. **Blood** has high dry strength but moderate resistance to water and damp atmospheres. Blood offers the most natural water resistant bonds of the uncross-linked protein adhesives (Frihart, 2007), offers some temperature resistance and is less susceptible to attack by mould and fungi than the other protein adhesives.

The limited technical properties of most bio-based adhesives means they are suitable for non-structural applications in interior environments. Casein however is suitable for use in structural applications in interior environments. The technical properties of protein resins can often be improved by cross-linking with other resins, usually with a substance like formaldehyde, or resins formed from polyamines and epichlorohydrine (see United States Patent 7252735, issued on August 7, 2007). Uncross-linked protein adhesives generally lack the required technical properties for use in the manufacture of WBP.

Protein adhesives are not technically suited to the existing plant and equipment. In addition, like most biomass materials, proteins are not uniform in composition as the source varies; therefore, the processes for using these proteins and the properties of the adhesives vary as the protein source changes.

Economic Feasibility

Protein based adhesives have the advantage that they are not influenced by oil prices unlike many synthetic resins. **Protein based** adhesives are not technically suitable for the plant and equipment or the wide range of WBP that are available. They are economically attractive when considering the cost but supply issues exist for some including blood and casein.

More specifically:

- soy is available in large quantities and is low cost (Frihart, 2007);
- it is claimed that casein glue can be produced for less than 25% of the cost of synthetic adhesives (Berge, 2009). However the casein raw material is costly and casein adhesives are more expensive than soy based adhesives (BRE, 2007); and
- blood is expensive and supply is limited.

Environmental and Health Concerns

Protein based adhesives are significantly more environmentally friendly than synthetic resins. They are made from renewable resources and are non-toxic. Protein adhesives do not contain any carcinogenic substances however potential risks arise when inhaled and many people are also allergic to particular proteins. Health and safety concerns surround the use of blood with regards the possibility of odour and vermin in factories and the fact the blood can carry potentially serious health risks. As a result, the use of blood in manufacturing will require specific precautions to be taken.
Furthermore, the crosslinkers that are needed to produce technically suitable boards can also have health and safety issues.

Tannin Adhesives

Background

Tannins are naturally occurring materials which contain phenols and are found in plants. Tannins are successfully used in the wood industry however only to a small extent and predominantly in the southern hemisphere (Dunky et al, 2002).

Technical Feasibility

Tannin adhesives are generally of lower performance than synthetic resins and also have high viscosity. The inconsistency of tannins (which is influenced by factors such as growing conditions) results in varying compositions which makes the manufacture of consistently performing adhesives difficult. The inconsistency of tannins also produces varying degrees of reactivity. Tannins have a short pot life and do not create strong adhesion properties (Papadopoulou, 2008).

Uncross-linked tannin adhesives generally lack the necessary properties for use in WBP. As a result, formaldehyde is often used in the preparation, setting and curing of tannin adhesives

(Pizzi, 2003b) to produce a higher performing adhesive. In addition, water resistant bonds can be created when tannins are polymerised with formaldehyde.

Economic Feasibility

Tannins are expensive and availability is limited. Tannins are attractive as wood adhesives because they are more reactive than phenol; however they are also more expensive than phenol.

Tannins exist in high enough concentrations to be commercially viable only in a few species in a few countries but are not available in large enough quantities to compete with synthetic adhesives. Achieving high production yields and the appropriate quality of tannins for adhesives is costly (Li and Maplesden, 1998). It is unlikely that using tannins in wood adhesives (particularly in Europe) is sustainable i.e. there are unlikely to be sufficient resources to support supply.

Environmental and Health Concerns

Tannins are a renewable resource and have been used to obtain the low formaldehyde emission levels required for environmentally friendly adhesives. The majority of tannin based adhesives (which use formaldehyde as a cross-linker) have low formaldehyde emissions however the complete removal of formaldehyde from the adhesive formulae is being considered and is believed to be possible (BRE, 2007).

Lignin Adhesives

Lignin is a natural resin that is found in in all plant material (Berge, 2009). It is naturally abundant; however it is most often obtained as a by-product in wood pulping processes (Dunky et al, 2002). Lignin on its own has not been used in an adhesive to date however many wood adhesives use lignin as a co-reactant with phenol and formaldehyde to create a product with increased or extended properties.

Technical Feasibility

Although lignins are phenolic derivatives, they are very different from tannins. Lignin based adhesives generally require long curing times and high curing temperatures. Lignin is dark in colour (Petrie, 2012) and its composition is not consistent. Lignin based adhesive formulations tend to be corrosive or hard on equipment and lignin in the formulation slows down the panel pressing time which results in a loss of mill productivity (Pizzi, 2003b). Like other bio-based adhesives, lignin is not available in constant quality or chemical structure and therefore not all lignin will have the same reactivity. However, lignin has a polyphenolic structure and is a promising phenol replacement in resin synthesis (Papadopoulou, 2008). To date, lignin has been prepared with formaldehyde or other aldehydes and has shown to yield panels with properties that are comparable to conventional formaldehyde-based resins (Papadopoulou, 2008).

Economic Feasibility

Lignin is available in large quantities and at a low cost – either from nature or as a by-product from pulp mills. There are two main types of lignin: treated and non-treated. Only treated is currently commercially available (Rescoll, 2009). It is claimed that the industrial use of wood adhesive formulations containing up to 50% lignin did occur but has been discontinued due to economic reasons (Pizzi, 2003b).

Environmental and Health Concerns

Lignin based wood adhesives are generally prepared with formaldehyde or other aldehydes and lignin typically replaces phenol rather than formaldehyde in the creation of adhesives therefore the risks associated with formaldehyde are still present for both workers and consumers. Formaldehyde chemistry is typically involved in the production of lignin-based adhesives; however, some non-formaldehyde adhesive systems have been investigated.

4.3.6 Summary

A summary of the main characteristics of each of the alternatives is provided in Table 4.6 overleaf.

Table 4.6: Summary of the Characteristics of Alternative Substances			
Resin	**Technical Feasibility**	**Economic Feasibility**	**Environmental/Health Considerations**
Formaldehyde-based resins			
Phenol formaldehyde resins (PF)	- Good weather resistance, durability, adhesive properties and stability - Suitable for exterior, structural grade boards e.g. used in particleboard grade P3, P5 P7 and OSB in the past - Requires high temperature curing and long press times - Suitable for existing equipment and processes - Dark colour	- More expensive than UF (double to triple the price) but cheaper than other formaldehyde-based resins - Increased adhesive consumption required. - Expected loss of production capacity	- Low/no formaldehyde emissions from cured product; no risks to consumer of formaldehyde emissions - Extent of actual risk reduction for workers uncertain as there is continued use of formaldehyde - Concern for worker health due to health risks when manufacturing/using phenol - Environmental concerns when using phenol
Resorcinol formaldehyde (RF) and phenol-resorcinol formaldehyde (PRF) resins	- Good weather resistance, durable, cure at room temperature - Suitable for interior, exterior and humid environments - Suitable for existing equipment and processes - Produces dark colouration	- Expensive due to the high cost of resorcinol; approximately four times the price of UF resins - Supplies of resorcinol may not be sufficient to meet the needs of the WBP industry	- Low/no formaldehyde emissions from cured product; no risks to consumer of formaldehyde emissions - Resorcinol on CoRAP for evaluation in 2014 - Extent of actual risk reduction for workers uncertain as there is continued use of formaldehyde - Worker health concerns regarding both phenol and resorcinol
Melamine formaldehyde (MF) and melamine urea formaldehyde resins	- Good weather and water resistance, clear and strong - Suitable for interior and semi-exterior panels - Suitable for existing equipment and processes - Similar to UF in terms of processing and applications	- MF is expensive; melamine three times more expensive than urea - MUF is cheaper than MF (more expensive than UF) depending on the quantity of melamine used - Melamine capacity to meet WBP industry demand is uncertain	- Low/no formaldehyde emissions from cured product; no risks to consumer of formaldehyde emissions - Extent of actual risk reduction for workers uncertain as there is continued use of formaldehyde

Table 4.6: Summary of the Characteristics of Alternative Substances			
Resin	**Technical Feasibility**	**Economic Feasibility**	**Environmental/Health Considerations**
Synthetic substances			
Polymeric Diphenylmethane Diisocyanate (p-MDI)	- Excellent strength, heat, water and humidity resistance - Suitable for exterior grade boards - Not suited to existing plant and equipment	- More expensive than UF and PF; costs around four times as much as UF - Smaller dosage required - Major supply issues; cannot meet WBP industry demands - Cost of achieving suitable plant and equipment - Additional costs of maintaining safe operations in plants due to hazards	- No formaldehyde emissions from cured product; no risks to consumers of formaldehyde emissions - Potential worker exposure to isocyanates (risk of occupational asthma) - Worker health risks due to contents of p-MDI, particularly MDI
Emulsion Polymer Isocyanates (EPI)	- Excellent high dry/wet strength, durable bonds, cold cured and fast setting speeds - Short pot life - May be suitable for use with existing equipment - Additional process steps and equipment required for mixing and metering and to manage tackiness of EPI - Sticks to metals	- High cost - Additional processing steps and equipment required	- No threat to the environment - No formaldehyde emissions and inert when properly hardened - Potential worker exposure to isocyanate during manufacture
Polyurethanes	- High wet/dry strength - Resistance to water and damp atmospheres - Cure well at room temperature - Sticks to press platens, stains easily	- High cost, may be prohibitive - Additional release agent required to avoid sticking to the press platens	- Potential worker exposure to isocyanates such as MDI - IARC group 3 substance

Table 4.6: Summary of the Characteristics of Alternative Substances			
Resin	**Technical Feasibility**	**Economic Feasibility**	**Environmental/Health Considerations**
Epoxy Adhesives	- Excellent moisture and weather resistance and strong bonds - Additional metering and mixing equipment required - Can be difficult to use and require long cure times	- Expensive and unattractive market price - Typically used at greater weights per bonded surface	- Cured epoxy resins are inert - Potential for health risks to workers as many components are toxic or irritants - Potential environmental concerns
PVA and EVA	- Good dry strength and easy to use - Poor moisture resistance and thermoplastic - Lack technical characteristics required for use in WBP	- Significantly more expensive than UF	- Environmentally friendly - No health risks; low/no VOCs and solvent free
Natural/Bio-based Adhesives			
Protein Glues	- Poor water/mould resistance and limited durability - Uncross-linked glues generally lack required technical properties - Requires chemical cross-linker (usually formaldehyde) to be practical to be technically viable	Generally low cost; however, critical supply problems are likely to exist for blood and casein	- No formaldehyde emissions from final product - Environmentally safe - Health and safety concerns exist over the use of blood and in relation to additional crosslinkers needed to produce technically suitable boards
Tannins	- Low performance - Inconsistency of the material difficult to manufacture with consistent properties - Short pot life and weak bond formation - Requires chemical cross-linker (usually formaldehyde) to be practical to be technically viable	Expensive (particularly in Europe) and supply is limited	- No health/environmental concerns for uncross-linked tannin adhesives - Extent of actual risk reduction when cross-linked using formaldehyde is unclear

Table 4.6: Summary of the Characteristics of Alternative Substances			
Resin	**Technical Feasibility**	**Economic Feasibility**	**Environmental/Health Considerations**
Lignin Adhesives	- Long cure times and high cure temperature - Can be corrosive to machinery - Requires chemical cross-linker (usually formaldehyde) to be practical to be technically viable	Available in large quantities at low cost	- No health/environmental concerns for uncross-linked lignin adhesives - Extent of actual risk reduction when cross-linked using formaldehyde is unclear

Colour Codes	*Not satisfactory*	*Satisfactory*	*Neither satisfactory nor wholly unsatisfactory*

4.4 Discussion on Technical Feasibility

4.4.1 Key Aspects

In discussing the technical feasibility of the alternative substances, there are three key interrelated aspects to consider. These are the suitability in relation to:

- **existing plants, equipment and production processes**, for instance, the plant size, structure and location, production permits, relevant equipment, etc.;
- **technical selection criteria for the WBP manufacturer** (e.g. physico-chemical properties, press times, curing times, hydrolysis resistance, hardening temperature, etc.), taking into account, the **range of WBP**, for instance, the feasibility of a given alternative substance to all seven grades of particleboard; and
- **downstream user, client or market requirements**, for instance, in relation to the ability to meet regulatory pressures, safety requirements, product guarantees, lifetime and recycling requirements and appearance requirements in furniture (e.g. adhesive colour).

These aspects are discussed below.

4.4.2 Suitability with Existing Plants, Equipment and Processes

When considering if an alternative substance is technically suitable, it is important to consider whether the plants and equipment currently used can be (easily) deployed in the event of a switch.

Most of the companies producing WBP run **highly integrated production processes**. In some cases, WBP manufacturers also produce their own formaldehyde and/or resins. If the non-formaldehyde-based resins are adopted, companies using formaldehyde-based resins could find some of their existing equipment has become (somewhat) obsolete and they need new equipment and storage tanks to manufacture, transport and store the raw materials for manufacture of an alternative product. For instance, while UF resins are manufactured by reacting formaldehyde and urea and condensing the polymer to a desired molecular weight distribution, the production of MDI (and subsequently, p-MDI) is far more extensive (involving more chemicals) and complex, as shown in Figure 4.1. In addition to the manufacture of MDI and p-MDI through the reaction of phosgene and MDA, hydrogen chloride is also formed which has to be converted or used in some way.

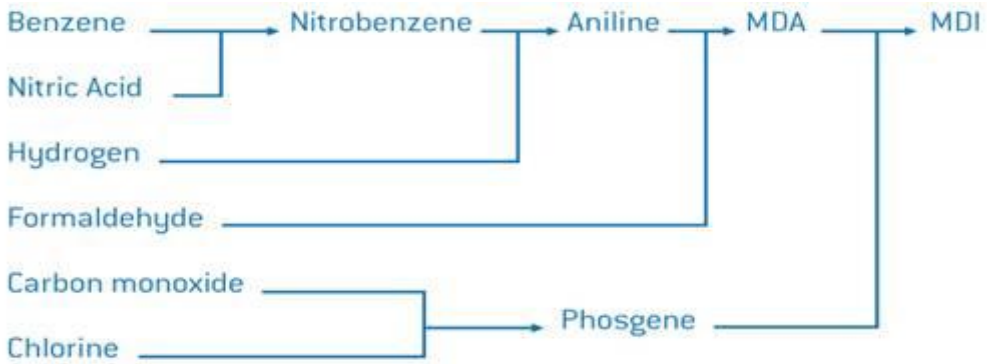


Figure 4-1: Raw Materials Required for Manufacture of p-MDI (Borsodchem, nd)

On the other hand, as shown in Figure 4.2 below, a switch to other formaldehyde based resins with less formaldehyde releases would require minimal changes to the overall process (even if there may be a need for structural changes due to health and safety issues for the phenol-based resins).

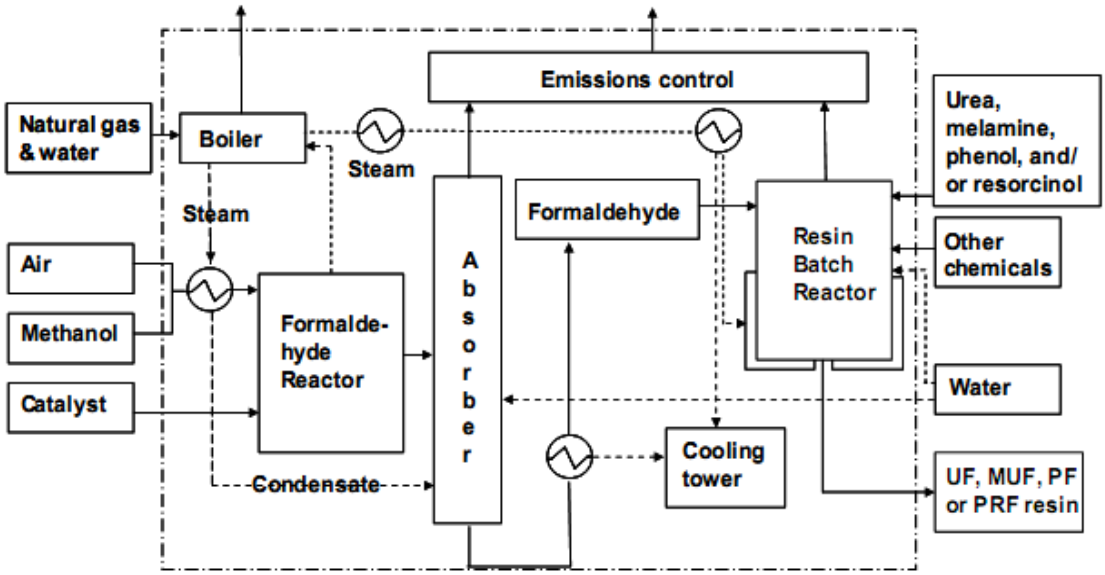


Figure 4-2: Process for Manufacture of Formaldehyde based Resins (Wilson, 2009)

In addition to changes in the physical infrastructure, the **production processes for the alternatives** are quite different and bring different challenges. For example, emulsion polymer isocyanate (EPI) adhesive systems are two-component systems that are based on a reaction of a mixture of a water based emulsion polymer (e.g. PVA, EVA, SB or acrylic) and an isocyanate hardener/cross linker (for example MDI, HDI or p-MDI). The two components have to be mixed prior to use which requires additional process steps and equipment. EPI has a short pot life and, as a result users, have a limited time to apply the adhesive before the performance of the adhesive begins to reduce. EPI also needs additional process steps and equipment to manage metering and mixing, and the high tackiness of EPI makes handling difficult.

In practice, **WBP production plants** are built according to the specific requirements of the type of WBP to be produced, the adhesives to be used and raw materials to be used in the production processes. UF resins are currently used at the vast majority of plants due to their technical properties and cost and most plants can produce all their WBP based on UF resins. On the other hand, p-MDI is only used in relatively small quantities and existing WBP installations are not designed to produce all their WBP based on p-MDI. Plant alterations will only be possible at some plants producing WBP but not all and those facilities that are suitable for alteration can only be altered at significant cost to the companies.

In addition, the **equipment** used to make both raw and laminated boards using formaldehyde-based resins (UF resins) cannot be used to make WBP with the alternative substances. For instance, wood adhesives including phenolic, melamine, urea and isocyanate adhesives must be cured at high temperatures and require expensive, heated presses. Natural alternatives (e.g. protein glues) are unlikely to be compatible with these heated, high frequency, presses. Similarly, cold presses or clamps may be satisfactory for room-temperature curing adhesives (e.g. EPI adhesives), however, the long curing time in

production can be a constraint for some production processes/equipment. In practice, it is likely that there will be a need for new equipment with a switch to some of the alternatives and, in some cases, the building of a new plant in a different location.

In addition to the structural changes to the plant, it is necessary to consider whether or not the plant can meet the **legal requirements** associated with use of the alternative substances. For example, the majority of existing WBP installations do not have a permit to use p-MDI and, in some EU countries, the use of p-MDI for industrial production is restricted. The building and permitting process for a p-MDI plant is very complex and is mainly feasible on an isolated chemical industrial park (e.g. where the production of phosgene, a substance used in chemical weapons and required for p-MDI production, can take place). Furthermore, phenol and p-MDI are considered more dangerous than UF resins in terms of their societal risk (i.e. in terms of the potential outcome from a major accident involving large quantities of these substances, as set out under the Seveso Directive) and, as a result, cannot be stored/housed in the same conditions, quantity and/or manner as UF resins. More stringent controls and structures will be required; for instance, plants storing/manufacturing phenol cannot be located near to communities. The risk to communities of using PF in this case are higher than UF, and therefore must be considered against the potential risks to workers from urea formaldehyde resins.

4.4.3 Suitability against Technical Selection Criteria

There are a number of key technical criteria which a WBP manufacturer would need to take into account in selecting an alternative substance. These relate to the different functional characteristics which each alternative substance:

- possess inherently (e.g. the physico-chemical properties impacting on binding ability);
- brings to the end product/WBP (e.g. susceptibility against wood species); and
- brings to the production process (press and curing times, efficiency, etc.) .

Table 4.7 provides an example comparison of technical selection criteria, which are critical in determining whether an alternative substance is suitable for the end uses intended.

Table 4.7: Comparison of Technical Selection Criteria for Formaldehyde Resins and p-MDI

	UF	MF	PF	p-MDI
Necessary Hardening Temperature	Low	Medium	High	Low
Susceptibility Against Wood Species	High	Medium	Low	Low
Efficiency	Low	Medium to High	Medium to High	High
Manipulation	Easy	Easy	Easy	Difficult
Resistance Against Hydrolysis	No	High	High	High
Use in Humid Conditions	No	Yes	Yes	Yes
Formaldehyde Emissions	Can be used in E1 wood	<UF emissions	Almost no emissions	Almost no emissions
Press Time	Short	Medium	Medium to Long	Short
Resistance against Boiling Water	No	High	High	High
Polymer formed	Thermoset	Thermoset	Thermoset	Thermoset

Source: Chimar Hellas (2006); Dunky (2003)

However, across the entire range of WBP, there are in excess of 30 different specifications of WBP - grouped under the three main categories of plywood, particleboard and fibreboard. These panels have very different physical properties and characteristics, technical parameters and production processes. In addition, there is significant variety within each of the main categories of panel board, for instance, different grades of WBP available to meet different environmental conditions and also different levels of loading.

By way of example, according to standard EN 312, there are seven grades of particleboard (WPIF, 2008) which differ depending on whether it is to be used in dry or humid conditions and the level of loading of the board:

- P1- general purpose boards for use in dry conditions;
- P2 - boards for interior fitments (including furniture) for use in dry conditions;
- P3 - non load-bearing boards for use in humid conditions;
- P4 - load-bearing boards for use in dry conditions;
- P5 - load-bearing boards for use in humid conditions;
- P6 - heavy duty load-bearing boards for use in dry conditions; and
- P7 - heavy duty load-bearing boards for use in humid condition.

Each alternative substance could perform differently (against the above technical criteria set out in Table 4.5) for each of the different grades of particleboard. As a result, there is not a single alternative which is technically suitable across all these grades of WBP. **Any information or analysis on the feasibility of alternatives for WBP must be interpreted within the context of these specific WBP**.

Currently, a variety of resins (and alternative gluing systems) are used to produce the wide range of WBP that are available. Therefore, although UF resins are undoubtedly the most commonly used resins in the manufacture of WBP, they are not used exclusively. Taking one example, the resin/gluing system used will differ depending on whether the panel is to be suitable for interior or exterior use. Currently, UF resins are used for those WBP that will be used in interior environments only, as UF resins do not provide the water or moisture resistance required for exterior use. Table 4.8 below summarises the range of alternative substances that are currently available and the type of board they would be suitable for.

Table 4.8: Alternative Substances and Suitability to Types of Boards

Alternative Substance	**Suitability to Type of Boards**
UF resins	Structural and interior (short term high humidity)
Phenol formaldehyde	Structural and fully exterior
Resorcinol formaldehyde	Structural and fully exterior
Melamine formaldehyde	Structural and fully exterior
Melamine urea formaldehyde	Structural and limited exterior (short-term water soaking)
p-MDI	Structural and limited exterior
EPI	Structural and fully exterior
Epoxy	Structural and limited exterior
PVA and EVA	Non-structural and interior
Protein glues - Plant based (soybean, plant oil)	Non-structural and interior (except casein – structural and interior)

Table 4.8: Alternative Substances and Suitability to Types of Boards	
Alternative Substance	**Suitability to Type of Boards**
- Animal based (blood, casein)	
Tannins and lignins	Non-structural and interior

The situation is also further complicated because the resin that is used depends on the stage of the production process in question. For instance, hardboard, medium board, MDF, particleboard, OSB and plywood can be veneered and laminated with high and low pressure laminates, paper and PVC foils. Currently, MF and MUF resins are typically employed in lamination lines due to the strength that MF imparts to the surface, however in such boards it is likely that UF has been used in the production of the raw board. As a result, it is important to consider the technical feasibility of the alternative substance with regards to environmental conditions and level of loading as well as the requirements of the different parts of the board. For example, in the manufacture of OSB, p-MDI is suitable for use in the manufacture of the core board, however, it is likely that a different resin such as MUF would be used in the face layer as p-MDI in the face layer would cause adhesive build-up in the press platens. Using an alternative substance in the face layer also avoids the use of a release agent on the press platens. The suitability of the alternatives with each of these finishes may not always be technically possible (without further testing).

4.4.4 Suitability with Downstream User/Client Requirements

Any alternative substance, needs to be able to result in WBP which are technically suitable in terms of meeting client's needs. In simple terms, if an alternative is compatible with existing plant and equipment and in terms of the selection criteria of the manufacturer, but fails to satisfy the needs of the user, then it cannot be said to be technically suitable. These user needs could be driven by:

- **Regulatory pressures**: Adhesive resins used in the manufacture of the WBP influence the ability of the panel to meet the relevant European Standards and the Construction Products Regulation and thus to be placed on the EU market. Particleboards manufactured in Europe and used in construction must comply with European standard EN 312. Fibreboard must comply with European Standards EN 622-4 and EN 622-3 and plywood must comply with standards EN 314, EN 636, and EN 635. For construction products which require CE-marking, the mechanical and physical properties such as dimensional stability, bending strength and thickness swelling, as defined by European Standards are of utmost importance.

- **Lifetime considerations**: If it is necessary to move to an alternative substance, the manufacturer would have to ensure that the final product would meet any relevant requirements in terms of its reliability (e.g. in terms of product guarantees, lifetime performance, recycling properties, etc.). In order to achieve this, any alternative substance would need to go through a long process of evaluation which can be costly and time consuming. In this regard, a lot of the natural glues are at a disadvantage in the market place compared to the resins which have been developed, trialled and tested and are based on many years of practical experience with the gluing system.

- **Appearance**: In furniture and interior mill work, where appearance is all important, adhesive colour, ability to absorb stains and finishes and freedom from bleeding and

staining are critical factors (Vick, 1999). The urea-formaldehyde and polyvinyl acetate adhesives used in the furniture industry are formulated to give a tan or colourless joint with good acceptance of stain. This makes these two systems technically suitable for these applications; on the other hand, furniture manufacturers have noted a reduction in the quality of the panels produced using ultra-low emitting UF resins, when compared to standard UF resins.

4.5 Discussion on Economic Considerations

4.5.1 Key Aspects

In discussing the economic feasibility of the alternative substances, there are three main and interrelated aspects to consider. These are:

- **the increase in cost for manufacturers** using the alternative substance, where this could be based on any one or more of the following considerations:
- the unit cost of the alternative substance compared to UF resins;
- the dosage required (e.g. whether higher or lower compared to UF resins);
- changes to plant and equipment;
- changes to production processes (e.g. capacity and efficiency issues);
- increased cost of PPE (e.g. when substances with a different hazard profile are used); etc.
- **the increased cost for downstream users and consumers**, where this is linked to the cost to manufacturers (cost pass down); and
- **supply and availability** of the alternative substance.

4.5.2 Increased cost for manufacturers

Typically, the first consideration in assessing costs associated with switching to an alternative is the **direct cost increase per unit of the alternative substance** when compared to the substance that is currently used (in this case, UF resins). In this aspect, the vast majority of alternatives are significantly more expensive compared to UF resins. For example, PF resins are around three times more expensive (per kg) than UF (UF is estimated to cost €0.40/kg and PF €1.20/kg). Figure 4.2 below provides a cost comparison of the main alternatives to UF resins; while this information may be dated, it illustrates the point that a main attraction of UF resins is how cheap they are.

In this regard, it is important to mention that the California EPA undertook a review of alternatives prior to introduction of the CARB standards. According to CARB (2007), **UF resins modified with additives such as melamine and hexamine** are expected to be the first choice of manufacturers to achieve lower formaldehyde emissions as they are both low cost and versatile (CARB, 2007).

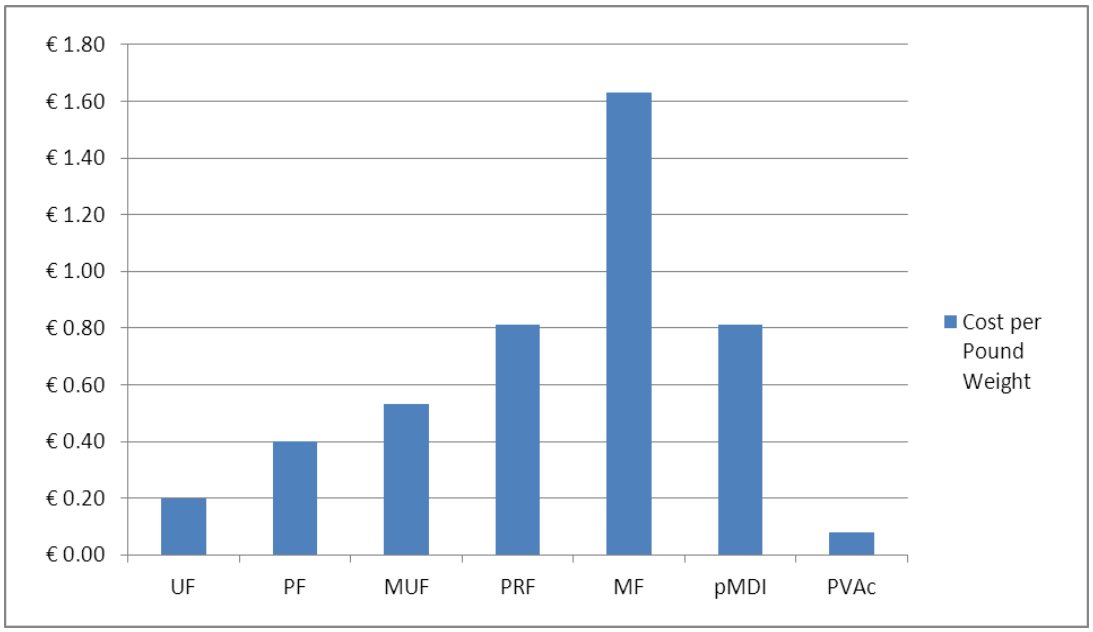


Figure 4-3: Comparative Costs of Alternatives to UF Resins

(University of British Columbia (nd), Iowa State University (nd))

In addition to the direct price increase, it is also necessary to consider the **dosage of the alternative substance** that is required to achieve the board's technical criteria as required under European standards and/or downstream user's requirements. The quantity (dosage) of the alternative substance may also be influenced by the particular type and grade of board being manufactured and the substrate used. By way of example, epoxy resins are not only significantly more expensive compared to formaldehyde-based resins, but when compared with other alternative substances (e.g. PVA and p-MDI), they are required in larger dosage quantities. Similarly, in addition to being around four times the cost of UF resins, it is necessary to use PF in larger quantities to achieve the same mechanical properties. On the other hand, while p-MDI is more expensive compared with formaldehyde-based resins (four times more expensive than amino-plastic resins, e.g. UF, and two times more expensive than phenolic resins, e.g. PF), a lower dosage of p-MDI is required to meet the same mechanical properties as currently achieved with UF resins. It is estimated that the quantity of p-MDI required is at least two times lower than that of UF resins, depending on the panel being produced. For example (Panels & Furniture Asia, 2009):

- to produce 3 mm sheets of MDF, approximately 11% UF resin is required but only 3% p-MDI is required to achieve a higher performing board in terms of swell resistance and internal bond;
- to produce more robust 12 mm MDF boards, approximately 10.5% MUF (containing 4% melamine) would be used but only 3% p-MDI is required to produce panels with similar internal bond but improved swell resistance; and
- for particleboard, 8% formaldehyde-based resin is required but only 2-3% p-MDI is required to meet the same standard.

While at one extreme, the high cost of EPI makes it prohibitive to use as a substitute for formaldehyde-based resins, there are a number of natural substances which are

economically attractive for use in WBP; however the limited technical characteristics of such alternatives do not currently permit the viable, widespread use in WBP currently. For example, soy beans are available in large quantities and at low cost and casein glue can be produced for approximately 25% of the cost of synthetic adhesives, although casein raw materials are costly. However, there are significant technical limitations to the use of these alternative substances and often a cross-linker is needed to improve the technical properties, and this cross-linker is often formaldehyde.

In addition to the above, there are also the costs companies will incur from **new or re-furbished plants and equipment**. Most of the companies producing WBP run highly integrated production processes. In some cases, WBP manufacturers also produce their own formaldehyde and/or resins; effectively, formaldehyde is manufactured and transferred by pipes to where the UF resins are produced and these are transported by pipes to where WBP production takes place. If any of the alternatives are adopted (apart from the formaldehyde-based resins), companies with such a set-up will find their existing equipment has become obsolete and that they need new equipment and storage tanks to manufacture, transport and store the raw materials and final alternative product. For manufacturing companies that have located their plants next to suitable transport hubs (e.g. ports) or companies (to reduce transport costs), there will also be additional costs.

It is also important to bear in mind the costs incurred by manufacturers in **changing production processes, manufacturing techniques and systems** to meet the requirements of the alternative substance. For example, epoxy resins and EPI resins need additional mixing and metering which requires additional equipment and will impact upon the overall manufacturing system/process which has been established at the plant. It is expected that particularly specialized technology will be required to use epoxy resins. The cost of the adhesive and the additional or different application equipment must be balanced against the comparable cost factors for substituted adhesives. There could also be disproportionate impacts on some companies, particularly small companies, from a forceful move to alternative substances, if they do not have the R&D and/or knowledge of how to use the alternatives and how to alter manufacturing processes to accommodate alternatives. As a result such companies could be effectively forced out of the market.

Also, some alternatives may also offer the potential for savings in the total production costs as expenditure on, for example, energy consumption may be reduced. For example, while on the one hand, p-MDI may offer lower production costs as it has faster production rates and lower press temperatures and there is also the potential for increased mill productivity and savings in drying, blending and pressing. On the other hand, some alternatives lead to loss of capacity and overall plant efficiency. For example, for ultra-low UF resins, the curing speed is very slow and the loss of capacity is in the range of 20% – 50%.

There are also costs associated changes in **health and safety equipment** associated with switching to alternatives, when substances with a different hazard profile are used). On the one hand, there are the costs associated with personal protective equipment. For example, there may be increased costs due to the relative difficulty of handling and applying EPI. Companies will also incur significant costs in ensuring that workers have the necessary PPE and training to manage the risks associated with p-MDI. On the other hand, there are the costs at the site level, for instance, the requirements to comply with the Seveso Directive when handling and storing substances such as phenol, phosgene, etc. compared to urea.

4.5.3 Increased cost for downstream users and consumers

Most of the alternatives identified will result in increased manufacturing costs which are likely to be passed on to consumers. The size of the cost increase for consumers will depend on the alternative chosen. It is clearly the case that the price increase will be acceptable to some downstream users and consumers – as more expensive, non/less formaldehyde releasing WBP are available on the market currently; however, a price premium is currently paid by these customers for such panels.

Finally, despite the low cost nature of the natural alternatives, there is also the ethical question of using a potential food stock (e.g. soy) as an adhesive for the production of WBP and the impact this has on the availability and price of food for EU consumers (and globally).

4.5.4 Supply and Availability

In addition to the actual cost to the manufacturer of the alternative substance, there is also the issue of the **availability** of the alternative substances in the event of a wholesale shift of the market.

Supply issues are likely to be highly problematic for both synthetic resins such as p-MDI and for natural substances such as blood and casein. Problems from supply may arise if there is simply not enough of the alternative substance produced to sustain the additional demand from the WBP industry. There is also the possibility that demand from other industries already uses all of the alternative substance and additional demand from the WBP industry may increase the level of competitiveness for the alternative and increase the price paid for it. For example, it is widely acknowledged that there is insufficient capacity currently for p-MDI to meet the needs of the WBP industry. Even if it was agreed that there was a need to move to p-MDI, no additional p-MDI will be produced globally till 2020. Furthermore, due to the complex permitting procedures it is unclear, if, where, and when new capacities will be available. It is estimated that an investment of €20 billion is needed, if p-MDI is to meet the demands of the WBP industry. There are also questions regarding the availability of resorcinol and the production capacity for phenol is lower than that of urea. There are also supply issues for a number of natural solutions such as blood and casein.

4.6 Discussion on Risk Reduction Capacity (Human Health)

4.6.1 Key Aspects

The use of alternatives should not result in greater or equal risks to humans and the environment. In discussing the overall risk reduction associated with switching to an alternative substance, it is necessary to consider three key questions:

- Can formaldehyde resins replace formaldehyde resins – and still result in a net risk reduction?
- Is there a direct relationship between the type of resin/adhesive used and emissions of formaldehyde?
- Are the risks associated with alternatives more acceptable?

4.6.2 Can formaldehyde resins replace formaldehyde resins?

In assessing the risk reduction capacity of alternatives, it is important to clarify that the extent of releases of formaldehyde from WBP varies by the type of formaldehyde-based resin used. Urea formaldehyde (UF) resins are the most commonly used formaldehyde resins in the manufacture of WBP. There are other formaldehyde-based resins (PF, MF, MUF, RF, and PRF) which release little to no formaldehyde from the cured product and, as such, can be considered a substitute for UF resins when considering the risk of concern. The use of these resins effectively reduce, if not eliminate, the overall risk to consumers of formaldehyde emissions from the final, cured product.

In addition, there are also ultra-low UF resins which have been developed to release significantly lower levels of formaldehyde from the cured product than standard UF resins; effectively, all UF resins are not by definition hazardous to health. UF resins can also be combined with MF resins, co-reacted with MF resins (MUF) or have scavengers/additives added in to result in lower emissions of formaldehyde from the wood substrate. For this reason, a restriction on the use of all formaldehyde-based resins in the manufacture of WBP will be a disproportionate and illogical approach to addressing any risks of concern.

Following the reclassification by IARC in 2004, the members of EPF agreed on a voluntary restriction to produce only wood-based panels of at least E1 quality, since the limit value in European standards and regulations of this class has been based on the WHO indoor guideline value and can thus be considered to be safe. This has resulted in a serious shift towards using lower formaldehyde-based resins than standard UF. However, as only few EU Member States have imposed an E1 restriction on wood-based panels and finished products, consumers are still exposed to imported higher emitting panels of E2 quality (and in isolated cases E3 has been reported for imports from China).[2]

4.6.3 Is there a relationship between resin used and emission?

It is also important to clarify that there is not necessarily a direct relationship between the substance/resin used and the reduction in risk from formaldehyde. There are three possible categories, in this regard.

- Firstly, there are the alternatives which mean that the risks from formaldehyde are reduced to zero. In this context, it is important to note that formaldehyde is emitted naturally from wood and as a result there will always be a very small amount of formaldehyde emitted from WBP regardless of the resin used.

- There are some of the alternatives which while not formaldehyde-based, do **contain formaldehyde in one form or another**. For instance, although p-MDI does not contain formaldehyde, formaldehyde is used in its manufacture. Also, some of the protein glues require a cross linker based on formaldehyde or formaldehyde-based resins to improve their technical feasibility.

[2] E1: 0.1 ppm; E2: 1 ppm; E3: 2.3 ppm; all based on small chamber testing according to specified testing requirements

- For the **formaldehyde-based resins**, the amount of formaldehyde released does not depend solely on the type of resin used but also on the technology used to manufacture the WBP, the particular substrate (wood) used in the manufacture, the temperature of curing and also the proprietary knowledge of the WBP producer. In some cases, environmental conditions e.g. humidity indoors, may influence the level of releases.

In this latter context, it is important to understand that while some WBP manufacturers have invested significantly in R&D and are able to achieve very low formaldehyde releases using UF resins through alterations to the resin recipe or the manufacturing process, others are unable to do this. For companies with the experience and knowledge of alternatives it may be easier to move to an alternative system (especially if they manufacture only one type of WBP) and publicise this alternative as being the solution. Those companies without any knowledge or experience of alternatives may not be able to move as easily, or at all, to alternative substances.

For this reason, a restriction on the use of releases of formaldehyde would appear to be a more realistic approach to take.

4.6.4 Are the risks associated with alternatives more acceptable?

For some of the alternatives, there is the question of whether the trade-off in risks is more acceptable. Some of the alternative substances pose risks to workers and consumers which are different to those associated with using formaldehyde-based resins. In order to be a proportionate response to the risk in question, it is necessary to consider if the risks associated with the alternative substance are an improvement over those associated with the use of formaldehyde based resins (and UF resins, in particular). For example,

- assuming that UF resins were to be replaced with PF resins, the risk to consumers of formaldehyde emissions from the cured product would be significantly lower. However, there are societal risks associated with the manufacture and use of phenol especially when compared to urea which is a relatively safe substance.

- although formaldehyde is a building block in the production of p-MDI, there are no emissions of formaldehyde from the final cured product, therefore the risk of emissions of formaldehyde from the final, cured product are low. However, the occupational risks of using p-MDI in the production of WBP cause concern and MDI is also of concern, as regards consumer exposure.

- risks to workers health are also possible when using epoxy resins and EPI, and although blood does not contain any chemicals, there are health and safety issues associated with using blood in an industrial setting.

4.7 Summary

In developing any strategy for reducing the risks relating to a given substance, it is important to consider the availability of alternatives for the applications of concern, where this includes alternative substances, technologies and/or processes. The aim of assessing alternatives is to provide information on whether the equivalent function provided by the substance can be obtained by other substances or techniques and for assessing the net

impact of the proposed RMM to human health and the environment. Such considerations are important since any proposed risk management measures (RMMs) may instigate a shift to such alternatives. In this context, an analysis of alternatives can be helpful in defining a proportionate restriction that is targeted to the identified risk.

It is, however, of note that the Annex XV dossier guidance indicates that the depth of the analysis of alternatives (beyond documenting what is readily available) will rely on the decision of the Authority. The level of effort that is to be put into this aspect and the documentation of available information will be a matter of judgment and up to the Authority. The Authority is expected to take a flexible approach so that the time and effort allocated to the assessment of alternatives is proportional to the needs of each case.
This Section has reviewed alternatives to formaldehyde in WBP. A number of alternatives to formaldehyde, and particularly urea formaldehyde resins, have been identified which may be suitable in selected aspects for use in the manufacture of some WBP. These can be grouped into:

Each alternative has been discussed in detail and particular emphasis has been placed on discussion of:

1. the **technical feasibility** of the alternative substances in terms of suitability to the range of WBP available, existing plant and equipment and other technical properties;
2. the **economic feasibility** of the alternative substances which considers the cost of the alternative substances and dosage required when compared to UF resins, and also the availability of the alternatives; and
3. the **environmental and health** concerns which consider the possible risks to the environment and health (of consumers and workers) of using the alternative substances. It considers specifically whether or not using the alternative substance actually reduces the level of risk. In considering the human health and environmental effects of the identified alternatives, it is important to note that some of the alternatives described are mostly used in their polymeric form. The nature (and chemistry) of polymers means that an assessment of the human health risks of alternatives to UF resins is often complicated and the properties of a substance in its monomeric form, are unlikely to be appropriate and/or relevant for assessing the safety of the polymeric form.

Alternative **formaldehyde-based adhesives** have been considered as potential alternatives to UF resins as they emit significantly lower levels of formaldehyde from the final, cured product. Although such substances will generally be technically suitable for the existing equipment and manufacturing processes, the economic feasibility for most is questionable and the potential health issues posed by substances such as phenol raise additional concerns.

The **non-formaldehyde based adhesives** identified will also emit lower levels of formaldehyde from the finished product. However, when compared with UF resins, they are all significantly more expensive. In addition, supply issues for substances such as p-MDI raise concerns over the feasibility of using such substances to replace formaldehyde in WBP as there is not enough of the substance produced to meet the needs of the WBP industry. A lack of compatibility with existing plant and equipment and the possibility of additional equipment and process steps being required also make the use of the alternative substances more difficult and costly. Finally, although the risk from formaldehyde has been eradicated,

the health risks associated with substances such as isocyanates arguably do not make the manufacture of WBP any safer for workers.

Natural and bio-based adhesives such as casein, blood, tannin and lignin are also considered as possible alternatives to formaldehyde-based resins. However, in the uncross-linked form these substances lack the essential properties required for WBP manufacture. As a result they are often cross-linked with substances such as formaldehyde which does not reduce the risk of formaldehyde emissions. In addition, supply issues and incompatibility with existing plant and equipment make the switch to such substances even more difficult for manufacturers of WBP.

Overall, two key conclusions have been drawn based on the analysis:

- Firstly, that none of the, apparently, technically feasible alternatives to high-emitting UF resins is currently suitable across all grades of WBP. Some alternatives appear to be useful in specific applications and the WBP industry already uses these alternatives, although not on a universal/harmonised basis.

- Secondly, these alternatives do result in a different set of risks, which appear to be currently manageable because of the relatively 'small-scale' extent of use. There are also trade-offs associated with switching to any alternative on a large-scale basis. These trade-offs include deciding between:

    - **Safety for consumers versus risks to workers and society:** p-MDI has potentially higher risks to workers and society (e.g. relating to phosgene) but results in no formaldehyde releases in the home. Formaldehyde is also used in the production of p-MDI, and as such, an increase in demand for p-MDI would necessitate an increase in use of formaldehyde in the workplace.
    - **Safety of the final substance *versus* risks from building blocks of concern**: While use of p-MDI reduces formaldehyde in the home, MDA used in production of p-MDI is a substance of very high concern (SVHC) for its potential CMR properties.
    - **Additional health benefits *versus* additional costs associated with switching**: In this context, it is recognised that there are approaches which can be used to reduce releases of formaldehyde from WBP (including use of low-emitting UF resins and production of WBP to a higher European standard, i.e. E1plus) which would result in significant health benefits and lower costs to industry compared with the uncertain health benefits and high costs associated with a complete switch to non-formaldehyde-based resins. Also, while p-MDI is (currently) the most technically suitable non-formaldehyde based alternative, a wholesale switch to p-MDI could result in a cost increase of up to 600%, depending on how this switch is implemented. This would impact on the ability of consumers to purchase these WBP and the economy more broadly.
    - **Technical feasibility *versus* potential future availability**: Resorcinol and p-MDI are both technically suitable, but there are not enough supplies of these to support a complete move away from formaldehyde-based resins. There may also be (unintended) impacts for instance on food supply and availability associated with the use of bio-based alternatives (including supply issues for blood).

Overall, taking into account the information on alternatives, it is clear that the most appropriate RMO must focus on the key concern which is releases of formaldehyde from WBP, rather than on focusing solely on switching away from formaldehyde-based resins as a family. The analysis of alternatives indicates that there are other formaldehyde-based resins (PF, MF, MUF, RF, and PRF) which release little to no formaldehyde from the cured product and, as such, can be considered as substitutes for high-emitting UF resins. The use of these resins effectively reduce, if not eliminate (to background levels), releases of formaldehyde from WBP and avoid adverse effects on the health of consumers. Some companies are currently able to reduce releases of formaldehyde based on years of R&D and investment and such information/know-how is commercially confidential.

Table 4.9: Summary of Technical, Economic and Environmental and Health Suitability Aspects											
	PF	**RF/ PRF**	**MF/ MUF**	**Epoxy**	**PVA/ EVA**	**EPI-based**	**p-MDI-based**	**Polyurethanes**	**Protein based**	**Tannins**	**Lignin**
Technical Feasibility											
- Plant/equipment	X	✓	✓	X	X	✓	X	X	X	X	X
- Products: Interior	✓	✓	✓	✓	✓ (limited)	✓	✓	✓	✓	✓	✓
- Products: Exterior	✓	✓	✓	✓	X	✓	✓	✓ (limited)	X	X	X
Economic Feasibility											
- Cost	X	X	X	X	X	X	X	X	✓	X	✓
- Supply/Availability	✓	X	?	?	✓	?	X	?	X	X	✓
Environmental Suitability	X	X	✓	X	✓	✓	X	X	✓	✓	✓
Health Suitability											
- Consumers	✓	✓	✓	✓	✓	✓	✓	✓	✓*	✓*	✓*
- Workers	X	X	X	X	✓	X	X	X	✓*	✓*	✓*
- Reduction in overall risk	X	X	✓	X	✓	X	X	X	✓	✓	✓

Suitable: ✓ (yes); X (no); ? (unknown)
Note: *indicates that the tick (✓) is only applicable if no cross-linker is used. The actual health impact will depend on the nature of the cross linker used (e.g. formaldehyde, epichlorohydrin, etc.)

5. EXISTING LEGAL REQUIREMENTS AND POTENTIAL RISK MANAGEMENT OPTIONS

5.1 Introduction

This section provides an overview of the various risk management options that are currently in place, or are likely to be implemented, to control the emissions and exposure to formaldehyde. It covers the range of EU-wide legal instruments, as well as voluntary measures, which could be applied to address the concerns relating to formaldehyde. The analysis of the effectiveness of the existing controls will provide the basis of assessing whether these controls are sufficient to address any identified risks and, where not, what additional controls (or tightening of existing controls) may be required.

The follow sections cover the instruments which are of relevance for addressing emissions and exposure to formaldehyde, in particular:

- the CLP Regulation (Section 5.2);
- the REACH Regulation (Section 5.3);
- the Chemical Agents Directive (CAD) (Section 5.4);
- occupational exposure limit (OEL) values (Section 5.5);
- the Volatile Organic Compounds (VOC) Directive (Section 5.6);
- indoor air guidelines (Section 5.7) and labelling schemes across the EU (Section 5.8); and
- controls specific to wood-based products, where this includes voluntary action by industry (Section 5.9).

5.2 CLP Regulation

5.2.1 Measures Currently in Place

Within the EU, formaldehyde is subject to the classification and labelling system established by the CLP Regulation (EC) No 1272/2008. The CLP Regulation amended and repealed the Dangerous Substances Directive (67/548/EEC) (DSD) and the Dangerous Preparations Directive (1999/45/EC) (DPD) and amended the REACH Regulation (EC) No 1907/2006 (EU, 2008). The CLP also aligns EU regulation with the Globally Harmonised System of Classification and Labelling of Chemicals which is used internationally. The CLP Regulation entered into force on 20 January 2009; however, the deadline for substance classification under CLP was 1 December 2010 and for mixtures is 1 June 2015. The CLP Regulation will therefore replace all current rules on the classification, labelling and packaging of substances after 1 June 2015 (EC, 2012).

Under the CLP Regulation, there are two possible hazard categories for carcinogens:

- Category 1: known or presumed human carcinogens;
  - Category 1A: known to have carcinogenic potential for humans and classification is based on human evidence
  - Category 1B: presumed to have carcinogenic potential for humans and classification is largely based on animal evidence

- Category 2: suspected human carcinogen.

According to this system of classification, formaldehyde is currently classified as a *Category 2 carcinogen* which is the lowest category of carcinogenic hazard. Under the DSD/DPD system, formaldehyde was classified as a *Category 3 carcinogen* (limited evidence of a carcinogenic effect), which was the lowest EU category for suspected carcinogens within the classification used at the time. Table 5.1 summarises the current and previous classification of formaldehyde.

Table 5.1: Classification and Labelling of Formaldehyde under CLP Regulation and Directive 67/548/EEC

CLP Regulation (Current Entry)			**Dangerous Substances Directive (Previous Entry)**		
Hazard Class and Category Code	**Hazard Statement Code(s)**	**Specific Concentration limits**	**Classification**	**Labelling**	**Concentration Limits**
Carcinogen Category 2	H351	Skin Corr. 1B; H314: C ≥ 25% STOT SE 3; H335: C ≥ 5% Skin Sens. 1; H317: C ≥ 0,2% * Eye Irrit. 2; H319: 5% ≤ C < 25% Skin Irrit. 2; H315: 5% ≤ C < 25%	Carcinogen Category 3; R40	T	T; R23/24/25: C≥25%
Acute Tox. 3*	H331		T; R23/24/25	R; 3/24/25-34-40-43	Xn; R20/21/22: 5% ≤ C< 25%
Acute Tox. 3*	H311		C; R34	S; (1/2-) 26-36/37/ 39-45-51	C; R34: C≥25%
Acute Tox. 3*	H301		R43		Xi; R36/37/38: 5% ≤C<25%
Skin Corr. 1B	H314				R43: C≥0.2%
Skin Sens. 1	H317				
Source: EC (2008)					

On the international scene, formaldehyde was reclassified by the International Agency for Research on Cancer (IARC; part of the World Health Organisation) in 2004 as carcinogenic to humans (Group 1) (IARC, 2006). Previously, formaldehyde was considered by IARC to be potentially carcinogenic to humans and was classified as a Group 2A carcinogen (probably carcinogenic to humans). The reclassification was considered necessary by IARC on the basis that there is 'sufficient evidence' in humans and experimental animals for the carcinogenicity of formaldehyde (IARC, 2006). The classification of formaldehyde as a Group 1 human carcinogen was reaffirmed by IARC in 2009, on the basis that the epidemiological evidence on leukaemia has become stronger, and new mechanistic studies support a conclusion of *sufficient evidence* in humans (IARC, 2009).

In 2011, formaldehyde was reclassified by the US Department of Health and Human Services' National Toxicology Program (NTP) as a '*known human carcinogen*' (NTP, 2011). Formaldehyde was first classified in the USA as '*reasonably anticipated to be a human carcinogen*' and featured in the Second Annual Report on Carcinogens in 1981. The 2011 reclassification was published in the Twelfth Annual Report on Carcinogens and was supposedly based on increased evidence of carcinogenicity in humans and the availability of sufficient evidence to support this claim.

In July 2012, Safe Work Australia updated the entry in HSIS for formaldehyde to reflect recommended changes in classification. The update includes a change to the carcinogen classification from category 3 (*limited evidence of a carcinogenic effect*) to category 2 (*may*

cause cancer by inhalation) and is made in accordance with the Approved Criteria for Classifying Hazardous Substances (Safe Work Australia, 2012).

5.2.2 Potential Future Measures

In October 2011, an Annex XV Classification and Labelling dossier prepared by the French Competent Authority was published on the ECHA website proposing the reclassification of formaldehyde as a Carcinogenic Cat 1A and Mutagenic Cat 2 substance. This dossier is currently was assessed by ECHA's Committee for Risk Assessment (RAC) in accordance with the relevant procedure under the CLP Regulation. In December 2012, the European Chemical Agency (ECHA) announced the adoption of a scientific opinion of the RAC proposing that formaldehyde be classified as Carcinogen Category 1B and germ cell Mutagen Category 2 under the CLP Regulation. In reaching their opinion, the RAC considered that the science relating to human exposure could not support classification as a Carcinogenic Cat 1A substance, opting instead for the lower category 1B (presumed human carcinogen) which is based on nasopharyngeal cancer (an extremely rare cancer in Europe). This proposal will be considered by the Commission and EU Member States and a new classification for formaldehyde (with implications for labelling) is planned to be adopted by 2015. If this proceeds, the use of formaldehyde will be subject to control under the **Carcinogens and Mutagens Directive (CMD)**.

The CMD aims at the protection of workers from risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens at work. Based on a determination and assessment of risks by the employer, it provides a step-by-step approach for risk control, ranging from replacement of the substance to measures that limit the quantities of a carcinogen at the place of work and keeping as low as possible the number of workers exposed or likely to be exposed. Further requirements are the use of existing appropriate procedures for the measurement of carcinogens, the application of suitable working procedures and methods, the use of collective and/or (where exposures cannot be avoided by other means) individual protection measures. Provisions are made for employers to ensure that workers receive sufficient information and appropriate training as well as for Member States who shall establish arrangements for carrying out relevant health surveillance of workers. Furthermore, the possibility to set OEL values is laid down in the Directive.

5.3 REACH Regulation

5.3.1 Measures Currently in Place

Exposure Scenarios, Chemical Safety Reports and SDS

Formaldehyde is manufactured in quantities larger than 1,000 tonnes per year; as a result, the substance had to be registered under the REACH Regulation by the end of November 2010. Such registration has been undertaken and it required a chemical safety assessment (CSA) and report (CSR). As per the provisions of the Regulation, the CSA has included the preparation of exposure scenarios setting out conditions for the safe use of the substance, based on the REACH methodology for deriving derived no-effect levels (DNELs) (see Table 5.2). Extended safety data sheets (SDS) will provide downstream users with the information they require on the operating conditions and worker protections measures required in order

to ensure that exposures are controlled to safe levels. The development of ESs, CSRs and SDSs is typically informed by information provided by downstream users up the supply chain. Assuming that downstream users adhere to the ES documented in the SDS, exposures to hazardous substances such as formaldehyde should be controlled and the potential for residual health impacts should be minimised.

Evaluation

Formaldehyde was recently included on the first Community Rolling Action Plan (CoRAP) published on 29 February 2012. The CoRAP contains substances for which there is a suspicion that their manufacture and/or use could pose risks to human health or the environment and substance evaluation is the process under REACH that allows for clarification of such risks. The first CoRAP lists 90 substances for evaluation between 2012 and 2014 by Member States Competent Authorities under the substance evaluation process. 36 substances are being evaluated in 2012 by 17 Member States. In 2013 and 2014, the aim is to evaluate at least 23 and 31 substances, respectively.

Formaldehyde is one of the substances which are to be evaluated in 2013 by the French and Dutch authorities. The initial grounds for concern for formaldehyde relate to carcinogenic, mutagenic and reprotoxic (CMR) properties, wide dispersive use, worker exposure and high aggregated tonnage. It is worth noting that the indication of the ground of concern does not limit the evaluation made by the Member States, since the Member States may also focus their assessment on any other area that gives rise to concern during the evaluation.
If the evaluating Member States conclude that further information is required, a legally binding request for further information will be issued to the registrants of that substance. This request might go beyond the standard information requirements of REACH (Annexes VII to X) and may pertain to the intrinsic properties of the substance or its exposure. For example, registrants may need to provide studies on mode of action or monitoring of concentration levels in organisms or the environment.

Once this information has been assessed, the evaluating Member State will complete the evaluation and consider whether and how to use the information obtained for the purposes of Community level risk management measures[3]. The conclusion can also be that the risks are sufficiently under control with the measures already in place. ECHA will inform the Commission, the registrants and the other MS about the conclusions (ECHA, 2012).

ECHA indicates the following possible options after the substance evaluation:
"If, after review of the available and new data, the evaluating Member State considers that the use of the substance poses a risk, it may then proceed with follow-up actions to substance evaluation.
The following options may address the concern:

- A proposal for harmonised classification and labelling for carcinogenic, mutagenic or toxic to reproductions, respiratory sensitisers or other effects.
- A proposal to identify the substance as a substance of very high concern (SVHC).
- A proposal to restrict the substance.

[3] These could be EU-wide risk management measures such as restrictions, identification of substances of very high concern, harmonised classification or other actions outside the scope of REACH.

- Actions outside the scope of REACH such as a proposal for EU-wide occupational exposure limits, national measures or voluntary industry actions." (ECHA, nd3).

Of course, when there are no (remaining) concerns, the evaluation may also in the end conclude that the risks are sufficiently under control with the measures already in place.

The updated CoRAP list of 20 March 2013 provides some additional specific information on the evaluation process. The designated Member States have 12 months to evaluate substances specified for 2013 starting from the date of publication of this CoRAP update. Where necessary, Member States will prepare a draft decision for requesting further information to clarify the suspected risks. In the draft decision the Member State can propose to request any information relevant for the risk assessment of the substance. The first draft decisions for the substances listed in 2013 need to be submitted to ECHA by 19 March 2014. ECHA will forward any draft decisions to the registrants for comments without undue delay. Draft decisions will also be reviewed by the other Member States and ECHA. If proposals for amendment are made, the MSC is also involved in decision-making before the decision becomes effective. In cases of unanimous agreement in MSC ECHA will take the final decision; otherwise the decision will be taken by the European Commission.

5.3.2 Potential Future Measures

Restriction

The restrictions procedure under REACH could be triggered under two separate scenarios - the first scenario relates to the results of the evaluation process (described above), while the second scenario relates to the proposed reclassification of formaldehyde. In addition it is also possible that any Member State could decide to table a restriction proposal, irrespective of the outcome of the above procedures (even if this is currently considered unlikely).

Under the first scenario, where the Commission or a Member State considers the measures documented in the CSRs for the substance and communicated as RMMs/OCs in ESs to be insufficient and the risks to human health and the environment are not adequately controlled, a community-wide restriction on the manufacturing, marketing or use of a substance may be introduced under the Restrictions procedure. In order to introduce restrictions under REACH, the relevant procedure, regulated by Articles 69-73 of REACH, has to be followed, involving both the analysis of the risks to human health or environment and the socio-economic impact of the restriction. In this context, if a MS considers that there is a risk to human health or the environment that needs to be addressed it has the obligation to prepare an Annex XV restriction dossier, as required by Article 69(4) of REACH.

Under the second scenario, if formaldehyde is formally reclassified as Carcinogen Category 1B and/or Mutagen Cat 2, a restriction on consumer use of formaldehyde will be triggered via entry 28 and 29 of the REACH Annex XVII which states that:

> *"Substances which appear in Annex I to Directive 67/548/EEC classified as carcinogen category 1 or carcinogen category 2… shall not be used in substances and preparations placed on the market for sale to the general public in individual concentration equal to or greater than: either the relevant concentration specified in*

Annex I to Directive 67/548/EEC, or the relevant concentration specified in Directive 1999/45/EC.

Substances which appear in Annex I to Directive 67/548/EEC classified as mutagen category 1 or mutagen category 2…. must be marked legibly and indelibly as follows: "Restricted to professional users".

It is important to note that, while the restriction described under the second scenario is automatically triggered as a result of reclassification with no further action required from the Commission or MS authorities (apart from enforcement and monitoring action taken at the Member State level), the restriction described under the first scenario can only be introduced if a Member State (or ECHA at the request of the European Commission) actively pursues it and prepares a justified proposal in the form of an Annex XV dossier. Note, however, that if formaldehyde is formally classified as Carcinogen Category 1B and/or Mutagen Cat 2, the Commission could, in theory, use a 'fast track' procedure to restrict the use of formaldehyde in articles.

This "fast track" procedure is based on Article 68(2)[4] of REACH and does not require development of an Annex XV dossier. The amendment of Annex XVII of REACH will be via the "comitology" procedure (i.e. the legislative act is adopted by the Commission following an opinion of the EU REACH Committee and a three-month scrutiny period by the European Parliament and the Council).

Authorisation

The authorisation procedure under REACH could be triggered under two separate scenarios - the first scenario relates to the proposed reclassification of formaldehyde, while the second relates to identification of formaldehyde as a substance of equivalent concern.

Under the first scenario, the authorisation requirement may only be triggered if: (a) formaldehyde is reclassified as a Carcinogen Cat 1B and Mutagen Cat 2 and (b) Member States or ECHA (on the European Commission's request) decide to prepare an Annex XV Substance of Very High Concern (SVHC) for the substance. REACH includes provisions (Article 57) for the identification of SVHC where they meet, amongst others, the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) Category 1A or 1B under CLP. Such SVHCs may be prioritised by national Competent Authorities or ECHA (at the request of the European Commission) for inclusion on a 'Candidate List'; this represents the first step to the substance being subject to Authorisation. From then on, if the substance is prioritised (on the basis of a procedure and criteria that have been set out by ECHA, it will be added to Annex XIV of the Regulation and its use beyond a set 'sunset date' will only be legal for those users who have obtain an Authorisation in advance.

[4] Article 68(2): For a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply.

Under the second scenario, SVHC substances may still be identified on a case-by-case basis where there is "*scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern…"*. In essence, formaldehyde could be identified as a substance of equivalent concern (for instance, based on the findings of the evaluation process) and, as such, could be subject to the authorisation route. Similar to the earlier scenario, it will still need to prioritised by national Competent Authorities or ECHA (at the request of the European Commission) for inclusion on a 'Candidate List'.

Authorisation is aimed at ensuring that the risks of SVHCs are properly controlled and that such substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. Manufacturers, importers and downstream users applying for Authorisations would therefore be required to analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution. Under the Authorisation procedure, a substance cannot be placed on the market or used after a given date unless a specific authorisation is granted or the use is exempted.

5.4 CAD Provisions

5.4.1 Measures Currently in Place

The Chemical Agents Directive (98/24/EC) (CAD) was introduced in order to provide measures to protect workers from the risks of chemical agents present in the workplace. It lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents.

Under the CAD, an employer 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. The employer must be in possession of a risk assessment which must be kept up-to-date, particularly if there have been significant changes or if the results of health surveillance show it to be necessary. In the case of activities involving exposure to several hazardous chemical agents, the risks must be assessed on the basis of the risk presented by all such chemical agents in combination. The employer must review the risk assessment that he made and the measures provided to eliminate or reduce these risks. Specific requirements under the CAD include:

- **Prevention or control of exposure**: The employer must ensure that the risk is eliminated or reduced to a minimum, preferably by substitution (replacing a hazardous chemical agent with a chemical agent or process which is not hazardous or less hazardous) (Article 5). Where substitution is not possible, exposure must be controlled through specific protection and prevention measures using a strict hierarchy of controls (see Article 6(2)). In order of priority, this includes: good design and engineering controls at source; collective protection measures (e.g. ventilation); and individual protection measures such as personal protective equipment (PPE). Comparative hazard evaluation, based in part on hazard classification, is essential.

- **Selection and use of PPE**: Use of PPE, where exposure cannot be adequately controlled by other means, must be appropriate for the risks involved and conditions at the place

where exposure may occur. It must also be effective in preventing, or adequately controlling, risk without increasing overall risk to health and safety. A correct understanding of the risk is essential when selecting PPE (e.g. appropriateness of respirator or gloves). 'R' and 'S' phrases contained in SDS and on labels give advice on the need for PPE and sometimes advise on the type of PPE.

- **Monitoring**: The employer must regularly measure chemical agents which may present a risk to workers' health, in relation to the OEL values and must immediately take steps to remedy the situation if exceeded. Member States must introduce arrangements for carrying out appropriate health surveillance of workers for whom the results of the assessment made by the employer reveal a risk to health. Individual health and exposure records must be made and kept up-to-date for each worker who undergoes health surveillance and the individual worker must have access to his personal records.

- **Accidents**: The employer must establish procedures (action plans) which can be implemented in the event of an accident, incident or emergency related to the presence of hazardous chemical agents at the workplace

- **Information provision**: The employer must inform workers on: emergency arrangements; on the results of the risk assessment; on the hazardous chemical agents present at the workplace with access to safety data sheets; by training on the appropriate precautions and on the personal and collective protection measures that are to be taken.

5.4.2 Potential Future Measures

Two possible further measures could be introduced under the CAD: the first relates to the setting of occupational exposure limit (OEL) values, while the second relates to potential prohibitions on the production, manufacture or use at work of specified chemical agents and activities involving these chemical agents.

For the first, the CAD provides for the drawing up of indicative and binding OEL values as well as biological limit values at Community level. For any chemical agent for which an indicative occupational exposure limit value (IOELV) is established at Community level, Member States must establish a national OEL value, taking into account the Community limit value. Similarly, binding OEL values and binding biological limit values may be drawn up at Community level taking into account feasibility factors. For any chemical agent for which a binding occupational exposure or biological limit value is established at Community level, Member States must establish a corresponding national binding occupational exposure or biological limit value that does not exceed the Community limit value.

For the second scenario, Annex III to the Directive 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 four substances are on this list.

5.5 Occupational Exposure Limit Values

5.5.1 Measures Currently in Place

National OELs across EU-28

Occupational Exposure Limits (OELs) are limits set by national authorities or institutions for hazardous compounds which may be present in the air within a workplace. OELs are set to prevent and or limit the exposure of workers to dangerous substances and also to protect those workers who are likely to be exposed to such substances. Concern regarding the exposure of workers to formaldehyde has led to the development of OELs in many countries. Table 5.2 below provides an overview of the OELs in place in various European countries.

Table 5.2: Occupational Exposure Limits (OELs) for Formaldehyde in European Countries

No	Country	Limit	Types*
1	United Kingdom	2.0ppm	TWA
2	Ireland	2.0ppm	TWA
3	Greece	2.0ppm	TWA
4	Romania	1.0ppm	TWA
5	Bulgaria	1.0 mg/m^3 (~0.8ppm)	TWA
6	Sweden	0.5ppm	TWA
7	Slovenia	0.5ppm	TWA
8	Norway***	0.5ppm	TWA
9	Lithuania	0.5ppm	TWA
10	Hungary	0.5ppm	TWA
11	France	0.5ppm	TWA
12	Estonia	0.5ppm	TWA
13	Czech Republic	0.5ppm	TWA
14	Austria	0.5ppm	TWA
15	Germany	0.5ppm**	TWA
16	Poland	0.5mg/m^3 (~0.4ppm)	TWA
17	Latvia	0.5mg/m^3 (~0.4ppm)	TWA
18	Switzerland***	0.3ppm	TWA
19	Spain	0.3ppm	STEL
20	Slovakia	0.3ppm	TWA
21	Portugal	0.3ppm	Ceiling
22	Italy	0.3ppm	Ceiling (STEL)
23	Finland	0.3ppm	TWA
24	Denmark	0.3ppm	TWA & STEL
25	Belgium	0.3ppm	Ceiling
26	Netherlands	0.15 mg/m^3 (~0.12ppm)	TWA

Sources: Arbeits Inspektion (2011), Arbejds Tilsynet (2005), Chimar Hellas (2008), EFBWW (2009), EMLA (2000), HSA (2011), Feder Chimica (2003), ILO (2011), INRS (2012), Instituto Português da

Table 5.2: Occupational Exposure Limits (OELs) for Formaldehyde in European Countries			
No	**Country**	**Limit**	**Types***
Qualidade (2007), Labklājības ministrijas iesniegtajā redakcijā (2007), Ministry of Labour and Social Policy, Ministry of Health (Bulgaria) (2011), SER (2006), Service Public Fédéral, Emploi, Travail et Concertation Social (2010), Sosiaali-Ja Terveysministeriö (2009),: *For Malta, an OEL does not exist and for Cyprus, Luxembourg and Croatia, the situation is unknown* **TWA: time-weighted average, STEL: short-term exposure limit.* ***In Germany, a limit value of 0.5ppm has been suspended and a new proposal of 0.3ppm has been proposed, however this has not yet been implemented.* **** Not in EU-27*			

While it is important to note that some of this information may have changed since, it seems to be the case that a third of Member States have set their national OEL at 0.3ppm, while another third have set theirs at 0.5ppm. More recently, France is considering an OEL of 0.2ppm (Levy, 2012) and both the UK and Ireland are in the process of changing the current national OEL for formaldehyde (Health and Safety Authority, 2011; HSE, ndc).

5.5.2 Potential Future Measures

Overview

Over the last decade (prior to which most of the above OELs were fixed), policy making within the EU has shifted from domestic limit setting to adoption of European limits. This reflects increasing efforts at the European level to develop and apply similar levels of control across the EU, avoid duplication of risk assessment work at the domestic level, and help ensure that there is a level playing field among EU Member States.

Developments in the future are likely to relate to the agreement of a harmonised EU-wide OEL and the nature of this OEL based on discussions: at the Scientific Committee on Occupational Exposure Limits (SCOEL), between Member States, under REACH and the international level. These are discussed further below.

SCOEL OEL

In 2008, the European Commission's SCOEL proposed an indicative OEL for formaldehyde. SCOEL (2008) noted that formaldehyde was a carcinogen with a practical threshold and as a result proposed an IOELV for formaldehyde of **0.2ppm** (8 hour TWA) and **0.4ppm** (STEL). These values took into account possible inter-individual differences in susceptibility to irritation by formaldehyde, which may be expected based on the entire body of data. Short-term irritation may be prevented by a 15min-STEL of 0.4ppm and this STEL is set below the threshold for objective eye irritation. At these levels, no systemic effect of formaldehyde is to be expected (Worksafe BC, 2009). These limits were proposed considering the 'preferred value approach' and because they took into consideration particularly sensitive persons and the necessary safety margin to the onset of irritation-induced cytotoxicity/cell proliferation.

Table 5.3 presents an overview of OELs proposed by other credible institutions.

Table 5.3: Summary of Recommended OELs by Institutions		
	TWA (ppm)	**STEL (ppm)**

Table 5.3: Summary of Recommended OELs by Institutions		
	TWA (ppm)	**STEL (ppm)**
American Conference of Governmental Industrial Hygienists (ACGIH, 2001)	-	0.3
Dutch Expert Committee on Occupational Standards (NL) & Nordic Expert Group (NEG) (2003)	0.12	0.42
DFG/MAK (Germany, 2006)	0.3	0.6
NICNAS (Australia)	0.3	0.6
Source: Bolt (2012)		

Indicative OEL

As discussed earlier, Indicative Occupational Exposure Limit Values (IOELVs) are European health-based limits that are set to protect the health of workers in the European Union from the ill-health effects of hazardous substances in the workplace. Their legal status derives from the CAD. The 1st IOELV Directive (2000/39/EC) setting limits for 63 substances was introduced in 2000, followed by a 2nd IOELV Directive (2006/15/EC) containing limits for a further 33 substances.

Discussions regarding an IOELV for formaldehyde were first conducted by SCOEL between 2005 and 2007; in 2008, formaldehyde was included on a draft list of 20 substances to be included in the 3rd IOELV Directive establishing a third list of IOELVs in implementation of the CAD. Inclusion of formaldehyde in the 3rd IOELV Directive was aimed at aligning the OELs for formaldehyde throughout the EU. In spite of it being approved by the Advisory Committee on Safety and Health at Work, formaldehyde was not included in the published 3rd IOELV 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 IOELV Directive in 2008 following objections from the WBP industry (HSE, 2008).

It is understood that SCOEL is currently reviewing its formaldehyde recommendation in preparation for a new list of IOELVs. Formaldehyde is one of 41 candidate substances currently being reviewed for the 4th IOELV Directive (Wriedt, 2012).

Binding OEL

As noted earlier, binding OEL values and binding biological limit values may be drawn up at Community level taking into account feasibility factors. When formaldehyde was proposed for an indicative OEL in 2008, the wood panel industry noted that the expenditure required to implement the IOELV proposed by SCOEL was excessive when compared to the potential health effects. The wood panel industry also claimed that higher costs would be incurred if the 0.2ppm (TWA) IOELV was imposed rather than a limit of 0.3ppm or 0.5ppm. Furthermore, the UK Health and Safety Executive also stated that their own studies had shown that an IOELV of 0.3ppm also had merit (HSE, 2008). Consequently, UK HSE proposed that formaldehyde be removed from the 3rd IOELV Directive and a binding limit taking into account socio-economic factors be introduced in due course (HSE, 2008). It is understood that there are 26 candidate substances currently being considered for binding OELs (Wriedt, 2012).

OELs and DNELs

A key element of the CSA is the development of derived no-effect levels (DNEL) for effects where a threshold response is shown. The DNEL defines the level of exposure at which no adverse effects are anticipated and is precautionary in nature. Compliance by industry with this value would provide adequate protection, removing any need to consider additional OELs. In a sense, it is possible that worker DNELs established under REACH are likely to become 'defacto OELs' in the absence of a specific OEL for some companies and possibly countries, because they provide the target concentrations for proper control strategies to prevent worker injury and illness. Indeed, ECHA (2010) notes that where "*an EU Indicative Occupational Exposure Limit (IOEL) exists, the registrant may, under certain conditions, use the IOEL in place of developing a DNEL".* Where DNELs differ from OELs, this could potentially lead to short-term confusion while industry and regulators adjust to the new information becoming available. Indeed, such differences are likely given the very different basis for their respective derivations. Importantly, OELs are intended as specific occupational health and safety instruments while DNELs primarily define a risk level and are then used to establish what risk management measures are necessary (Kalberlah, 2007). Table 5.4 below sets out the DNELs for formaldehyde as set out in the ECHA dissemination portal (based on information from registration dossiers).

A comparison with the OELs shown in Table 5.2 would show that the DNEL for formaldehyde is more stringent than the OEL for a number of countries (i.e. over a third of Member States have OELs above 0.4 ppm). In this regard, it is important to recognise that the EC authorities acknowledge the possible divergence of OEL and DNEL values but place the onus to address these divergences on industry (EC, 2010)[5].

Table 5.4: Formaldehyde Derived No Effect Levels (DNELs)

	Workers	**General Population**
Acute/Short-term Exposure		
Dermal DN(M)EL	Exposure based waiving	-
Inhalation DN(M)EL	DNEL 1mg/m³	-
Long-term Exposure – Systemic Effects		
Dermal DN(M)EL	DNEL 240 mg/kg bw/day	DNEL 102 mg/kg bw/day
Inhalation DN(M)EL	DNEL 9 mg/m³	DNEL 3.2 mg/m³
Oral DN(M)EL	-	DNEL 4.1 mg/kg bw/day
Long-term Exposure – Local Effects		
Dermal DN(M)EL	DNEL 37 µg/cm²	DNEL 12 µg/cm²
Inhalation DN(M)EL	DNEL 0.5 mg/m³	DNEL 0.1 mg/m³
Source: ECHA (nd)		

[5] EC (2010) notes that *"where both a national OEL and a DNEL (for both the same duration and the same route of exposure) have been derived for a substance, and the risk management measures in the safety data sheet are significantly more restrictive, employers continue to remain responsible for the protection of their employees, and should seek to resolve the situation with their suppliers and, as appropriate, with the relevant national authorities".*

5.6 Directive on Industrial Emissions

5.6.1 Measures Currently in Place

Directive 2010/75/EU (Industrial Emissions Directive) replaces seven Directives including Directive 1999/13/EC concerning the reduction of emissions of Volatile Organic Compounds (VOC) (Europa, 2011). Directive 2010/75/EU entered into force in January 2011 and Member States had until January 2013 for transposition (Europa, 2011). In this context, it is important to note that Directive 2008/112/EEC amended the VOC Directive (1999/13/EC) and adapted it to the CLP Regulation (EC No 1272/2008); however, Directive 2010/75/EU definitively replaces the VOC Directive (Europa, 2011).

Directive 2010/75/EU aims to limit emissions of VOCs due to the use of organic solvents in certain activities and installations 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.

Taking into account that Directive 2010/75/EU is focussed on emissions "*due to the use of organic solvents*", **it is important to clarify that the VOC-related aspects of this Directive do not apply to use of formaldehyde in WBP, 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**.

The Directive covers emissions of VOCs from certain activities and installations which are listed in Annex VII (Part 1) of the Directive. Annex VII includes:

- adhesive coating (any activity in which an adhesive is applied to a surface, with the exception of adhesive coating and laminating associated with printing activities);
- coating activity: any activity in which a single or multiple application of a continuous film of a coating is applied to: vehicles (including new cars, truck cabins, vans and trucks, buses and trailers), metallic and plastic surfaces, wooden surfaces, textile, fabric, film and paper surfaces and leather (it does not include the coating of substrate with metals by electrophoretic and chemical spraying techniques. If the coating activity includes a step in which the same article is printed by whatever technique used, that printing step is considered part of the coating activity. However, printing activities operated as a separate activity are not included, but may be covered by Chapter V of the Directive if the printing activity falls within the scope thereof);
- manufacturing of coating mixtures, varnishes, inks and adhesives (the manufacture of the above final products, and of intermediates where carried out at the same site, by mixing of pigments, resins and adhesive materials with organic solvent or other carrier, including dispersion and pre-dispersion activities, viscosity and tint adjustments and operations for filling the final product into its container);
- wood impregnation (any activity giving a loading of preservative in timber);
- wood and plastic lamination (any activity to adhere together wood and/or plastic to produce laminated products).

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:

- by installing equipment to reduce emissions to comply with the emission limit values and the fugitive emission values, or total emission limit values; or
- 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.

5.6.2 Potential Future Measures

Solvents or mixtures likely to have a serious effect on human health because of their content of VOCs (classified as carcinogens, mutagens, or toxic to reproduction), must be replaced by less harmful substances or mixtures. Article (58) of Directive 2010/75/EU states that:

> *"Substances or mixtures which, because of their content of VOCs classified as carcinogens, mutagens or toxic to reproduction under [CLP] Regulation… shall be replaced, as far as possible and by taking into account the guidance referred to in Article 7(1), by less harmful substances or mixtures within the shortest possible time."*

Article 64 of the IED Directive states that:

> *The Commission shall ensure that an exchange of information with Member States, the industry concerned and non-governmental organisations regarding the activities concerned on the use of organic substances and their potential substitutes takes place. It shall consider the questions of:*
>
> - *fitness for use,*
> - *potential effects on human health and occupational exposure in particular;*
> - *potential effects on the environment, and*
> - *the economic consequences, in particular, the costs and benefits of the options available,*
>
> *with a view to providing guidance on the use of substances and techniques which have the least potential effects on air, water, soil, ecosystems and human health.*

Table 5.5: Threshold and Emission Limit Values from Directive 2010/75/EU (Annex VII, Part 2)						
Activity (solvent consumption threshold in tonnes/year)	**Threshold (solvent consumption threshold in tonnes/year)**	**Emission limit values in waste gases (mg/Nm³)**	**Fugitive emission values (percentage of solvent input)**		**Total emission values**		**Special Provisions**
			New	Existing	New	Existing	
Coating of wooden surfaces (>15)	15-25 >25	100 (1) 50/75 (2)	25 20				1. Emission limit applies to coating application and drying processes operated under contained conditions. 2. The first value applies to drying processes, the second to coating application processes.
Wood impregnation (>25)		100 (1)	45		11 kg/m³		1. Emission limit value does not apply for impregnation with creosote.
Wood and plastic lamination (>5)					30 g/m²		
Adhesive coating (>5)	5-15 >15	50 (1) 50 (1)	25 20				1 If techniques are used which allow reuse of recovered solvent, the emission limit value in waste gases shall be 150.
Manufacture of coating preparations, varnishes, inks, and adhesives (>100)	100-1,000 >1,000	150 150	5 3		5% of solvent input 3% of solvent input		The fugitive emission value does not include solvent sold as part of a coatings preparation in a sealed container.
Other coating, including metal, plastic, textile (5), fabric, film and paper coating (>5)	5-15	100 (1) (4)	25 (4)				1. Emission limit value applies to coating applications and drying processes operated under contained conditions. 2. The first emission limit value applies to drying processes, the second to coating application processes. 3. For textile coating installations which use techniques which allow reuse of recovered solvents, the emission limit applied to coating application and drying processes taken together shall be 150. 4. Coating activities which cannot be applied under contained conditions (such as shipbuilding, aircraft painting) may be exempted from these values, in accordance with Article 59 (3). 5. Rotary screen printing on textile is covered by activity No. 3.
	>15	50/75 (2) (3) (4)	20 (4)				

5.7 Indoor Air Guidelines

5.7.1 Measures Currently in Place

Member States

Although, indoor air levels of formaldehyde are not generally the subject of legislation, a number of Member States have developed indoor guideline values (NCBI, nd; WBPI, 2012a).

- In the UK, formaldehyde has been assigned a Maximum Exposure Limit (MEL) of two parts per million (ppm) by the UK HSE. In 2004, the Committee on the Medical Effects of Air Pollutants (COMEAP) recommended a limit value of 100 µg m^{-3} (0.5 h) for indoor formaldehyde.

- Germany established an indoor guideline value of 0.1ppm in 1977; in 2006, the Federal Institute for Risk Assessment (BfR) and the Federal Environment Agency stated that a revision of this guideline value is not required. The same value of 0.1ppm is currently used as a maximum permissible indoor level in Sweden, although a further reduction to 60 µg m^{-3} appeared to be under discussion.

- In France, the French Agency for Environmental and Occupational Health Safety (AFSSET) has proposed guideline values of 10 µg m^{-3} and 50 µg m^{-3} for long-term and short-term exposure (2 h), respectively, while the Danish guideline value of 0.15 mg m^{-3} does not appear to have been revised since 1990.

- In Finland, indoor climate is classified as S1 (individual indoor climate), S2 (good indoor climate), and S3 (satisfactory indoor climate), in which formaldehyde target values were set as 30 µg m^{-3}, 50 µg m^{-3}, and 100 µg m^{-3}, respectively.

- An indoor formaldehyde level was specified by the Norwegian Health Directorate (NHD) in 1990 in the Guidelines for Indoor Air Quality, in which a 24-h average indoor formaldehyde level was set at 60 µg m^{-3}. Stranger et al. cite a guideline value of 100 µg m^{-3} (0.5 h exposure), applicable in Norway since 1999.

- The Polish Ministry of Health and Social Welfare issued a decree aimed at reducing the pollutants emitted by building materials and furnishings in inhabited enclosed areas. The maximum allowable concentrations for formaldehyde, categorised as Category A (up to 24 h exposure per day) and Category B (8–10 h exposure per day), are 50 µg m^{-3} and 100 µg m^{-3}, respectively.

European Commission

The European Commission (EC) has been active in gathering data regarding indoor air quality and actively promoting actions for healthy indoor air for a number of years. The ECA (European Collaborative Action on Urban Air, Indoor Environment and Human Exposure), supported by the JRC, has been studying air quality for 22 years. The research conducted by the ECA considers both outdoor and indoor sources of pollution in relation to human health and comfort and its' work can be used as a basis for a harmonised approach to urban air quality management to minimise exposure to pollutants (Kephalopoulos et al, nd).

The ECA has published 27 reports since 1988, recent activity with regards indoor air quality includes:

- report number 24 on the "Harmonisation of existing indoor material emissions labelling systems in the EU: inventory of existing schemes" which was published in 2005; and
- report number 25 on "Strategies to determine and control the contributions of indoor air pollution to total inhalation exposure (STRATEX)" which was published in 2006.

Action 12 of the European Commission's 2004-2010 Environment and Health Action Plan aimed to specifically improve indoor air quality by reviewing and adjusting risk reduction policy. A number of pre-normative research projects have been conducted (funded by several Directorate Generals within the European Commission) as part of the 2004-2010 Environment and Health Action Plan and prior to its introduction. The majority of studies to date appear to have focused on the impact of indoor air quality on human health. The most important data gathering projects have been:

- the **THADE** project (2002-2004) (Towards Healthy Indoor Air in Dwellings in Europe) was funded by **DG SANCO** and identified formaldehyde as one of the main health determinants in dwellings. It advised devising product control and labelling systems for building products and household chemicals and for formaldehyde in particular the project advised controlling the source of formaldehyde pollution as the most effective reduction method (EFA, 2004).

- the **INDEX** project (2002-2005) (Critical Appraisal of the Setting and Implementation of Indoor Exposure Limits in the EU) was carried out by the **EC Joint Research Centre** (JRC, 2004) and was funded by DG SANCO. The aim of INDEX was to identify priorities and to assess the needs for a Community strategy and action plan in the area of indoor air pollution by: (a) setting up a list of compounds to be regulated in indoor environments with priority on the basis of health impact criteria; (b) **providing suggestions and recommendations** on potential exposure limits for these compounds, and (c) providing information on links with existing knowledge, on-going studies, legislation etc. at world scale. Formaldehyde was one of the substances given highest priority in this project (JRC, 2008). The following **management options** for formaldehyde were suggested by the project (JRC, 2004):
    - restrict emissions of formaldehyde from building products, furnishings and household/office chemicals; and
    - discourage the use of formaldehyde containing products.

- the **AIRMEX** project (European Indoor Air Monitoring and Exposure Assessment Project) (2003-2007) conducted by the **JRC** aimed to evaluate the relationship between indoor air pollution and human exposure to pollutants with the focus on public buildings (JRC, 2011b). The project monitored indoor, outdoor and individual exposure to selected chemical compounds across Europe and formaldehyde was one of the carbonyls monitored in the project.

- the **EnVIE** project (2003-2008) was funded by **DG Research** and aimed to increase the understanding of the EU-wide public health impacts of indoor air quality. The project identified the most widespread and significant indoor causes for particular health impacts and evaluated the existing and optional building and housing related policies for

controlling them (Indoor Air ENVIE, 2010). The EnVIE project has been effectively extended and updated by the **IAIAQ** project (Promoting Actions for Healthy Indoor Air).

The EC has also emphasised the significance of emissions from construction products as sources of indoor pollution and a number of research and awareness projects have addressed this issue. The **BUMA** project (2006-2009) was funded by DG SANCO and aimed to address human exposure to air hazards emitted by building materials commonly used in Europe. The project collected and reviewed the emission factors from construction products covered by the CPD and others (BUMA Project, nd). The BUMA project oversaw the creation of a database of quantified building material emissions and exposure data and includes data on formaldehyde emissions from construction products such as particleboard and MDF (Bartzis, 2010). The **HealthyAIR** project (2007-2010) was partly funded by DG SANCO and addressed the effects of construction products on indoor air. The project aimed to define, initiate and develop activities that improve indoor air quality and reduce exposure to indoor air pollution sources, in particular construction products (Cranfield University, nd). Furthermore, in 2007, under the German EU presidency, the *"Construction Products and Indoor Air Quality – Emissions Reduction in the EU"* took place in Berlin. The conference focused on the importance of harmonised procedures to allow the consistent evaluation of construction products in all EU Member States. The conference discussed potential harmonised approaches and possible ways to reduce exposure to emissions (Umweltbundesamt, 2007).

In 2005, DG SANCO mandated the Scientific Committee on Health and Environmental Risks (SCHER) to deliver an opinion on a possible risk assessment strategy to support policy on the indoor air issue. Within the opinion, SCHER considers formaldehyde to be a *"compound of concern to the indoor environment"* (SCHER, 2007). Furthermore, the SCHER opinion agrees with the INDEX classification of formaldehyde as a high priority chemical. However, it also states that concern may differ in different countries due to varying exposure levels across Europe. In 2006, DG SANCO established an expert working group to follow up on the opinions of the Scientific Committee. DG SANCO has also established an Indoor Air Quality (IAQ) Strategy Action Plan (2007-2010). Implementation of the Action Plan involves:

- prioritising IAQ pollutants and health effects;
- providing guideline values;
- monitoring exposure patterns and health effects;
- identifying and improving sources of indoor air pollution; and
- reducing exposure patterns of key IAQ pollutants.

Increasing awareness of indoor air quality and the introduction of a harmonisation framework for indoor products labelling schemes in the EU have also been incorporated into the DG SANCO IAQ Strategy Plan (2007-2010) as ways to reduce exposure to indoor air pollution.

WHO

In 2010, formaldehyde was included in the World Health Organisation's (WHO) first indoor air quality guidelines on indoor chemicals (WHO, 2010). The WHO indoor air quality guidelines are intended to prevent health risks from pollutants which are often present indoors in concentrations of concern for health. The Guidelines consider various levels of economic development, cover all relevant population groups and enable feasible

approaches to reduce health risks from exposure to the pollutants in various regions of the world. They also include background material summarizing the evidence on health risks and consider existing national and international guidelines and experience in regulating indoor air quality. The guidelines establish targets at which health risks are significantly reduced. For formaldehyde, it is considered that indoor sources are the dominant contributor of exposure to formaldehyde. A 30-minute guideline of 0.1 mg/m3 is recommended to prevent sensory irritation in the general population. This guideline, valid for any 30-minute period, also prevents the effects of long-term exposures on lung function or on the risk of nasopharyngeal cancer and myeloid leukaemia. The use of low-emitting building materials and products, and preventing exposures to environmental tobacco smoke and other combustion emissions, is recommended for minimising exposure-related risk. In addition, ventilation is noted for reducing indoor exposure to formaldehyde (WHO, 2010).

These guidelines are targeted at public health professionals involved in preventing the health risks of environmental exposures, as well as at specialists and authorities involved in the design and use of buildings, indoor materials and products. They also indicated to provide a scientific basis for legally enforceable standards (WHO, 2010) and are feeding into various on-going initiatives involving the European Commission.

5.7.2 Potential Future Measures

Building upon the data on indoor air quality gathered through the projects discussed above, the EC now appears to be focusing on the harmonisation of indoor air activities to reduce exposure to indoor pollution and to create a consistent and uniform approach across all EU Member States. The creation of an EU level indoor products labelling scheme seems to be central to this harmonisation. In 2010, the process of developing and implementing a framework for the harmonisation of indoor material labelling schemes in Europe was advanced following an initiative co-ordinated by the EC's Joint Research Centre and supported by DG ENTR, DG SANCO, DG ENV and DG ENER (JRC, 2010). In June 2010, the JRC organised a workshop on a *"Harmonised framework for indoor material labelling schemes: challenge with a global perspective".* Formacare participated in the workshop via CEFIC (Formacare 2010). The workshop fits to and is the first demonstrator of the JRC Platform/Task Force on the *"Safe, Healthy, Energy Efficient and Sustainable Buildings in the EU"* (Kephalopoulos, 2010).

In 2012, the European Collaborative Action (ECA) Group established a working group of 27 European experts to oversee the development and introduction of an EU harmonised indoor products labelling scheme (ECA, 2012). Also in 2012, the ECA published report number 27 on the *"Harmonisation framework for indoor products labelling schemes in the EU"* which provides a summary of the consensus achieved so far on a harmonised framework for labelling schemes in Europe by the working group. In August 2012, DG ENT published a tender for a study to analyse the existence of specific needs for information on the content of dangerous substances in construction products within the context of the Construction Products Regulation (DG ENTR, 2012).

Although there is currently no EU-wide legal framework on indoor air quality, research projects are continuing and it is understood that a revision of the INDEX report (taking into account the WHO findings) has been undertaken (Formacare, 2010).

5.8 Product Labelling

5.8.1 Measures Currently in Place

A number of labelling schemes are already in place at both the national and European levels which have their own specific requirements for testing and criteria for product evaluation. These schemes are, for the most part, voluntary; some are government schemes and others are private/industry based and promoted. Table 5.7 (overleaf) summarises some of the existing labelling schemes which relate to formaldehyde in various products. To date, the most significant labelling schemes for indoor products (within Europe) are:

- **AgBB** (Germany): AgBB (the Committee for Health Related Evaluation of Building Products) has developed a testing and evaluation procedure for VOC emissions from building products suitable for indoor use after 3 and 28 days (Umweltbundesamt, 2012). The AgBB specifications are based on a 1997 report by the European Collaborative Action (ECA) (Indoor Air Quality and Its Impact on Man) which provided a science-based and harmonised starting point should a country wish to establish an evaluation scheme at national level. The AgBB scheme is applicable to all types of construction products relevant to indoor air; it is a mandatory scheme (through inclusion on the approval procedure for selected construction products by the Deutsches Institut für Bautechnik) and is promoted by the German government (European Healthy Air Project, nd).

- **M1 Emission Class for Building Material** (Finland): the M1 Emission Class for Building Material was developed by the Finnish Society of Indoor Air Quality and Climate in 1995. The scheme aims to enhance the development and use of low-emitting building materials through the voluntary labelling of building products with low TVOC emissions. There are 3 emission classes within the scheme with M1 being applied to those products with the lowest emission rates and M3 to those with the highest. Table 5.6 below summarises the criteria for formaldehyde emissions for both M1 and M2 emission classes. Although voluntary, the scheme is promoted by the Finnish government.

Table 5.6: Formaldehyde Criteria for M1 and M2 Emission Classes

Examined Qualities	M1 (mg/m²h)	M2 (mg/m²h)
Emission of formaldehyde	<0.05	<0.125
Source: ECA (2012)		

- **AFFSET Protocol** (France): The AFSSET (French Agency for Environmental and Occupation Health and Safety) protocol is a health related protocol for the evaluation of VOC and formaldehyde emissions from building products (ECA, 2012). It was originally introduced in 2006 and was based on the framework proposed by the ECA 1997 report and the German AgBB scheme. The protocol was originally applied on a voluntary basis for solid products, however, it has become mandatory in 2012 (see below) and has also been extended to include liquid products (European Healthy Air Project, nd).

- **Indoor Climate Label** (Denmark): The Indoor Climate Label is a voluntary scheme for the labelling of building materials and products which have low emissions of VOCs and aldehydes. The use of carcinogenic compounds which belong to IARC Category 1 are prohibited in the emissions from products with the Indoor Climate Label; this does not, however, apply to formaldehyde.

Table 5.7: Summary of Existing Labelling Schemes (with limits) of Relevance to Formaldehyde							
	EMICODE	**Environmentally Friendly Label (Croatia)**	**The Indoor Climate Label (Denmark)**	**European Eco-Label**	**Blue Angel (Germany)**	**Nordic Swan**	**TCO Development (Sweden)**
Products Covered by the Labelling Schemes (✓ for those with established tests)							
Adhesives	✓	✓			✓	✓	
Coatings and Paints		✓	✓	✓	✓		
Other wall coverings					✓		
Flooring underlay	✓						
Other flooring installation products	✓		✓		✓	✓	
Floor coverings			✓			✓	
Carpets			✓			✓	
Textiles			✓			✓	
Furniture			✓	✓*		✓	✓
Wood board, fibre board etc.					✓	✓	
Doors and Windows			✓				
Construction materials/products			✓				
Ceilings			✓				

Source: UK Department for Communities and Local Government (2011)
Note: * tests are proposed/under development

5.8.2 Potential Future Measures

France

In March 2011, the French government announced a regulation requiring the mandatory labelling of construction products installed indoors with their emission classes, based on emission testing. The Regulation includes construction products installed indoors such as floor and wall coverings, doors and windows, panels for room partitions and suspended ceilings as well as paints and lacquers. From 1 January 2012 products placed on the market must be labelled with the emission class based on emissions after 28 days. The basis of testing is ISO 16000-11 (Eco-Institut, ndb). In February 2013, further specifications were added to the regulation for the sampling of paints, varnishes, coatings, sealants and other paint and varnish products (Eco-Institut, ndb). For those products already on the market on the 1 January 2012, labelling is required from the 1 September 2013. **Error! Reference source not found.** below presents the emission classes (where emission class C has the highest level of emissions and A+ the lowest) and associated limit values for formaldehyde and also includes the total of permitted volatile organic compounds for each emission class.

Table 5.8: VOC Emission Classes and Emission Limits (µg/m^3)

	C	B	A	A+
Total VOC	>2000	<2000	<1500	<1000
Formaldehyde	>120	<120	<60	<10

Germany

Within Germany, as well as the CE marking required at EU level, there is also the 'Ü mark' which imposes additional and compulsory requirements on the VOC emissions from certain construction products to be used indoors. The Ü mark is administered by the German Institute for Construction Technology (DIBt) and defines additional specifications if EU CE marking does not cover all necessary issues for the German authorities. Those products listed which are installed in Germany in places which are marketed as locations where people stay longer than 'transiently' require the Ü mark. Most floor coverings are made for rooms with this purpose (Eurofins, 2012).

The "Ü" mark is placed on the product following conformation of conformity by the DIBt in accordance with AgBB requirements, and a monitoring contract with a "ÜZ" certification body has been signed. The AgBB requirements set limits for (Eurofins, 2012):

- carcinogens after 3 and 28 days;
- total VOC after 3 and 28 days;
- total semi-VOC after 28 days;
- single VOC compounds with LCI limit values after 28 days; and
- single VOC compounds without such limits after 28 days.

To obtain the Ü mark the manufacturer must provide the chemical composition and test results for VOC emissions from the product. Tests are only accepted from laboratories recognised by the DIBt. The products which require the Ü mark are (Eco-Institut, nd):

- resilient, textile and laminate floor coverings (since 2005) (as covered under EN 14041 standard);
- Parquet and wood flooring (since 2011) (as covered under EN 14342 standard);
- parquet adhesives and coatings (since 2011); and
- floor covering adhesives and flooring underlays (since 1 January 2012).

On 21 June 2012, the European Commission referred Germany to the European Court of Justice for failing to respect EU rules governing the harmonisation of the marketing of construction products. The EU considers the Ü mark a barrier to trade as it imposes additional requirements for products which are already covered by European harmonised standards and bear the CE mark. This makes it more difficult for manufacturers (whose products have the CE mark) to sell their products on the German market.

Other EU Developments

The presence of different national labelling schemes may create barriers to trade (due to different criteria and types of materials in question) and also may cause confusion for the end consumer (ECA, 2005). It is widely recognised that a Europe-wide harmonised labelling scheme for emissions from indoor products is required. This has been recognised by the European Commission and work has already been conducted with regards harmonisation at the European level. ECA (European Collaborative Action) has established a working group of 27 European experts to oversee the development and introduction of a harmonised indoor products labelling scheme within the EU. While a harmonised scheme has not yet been established, it is likely that any such scheme would evolve from those already implemented and experiencing success in individual Member States (ECA, 2012).

LCI Values

LCI values are the 'Lowest Concentration of Interest' values which are auxiliary parameters used in the health-related evaluation of emissions of individual substances from building products (Umweltbundesamt, 2012). LCI values should be derived on the basis of either air quality guidelines or occupational exposure limits as parameters for the assessment of the health risk resulting from exposure to chemicals emitted from building materials (IHCP-JRC, 2012). The concept of LCI values has been developed in the German AgBB scheme and in the French AFSSET (now ANSES) protocol for the health related evaluation of VOC emissions of building products (IHCP-JRC, 2012).

It is important to distinguish LCI values from the Indoor Air Quality guidelines (IAQG). IAQG intend to give a safe level of exposure over a lifetime while LCI values are only to be used as a comparative value concerning the emissions of products at the 28th day of measurements and for testing chamber conditions described in the horizontal standard prepared by CEN TC 351. Therefore, LCI values are to be considered "safe" for single products at the 28th day of emission (JRC, 2011).

Work is currently on-going in the harmonisation of indoor air related activities within the EU. The aim is to create an EU harmonised list of LCI values for approximately 170 chemicals and their toxicological thresholds relevant to human health by the end of 2012. The notification regulations used in Germany and France (which already have published lists of LCI values) form the basis for the harmonisation process (EC, 2012b).

5.9 Wood Products

5.9.1 Construction Products Regulation

The Construction Products Directive (CPD) (89/106/EEC) was introduced in 1988 with the aim of removing the technical barriers to trade in construction products in Member States of the EU. The CPD introduced harmonised technical specifications and the mandatory CE marking of construction products in most Member States of the EU (from 2004) in order to show compliance with the Directive. For over a decade, it has been mandatory for manufacturers/suppliers of WBP intended for '*incorporation in a permanent manner in construction works*' to be able to demonstrate that their products, and therefore the structures they are built into, will comply with the CPD (TRADA, 2005). The CPD was implemented through national transpositions of the Directive into the national laws of Member States and the most straightforward route to achieving compliance was by complying with the harmonised standard for WBP, *EN 13986: 2004 Wood-based panels for use in construction - Characteristics, evaluation of conformity and marking*.

In all EU Member States (apart from the UK, Ireland, Sweden and Portugal), the only way to show compliance with the CPD was by CE marking; in other words, compliance with the Directive was mandatory EU-wide but applying the CE mark was not (SSTA, 2012). In the UK, compliance could be demonstrated by an independent assessment and certification of fitness for purpose for a specific end use. In practice, some of the WBP produced in these countries (e.g. the UK) are internationally traded and hence carry the CE mark (TRADA, 2005).

In discussing the scope of the CPD, it is important to note that whilst the requirements for panels for use in construction are covered by the CPD and the harmonised CEN standard, these systems are not necessarily applicable to non-construction applications (e.g. furniture, shop fittings, packaging and transport). As noted in WPIF (2008), because the end use of a panel is often unknown at the time of manufacture; in practice, many general purpose products used in non-construction applications may still be those produced in accordance with the requirements of the CPD and/or EN specification standards (particularly if this suits the control system in operation at the factory). This is however, not compulsory and an alternative specification can be agreed between the customer and supplier (WPIF, 2008).
The Construction Products Regulation (CPR) (305/2011/EU) entered into force in March 2011 and repeals the Construction Products Directive (CPD). Significant parts of the main articles of the CPR will apply from 1 July 2013 and as a result the CPD remains in application until this date. Unlike the CPD, there is no option for countries to opt out of the CPR and as a result the CE marking of construction products will be required in all EU Member States from July 2013.

The CPR requires that all construction products bear the CE marking before being placed legally on the European market. For WBP to receive the required CE mark they must comply with harmonised 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 the mechanism by which specific products such as plywood, flaxboard, particleboard, MDF, OSB, CBPB and fibreboard are able to satisfy the CPD (WPIF, 2008).

5.9.2 European Standards

One of the initial steps taken to reduce formaldehyde emissions was to standardise 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 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. 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.

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.

Table 5.9 overleaf presents the limit values for which WBP must comply to be classified as either E1 or E2 according to Annex B of EN 13986. Importantly, these tests are not required for those WBP to which no formaldehyde containing materials were added during production or in post-production processing. These WBP may be classified E1 without testing (Schwab et al, nd). For example, MDI based panels are automatically classified to E1 standard without testing (EC, 2010).

It is important to bear in mind that the procedure to be followed by notified bodies (who are required to attest to the conformity of WBP as required for CE marking of WBP) to grant and maintain the Certificate of Factory Production Control has four parts (GNB-CPD, 2010):

- the application;
- the initial inspection of the factory and the Factory Production Control (FPC system);
- the issuing of the certificate; and
- the continuous surveillance (audit) of the FPC system.

Table 5.9: Limit Values for E1 and E2 WBP

		E1 WBP			E2 WBP		
		Unfaced	**Unfaced**	**Coated, overlaid or veneered**	**Unfaced**	**Unfaced**	**Coated, overlaid or veneered**
		Particleboard OSB MDF	Plywood Solid Wood Panels LVL	Particleboard OSB, MDF Plywood Solid Wood Panels Fibreboards (wet process) Cement Bonded-Particleboards, LVL	Particleboard OSB, MDF	Plywood Solid Wood Panels	Particleboard OSB, MDF Plywood Solid Wood Panels Fibreboards (wet process) Cement Bonded-Particleboards
Initial Type Testing*	**Test Method**	ENV 717-1			ENV 717-1		
	Requirement	Release ≤0.124 mg/m³ air			Release ≥0.124 mg/m³ air***		
	Test Method				EN 120	EN 717-2	
	Requirement				Content > 8mg/100g to ≤30mg/100g ovendry board	Release > 3.5mg/m²h to ≤8mg/m²h Or >5mg/m²h to ≤12mg/m²h within 3 days after production	Release > 3.5mg/m²h to ≤8mg/m²h
Factory Production Control	**Test Method**	EN 120	EN 717-2		EN 120	EN 717-2	
	Requirement	Content ≤ 8mg/100g oven dry board**	Release ≤3.5mg/m²h Or ≤5mg/m² within 3 days after production	Release ≤3.5mg/m²h	Content > 8mg/100g to ≤30mg/100g ovendry board **	Release > 3.5mg/m²h to ≤8mg/m²h Or >5mg/m²h to ≤12mg/m²h within 3 days after production	Release > 3.5mg/m²h to ≤8mg/m²h

Source: WPIF (2008)

** For established products, initial type testing may be done on the basis of existing data with EN 120/EN717-2 testing, either from factory production control or from external inspection.*

*** experience has shown that to guarantee compliance with the limits the rolling average of the EN 120 values found from the internal factory control over a period of 6 months should not exceed 6.5mg formaldehyde/10-0g panel mass for particleboards and OSB or 7mg formaldehyde/100g panel mass for MDF.*

**** the corresponding upper requirement limits for E2 boards are found from the EN 120 or ENV 717-2 factory production/external control tests*

Table 5.10 below summarises the information presented in Table 5.9.

Table 5.10: Summary of Current Formaldehyde Emission Limits for WBP in Europe		
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)
Source: Athanassiadou et al, 2009		

Table 5.11 below provides a clarification of the different units used in the measurement of formaldehyde and referenced throughout this report.

Table 5.11: Clarification of units used for criteria related to emission of formaldehyde from articles or products
Criteria for and values representing emission of formaldehyde from articles or products are generally expressed in either emitted mass per square meter of emitting material per time (e.g. mg/m2/hour) or in concentrations reached in specific, standardised, emission tests (e.g. ppm or mg/m3) (at equilibrium). Criteria or values on emission of formaldehyde are very dependent on the conditions and methods of the emission test used. Factors influencing the values in these tests and leading to differences in results of different tests include the surface area of emitting material per volume of room (loading rate), the temperature in the test chamber, the air exchange rate and the relative air exchange per surface area of emitting material. Emission values or criteria (expressed in concentration units) are <u>not</u> estimates of concentrations in real life situations, because such situations can differ substantially from the standardized conditions in the emission tests.

In addition to the above obligatory standard, the industry also has further standards which are of relevance. For instance, the WPIF have produced an Industry Standard for non-construction products (IS (WPIF) 1/2002 "*Wood-based panels: Particleboards, Fibreboards and Oriented Strand Boards (OSB) for non-construction uses*"). This Industry Standard specifies the requirements for a number of types and classes of non-load-bearing WBP for supply in circumstances where they are not intended, by either the vendor or the purchaser, to be used for construction purposes in the building or civil engineering sectors. The standard defines a series of types of particleboards, fibreboards and OSB (plywood and flaxboard are not included at present). For each type, the standard defines (WPIF, 2008):

- mean tolerances of nominal dimensions, straightness, squareness and flatness;
- mean quality levels for bending strength, modulus of elasticity, internal bond, surface;
- soundness, screw withdrawal, thickness swelling
- formaldehyde content/release; and
- moisture content.

Note also that products outside the scope of EN 13986 may be CE marked through a European Technical Approval (ETA) using a European Technical Approval Guideline (ETAG) or a Common Understanding of Assessment Procedure (CUAP) (TRADA, 2005).

5.9.3 National Regulations

There is existing legislation in various MS 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) are allowed to be placed on the market in these countries.

- In the **Netherlands**, the Fibreboard Act of 1986 places restrictions on the content and release of formaldehyde from WBP. It establishes that the maximum formaldehyde content of fibreboard (which is defined as board consisting of small particles of wood or other lignocellulose containing materials, tied together by an organic substance) is 10mg per 100g absolute dry board. Furthermore, the maximum formaldehyde emission from fibreboard is set at 0.1ppm (concentration in the relevant emission test). This legislation does not apply to fibreboard used in or intended for use in furniture (CBI, 2011b) but applies to domestic manufacturers and those importing fibreboard to the Netherlands.

- In 1990, **Austria** introduced restrictions on certain formaldehyde containing substances, preparations and finished products. Under these restriction, WBP (particleboards, coated particleboards, wood-core plywood, veneer plywood panels, single- or multi-layer solid timber panels (natural wood panels) and fibreboard panels, including MDF) are not to be placed on the market if they exceed emissions of 0.1ppm (in a test chamber) (IHS EIA Track, 2011). Furniture, wall panels etc. are not be placed on the market if they do not comply with these requirements (RIS, 2013).

- In 1991, **Sweden** introduced restrictions on formaldehyde emissions from WBP (particleboard, fibreboard, and others). The Swedish regulations (KIFS 1989:5 and KIFS 1993:3) indicate that emissions of formaldehyde from WBP should not lead to concentrations exceeding 0.13mg/m³ (~0.14ppm) of formaldehyde, when testing according to the Swedish Standard SS270236 (EC, 1990). All Swedish manufactured wood products must meet this requirement and it is also required of imports of wood products (Husbyggaren, 2007).

- Within **Germany**, the Chemical Regulation of 14 October 1993 imposes restrictions on the use of formaldehyde in WBP. All WBP (whether coated or uncoated) marketed in Germany must fall within emission class E1 of the European Standard and therefore all panels must not exceed emission levels of 0.1ppm (defined as a concentration in the relevant emission test). Chipboard, carpenter boards, furniture panels, veneer panels and fibreboard which are used in the building and furniture industries are covered by this legislation. Furthermore, the legislation also prohibits the marketing of furniture containing fibreboard that does not comply with the 0.1ppm limit (concentration as measured in the relevant emission test). Importantly, this legislation applies to products manufactured and sold within Germany and also to products which are imported (CBI, 2011).

- In **Italy**, restrictions on WBP with formaldehyde emissions which are higher than 0.1ppm (concentration in relevant emission test - E1 standard) were introduced from December

2008 (). This applies to WBP and furniture made with WBP as well as semi-finished and finished products containing formaldehyde. It was introduced into Italian law by the Ministry of Labour, Health and Social Policy through Ministerial Decree 10/10/2008 (Panguaneta, 2013; Xilo1934, 2012; Tumidei Spa, 2012).

- In 2009, **Greece** introduced limits on formaldehyde emissions from furniture and WBP. The regulation states that it is necessary for WBP and furniture to comply with (at least) the E1 formaldehyde emission standard. This applies to locally produced WBP as well as imported WBP. The restriction covers particleboard, fibreboard (including MDF), OSB and plywood and also applies to coated and veneered WBP and also to furniture manufactured using WBP (Mantanis et al, nd).

- In **Denmark**, under current chemicals regulations, particleboard, plywood and other WBP containing formaldehyde emitting glue may only be used in furniture and furnishings if they release no more than 0.15mg/m³ of formaldehyde when tested in a climate chamber (Danish EPA, 2011). If a company is unable to provide documentation of the fulfilment of this requirement, they are permitted to use WBP with a maximum free formaldehyde content of 25mg per 100g dry matter in the panel (Danish EPA, 2011). This regulation applies to both those who produce WBP, furniture and furnishings and those who import them. Under buildings regulations in **Denmark**, WBP containing glue that emits formaldehyde can only be used if it is proven that the emission of formaldehyde does not result in an unhealthy indoor climate (Danish Ministry of Economic and Business Affairs, 2007). This functional requirement is complied with if the CE marking shows that the WBP complies with the E1 standard (EN 13986). Importantly, this regulation applies only to WBP which contain glue that emits formaldehyde, therefore WBP manufactured using PF, RF or isocyanates are not included in this restriction (Danish Ministry of Economic and Business Affairs, 2007).

5.9.4 Industry Voluntary Agreement

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 emission levels for WBP than existing European standards. 'E1plus' requires formaldehyde release of 0.08mg/m³ (corresponding to 0.065ppm concentration in relevant emission test) for wood based materials used in construction, using the chamber method EN 717-1. It is intended that the 'E1plus' category will be included in a new version of the European Standard EN 13986, potentially in early 2013 (Haas Group, nd). 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) (Fraunhofer WKI, 2012):

- particleboard;
- OSB;
- MDF;
- flaxboards;
- plywood;
- LVL;
- solid wood panels;
- fibreboards; and
- cement bonded particleboards.

5.9.5 International Developments

US

In the US, formaldehyde is regulated by a number of agencies. The most important and stringent changes to formaldehyde standards were first introduced in 2007 and approved in April 2008 by the Office of Administrative Law. The California Air Resources Board (CARB) passed a law limiting the amount of formaldehyde emissions from composite wood products (i.e. particle board, medium density fibreboard (MDF) and interior plywood) and finished goods (e.g. doors, windows, furniture and other finished products) that contain composite wood products that are sold, supplied, used, or manufactured for sale in California.

Prior to the introduction of CARB standards, in the USA, formaldehyde emission limits for particleboard and MDF were 0.30 ppm according to national voluntary standards ANSI A208.1 and 2 respectively. The limit for industrial plywood was also 0.30ppm while plywood wall panels were 0.20 ppm (Athanassiadou et al, 2009).

As shown in the Table below, from January 1, 2009, the CARB Phase 1 formaldehyde emission regulation took effect for hardwood plywood, particleboard, and MDF. More stringent CARB 2 emission regulation became obligatory through a phased introduction between 2010 and 2012.

Table 5.12: CARB Emission Limit Values

Effective Date	Phase	Emission Limits (ppm)			
		Hardwood Plywood		Particleboard	MDF
		Veneer Core	Composite Core		
Jan 2009	CARB 1	0.08	0.08*	0.18	0.21
Jan 2010	CARB 1	0.05			
Jan 2011	CARB 2			0.09	0.11
Jan 2012	CARB 2		0.05		-

In addition to a phased introduction of the CARB standards, a significant lead-in period was provided for manufacturers, distributors and retailers of affected products allowing them time to comply with the new standards. However, due to slow sales and the poor economic climate, many extensions have been made to allow the market to adapt to the new

standards. For example, in California in February 2012, the CARB advised that it would be possible for retailers to continue selling finished goods regardless of type, until 31 December 2013 (SGS, 2012). This is one of many extensions to sell through dates that have been made since the introduction of CARB emission standards in California.

The CARB system uses the ASTM E-1333-96 test method and measures the formaldehyde concentration in the air and the emission rate from wood products (ASTM, 2013). As of 2009, 16 other states in the US had adopted CARB rules and, as such, the legislation has broader implications. On 7 July 2010, *the 'Formaldehyde Standards for Composite Wood Products Act'* was signed into law in the US. The Act adopts the emission standards for composite wood products (hardwood plywood, MDF and particleboard) established by CARB and implemented in the State of California. The Act will apply on a national scale from January 2013 (EPA, 2011; Chimar Hellas, 2011).

Because CARB standards are now being extended across much of the US, some major European-based manufacturers and retailers have opted to standardise their output so that it can be marketed across all their markets and hence are including CARB 2 in their procurement specification in Europe (Medite, nd). It is expected that Europe and Asia will follow US trends closely due to the global nature of trade. This could have significant implications as Europe's E1 class emission limit for hardwood plywood is currently 0.1 ppm (test method EN120).

For CARB, all testing must be conducted in accordance to ASTM E1333 (Large Chamber Test Method). Research conducted during the promulgation of the CARB standard clearly showed that polyvinyl acetate, soy-based and MDI based adhesives had negligible levels of formaldehyde, if any, during the chamber testing. CARB exempts these adhesive products from third-party testing but requires the board manufacturers to perform on-going testing. It is, however, not mandatory that all adhesives used be formaldehyde-free (Franklin Adhesives, nd). Special conditions are also in place for manufacturers of hardwood plywood, particleboard and MDF which are manufactured using ULEF, for example they are able to test their products less frequently.

Japan

The Japanese formaldehyde emission standards are one of the most stringent formaldehyde emission standards in the world. They were introduced in 2002 following concern for public health due to poor indoor air quality (Sick House Syndrome) and with the aim of reducing VOCs in indoor air (Franklin Adhesives and Polymers, nd). Emissions of formaldehyde have been restricted under these standards and since 2003, there have been specific testing and certification requirements for building materials containing formaldehyde (primarily composite wood products) (Franklin Adhesives and Polymers, nd).

The Japanese standard uses a tiered system which goes from one-star (*) to four-stars (****); with four stars representing the lowest formaldehyde emissions and one-star the highest (Franklin Adhesives and Polymers, nd). F**** is widely considered to be the most stringent emission level and is close to the formaldehyde emission levels of solid, untreated wood (Athanassiadou et al, 2009). The Japanese standards use mg/m^2h as the unit of measure which refers to the level of emissions of formaldehyde from WBP while other standards use units of concentration (such as ppm) to express the concentration of

formaldehyde in the air following testing. Products with emission levels which are categorised as F* are high emitting and their use is prohibited in Japan. Only WBP certified as F**** are permitted for use in all interior applications. The use of WBP certified as F** and F*** is subject to additional restrictions based upon the type of room and frequency of ventilation (MLIT, 2003). Table 5.13 below summarises the Japanese formaldehyde emission standards. All testing is done in accordance with either JIS A 1460-2001 (desiccator method) or JIS A 1901-2003 (small chamber method). All products being placed on the Japanese market must be approved by the Ministry of Land, Infrastructure and Transport.

Table 5.13: Japanese JIS/JAS Formaldehyde Emission Standards from WBP

	mg/m²h	mg/L	ppm (approximate)	Restrictions
F*	>0.12			Use prohibited
F**	>0.02 - <0.12	1.5 – 2.1	HWPW/PB – 0.14 MDF – 0.10	Limited area of use (dependent on type of room & ventilation)
F***	>0.005 - <0.02	0.5 – 0.7	All products 0.07	
F****	Up to 0.005	0.3 – 0.4	All products 0.04	None

Source: CWC (ndb); BCJ (2009)
Note: HWPW – hardwood plywood; PB – particleboard; MDF – medium density fibreboard

Australia

The Engineered Wood Products Association of Australasia (EWPAA) has introduced a formaldehyde testing and labelling program which has been adopted by industry in both Australia and New Zealand. Manufacturers complying with the program are able to brand their product with the appropriate formaldehyde emission class, which are provided in Table 5.14 below. A 'Super E0' class which has extremely low emission levels of 0.3 mg/L is also part of the EWPAA program; however this is an industry limit only and is not incorporated into national standards (EWPAA, 2011). These emission classes (with the exception of Super E0) have also been incorporated into the Australia and New Zealand national product standards.

Table 5.14: EWPAA Formaldehyde Emission Labelling Program

	Emission Limit (mg/L)	Emission Limit (ppm)
Super E0	≤ 0.3*	
E0	≤ 0.5	≤ 0.041
E1	≤ 1.0	≤ 0.08
E2	≤ 2.0	≤ 0.16
E3	> 2.0	> 0.16

Source: EWPAA (nd)
Note: * the Super E0 classification is an industry limit only.

6. DESCRIPTION OF POTENTIAL RISK MANAGEMENT OPTIONS

6.1 Potential RMOs

6.1.1 Overview

Section 5 identified the range of potential risk management options (RMOs) which may be considered for addressing the concerns and/or risks associated with formaldehyde. The RMOs which are potentially of the most relevance are:

a) harmonised classification and labelling;
b) introduction of restrictions under REACH;
c) introduction of a harmonised OEL value;
d) inclusion in the REACH Candidate list and the Authorisation process; and
e) introduction of additional voluntary measures.

These are considered below.

6.1.2 A - Harmonised Classification and Labelling

As noted in Section 5, ECHA recently announced the adoption of a scientific opinion of the RAC proposing that formaldehyde be classified as carcinogen category 1B and germ cell mutagen category 2 under the CLP Regulation. This proposal will be considered by the Commission and EU Member States and a new classification for formaldehyde (with implications for labelling) could be adopted by 2015. This RMO is, therefore, already under consideration within the right channels and procedures under the CLP Regulation.

6.1.3 B - Restrictions

As noted in Section 4, the most appropriate RMO must focus on the area of key concern which is releases of formaldehyde from WBP. This is because restrictions on formaldehyde or formaldehyde-based resins in WBP are unlikely to be either appropriate or proportionate for dealing with the key concerns.

EC (2013) also notes that there are potential synergies between the Construction Products Regulation (CPR) (305/2011/EU) and the REACH Regulation, wherein information collected by duty holders under one piece of legislation could be relevant to the other. It particularly notes that while harmonised standards will not address chemical safety as such, but they provide test methods which allow manufacturers to show compliance with relevant chemicals legislation (e.g. REACH restrictions).

Currently, for WBP to comply with the CPR and receive the CE mark, they must comply with the Harmonised European Standard *EN 13986,* which sets the minimum safety requirements for WBP. Annex B of EN 13986 establishes two classes of WBP, E1 and E2, based on formaldehyde emissions. 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. Over the last few years, there has been a lot of scientific and technical work which has gone into updating the

Harmonised Standard EN 13986. Of key relevance, is the proposed inclusion of a new formaldehyde class in Annex B known as E1plus (in addition to E1 and E2). This European Standard is not intended to be applicable to WBP for use in non-construction applications.

In order to maximise synergies between the CPR and REACH Regulations, two possible restrictions could be considered:

- **Restrictions 1**: Restrictions on WBP with formaldehyde emissions equal to or higher than E1 emission standard (defined as a concentration of 0.1ppm in the relevant emission test); and

- **Restrictions 2**: Restrictions on WBP with formaldehyde emissions equal to or higher than the E1plus standard (defined as a concentration of 0.065ppm in the relevant emission test).

6.1.4 C - Harmonised OEL

As discussed in Section 5, there are various national OELs for formaldehyde across the EU Member States. There are also on-going regulatory discussions regarding an OEL at the EU level; SCOEL is currently reviewing its formaldehyde recommendation in preparation for a new list of IOELVs and formaldehyde is one of 41 candidate substances currently being reviewed for the 4th IOELV Directive (Wriedt, 2012).

A key element of the CSA is the development of derived no-effect levels (DNEL) for effects where a threshold response is shown. The DNEL defines the level of exposure at which no adverse effects are anticipated and is precautionary in nature. However, EC (2010) notes that "*where both a national OEL and a DNEL (for both the same duration and the same route of exposure) have been derived for a substance, and the risk management measures in the safety data sheet are significantly more restrictive, employers continue to remain responsible for the protection of their employees, and should seek to resolve the situation with their suppliers and, as appropriate, with the relevant national authorities*".

If formaldehyde is reclassified as discussed earlier, it is possible that a binding OEL could be introduced under the Carcinogens and Mutagens Directive. In this context, it is noted that during negotiations for the 3rd IOELV Directive, it was proposed that formaldehyde be removed from the 3rd IOELV Directive and a binding limit taking into account socio-economic factors be introduced in due course – an IOELV of 0.3ppm was indicated as having merit according to studies undertaken by the UK HSE (UK HSE, 2008).

Two possible OELs could be considered:

- **OEL 1**: Introduction of a harmonised OEL of 0.4ppm (TWA) in line with the DN(M)EL of 0.5 mg/m³ (~0.4 ppm) in the CSR; and

- **OEL 2**: Introduction of a harmonised (binding) OEL of 0.3ppm (TWA) in line with the existing proposal of a binding OEL of 0.3ppm or of an even lower value (0.2ppm).

6.1.5 D - Inclusion in the REACH Candidate list and the Authorisation process

As discussed in Section 5, the authorisation requirement may only be triggered if (a) formaldehyde is reclassified as a Carcinogen Cat 1B and Mutagen Cat 2 and (b) Member States or ECHA (on the European Commission's request) decide to prepare an Annex XV Substance of Very High Concern (SVHC) dossier for the substance. This RMO is, therefore, dependent on the outcome of other regulatory developments which are uncertain.

6.1.6 E - Voluntary Measures

As noted in Section 5, there are a number of labelling schemes which are already in place at both the national and European levels which have their own specific requirements for testing and criteria for product evaluation. These schemes are, for the most part, voluntary; some are government schemes and others are private/industry based and promoted. There is also the industry agreement amongst the members of the European Panel Federation (EPF) to produce only E1 boards. It is, therefore, the case that there is scope for further RMOs to be introduced as part of an industry voluntary agreement.

6.2 Scenarios

6.2.1 Need for Scenarios

A consideration of the RMOs identified above for consideration highlights a number of problems which may complicate their assessment.

Firstly, discussions on revised classification and labelling are currently on-going and the final outcome of these discussions cannot be pre-judged. Currently, the findings of the risk assessment reports (See Section 3) indicate that risks are currently adequately controlled; however, there is the REACH evaluation procedure which is also on-going and which may conclude that there are risks (or not) and, if so, the findings of this exercise could impact on the identification of the most appropriate RMOs. Although a standalone RMO, the relevance of the Authorisation process for managing any risks from formaldehyde depends on the outcome of the reclassification.

Taking into account all of these variables, three scenarios have been considered, with each scenario composed of a number of RMOs and RMMs for workers and consumers, as follows:

- **Scenario 1** is the **Baseline Scenario** and anticipates that no further risk management action is required beyond those existing at present. It assumes full compliance with the current legal requirements under REACH (and other relevant legislation); in particular, the requirement to ensure the safe use of the substance for each exposed population during all the lifecycle stages of the substance, including the waste stage and the article service life, where applicable.

- **Scenario 2** is a **Risk-based Scenario** which considers the most appropriate RMO based on the risk assessment (see Manen-Vernooij *et al.*, 2013 and Marquart *et al.*, 2013). RMOs considered under this Scenario are intended to ensure an adequate level of protection for EU workers and consumers, avoid confusion for employees and employers in ensuring such protection, minimise the potential for unfair competition

between economic operators on the EU market and enhance the harmonisation of the internal market. In this regard, two specific RMOs are considered:

- For **workers**, introduction of a harmonised OEL at 0.4, 0.3 or 0.2 ppm; and
- For **consumers**, restrictions on WBP with formaldehyde emissions equal to or higher than E1 or E1plus emission standard (defined as a concentration of 0.1ppm in the relevant emission test)

In this Scenario, also the potential impacts of a revised classification for formaldehyde, taking account of on-going discussions at the EU level, are taken into account. Relevant elements under this part of the Scenario are:

a) New harmonised classification and labelling will be introduced under the **CLP Regulation**;

b) Substitution of formaldehyde and risk management will be required **under the Carcinogens and Mutagens Directive (CMD)**;

c) Substitution of formaldehyde will be required under the **Industrial Emissions Directive (IED)**[6];

d) Registrants would be required to **update their registration dossiers**, including CSRs;

e) **Restrictions** on consumer use introduced under the REACH Regulation;

f) Protection of young people and pregnant workers will be required under specific EU legislation.

- **Scenario 3** is the **Authorisation Scenario** and considers a situation where formaldehyde is subject to the Authorisation Procedure under REACH. Note that if reclassification of formaldehyde does not go through, it is unlikely that Scenario 3 will be implemented. This means that the benefits of Scenario 3 cannot be compared against the baseline (as for Scenario 2) but against the benefits of Scenario 2.

[6].VOC Directive 1999/13/EC "on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations" will be repealed by the IED (2010/75/EU)directive as of January 2014, which is already applicable to all industrial emissions, not only solvents. The IED directive is currently not yet implemented in many member states

7. COMPARISON OF POTENTIAL RISK MANAGEMENT OPTIONS

7.1 Criteria for Assessment of Risk Management Options

There are three key criteria when assessing and comparing further RMOs; these are:

- **effectiveness**: the measure must be targeted at the risks and routes of exposure identified by the risk assessment. The measure must be capable of reducing the risks that need to be limited within and over a reasonable period of time;
- **practicality**: the measure should be implementable, enforceable and as simple as possible to manage. Priority should be given to commonly used measures that could be carried out within the existing infrastructure (though not to the exclusion of novel measures); and
- **monitorability**: monitoring should be possible to allow the success of risk reduction to be assessed.

The following sections analyse the identified RMOs and Scenarios taking into account the above criteria. Note that, under REACH, possible restrictions are to be assessed against the first three key criteria (effectiveness, practicality and monitorability) while economic impacts are considered separately under the Socio-economic Analysis (SEA) module.

7.2 Effectiveness of Potential Risk Management Options

7.2.1 Scenario 1

Workers

Scenario 1 (the baseline scenario) describes the current situation and assumes that there are no unacceptable risks to workers from formaldehyde, taking into account existing RMMs. All exposure scenarios have been calculated to be safe using monitoring data and models. The risk assessment/CSR also indicates that adequate control of the risks to workers is possible under specific OCs and applying specific RMMs. Effectively, Scenario 1 anticipates that:

- the on-going reclassification of formaldehyde as a Carcinogenic Cat 1B and Mutagenic Cat 2 substance is found to be scientifically unjustified and, as such, will not be implemented;
- the substance evaluation under REACH concludes that the risks are adequately controlled; and
- there are no changes from the existing OEL values across the Member States.

No additional RMOs are proposed under Scenario 1 and, as such, there is no additional effort required from stakeholders to minimise, as far as technically and practically possible, exposure to and emissions of formaldehyde.

Taking into account the present concerns of regulatory authorities, it is questionable whether Scenario 1 can be considered effective moving forwards. For workers, the existence of divergent OELs across EU Member States as shown in Table 5.2 would appear to suggest that certain workers are not being adequately protected (or at best, being wrongly informed) about the risks. At one extreme, the Netherlands has an OEL of 0.12ppm while the UK, Ireland and Greece have an OEL of 2ppm. These variations in national OELs are due to differences in assessment approaches, rather than relating to the actual risk of formaldehyde itself and, as such, may be considered a cause for concern by some authorities. In addition, the DNEL for formaldehyde is more stringent (lower) than the OEL for a number of countries, which according to EC (2013) indicates that "*the employer has obtained new scientific information which indicated that the OEL does not provide the appropriate level of protection".* In this regard, it is worth noting that EC (2010) indicates that addressing the issue of the divergence of OEL and DNEL values is the responsibility of the industry.

Consumers

Similar to the above, Scenario 1 assumes that there is no need for additional risk management for consumers. On this basis, Scenario 1 is unlikely to result in any change in current controls on formaldehyde exposure.

Considering the concerns of regulatory authorities, especially with regard to carcinogenicity, it is questionable whether Scenario 1 can be considered effective moving forwards, particularly as it will not require companies to shift to alternatives where possible. More generally, the EU would appear (at the present time) to be lagging behind other major countries in terms of initiatives and schemes (voluntary and regulatory) which have been put in place to encourage companies to produce WBP with lower formaldehyde emissions. Table 7.1 provides a summary comparison of formaldehyde emission standards in Europe, US, Japan and Australia.

Table 7.1: Comparison of Formaldehyde Emission Standards in Europe, USA, Japan and Australia (ppm)

Europe	USA CARB	Japan	Australia
E2 (≥0.1)			E3 (≥0.16)
E1 (≤0.1)	Phase 1 (0.08-0.21)	F** (0.10-0.14)	E2 (≤0.16)
	Phase 2 (0.05-0.13)	F*** (0.07)	E1 (≤0.08)
		F**** (0.04)	E0 (≤0.041)
Source: CARB (2007); Chimar Hellas (2008); CWC (ndb); EWPAA (nd)			

Within the EU, there are also a few countries which have restricted the use of E2 WBP, with only E1 WBP allowed. The risk assessment also indicates that a reasonable worst-case exposure scenario of a wardrobe in a European Reference room with both ceiling and floor made up of wood-based products, conforming to the E1 emission standard resulted in a maximum formaldehyde concentration of 0.093 mg/m^3 which is below the DNEL of 0.1 mg/m^3. Within this context, it is questionable whether Scenario 1 can be considered

effective in controlling risks relating to formaldehyde for consumers and authorities are likely to require action whether for precautionary reasons, addressing the risk of cumulative exposure or for market harmonisation reasons.

Overall, Scenario 1 neither addresses the risks of concern nor reduces current exposure to levels that allow for adequate control of these risks.

7.2.2 Scenario 2

Workers - OELs

Currently, OELs are set by competent national authorities or other relevant national institutions as limits for concentrations of hazardous compounds in workplace air.

There are varying OELs currently existing across Member States, mainly due to divergences in assessment approaches of the actual 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.

The first option in this Scenario is the introduction of a harmonised EU-wide OEL of 0.4ppm (TWA). This could be done an indicative OEL value under Art 3 (3) of the Chemical Agents Directive, or, if formaldehyde is reclassified as Carc. 1B, it could be a binding OEL introduced under the Carcinogens and Mutagens Directive. BOELVs take account of socio-economic and technical feasibility factors as well as the factors considered when establishing IOELVs. As noted in Art 3 (4) Council Directive 98/24/EC, when setting a BOELV policy considerations are of major importance.
In practice, for 24 MS[7], an OEL of 0.4ppm will imply:

- Significant changes in **five MS**: Greece, Ireland, United Kingdom with a current OEL of 2.0ppm, as well as Bulgaria (0.8ppm) and Romania (1ppm);
- Minimal changes in **eight MS** (with an OEL of 0.5ppm)**:** Austria, Czech Republic Estonia, France, Hungary, Lithuania, Slovenia and Sweden;
- No change in **two MS** (with an OEL of 0.4ppm): Latvia and Poland; and
- a more stringent OEL continuing to be in place in **nine MS** (countries which currently have an OEL lower than 0.4ppm): Belgium, Denmark, Finland, Germany, Italy, Portugal, Slovakia, Spain and Netherlands.

Overall, workers in 13 MS would be impacted by the introduction of a harmonised OEL, where this provides more clarity regarding risk communication and ensures adequate control of the risks in the workplace.

For nine MS, there would be a continuing situation whereby the national OELs are more stringent than the DNEL and, as such, are likely to be more protective – although the

[7] For Malta, an OEL does not exist and for Cyprus, Luxembourg and Croatia, the situation is unknown.

benefits of such additional protection are uncertain (seeing as there is adequate control of workplace risks at 0.4ppm).

One potential advantage of introducing the harmonised OEL under the CAD is that Member State authorities can still deviate from the indicated value in accordance with national legislation and practice. In this regard, Scenario 2 is flexible enough for those MS who wish to retain a more stringent OEL. Furthermore, a harmonised OEL of 0.4ppm (at the EU level) will help to ensure an appropriate level of protection for EU workers, avoid confusion for employees and employers in ensuring such protection, minimise the potential for unfair competition between economic operators on the EU market and enhance the harmonisation of the internal market.

The second option is to set a harmonised EU-wide (indicative or binding) OEL at a lower level of either 0.3ppm or 0.2ppm.

In practice, an OEL of 0.3ppm will imply:

- Significant changes in **five MS**: Greece, Ireland, United Kingdom with a current OEL of 2.0ppm, as well as Bulgaria (0.8 ppm) and Romania (1ppm);
- Minimal changes in **ten MS** (with an OEL of 0.4 and 0.5ppm)**:** Austria, Czech Republic Estonia, France, Hungary, Lithuania, Slovenia, Sweden Latvia and Poland;
- No change in **eight MS** (with an OEL of 0.3ppm): Belgium, Denmark, Finland, Germany, Italy, Portugal, Slovakia, Spain; and
- A more stringent OEL being in place in **one MS** (with an OEL lower than 0.3ppm): Netherlands.

Overall, workers in **15 MS** would benefit from the introduction of a harmonised OEL at 0.3ppm, where this provides more clarity regarding risk communication and ensures adequate control of the risks in the workplace. No further action will be required in **eight MS** which already have an OEL of 0.3ppm and this would ensure clear risk communication and harmonisation.

In practice, an OEL of 0.2ppm will imply:

- Significant changes in **twenty three MS**: all MS, except The Netherlands, have a higher OEL now;
- A more stringent OEL being in place in **one MS** (with an OEL lower than 0.2ppm): Netherlands.

Overall, workers in **23 MS** would benefit from the introduction of a harmonised OEL, where this provides more clarity regarding risk communication and ensures adequate control of the risks in the workplace. No further action will be required in **one MS** which already have an OEL lower than 0.2 ppm and this would ensure clear risk communication and harmonisation.

The main advantage of a binding OEL is that for any chemical agent for which a BOELV value is established at EU level, Member States must establish a corresponding national binding OEL value which can be stricter, but cannot exceed the Community limit value (see Art 3 (5) Council Directive 98/24/EC). As noted earlier, a comparison of national limits would show that there are significant differences in OELs which do not correspond to differences in health risks in the respective populations, but to different scientific opinions and

approaches. In this context, a binding OEL is likely to result in additional more stringent controls on workers. An indicative OEL may also lead to more harmonisation, but each MS is allowed to decide to base its OEL on this indicative OEL or to deviate (also upwards) from this value.

The main drawback or OELs lower than 0.4ppm is that, according to the DNEL set by the Formaldehyde consortium, such a lower value does not lead to real reduction of risks.

Workers - Reclassification

In this Scenario 2, also reclassification of formaldehyde will be considered.
In December 2012, the European Chemical Agency (ECHA) announced the adoption of a scientific opinion of the Risk Assessment Committee (RAC) proposing that formaldehyde be classified as Carcinogen Category 1B and germ cell Mutagen Category 2 under the CLP Regulation. This proposal will be considered by the Commission and EU Member States and a new classification for formaldehyde could be adopted by 2015.

If formaldehyde is classified as Carcinogen Cat 1B and Mutagen Cat 2, manufacturers will be required, under the CLP Regulation, to **update their notification to the Classification & Labelling (C&L) Inventory**. The C&L Inventory is a database which contains classification and labelling information on substances notified under the CLP Regulation and registered under the REACH Regulation. It is a tool for hazard communication and a source of basic information on substances placed on the market which meet the criteria for classification as hazardous or are subject to registration, for suppliers of substances, the general public and Member State Competent Authorities (MSCAs). It is also an important tool for hazard communication and risk management, e.g. when MSCAs assess the need for potential Authorisations and Restrictions of hazardous substances under REACH.

There will also be a **requirement for registrants to update their registration dossiers** in line with this development. They will need to demonstrate that their ES and CSR adequately address this new classification (i.e. that the RCR for the various ES is still <1). Also, the revised classification as well as any changes to the ES should also be included in their updated SDS. More broadly, the SDS may need to be updated to reflect updated RMMs & OCs (measures at the site level) which may be relevant for ensuring that any risks are adequately controlled, where these may include, for example, ventilation systems and improved controls at a site-specific level. This approach should be effective as it is specifically targeted at sites of concern and requires the use of techniques which are assumed to be already known to the industry.

Compliance with the Carcinogens and Mutagens Directive will also be required. Compared with the current situation, the CMD requires a higher level of worker protection than currently required under CAD, including:

- carcinogen and mutagen-specific risk assessments “in the case of any activity likely to involve a risk of exposure” (Article 3.2);
- a requirement to reduce and/or substitute, where technically possible, the carcinogenic and/or mutagenic products by other, not or less dangerous products (Article 4); and

- where not technically possible to reduce or substitute, a series of requirements are imposed.

Error! Reference source not found. provides a comparison of the regulatory situation under the CAD and CMD.

Table 7.2: Comparison of the regulatory situation under CAD and CMD		
Obligations for the employer	**Current situation under existing legislation (CAD)**	**Situation under CMD**
- Intended level of protection	Establish minimum EU level of worker protection but open to MS to impose more stringent requirements	Establishment of minimum EU level of protection, requirement to eliminate or minimise use
- Scope	All hazardous chemicals under Annex VI of CLP regulation, including amongst others, Cat 1A, 1B and 2 CMRs	Category 1A and 1B carcinogens (according to CLP) included into CMD (i.e. not Reprotoxin Cat 2)
- Substitution	Risks must be eliminated or reduced to a minimum using a hierarchy of prevention measures, with substitution as the preferred means to achieve this. There is a weaker impetus for replacement than under CMD	Companies would be under increased pressure to substitute carcinogens under the CMD wherever technically feasible or adopt closed system approaches
- if substitution not possible, protection and prevention measures	There are existing requirements for measures to minimise exposure under CAD Hygiene and individual protection are addressed under general principles	If elimination not technically feasible, exposure must be minimised by use of all technically possible means. Stringent requirements regarding hygiene and individual protection Specific requirements regarding amount of substance to be held and to limit access to at-risk areas
- Information and training for workers	Provision of training and information to workers required	More stringent requirements regarding provision of training and information to workers (training must be sufficient to allow workers to be able to assess if Directive is correctly applied)
- Health surveillance	Health surveillance is compulsory for work with a chemical agent for which a binding biological limit value has been set. Individual health and exposure records must be made and kept up-to-date for each worker who undergoes health surveillance	The health of all exposed worker should be adequately monitored and a file kept for at least 40 years from end of exposure
Consultation and participation of workers	Consultation and participation of workers and/or their representatives must take place in accordance with Article 11 of Directive 89/391/EEC	Detailed requirements are explicitly placed on the employer regarding the nature and extent of consultation, participation and information exchange with workers
Other aspects		Duty on employers to record and retain information on risk assessment, exposures, workers potentially exposed and their health for 40 years. Duty on employers to provide information on why substance is used, protective measures in place and numbers exposed to competent authorities on request

The CMD essentially provides a step-by-step approach for risk control, ranging from replacement of the substance, to measures that limit the quantities of a carcinogen at the workplace and keeping as low as possible the number of workers exposed, or likely to be exposed, based on a determination and assessment of risks by the employer. Further requirements include the use of existing appropriate procedures for the measurement of carcinogens and the application of suitable working procedures and methods. Provisions are made for employers to ensure that workers receive sufficient information and appropriate training as well as for Member States who shall establish arrangements for carrying out relevant health surveillance of workers. Furthermore, the possibility to set OEL values is laid down in the Directive.

Specific stringent requirements apply for young persons and pregnant workers under the **Young Workers Directive (94/33/EC) (YWD) and Pregnant Workers Directive (92/85/EEC) (PWD) respectively**. Article 6(1) of PWD provides that pregnant workers may, under no circumstances, be obliged to perform duties for which the assessment has revealed a risk of exposure to the agents and working conditions listed in Annex II, Section A which would jeopardise safety or health. If any of these chemicals are present in the workplace and the workforce includes women of child-bearing age, then the risk assessments must take into account the effects that these substances or processes can have, not just on an expectant or potential future mother but also on the unborn or recently delivered child. The chemical agents and associated work processes which are referred to in the PWD cover: substances labelled with the risk phrases R40, R45, R46, R49, R61, R63, R64 and R68 (i.e. limited evidence of carcinogenic effects, may cause cancer, may cause inheritable genetic damage, may cause cancer by lung inhalation, may cause harm to the unborn child, possible risk of harm to the unborn child, may cause harm to breastfed babies and possible risk of irreversible effects); preparations labelled on the basis of Directive 1999/45/EC; chemical agents and industrial processes in the CMD. The YWD also prohibits the employment of young people for work involving these agents.

Taking the above measures into account, it can be concluded that, due to reclassification, employers will be required to ensure a high level of protection for their workers, as well as provide information to them, which taken together is likely to ensure that exposure is reduced to a level which ensures adequate control of the risks. Also of importance is that the measures identified are directly targeted at the risks of concern, carcinogenicity in particular. These measures should come into effect as soon as reclassification is formalised and, as such, it is possible that the effects could be felt as early as 2014.

That said, the extent of the risk reduction which will be observed will depend on the approach taken by individual MS authorities in interpreting the CMD substitution requirement. If a strict interpretation is adopted (i.e. no formaldehyde-based resins), there is the question of whether the trade-off in risks associated with some of the alternatives is more acceptable. Some of the alternative substances (e.g. p-MDI) pose risks to workers and consumers which are different to those associated with using formaldehyde-based resins. There are also interpretation issues; for instance, some of the alternatives which are not formaldehyde-based, do contain formaldehyde in one form or another (e.g. as a cross-linker). In this context, it is important to bear in mind that the CMD was introduced at a time when it was generally considered by the scientific community that 'no-effect threshold levels' could not be reliably established for carcinogens or mutagens. The control regime

presented in CMD is, therefore, based on the principles of occupational exposure occurring only when there is no alternative substance/system available and with the greatest possible reduction in exposure.

Another relevant consideration is the fact that, according to both the SCOEL and the Formaldehyde REACH consortium, the critical effect of formaldehyde is irritation and not carcinogenicity and that an OEL that protects against irritation will also protect against potential carcinogenicity. In that respect, a properly enforced OEL will be just as effective as the measures following due to reclassification.

Consumers - Restrictions

Scenario 2 introduces EU-wide restrictions on WBP with formaldehyde emissions equal to or higher than E1 or E1plus emission levels (defined as 0.1ppm, respectively 0.065ppm concentration in relevant emission test).

Restrictions based on the E1 emission levels effectively extends the existing industry voluntary agreement (VA) restricting manufacture, use and sale of E2 WBP across the EU (instead of applying to only members of the European Panels Federation (EPF) only). It also harmonises restrictions on E2 WBP which already exist in five EU countries across the EU.

The advantages of a restriction based on E1 emission levels can be summarised as follows:

- the restriction is targeted at a route of exposure of concern (i.e. WBP and imports of high-formaldehyde releasing WBP) and the relevant actors in the supply chain;
- the restriction will not be limited to EPF members and/or signatories to the voluntary agreement, but rather to all EU manufacturers and importers of WBP. Note that it is possible that, despite the EPF voluntary agreement, the quantity of E2 WBP produced in the EU could exceed the quantity of imports;
- the restriction will ensure that E2 WBP cannot be imported and placed on the EU market. It will also protect the EU from becoming a new market for sales of high formaldehyde-releasing wood, which would have been sent to the US prior to the introduction of the *Formaldehyde Standards for Composite Wood Products Act* (note that Class 1 WBP can be up to double the price of E2 WBP);
- there should be no change from the current situation regarding risks from alternatives, as the vast majority of EU companies are able to and currently manufacture WBP which comply with the proposed restrictions;
- the restriction will also ensure that there is no legal loophole in targeting the use of formaldehyde as an intermediate in resin production and then in WBP; and
- there will be a reduction in risks for some homes as a result of the E1 restrictions.

Consumers - reclassification

If formaldehyde is classified as Carcinogen Category 1B, a ‘fast-track’ restriction on consumer use of formaldehyde as a substance, in a preparation or in an article can be

triggered via Article 68(2)[8] of REACH and does not require development of an Annex XV dossier.. Note also that under the Biocidal Products Directive (98/8/EC), CMR substances shall also not be authorised for marketing to, or use by the general public. Note that by effectively restricting consumer use, this restriction may result in positive impacts on the health of workers, although the changes resulting from such a restriction might also lead to increased risks from other hazards (chemical or non-chemical).

Overall evaluation of Scenario 2 and its options

OEL of 0.4ppm and restriction based on E1 criteria, with or without reclassification

By harmonising national requirements, Scenario 2, with an OEL of 0.4ppm and a restriction of wood panel boards with an emission level higher than E1 concentration, could be said to ensure a good balance between costs and benefits and is likely to be considered cost-effective, taking into account that the risks are adequately controlled at present (See Section 3). The proposed RMOs are also consistent with existing legal requirements, especially as they take forward existing national restrictions and harmonised standards. A harmonised OEL and restriction proposal will take some time to be agreed; however, as the industry is in support of both RMOs with these options (OEL of 0.4ppm and restriction based on E1 criteria) it is possible that Scenario 2 could be quickly agreed and the effects could be felt from 2016 onwards.

Overall, it can be concluded that Scenario 2 with these options is targeted at the identified sources of exposure which are of concern and is likely to ensure reduction of the exposure to a level that allows appropriate control of identified risks in a reasonable timeframe. The extent to which the efforts required from industry correspond to the adverse effects avoided, depends on the interpretation of the CMD enforced by MS. If there is reasonable implementation of the CMD requirements, then it is likely that there will be a good balance between costs and benefits under Scenario 2 with the proposed OEL and restriction.

A key benefit of reclassification within this Scenario is that, by virtue of the new OEL being a binding OEL value, Member States cannot deviate from it and, as such, a level playing field will be maintained across the EU. This is also important, taking into account, the latest view of the Commission on OELs and DNELs (EC, 2013) which states that the lowest level between an OEL and DNEL is the one to be complied with by an employer[9]. Having a binding OEL eliminates this problem in future and also ensures a high level of protection for workers.

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8 Article 68(2): For a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply.

9 "The Commission services are of the view that OELs and DNELs (for both the same duration and the same route of exposure) may co-exist, and in some circumstances may apply simultaneously to some work activities. In certain cases, where the guidance allows the registrant to use OEL instead of deriving DNEL, the problem of two different values would not arise. In other cases, it is the Commission's view that, in principle, the lowest level should be complied with by the employer. The binding OEL needs to be always complied with by the relevant employer. In cases when the DNEL is lower than the OEL, the compliance with DNEL is based on the premise that the registrant could not use OEL instead of deriving DNEL for the same exposure route and duration, as he has obtained new scientific information which indicated that the OEL does not provide the appropriate level of protection".

OEL lower than 0.4ppm and restriction based on E1plus criteria, with or without reclassification

Regarding the option of a more stringent OEL at 0.3 or 0.2ppm and a restriction based on E1plus criteria, it can be concluded that these do not clearly produce a lower risk to workers than the option of an OEL at 0.4ppm and a restriction on the basis of E1 criteria. Whereas an OEL of 0.4ppm is already considered sufficiently protective, further lowering of the OEL may lead to a lower probability of any exposure level to be above 0.4 ppm, but at increased costs, that may indirectly be detrimental to the workers, either via lower emphasis on other risks in companies or via plant closures and unemployment.

In terms of effectiveness, harmonising restrictions on the basis of the E1plus emission levels should provide a high level of protection for EU citizens as a result of the restrictions. If such an emission level should be achieved by using an alternative, there may be concerns for workers who may be exposed to risks as a result of some of the alternatives. However, the fact that the restriction does not prescribe how to achieve the 0.065ppm (concentration in relevant emission test) limit means that companies are likely to take great care in selecting the technical means for achieving the standard.

The effect of a reclassification in with these options is the same as with the option of an OEL of 0.4ppm and a restriction based on E1 emission levels.

This restriction is likely to entail significant investment and costs to some companies (and industry in general) and society; as such, it is unlikely that Scenario 2 could be quickly agreed and, at the earliest, any effects could be felt from 2018 onwards. In addition, based on the current risk assessment, it cannot be stated with certainty that the benefits associated with introducing the E1plus standard outweigh the costs which will be incurred by industry and EU citizens.

The proposed RMOs are consistent with existing legal requirements, although harmonised standards and testing requirements for the E1plus need to be introduced within the Construction Products Regulation framework.

7.2.3 Scenario 3

Authorisation is aimed at ensuring that the risks of substances of very high concern (SVHCs) are properly controlled and that such substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. Manufacturers, importers and downstream users applying for authorisations would therefore be required to analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

The inclusion of formaldehyde on the candidate list is unlikely to be effective in reducing exposure to formaldehyde, as it does not specify risk management measures to be taken. However, it does mean that companies will 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.

When included on the Annex XIV list, companies will have to ask for an Authorisation to be able to continue the placing on the market and maintain use of the substance. As part of the Authorisation procedure, companies will have to develop a substitution plan (if suitable alternatives are found). For workers, it should be noted that the CMD and VOC Directive also require substitution and, as such, it is unclear the actual scale of additional benefits under Scenario 3 compared with Scenario 2.

If formaldehyde is identified as an SVHC, manufacturers will be required to comply with Article 33 of the REACH Regulation which places a duty on manufacturers to communicate information on substances in articles, as follows:

1. *Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.*
2. *On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.*

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

For consumers, the disadvantage of the Authorisation route is that imported articles containing formaldehyde would still be allowed, so exposure could possibly continue. Intermediate uses are also excluded from the Authorisation regime (this is important since formaldehyde is mainly used as intermediate). Similar to the lower OELs and the more stringent restrictions evaluated as options under Scenario 2, authorisation is also likely to entail significant costs to companies/industry, it is unlikely that this could be completed quickly and, at the earliest, any effects could be felt from 2018 onwards.

Overall, it is unclear whether there would be a significant difference in the risk reduction capacity under Scenario 3, considering that Scenario 2 would allow for a more targeted action at the sources of risk. While Authorisation provides a blanket approach to the issues of cumulative risk, Scenario 2 is likely to achieve the same end result for consumers. Authorisation is unlikely to be effective as the risk from imported articles is not covered by this route and also intermediate use is excluded. As a result, Scenario 3 may also be considered disproportionate in terms of the adverse effects avoided. On the positive side, the specific rigour applied to assessment of alternatives under authorisation would mean that any concerns relating to an increase in risks from the use of certain alternatives are unlikely to materialise.

7.3 Practicality of Potential Risk Management Options

7.3.1 Scenario 1

The baseline scenario involves no change from the status quo.

7.3.2 Scenario 2

Workers - OELs

For companies in around a third of Member States, there is unlikely to be any practical change if the OEL is chosen at 0.4ppm as they should already be complying with a national OEL of 0.3ppm. The largest change would be seen at 0.2ppm.

Practically speaking, a revised OEL could easily be included in the 4th IOELV Directive (under the CAD); alternatively BOELs could be introduced under the CMD. If the establishment of a BOEL takes time to agree and to implement, there is the option under Article 12 (2) of the CAD, for the Commission to draw up practical guidelines of a non-binding nature to address the protection of the health and safety of workers from the risks related to chemical agents at work. These non-binding guidelines can be drawn up following consultation with the Advisory Committee on Safety, Hygiene and Health Protection at Work (in accordance with Decision 74/325/EEC). Member States will be required to take account of the guidance as far as possible in drawing up their national policies for the protection of the health and safety of workers.

Workers - Reclassification

Under Scenario 2, the procedure for amending the classification and labelling of substances at the EU level is well established. Changes will have to be made to SDS and the information communicated down the supply chain and there is also a fee to ECHA for updating a registration in line with the Fee Regulation (EC) No 340/2008.

The proposed RMOs are understandable to all affected and parties and authorities will be able to set up efficient supervision mechanisms and check compliance with the proposed RMOs, based on current approaches. The administrative burden associated with the RMOs can be considered to be proportional to the risks of concern, assuming a reasonable interpretation of the CMD substitution requirement.

Consumers – Restrictions

The procedure for restricting the marketing and use of substances at the EU level under REACH is well established and clear.
For restriction based on the E1 emission levels, there are no particular issues for the EU producers. However, the advantage of this RMO will be that consumers will also be protected against imports of high-emitting products from outside the EU.

There are two relevant points if a restriction is to be based at E1plus emission levels:

- **Proportionality**: Indoor air inhalation exposure occurs from plywood furniture and floor panels, textiles in furniture and curtains, carpets, wallpapers and insulation, etc. There is a potential risk that an overly stringent restriction may be disproportionate (as a risk management measure) to the imminence (i.e. whether there are threats of serious or irreversible damage) and degree of risks identified in some areas (for instance, where risks are due to elevated background concentrations and consumer behaviour (e.g. smoking)).

- **Timescale of implementation**: While there are on-going discussions already relating to the E1plus standard and it is indeed the case that some EU companies can already comply with the E1plus standard, there will be a need to have sufficient lead-in time for EU companies to adapt their production processes (and for some, develop new resin technologies and formulations) in order to comply with the restrictions. By way of comparison, companies in the US had between four and six years to prepare for the CARB Phase II standards; despite this, there was still a need last year to extend the deadlines for compliance

Overall evaluation

Overall, the proposed RMOs can be implemented by both industry and MS authorities. For an OEL at 0.4ppm and a restriction based on the E1 standard, no significant technical or practical issues are foreseen.

If the OEL would be set at a lower value, the technical difficulties of implementation are expected to increase, specifically at 0.2ppm.
For a restriction at the E1plus standard, compliance checking will be enhanced when the E1plus standards become a harmonised standard, recognised under the Construction Products Regulation. At present, it is not sure that the E1plus standard can be technically implemented by all stakeholders – especially for small companies. The administrative burden may also be considered disproportionate to the risks of concern and the means of implementation is currently unclear.

7.3.3 Scenario 3

Authorisation (under Scenario 3) would amount to a phasing out, with temporary use allowed only in specific authorised uses. In this respect, it is likely to be disproportionate (as a risk management measure) to the imminence and degree of risks identified in some areas. Authorisation is also not a practical RMO for addressing use of formaldehyde as an intermediate and imports of WBP. Finally, it is likely that significant costs (particularly the level of administrative burden) will be incurred by employers if the authorisation provisions are put in place, which may not be justified by the additional health benefits which would accrue – since, under Scenario 2, the use of formaldehyde may already be subject to strict control through the CMD, VOC and/or restrictions. In addition, there may be unintended impacts on the international market whereby the production of WBP containing formaldehyde is shifted to non-European countries.

Regardless, it is the case that any proposed RMOs can be implemented by stakeholders (even if the exact detail of the authorisation is not known at present) and authorities will be able to set up efficient supervision mechanisms and check compliance with the proposed

RMOs. The relevant RMOs will be understandable to all affected parties, even if there is the possibility that the administrative burden may also be considered disproportionate to the risks of concern, especially for small companies.

7.4 Monitorability of Potential Risk Management Options

7.4.1 Scenario 1

As the 'do nothing' option, there are no additional direct or indirect impacts or costs associated with monitoring.

7.4.2 Scenario 2

Workers - OELs

The OEL setting and enforcement process is straightforward and practical. The regulatory frameworks under which these measures will be introduced have existed for some time and sites should be familiar with negotiating their actions within these frameworks. In all Member States, employers are responsible for the control of hazardous substances in the workplace and ensuring that the relevant exposure limits are met. Authorities, for example Labour Inspectorates, oversee the employers' activities and may also take their own measurements.

The practical change depends on the OEL that is set. At an OEL of 0.4ppm, for companies in eight Member States with OELs at around 0.5ppm, small changes in an OEL are unlikely to lead to new control measures being necessary, as the same method of exposure control is likely to be already providing the necessary protection (HSE, 2008) – although this is clearly not the case for every marginal change in OEL. A change below 0.4 ppm, and certainly a change to 0.2 ppm, is considered to be far from marginal and to have a substantial impact, as indicated by the substantial increase in costs for 0.2 ppm/lower than 0.4 ppm compared to 0.4 ppm as estimated in Annex 1. The greatest impacts are therefore likely to be felt where there is a significant gap between the new OEL and the existing practice – which would be the case in Greece, Ireland and the United Kingdom.

In terms of implementability, a harmonised OEL would also have benefits in terms of clarifying the actual safe threshold for workers in view of varying OELs and DNELs, specifically if it is a binding OEL. EC (2010) notes that, where both a national OEL and a DNEL have been derived for the same substance, employers "*should seek to resolve the situation with their suppliers and, as appropriate, with the relevant national authorities".* Undertaking this task at a national level would be significantly onerous for both industry and authorities, there are, therefore, likely to be advantages associated the implementation of an EU-wide OEL.

Monitoring of compliance with a harmonised OEL will employ the existing monitoring networks that have been established as a result of Community-wide and national legislation on exposure control in the workplace. However, there are existing formaldehyde OELs in 24 Member States and, for these countries, there should be no additional costs associated with monitoring formaldehyde levels against a revised harmonised limit.

Workers – reclassification

Monitoring of compliance with the CMD should be straightforward, as this should employ the existing monitoring channels and procedures that have been established under national legislation across the EU.

There may be additional costs associated with setting up a workplace monitoring programme for some companies, although some of this information may already be collected as part of compliance with existing legislation.

Consumers - Restrictions

The procedure for restricting the marketing and use of substances at the EU level under REACH is well established, with a number of substances (57) already subject to restrictions. The website on restrictions of ECHA at writing of this report showed 20 submitted restriction proposal intentions. In this respect, it is a simple measure to introduce and implement and Member States are considered to have suitable procedures in place for implementing its requirements.

In discussing the practicality of restrictions, an issue to be borne in mind is the extent and magnitude of risks in the context of the existing risk management measures. The discussions in previous sections highlight a number of key points regarding practicality.

- **Relevance of existing controls**: Existing legislation already provides some powers for addressing some of the risks identified (this should be considered before recommending new or amending legislation). It is also possible that the implementation of existing controls could be made more efficient and, if so, this may remove the need for further controls. In this regard, national OELs can be updated as appropriate to reflect the changes in risk knowledge and best available techniques.

- **Implementability**: A restriction is practical in the sense that companies in the WBP sector have the necessary technology and techniques to comply with restrictive emission limits. Various alternatives are also available, although the cost and technological implications vary by type of alternative chosen by a company. The proposed restriction on WBP can also be implemented via (or taking account of) the harmonised standard (under EN 13968) or an industry voluntary agreement, underlined by existing standards.

- **Enforceability**: The restrictions route is also enforceable, as authorities will be able to check the compliance of relevant actors with the restriction. For the WBP sectors, the practicality of marketing and use restrictions also needs to be considered within the context of the international nature of some of the markets of relevance (particularly with regard to potential trade barrier issues). Restrictions also have the benefit of covering imports making it easier to enforce and ensuring that all relevant products are covered (not only EU-made ones).

- **Manageability**: The proposed restrictions are practical and understandable (being based on existing harmonised or industry standards) and takes into account the characteristics of the sector. For the wood sector specifically, a key advantage of the

restriction route is that manufacture and imported articles can be covered by the restriction ensuring that there are no disproportionate impacts. The restrictions route can also be used to cover intermediate use (formaldehyde is used as an intermediate for urea formaldehyde resins) and, as such, is well suited to the risks to be addressed.

- **Market harmonisation**: Practically speaking, another advantage of restrictions is the harmonisation of various national obligations. By regulating the use of formaldehyde (in for example in wood) on a European level, companies will not be confronted with several (different) pieces of national legislation depending on the national or international markets they supply.

Monitoring the implementation of restrictions on formaldehyde in the sectors of concern should be relatively straightforward, given that suitable systems have been established through previous restrictions. The industry (EPF) has experience of agreeing and enforcing restrictions on E2 WBP; some Member State authorities also have experience of enforcing similar restrictions in their countries. If formaldehyde is reclassified as a Carcinogen Cat 1B, authorities are also conversant with implementing restrictions on consumer uses of substances. Overall, it is expected that existing monitoring mechanisms would be sufficient for monitoring the restrictions. While there will be some additional costs associated with monitoring for the Member State competent authorities, these are likely to be marginal when considered against the entire portfolio of substances which they have to monitor (although this clearly depends on the specific conditions of the restriction).

In summary, E1 restrictions are a useful tool for controlling the risks associated with WBP. In practical terms, the harmonised standards will provide test methods allowing manufacturers to show compliance.

Consumers - reclassification

Monitoring of compliance with the 'fast-track' restrictions on formaldehyde in consumer uses should be straightforward, as this should employ the existing monitoring channels and procedures that have been established under the REACH Regulation.

7.4.3 Scenario 3

In theory, monitoring the impact of authorisation should be straightforward, employing the same monitoring channels and procedures that have been established under the REACH Regulation for restrictions. However, for formaldehyde, the situation will be rather more complicated and problematic.

Firstly, while an authorisation will apply fully to EU manufacturers and downstream users, the placing on the market or the use of an article (or WBP) which contains an Annex XIV substance (formaldehyde) is not subject to the authorisation requirement. This means that importers will be able to place WBPs on the EU market which do not comply with the authorisation requirements. Considering that these WBPs are likely to be cheaper than the low (or zero)-formaldehyde emitting WBPs, it is possible that the market for imported WBPs could grow significantly, affecting any trends which will found on the EU market.

While, it is the case that the incorporation of an Annex XIV substance into an article is a use which is subject to the authorisation requirement, for formaldehyde, two main problems arise:

- firstly, formaldehyde is used in resin form (mostly as UF resin) and is not incorporated directly into the WBP – the resin is incorporated directly into an article; and
- secondly, there may be no easy way of differentiating (at the border) between UF resins, MUF resins, PF resins and ultra-low UF resins once incorporated in the article.

Overall, it is considered that under Scenario 3, ease of monitoring will definitely be affected. The interpretation of data obtained on key indicators will also need more sophisticated analysis; for instance, while under Scenario 2, you will only need to monitor for the presence of high formaldehyde-releasing WBP, under Scenario 3, you will also need information on quantity of imports and EU-based production in order to interpret what a net reduction (or increase) signifies (i.e. whether there is an actual reduction in EU WBP and increase in imports of WBP with high formaldehyde levels).

Overall, it is possible to practically monitor compliance with any conditions placed under the authorisation process and the proposed RMOs do not require additional tasks which are beyond those currently undertaken by MS authorities. However, it is not clear that the potential costs are proportional to the risks avoided (seeing as indoor air is currently considered to comply with existing limits).

Table 7.3: Summary Comparison of RMO Scenarios Against Key Criteria of Effectiveness, Practicality and Monitorability Rated against key impacts as: very unsatisfactory (--), unsatisfactory (-), neutral (0), satisfactory (+), highly satisfactory (++)			
Criterion *(Parameter)*	**Scenario 2, option 1** **(0.4ppm OEL + E1 Restriction; with Reclassification)**[a)]	**Scenario 2, option 2** **(0.3 or 0.2ppm OEL + E1plus Restriction)**	**Scenario 3** **(Authorisation)**
Effectiveness			
Risk reduction capacity			
Does the RMO reduce the exposure to a level allowing adequate control of the identified risk?	**(+/++)** – Introducing an OEL of 0.4ppm (same as the DNEL) would ensure adequate control of risks and **workers** in around 13 MS would benefit from a reduction in the workplace OEL from current levels For **consumers**, there will be a further reduction in exposure as a result of the *E1 restrictions* or fast track restrictions in case of reclassification **(+)** – In case of reclassification, employers will be required to ensure a high level of protection for their **workers**, as well as provide information to them, which taken together is likely to ensure that exposure is reduced to a level which ensures adequate control.	**(++)** – Introducing an OEL of 0.3ppm will ensure adequate control of the risks and **workers** in around 15 MS would benefit from a reduction in the workplace OEL from current levels . At 0.2ppm, workers in almost all MS would benefit from a reduction in the workplace OEL from current levels. For **consumers**, there will be a further reduction in exposure as a result of the *E1plus restrictions* *(Both for workers and consumers there is however not necessarily a true reduction of risk, considering that the present situation is already without risks)*	**(+)** – For **workers**, no additional benefits to those under Scenario 1 and 2 are expected. For **consumers**, because authorisation will not cover imported articles, Scenario 2 will not result in any change from the current situation, although it is possible that other uses may be restricted and cumulative exposure reduced
Do the alternatives identified cause other risks to the human health or the environment?	**(0)** – The vast majority of EU companies are able to and currently manufacture WBP which comply with the proposed restrictions and, as such, no change from the current situation regarding risks from alternatives is expected **(0/-)** – In case of classification: some of the alternatives identified result in other risks to human health. The extent to which these risks materialise will depend on the approaches taken by individual MS authorities in interpreting the CMD substitution requirement (e.g. strict exclusion of MF and PF resins)	**(0/+)** – Some of the alternatives identified result in other risks to human health. These risks are unlikely to materialise under this option as companies would have a choice of alternatives (incl. using MF and PF resins) for meeting the requirements	**(+)** – Some of the alternatives identified result in other risks to human health. These risks should not materialise if the assessment of alternative under authorisation is done rigorously.

Table 7.3: Summary Comparison of RMO Scenarios Against Key Criteria of Effectiveness, Practicality and Monitorability Rated against key impacts as: very unsatisfactory (--), unsatisfactory (-), neutral (0), satisfactory (+), highly satisfactory (++)			
Criterion *(Parameter)*	**Scenario 2, option 1** **(0.4ppm OEL + E1 Restriction; with Reclassification)**[a)]	**Scenario 2, option 2** **(0.3 or 0.2ppm OEL + E1plus Restriction)**	**Scenario 3** **(Authorisation)**
How long will it take before the RMO has reduced the exposure level to an acceptable level?	**(+/++)** – A harmonised OEL and restriction proposal will take some time to be agreed. As the industry is in support of both RMOs, it is possible that Scenario 2 could be quickly agreed and the effects could be felt from 2016 onwards **(++)** – In case of reclassification: the proposed RMOs would come into effect as soon as reclassification is formalised. In theory, the effects should be felt from 2015 onwards	**(+)** – As this proposed RMOs entails significant investment and costs to some companies/industry (and society/consumers), it is unlikely that this option could be quickly agreed and, at the earliest, any effects could be felt from 2018 onwards	**(+)** – Similar to Scenario 2, option 2, authorisation entails significant costs to companies/industry, it is unlikely that this could be quickly agreed and, at the earliest, any effects could be felt from 2018 onwards
Proportionality			
Is the RMO targeted at the risks of concern? And: Does it inadvertently affect actors in the supply chain which are not associated with the identified risk?	**(+)** – The proposed RMOs are targeted at a route of exposure of concern (i.e. imports of high formaldehyde releasing WBP). It is unlikely that other actors not in the supply chain will be affected **(++)** – In case of reclassification: the proposed RMOs are targeted at the risks of concern. It is unlikely that other actors not in the supply chain will be affected	**(+/++)** – The proposed RMOs are targeted at an exposure source of concern – even if this may not be the most important source of formaldehyde in the home. It is possible that actors not in the supply chain may be affected	**(0/+)** – The nature of the final authorisation is unknown; however, by not targeting imports, Scenario 3 is not targeted at a route of exposure of concern and, as such, impacts on EU companies that are not necessarily responsible for the identified risk
Do the efforts needed from the actors to implement and enforce the RMO correspond to the adverse effects that are being avoided? Is there a good balance between costs and benefits and is the RMO cost-effective?	**(+)** – By harmonising national requirements, Scenario 2 could be said to ensure a good balance between costs and benefits and is likely to be considered cost-effective, taking into account that the risks are adequately controlled at present *(See Section 3 on Risk Assessment)* **(++)** – in case of reclassification, it could be said that the efforts required correspond to the adverse effects avoided and there is a good balance between costs and benefits (assuming a reasonable implementation of the CMD requirements *(See Section 4 on Alternatives)*	**(0/+)** – Considering that the risks are already adequately controlled, this option may be costly for authorities and industry specifically but at a societal level, it may prove to be cost-effective and beneficial	**(+)** – For **workers**, no additional benefits to those under Scenario 2 are expected and, as such, the effort required for authorisation may be disproportionate. For **consumers**, because authorisation will not cover imported articles, Scenario 3 may also be considered disproportionate in terms of the adverse effects avoided

Table 7.3: Summary Comparison of RMO Scenarios Against Key Criteria of Effectiveness, Practicality and Monitorability Rated against key impacts as: very unsatisfactory (--), unsatisfactory (-), neutral (0), satisfactory (+), highly satisfactory (++)			
Criterion *(Parameter)*	**Scenario 2, option 1** **(0.4ppm OEL + E1 Restriction; with Reclassification)[a)]**	**Scenario 2, option 2** **(0.3 or 0.2ppm OEL + E1plus Restriction)**	**Scenario 3** **(Authorisation)**
Is the RMO consistent with legal requirements already in place?	**(++)** – The proposed RMOs are consistent with existing legal requirements already in place, especially as it takes forward existing national restrictions and harmonised standards.	**(+)** – The proposed RMOs are consistent with existing legal requirements, although harmonised standards for the E1plus need to be introduced	**(+)** – At a more general level, authorisation could be consistent with existing legal requirements, depending on the final authorisation agreed
Overall Effectiveness *– taking into account risk reduction capacity and proportionality*	***(+/++) – Scenario 2 is targeted at the identified risks and ensures reduction of the exposure to a level that allows adequate control of identified risks in a reasonable timeframe*** ***– With regard to reclassification, its proportionality depends on the interpretation of the CMD by MS authorities***	***(+) – This option is targeted at the identified risks and ensures reduction of the exposure to a level that allows adequate control of identified risks in a reasonable timeframe – however, it may be a disproportionate response to the level of risks***	***(0/+) – Scenario 3 is not targeted at the identified risks neither does it ensure adequate control of identified risks in a reasonable timeframe – although, in the long term, it may be effective***
Practicality			
Implementability: Can the actors comply with the RMO?	**(++)** – The proposed RMOs can be implemented by both industry and MS authorities. The former have experience of voluntary restrictions, while some MS have national restrictions. All stakeholders can comply with the OEL. **(0/+)** – in case of reclassification: the extent to which the proposed RMOs can be complied with will depend on the approaches taken by individual MS authorities in interpreting the CMD substitution requirement (e.g. strict exclusion of MF and PF resins)	**(+)** – The proposed RMOs can be implemented by both industry and MS authorities. MS authorities have general experience of implementing restrictions. All stakeholders have experience of implementing OELs.	**(+)** – The proposed RMOs can be implemented by stakeholders – even if the exact detail of the authorisation is not known at present
Enforceability: Can the authorities set up efficient supervision mechanisms and check compliance?	**(+)** – Authorities will be able to set up efficient supervision mechanisms and check compliance with the proposed RMOs, based on current approaches	**(0/+)** – Supervision mechanisms will be based on current approaches; compliance checking will however be enhanced when the E1plus standards becomes a harmonised standard	**(+)** – Authorities will be able to set up efficient supervision mechanisms and check compliance with the proposed RMOs.

Table 7.3: Summary Comparison of RMO Scenarios Against Key Criteria of Effectiveness, Practicality and Monitorability Rated against key impacts as: very unsatisfactory (--), unsatisfactory (-), neutral (0), satisfactory (+), highly satisfactory (++)			
Criterion *(Parameter)*	**Scenario 2, option 1** **(0.4ppm OEL + E1 Restriction; with Reclassification)**[a)]	**Scenario 2, option 2** **(0.3 or 0.2ppm OEL + E1plus Restriction)**	**Scenario 3** **(Authorisation)**
Manageability: is it understandable to the affected parties? Is the means of implementation clear? Is the administrative burden proportional?	**(++)** – The proposed RMOs are understandable to all affected parties – especially since the industry have prior experience. The means of implementation is clear and the administrative burden can be considered proportional to the risks of concern	**(0/+)** – The proposed RMOs are currently not fully understandable to all affected parties – especially for small companies - in technical terms. The administrative burden may also be considered disproportionate to the risks of concern. The means of implementation is however clear	**(0/+)** – The proposed RMOs are understandable to all affected parties. The administrative burden may also be considered disproportionate to the risks of concern.
Overall Practicality	***(++) – The proposed RMOs are practical and proportionate. Both industry and regulatory stakeholders have prior experience*** ***(+) – In case of reclassification: the proposed RMOs are practical, although the interpretation of the CMD requirement is key***	***(0/+) – The proposed RMOs are practical – although there may be a lack of practicality for small companies and the admin burden may be considered disproportionate to the risks***	***0/+) – The proposed RMOs are likely to be practical – although there may be a lack of practicality for small companies and the admin burden may be considered disproportionate to the risks***
Monitorability			
Availability of indicators	**(+)** – It is possible to practically monitor the formaldehyde level in WBP imported into the EU. There are existing scientific methods for measuring these concentrations. **(+)** – It is possible to monitor the presence of substances used in the workplace for compliance with the CMD, as well as, ensure that the restrictions on consumer uses are respected.	**(0/+)** – It is possible to practically monitor the formaldehyde level in WBP imported into the EU. It is expected that there will soon be agreed scientific methods for measuring these concentrations	**(+)** – It is possible to practically monitor compliance with any conditions placed under the authorisation process
Ease of monitoring	**(+)** – The proposed RMOs do not require additional tasks which are beyond those currently undertaken by MS authorities. They are also straight-forward to set up and administer and the potential costs are likely to be proportional to the risk avoided (from imported WBP not meeting the E1 standard / carcinogenicity)	**(-/+)** – It is not clear that the potential costs of monitoring are proportional to the risk avoided (seeing as indoor air is currently considered to comply with existing limits). It may also not be easy, in the short-term, for authorities to enforce the E1plus standard until it is clearly defined	**(-/+)** – The proposed RMOs do not require additional tasks which are beyond those currently undertaken by MS authorities. However, it is not clear that the potential costs are proportional to the risk avoided (seeing as indoor air is currently considered in compliance with existing limits).

Table 7.3: Summary Comparison of RMO Scenarios Against Key Criteria of Effectiveness, Practicality and Monitorability Rated against key impacts as: very unsatisfactory (--), unsatisfactory (-), neutral (0), satisfactory (+), highly satisfactory (++)			
Criterion *(Parameter)*	**Scenario 2, option 1** **(0.4ppm OEL + E1 Restriction; with Reclassification)**[a)]	**Scenario 2, option 2** **(0.3 or 0.2ppm OEL + E1plus Restriction)**	**Scenario 3** **(Authorisation)**
Availability of monitoring mechanisms	**(+)** – The proposed RMOs are consistent with the existing monitoring responsibilities of the authorities.	**(+)** – The proposed RMOs are consistent with the existing monitoring responsibilities of the authorities.	**(+)** – The proposed RMOs are consistent with the existing monitoring responsibilities of the authorities. Current monitoring mechanisms are suitable or can be easily adapted.
Overall Monitorability	***(+) – The existing monitoring systems will allow for the impact of the proposed RMOs on the risks of concern to be checked (including whether risk reduction has been achieved in a proportionate manner)***	***(0/+) – The existing monitoring systems will allow for the impact of the proposed RMOs on the risks of concern to be checked (including whether risk reduction has been achieved in a proportionate manner) – although there are some doubts regarding the availability of scientific methods for checking compliance with the E1plus standard***	***(+) – The existing monitoring systems will allow for the impact of the proposed RMOs on the risks of concern to be checked (including whether risk reduction has been achieved in a proportionate manner)***

[a)] Reclassification is not necessarily part of this Scenario. However, the criteria of effectiveness, practicality and monitorability are described for the case that reclassification will occur.

8. SUMMARY ASSESSMENT OF SCENARIOS

8.1 Introduction

Section 7 analysed the different RMOs against the three key criteria of effectiveness, practicality and monitorability. This section summarises the key findings within the context of the scenarios described in Section 6.

8.2 Scenario 1 - Baseline

8.2.1 Workers

This is the baseline scenario and anticipates that no further regulatory action is taken relating to formaldehyde. It assumes full compliance with the current legal requirements under REACH (and other relevant legislation); in particular, the requirement to ensure the safe use of the substance for each exposed population during all the lifecycle stages of the substance, including the waste stage and the article service life, where applicable.

It is important to bear in mind that, currently, all exposure scenarios have been calculated to be safe using monitoring data and models. The risk assessment/CSR also indicates that adequate control of the risks to workers is possible under specific OCs and applying specific RMMs. However, it is recognised that there are some concerns, which need to be taken into account, in particular:

- on-going regulatory interest in formaldehyde evidenced by the number of on-going regulatory initiatives by different authorities (i.e. review of the CSR under the Evaluation procedure, consideration of OELs by DG EMPL/SCOEL and various initiatives by WHO and the EC);
- the potential reclassification of formaldehyde regarding carcinogenicity. In this context, it is important to ensure that formaldehyde is used in ways that lead to the minimisation of significant adverse effects on human health; and
- differences in the risk management approaches and/or risk communication which currently exist (especially as regards OELs across Member States).

The on-going regulatory activities and the differences between Member States are discussed and taken into account in Scenario 2.

8.2.2 Consumers

For consumers/EU citizens, based on the measured concentrations in real homes and the worst-case exposure scenarios, the risk assessment undertaken for this study concludes that the exposure of the general population due to the use of WBP made with formaldehyde based resins in Europe is below the DNEL and, as such, there is no unacceptable risk to consumers. This finding is particularly applicable where WBP conforming to the European E1 emission standard and proposed E1plus standard are used in the home.

8.2.3 Overall assessment

For Scenario 1, it is concluded that, taking into account the regulatory interest of authorities, it is important that **industry implements the operational conditions and RMMs shown to lead to safe use and that specific actions are taken to increase the certainty on the absence of adverse effects on human health**, where possible, even if these measures are precautionary by nature based on the results of the risk assessment.

8.3 Scenario 2 – Risk-based, with or without reclassification

8.3.1 Workers

OELs

Scenario 2 is a Risk-based Scenario which considers the most appropriate RMO based on the risk assessment. A key element of the CSA is the development of derived no-effect levels (DNEL) for effects where a threshold response is shown. The DNEL defines the level of exposure at which no adverse effects are anticipated and is precautionary in nature. Compliance by industry with this value (Inhalation DN(M)EL of 0.5 mg/m³ (~0.4 ppm) for workers) would provide adequate protection, removing any need to consider additional OELs.

Currently, OELs are set by competent national authorities or other relevant national institutions as limits for concentrations of hazardous compounds in workplace air. Currently, there are varying OELs across Member States, mainly due to divergences in approaches taken for the assessment of the actual risks of the chemical. As both industry and enforcement authorities require clear and sound limit values for reliable and consistent risk management, these limit values would benefit from harmonisation across the EU-27.

Based on the analysis undertaken, the most appropriate RMO is that **a harmonised OEL of 0.4ppm be implemented at the EU level as soon as possible**. This will help ensure an appropriate level of protection for EU workers, avoid confusion for employees and employers in ensuring such protection, minimise the potential for unfair competition between economic operators on the EU market and enhance the harmonisation of the internal market. In practice, workers in 13 MS with higher OELs would be impacted by the introduction of such an OEL, where this provides more clarity regarding risk communication and ensures adequate control of the risks in the workplace.

This recommendation can be carried out within the existing legal framework (CAD) and would require amendments to existing legal requirements and more effective enforcement of existing controls. Significant changes will be required in five MS: Greece, Ireland, United Kingdom with a current OEL of 2.0ppm, as well as Bulgaria (0.8 ppm) and Romania (1ppm), while minimal changes will be required in eight MS (with an OEL of 0.5ppm): Austria, Czech Republic, Estonia, France, Hungary, Lithuania, Slovenia and Sweden.

If reclassification also occurs, the harmonised OEL can be a binding OEL, introduced under the Carcinogens and Mutagens Directive. In this context, it is noted that during negotiations for the 3rd IOELV Directive, it was proposed that formaldehyde be removed from the 3rd IOELV Directive and a binding limit taking into account socio-economic factors be introduced

in due course – an IOELV of 0.3ppm was indicated as having merit according to studies undertaken by the UK HSE (UK HSE, 2008).
The advantage of a binding OEL is that Member States cannot deviate from it and, as such, a level playing field will be maintained across the EU.

The option of a harmonised OEL at 0.3 or 0.2ppm is also evaluated. A number of MS currently have national OELs which have been set at 0.3 ppm, while one MS has an OEL lower than 0.2ppm.

As discussed in Section 7, it is clearly the case that an OEL of 0.3 ppm is technically feasible for some companies and such an approach could provide a higher level of protection for workers. This is less clear for an OEL of 0.2ppm. However, this RMO is not proposed as the most appropriate RMO – at the present time – on the basis that (1) formaldehyde has neither been reclassified nor the REACH evaluation completed to necessitate a review of the DNEL and/or justify a more stringent OEL (2) there are relevant cost implications for the companies that would be affected of a more stringent OEL. Therefore, it cannot be concluded that there are substantial benefits of moving to a more precautionary value.

Cost estimates at different OELs

Costs of harmonised OELs are discussed in detail in Annex I. A brief summary is presented below.
An analysis of costs has been made for complying with OEL levels of 0.4, 0.3 and 0.2ppm. While the general conclusion of the risk assessment is that exposures in most industries can be maintained below 0.4ppm with feasible conditions and risk management measures, the perception of several representatives of plants in relevant industries is that already at 0.4 ppm additional improvements are needed, leading to costs. Annex 1 presents the results of the study of costs for relevant industry sectors at different levels of OELs.
One conclusion from that study is that it is difficult, and for some industry sectors impossible, to distinguish between costs needed for an OEL of 0.3 or 0.2ppm. 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.

One-off costs per plant (for other sectors) or production line (for wood based panel industry), for those plants or production lines that foresee the need to make improvements at 0.4ppm are estimated to be **on average**:

- Formaldehyde and resin manufacturers: € 512,000
- Use of formaldehyde as an intermediate: € 276,000
- Wood based panel industry: € 710,000 (for a plant needing only active supply of air for ventilation)
- Fertiliser industry: € 813,000

Very limited information was received on additional yearly operating costs. These were hardly reported at all by most industry sectors, while local extraction, which was one of the major risk management measured reported to be needed, will result in additional operating costs.
The only reasonably well-described set of additional yearly operating costs is for the wood based panel industry that estimates that at 0.4ppm the additional yearly costs will be around

€ 44,000 per year per production line. For formaldehyde and resin manufacture a rough estimation is made of additional operational costs of € 62,500 per plant.

At 0.2ppm, the one-off cost per plant or production line are expected to be higher than at 0.4ppm. The one-off costs for plants with more than zero costs at 0.2ppm (or, for wood based panel industry, at OEL below 0.4ppm) are estimated to be **on average**:

- Formaldehyde and resin manufacturers: € 1,669,000
- Use of formaldehyde as an intermediate: € 1,811,000
- Wood based panel industry: € 4,510,000
- Fertiliser industry: > € 813,000[10]

The additional yearly operational costs for the wood based panel industry, only sector with reasonable information on this parameter, is estimated **on average** at € 800,000 per production line per year for an OEL lower than 0.4ppm, on top of the additional yearly operational costs for 0.4 ppm. A rough estimation of the additional operational costs for formaldehyde and resin manufacturers at 0.2 ppm is € 125,500 per plant, but these costs are including the costs needed for 0.4 ppm.

A very rough estimate of total one-off costs at an OEL of 0.4ppm and an OEL of 0.2ppm/lower than 0.4 ppm has been made for the combined industry sectors studied. The results of that estimation are presented in Figure 8-1.

[10] Most respondents from the fertilizer industry provided the same estimates of costs for all three OEL levels, so no reasonable specific value at 0.2ppm can be given.

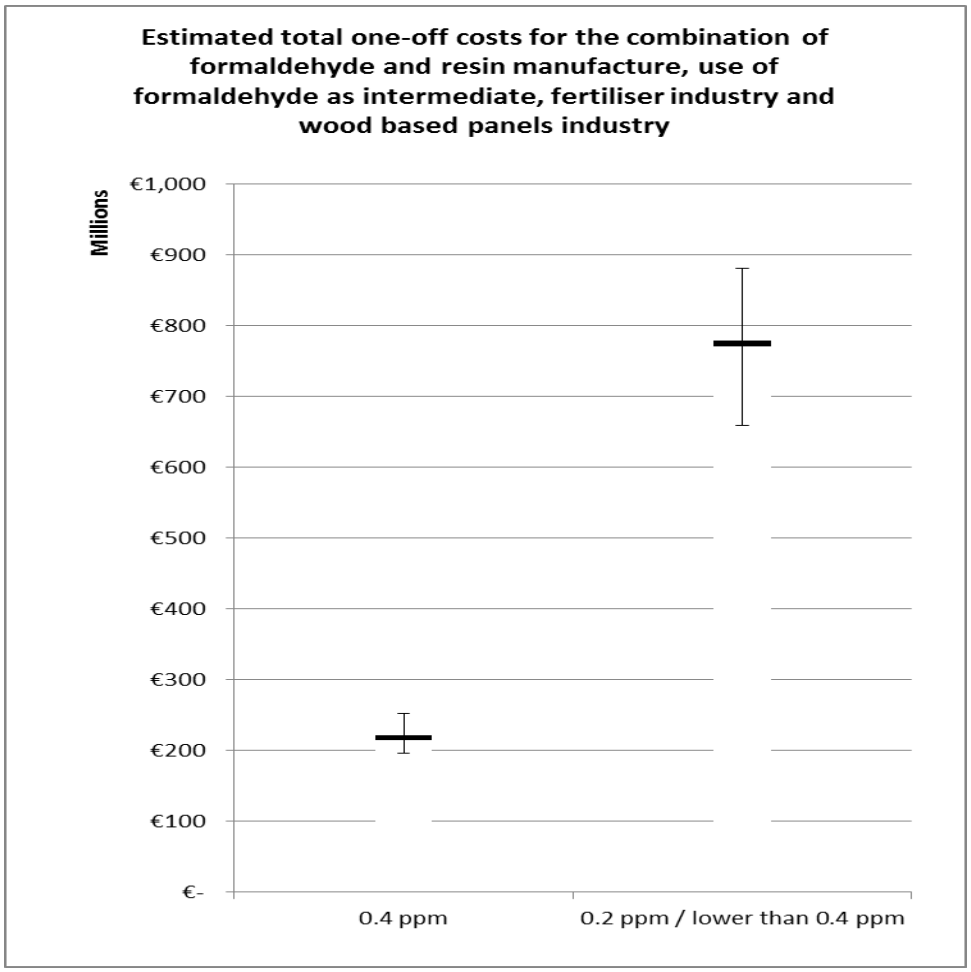

Figure 8-1. Total one-off costs for an OEL of 0.4ppm and OEL of 0.2ppm/lower than 0.4 ppm for the sectors 'manufacture of formaldehyde and resins', 'use of formaldehyde as an intermediate', 'wood based panel industry' and 'fertiliser industry'; the value at 0.2 ppm has been assigned the same value as at 0.4 ppm.

These estimates of total costs for the combined industry sectors do not yet account for several sectors for which no cost estimates were received, nor for the tyre and rubber industry, for which extrapolation was not possible.

The division of total one-off costs between the different industries is presented in Figure 8-2.

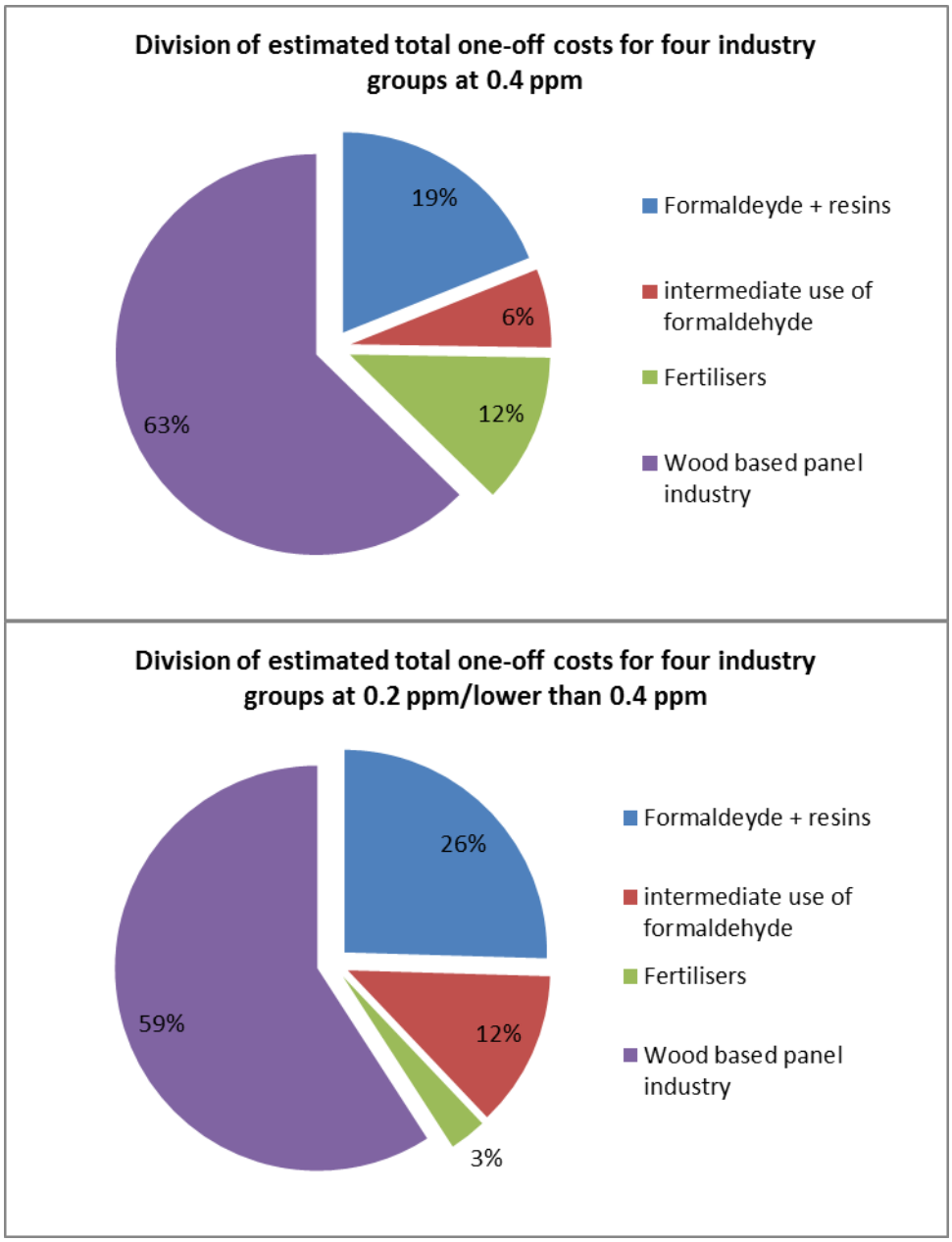

Figure 8-2. Relative contribution of four different industries to the total one-off costs for these industries to keep formaldehyde exposure below 0.4 ppm or below a value of 0.2 ppm (three industries) / lower than 0.4 ppm (wood based panel industry); based on average estimates.

According to the estimations, around 60% of one-off costs for both an OEL of 0.4 ppm and an OEL lower than 0.4 ppm will be for the wood based panel industry. This is largely caused by the large number of production lines in the wood based panel industry that are affected.

Reclassification

In October 2011, a dossier prepared by the French Competent Authority was published on the ECHA website concerning the reclassification of formaldehyde as a Carcinogenic Cat 1A and Mutagenic Cat 2 substance (ANSES, 2011). In December 2012, the European Chemical Agency (ECHA) announced the adoption of a scientific opinion of the Risk Assessment Committee (RAC) proposing that formaldehyde be classified as Carcinogen Category 1B and

germ cell Mutagen Category 2 under the CLP Regulation. In reaching their opinion, the RAC considered that the science relating to human exposure could not support classification as a Carcinogenic Cat 1A substance, opting instead for the lower category 1B (presumed human carcinogen) which is based on nasopharyngeal cancer (an extremely rare cancer in Europe). This proposal will be considered by the Commission and EU Member States and a new classification for formaldehyde could be adopted by 2015. Scenario 2 considers the potential impacts of this revised classification for formaldehyde.

If formaldehyde is reclassified as a Carcinogen Cat 1B and Mutagen Cat 2 substance, industry will be required to implement various RMMs and these will act to further control the releases/exposure to formaldehyde in the workplace. In particular, formaldehyde will be subject to control under the **Carcinogens and Mutagens Directive (CMD)**. The CMD aims at the protection of workers from risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens at work. Based on a determination and assessment of risks by the employer, it provides a step-by-step approach for risk control, ranging from replacement of the substance to measures that limit the quantities of a carcinogen at the workplace and keeping as low as possible the number of workers exposed, or likely to be exposed. Further requirements are the use of existing, appropriate procedures for the measurement of carcinogens and the application of suitable working procedures and methods. Provisions are made for employers to ensure that workers receive sufficient information and appropriate training as well as for Member States who shall establish arrangements for carrying out relevant health surveillance of workers. Furthermore, the possibility to set OEL values is laid down in the Directive.

New harmonised classification and labelling will also be introduced under the **CLP Regulation** and registrants would be required to **update their registration dossiers**, including CSRs. The protection of young people and pregnant workers will also be required under specific EU legislation.

It can be concluded that, if reclassification occurs, employers will be required to ensure a high level of protection for their workers, as well as provide information to them, which is likely to ensure that exposure is reduced to a level which ensures adequate control of the risks. Also of importance is that the measures identified are directly targeted at the risks of concern, carcinogenicity in particular.

8.3.2 Consumers

Restrictions

The Construction Products Regulation (CPR) (305/2011/EU) requires that all construction products bear the CE marking before being placed legally on the European market. For WBP to receive the CE mark, they must comply with the Harmonised European Standard *EN 13986,* which sets the minimum safety requirements for WBP. Annex B of EN 13986 establishes two classes of WBP, E1 and E2, based on formaldehyde emissions. 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.

Scenario 2 considers introducing EU-wide restrictions on WBP with formaldehyde emissions higher than E1 emission levels (defined as a concentration of 0.1 ppm in the relevant emission test). The advantages of such a restriction are as follows:

- it is **targeted at a route of exposure of concern** (i.e. WBP and imports of high-formaldehyde releasing WBP) and the relevant actors in the supply chain;
- it is **consistent with existing legal requirements**, especially as it takes forward existing national restrictions and harmonised standards already established under the CPR;
- it will **apply to all EU manufacturers and importers of WBP**, rather than being limited to signatories to the industry voluntary agreement and/or countries where there are national restrictions in place;
- it will help **ensure that the EU market does not become a new market for sales of high formaldehyde-releasing wood**, which would have been sent to the USA prior to the introduction of the *Formaldehyde Standards for Composite Wood Products Act* (signed into law in the US in July 2010) (note that E1 WBP can be up to double the price of E2 WBP);
- the vast majority of EU companies are able to and currently manufacture WBP which comply with the proposed restrictions and, as such, **it is feasible and practical**; and
- there would be **a further reduction in consumer exposure to formaldehyde** as a result of implementing restrictions which do ensure that E2 WBP are not placed on the EU market.

Taking the above into account, the most appropriate RMO would be **to introduce restrictions under the REACH Regulation on WBP with formaldehyde emissions higher than E1 emission levels** (0.1 ppm concentration in the relevant emission test) in order to ensure an adequate level of protection for EU citizens, avoid unfair competition on the EU market and enhance the harmonisation of the internal market. It is also recommended that adequate monitoring programmes are put in place to ensure compliance of imported WBPs with this restriction. This recommendation takes into account the findings of the risk assessment which shows that adequate control of the risks to EU citizens is possible when using E1 WBP.

Reclassification

If formaldehyde is classified as Carcinogen Category 1B, a 'fast-track' restriction on consumer use of formaldehyde (via entry 28 of Annex XVII) could, in principle, be triggered. Note also that under the Biocidal Products Directive (98/8/EC), CMR substances are also not authorised for marketing to, or use by, the general public.

Voluntary restrictions based on E1plus

Over the last few years, there has been a lot of scientific and technical work which has gone into updating the Harmonised Standard EN 13986 under Mandate M/113, as amended, given to CEN by the European Commission and the European Free Trade Association. Of key relevance is the proposed inclusion of a new formaldehyde class in Annex B known as E1plus

(in addition to E1 or E2). This European Standard is not intended to be applicable to WBP for use in non-construction applications.

An option in Scenario 2 considers a situation where EU wide restrictions are introduced under the REACH Regulation on WBP with formaldehyde emissions higher than the E1plus standard (defined as a concentration of 0.065 ppm in the relevant emission test). In this context, it is noted that a new law (the *Formaldehyde Standards for Composite Wood Products Act*) was introduced in the US in July 2010, which sets emission standards for composite wood products and will apply on a national scale from January 2013.

A comparison of the European and US standards (see Table 8.1) demonstrates that, for MDF, the current European E1 emission standard is more stringent than the recently introduced CARB Phase 1 and 2 standards in the US. For particleboard, the current European E1 emission standard is again more stringent than the CARB Phase 1, but less stringent than the CARB Phase 2 standards in the US; the proposed European E1plus emission standard is however significantly more stringent than CARB Phase 2 standard. For hardwood plywood, the proposed European E1plus emission standard is more stringent than the CARB Phase 1, but less stringent than the CARB Phase 2 standards. This would indicate that while the current European E1 emission standards are robust, there is some scope for improvement in order to ensure that risks to consumers are minimised to the extent possible. It is, however, important that any regulatory action taken is at an EU-wide level to avoid creating an unfair competitive advantage on the EU or international market.

Table 8.1: Comparison of International Composite Board Emission Standards

International emission standard	Products	Test method	Formaldehyde emission limits	ASTM E1333 equivalent	Emission compared to CARB-P1	Emission compared to CARB-P2
California Air Resources Board Phase 1 emission standard (**CARB-P1**)	HWPW	ASTM E1333	0.08ppm	0.08ppm	n.a.	n.a.
	PB	ASTM E1333	0.18ppm	0.18ppm		
	MDF	ASTM E1333	0.21ppm	0.21ppm		
California Air Resources Board Phase 2 emission standard (**CARB-P2**)	HWPW	ASTM E1333	0.05ppm	0.05ppm	n.a.	n.a.
	PB	ASTM E1333	0.09ppm	0.09ppm		
	MDF	ASTM E1333	0.11ppm	0.11ppm		
North America voluntary standards ANSI A208.1, A208.2	PW	ASTM E1333	0.2ppm	0.20ppm	150%	300%
	PB	ASTM E1333	0.3ppm	0.30ppm	67%	233%
	MDF	ASTM E1333	0.3ppm	0.30ppm	43%	173%
European E2 emission standard	PW	EN 120	30mg/100g	0.38ppm	375%	660%
	PB	EN 120	30mg/100g	0.38ppm	111%	322%
	MDF	EN 120	30mg/100g	0.38ppm	81%	245%
European E1 emission	HWPW	EN 717-1	0.12mg/m³	0.14ppm	75%	180%
	PB	EN 717-1	0.12mg/m³	0.14ppm	-22%	56%

Table 8.1: Comparison of International Composite Board Emission Standards						
International emission standard	**Products**	**Test method**	**Formaldehyde emission limits**	**ASTM E1333 equivalent**	**Emission compared to CARB-P1**	**Emission compared to CARB-P2**
standard	MDF	EN 120	8mg/100g	0.10ppm	-52%	-9%
Proposed European E1+ emission standard	HWPW	JIS A-1460	0.5mg/L	0.07ppm	-13%	40%
	PB	JIS A-1460	0.5mg/L	0.07ppm	-61%	-22%
	MDF	JIS A-1460	0.5mg/L	0.07ppm	-67%	-36%
Source: Table reproduced and adapted from the CWC website http://cwcfurnituregroup.ca/CWCV11/index.php?option=com_content&view=article&id=177&Itemid=343 HWPW: - Hardwood / Plywood; PW: - Industrial plywood; PB: - Particleboard; MDF: - Medium density fibreboard						

Overall, while it is clearly the case that the E1plus standards are technically feasible for some WBP and such an approach could provide a higher level of protection for consumers, this restriction is not proposed as the most appropriate RMO under this Scenario – at the present time - for the following reasons:

- **Disproportionate Impacts**: there will be significant costs for certain stakeholders as a result of a restriction. In addition, it cannot be stated with certainty that there will not be disproportionate impacts on specific countries, companies or SMEs as a result of restrictions. There is indeed the possibility for certain companies to gain a competitive advantage over others; however, the extent and implications of this advantage are not clear at this time.

- **Cost-Benefit Comparison**: Considering that the E1 standard does not result in unacceptable risks to citizens, it cannot be stated with certainty that the benefits associated with introducing the E1plus standard outweigh the costs which will be incurred by industry and EU citizens (e.g. through higher WBP prices). In this regard, it is worth noting that the benefits associated with the US regulations were higher than those that would apply under an EU restriction (the US industry voluntary standard was 0.30 ppm, while the EU voluntary standard is 0.1 ppm (test method EN120)).[11] It is possible that given time (see next point) the costs will reduce which will allow for a more favourable balance between costs and benefits.

- **Lead-in Time**: There will be a need to have sufficient lead-in time for EU companies to adapt their production processes (and for some to develop new resin technologies and formulations) in order to comply with the restrictions. For instance, companies in the US had between four and six years to prepare for the CARB Phase II standards; despite this, there was still a need last year to extend the deadlines for compliance.

[11] Prior to the CARB Standards, furniture manufactured in North America generally conformed to the American National Standard for Particleboard (ANSI A208.1), which is the North American industry *voluntary* standard, for formaldehyde emission levels (0.30 ppm for particleboards in the relevant emission test). Furniture manufactured in Europe conforms to the European E1 standard (0.1 ppm for particleboards in the relevant emission test).

- **Need for Derogations**: Finally, there are important differences between the EU and US WBP markets (e.g. market size, the nature of WBP used, the amount of WBP used in a typical home, regulatory history, etc.) which must be taken into account in considering the costs of restrictions. Furthermore, there may be a need to consider specific derogations for specific WBP and/or different limits for different WBP, taking into account technical issues, including the availability and feasibility of alternatives.

With the above in mind, the most appropriate RMO is that **the E1plus standard is introduced as an industry self-regulatory initiative**. With a view to minimising the likelihood of adverse effects from formaldehyde and encouraging research into alternative substances and technologies, companies should manufacture WBP with formaldehyde emissions equal to or lower than E1plus emission levels (0.065 ppm in the relevant emission test), in cases where this is technically suitable, economically feasible and does not result in higher risks to workers' health. Appropriate monitoring and (annual) reporting mechanisms must also be documented and established to report on the extent to which the E1plus standard is being taken up.

Costs and benefits for consumers

Costs and benefits for consumers are discussed in detail in Annex II.

8.3.3 Overall assessment

For Scenario 2 it is concluded that the RMO are effective, practical and can be monitored. For an OEL of 0.4ppm and a restriction based on an emission level according to the E1 criteria, most necessary tools are in place and since industry generally accepts these options, they can be implemented relatively quickly.

The estimated one-off costs for complying with an OEL of 0.4 ppm totalised over some of the most relevant sectors (formaldehyde and resin manufacturing, use of formaldehyde as intermediate, wood based panel industry and fertiliser industry) are estimated between 260 million Euros and 650 million Euros.
The estimated one-off costs increase substantially below 0.4ppm and the certainty of technical feasibility decreases. A rough estimation of total costs over some the above mentioned relevant sectors in the EU leads to a range between 540 million Euros and more 1,340 million Euros.
Total costs can be much higher if reclassification, if it occurs, results in substantial additional actions and costs. The costs specific for actions following from reclassification have not been estimated in this study.

It is highly questionable whether the possible benefits for an OEL lower than 0.4ppm and for a restriction based on E1plus criteria, which are considered to be limited due to the lack of a relevant risk in the present situation, are in balance with the disadvantages and costs for such RMO.

8.4 Scenario 3 – Authorisation

Scenario 3 is the Authorisation Scenario and considers the possibility to address the risks relating to formaldehyde using the Authorisation procedure under REACH. Based on the

analysis in Section 7, some of the potential drawbacks associated with this approach are set out below.

- **Lack of effectiveness in targeting imports of WBPs**: The authorisation process only addresses the placing on the market of substances and their mixtures - it does not affect the import of articles containing substances subject to authorisation. In practice, this will mean that (without restrictions) importers will continue to be able to place WBPs on the EU market which do not comply with the authorisation requirements. Considering that some of the imported WBP are likely to be E2 WBP or worse, this means that authorisation is likely to be ineffective in targeting the source of WBPs of concern.

- **Potential unintended impacts on market for imports**: As a general rule, the less formaldehyde released by WBP, the more expensive the price of the WBP. In general, high-formaldehyde emitting WBPs (i.e. E2 and worse) tend to be significantly cheaper than the lower (or zero)-formaldehyde emitting WBPs. With this in mind, it is reasonable to anticipate that the market for imported, cheaper, high-formaldehyde emitting WBPs could grow in the short-term, thereby, putting consumers at increased risk. It is also important to bear in mind that, as the CARB Phase 2 restrictions start to be implemented in the US, importers to the US will seek alternative markets for their products and their E2 WBP could end up in the EU, especially if there is a market access and a price advantage for the importers.

- **Potential impacts on economic leakage and loss of competitiveness for EU manufacturers**: This study estimates that there is a €10/m³ price advantage for imported E2 WBP, compared with E1 WBP. It also estimated that EU WBP manufacturers suffer a loss of around €7 million per year due to a lack of competitive advantage against imported E2 WBP. This economic leakage or loss will continue into the future. Assuming that authorisation is granted for only E1plus WBP, this means that the price advantage for importers importing E2 WBP, compared with E1plus WBP, would increase significantly beyond €10/m³ and the overall loss to EU WBP manufacturers would increase significantly. In this context, it is important to note that there is currently a legal case in the US involving the US plywood industry which filed an unfair trade petition with the US Department of Commerce and the US International Trade Commission regarding the alleged dumping of unfair and subsidised Chinese hardwood plywood imports onto the US market. The US industry claims that the imported products have an unfair competitive advantage over US manufactured plywood with Chinese plywood being sold up to 50% cheaper than plywood manufactured in the USA. It is also claimed that Chinese producers sell their products at more than 300% below fair value.

- **Effectiveness (Intermediates)**: Intermediate uses are also excluded from the Authorisation regime (this is important since formaldehyde is mainly used as an intermediate for production of urea-formaldehyde resins which are then used in WBP). On the other hand, restrictions could be based on existing harmonised or industry standards and linked to the Construction Products Regulation, and as such, are practical and understandable and importantly take into account the characteristics of the sector.

- **Challenges relating to monitoring and enforcement**: It is known that the incorporation of an Annex XIV substance into an article is a use which is subject to the authorisation

requirement. However, for formaldehyde, two main problems arise: firstly, formaldehyde is used in resin form (mostly as UF resin) and is not incorporated directly into the WBP – the resin is incorporated directly into an article; and secondly, once incorporated into the WBP, there is no easy way of differentiating (especially for imports) between UF resins, MUF resins, PF resins and ultra-low UF resins. Each of these different types of resins results in different levels of releases of formaldehyde, with PF resins in particular releasing very little formaldehyde.

- **Speed of risk reduction**: Authorisation is also likely to entail significant costs to companies/industry, it can be a much more protracted process than a restriction (if the preparation of the Authorisation applications is taken into consideration) and, at the earliest, any positive effects for consumers could not be felt for at least five years (2018 onwards).

- **Cumulative impact of other legal requirements**: Finally, it is important to bear in mind that, if reclassification proceeds, the use of formaldehyde may already be subject to strict control through the CMD and the VOC Directive. These legislations require substitution where technically possible and there is some concern that the significant costs (particularly the administrative burden associated with preparing applications) which will be incurred by employers if the authorisation provisions are put in place may not be justified by the additional health benefits which would accrue, taking into account the RMMs which would be put in place to comply with these legislation as well as restrictions or OELs (under Scenario 1).

Having considered the RMOs available for dealing with concerns relating to formaldehyde, it is concluded, inter alia, that targeted restrictions are a more appropriate RMO for dealing with concerns relating to WBP, taking into account the challenges highlighted above, in particular, due to the issue of imports.

8.5 Dealing with Residual Risks or Concerns

8.5.1 Workers

As noted in Section 1.2, the risk assessment currently concludes that risks are adequately controlled when specific operational conditions (OCs) and risk management measure (RMMs) are applied. Despite this, there is a distinct possibility that the industry will be required to invest significantly to further reduce emissions/exposure to formaldehyde due to:

- **the probability that formaldehyde may be reclassified as a Cat 1B carcinogen and Cat 2 mutagen**. If this happens, it is likely that a series of further controls and RMMs will be introduced (in order to comply with the CMD and other legislation) that will impact upon the emissions/exposure of workers and consumers to formaldehyde (and therefore, risks);

- **the introduction and implementation of a harmonised OEL** of 0.4 ppm across the EU. This will require significant investment in abatement equipment, as well as, other organisational measures so as to reduce emissions/exposure of workers to formaldehyde to comply with these limits;

- **a possible revision of the CSR and ES**. For instance, to reflect any updates to the worker risk assessment and indoor air assessment as a result of the Substance Evaluation procedure. Such a revision may also result in more stringent measures being put in place to protect workers.

Taking these into account, it is important to stress that, where there are concerns relating to the risks from formaldehyde from other industrial sectors, **further sampling, monitoring and analysis should be undertaken by industry** to confirm and characterise any risk from formaldehyde in such processes at specific industrial sites, taking into account the likely consequences of the measures put in place by industry to comply with the CMD and a harmonised OEL. This approach would help to clarify, inter alia, the actual residual risk which is applicable and ensure that proportionate measures are put in place, where risks are found.

8.5.2 Consumers

With regard to indoor air, it is important to bear in mind that, there are other initiatives which are currently in the pipeline which will also act (eventually) to reduce indoor exposure to formaldehyde. Firstly, assuming formaldehyde is reclassified, restrictions on its use in certain consumer products (e.g. in toiletries and household products) will be automatically triggered under the REACH Regulation. These restrictions will act to reduce the sources of formaldehyde in the home contributing to cumulative exposure. It is also expected that the E1plus standard will be implemented as soon as possible as a voluntary agreement and this will also act to reduce releases of formaldehyde from WBP. Also, of particular relevance are the World Health Organisation (WHO) indoor air guidelines and initiatives relating to indoor material labelling schemes.

In 2010, formaldehyde was included in the WHO first **indoor air quality guidelines** on indoor chemicals. These guidelines are targeted at public health professionals and authorities involved in the design and use of buildings, indoor materials and products and are also considered to provide a scientific basis for legally enforceable standards for preventing the health risks of environmental exposures (WHO, 2010). It is understood that these guidelines are currently feeding into various on-going initiatives involving the EC.

In 2010, the process of developing and implementing a framework for the harmonisation of **indoor material labelling schemes** in Europe was also significantly advanced following an initiative co-ordinated by the EC's Joint Research Centre and supported by DG ENTR, DG SANCO, DG ENV and DG ENER (JRC, 2010). In 2012, the European Collaborative Action (ECA) Group established a working group of 27 European experts to oversee the development and introduction of an EU harmonised indoor products labelling scheme (ECA, 2012). The European Commission is also exploring whether there are specific needs for information on the content of dangerous substances in construction products within the context of the **Construction Products Regulation** (DG ENTR, 2012). The Commission also notes that it will be particularly important to take into account REACH-generated data, and DNELs in particular, in developing EU lowest concentration of interest (LCI) values in the context of the Commission's EU-LCI harmonised framework for construction products (EC, 2013).

Taking these into account, it is important to stress that, where there are still concerns relating to the risks from formaldehyde on consumers, the potential impacts of these measures in the pipeline (in particular, the labelling proposals) should be considered before further RMOs are put in place. This approach would help to ensure that proportionate and effective measures are put in place.

9. PROPOSED RISK MANAGEMENT OPTION

9.1 Most Appropriate RMOs

The review of existing legal requirements (in Section 5) indicates that further actions relating to additional risk management can be carried out within the existing legal framework and would require more effective enforcement and/or amendments to existing legal and non-legal requirements.

This Section sets out the most appropriate risk management approach for managing the concerns relating to formaldehyde, taking into account:

- the findings of the workplace risk assessment;
- the assessment of consumer exposure (indoor air assessment);
- the situation with alternatives, as discussed under Section 4;
- the current (and foreseeable) controls/measures that impact upon the levels of risk associated with formaldehyde, as set out in Section 5 and Scenario 1;
- the comparative analysis undertaken for the purposes of identifying the most appropriate RMO, as set out in Section 7; and
- the information collected from various sources as documented in Section 9.

Based on an analysis of the current situation (Scenario 1), the study concluded that it is important that industry implements the operational conditions and risk management measures shown to lead to safe use and that specific actions are taken to increase the certainty on the absence of adverse effects on human health, where possible, even if these measures are precautionary by nature based on the results of the risk assessment. The study also highlights the fact that, if formaldehyde is reclassified as currently being discussed (part of Scenario 2), industry will be required to implement various RMMs and these will act to further control the releases/exposure to formaldehyde in the workplace.

In terms of the specific actions to be taken based on the findings of the risk assessment reports, the study concludes that the most appropriate RMOs are as follows:

- **RMO 1 (Workers): Introduction of a harmonised OEL of 0.4 ppm to be implemented at the EU level**. This will help to ensure an appropriate level of protection for EU workers, avoid confusion for employees and employers in ensuring such protection, minimise the potential for unfair competition between economic operators on the EU market and enhance the harmonisation of the internal market. In practice, workers in 13 MS with higher OELs would be impacted by the introduction of such an OEL, where this provides more clarity regarding risk communication and ensures adequate control of the risks in the workplace.

- **RMO 2 (Consumers): Introduction of restrictions under the REACH Regulation on WBP with formaldehyde emissions higher than E1 emission levels (0.1 ppm concentration in the relevant emission test)**. This will help in ensuring an adequate level of protection for EU citizens, avoid unfair competition on the EU market and enhance the harmonisation of the internal market. It is also recommended that adequate monitoring programmes are put in place to ensure compliance of imported WBPs with this

restriction. This RMO takes into account the findings of the risk assessment which shows that adequate control of the risks to EU citizens is possible when using E1 WBP.

- **RMO 3 (Consumers): Introduction of the E1plus standard as an industry self-regulatory initiative or voluntary agreement**. Under this initiative, companies should manufacture WBP with formaldehyde emissions lower than E1plus emission levels (0.065 ppm in the relevant emission test), in cases where this is technically suitable, economically feasible and does not result in higher risks to workers' health. Appropriate monitoring and (annual) reporting mechanisms must also be documented and established to report on the extent to which the E1plus standard is being taken up.

9.2 Risk related Justification for Risk Management Action

In December 2012, the European Chemical Agency (ECHA) announced the adoption of a scientific opinion of the RAC proposing that formaldehyde be classified as carcinogen category 1B and germ cell mutagen category 2 under the CLP Regulation. This proposal will be considered by the Commission and EU Member States and, if a new classification for formaldehyde is agreed, there is a need to ensure that workers and consumers across the EU are guaranteed a high level of protection from any potential risks.

At present, varying OELs currently exist across Member States, mainly due to divergences in assessment approaches of the actual risks of the chemical. There are also divergences in the nature of OELs between Member States where it varies between being obligatory, indicative and a recommendation. As both industry and enforcement authorities require clear and sound limit values for reliable testing and stable emissions control, these limit values would benefit from harmonisation across the EU-28. **An EU harmonised OEL would also help define an appropriate and adequate level of control**.

In late 2011, negotiations began on the next (4th) list of EU Indicative Occupational Exposure Limit (OEL) values. It is understood that formaldehyde is a candidate substance for an OEL in this Directive. As noted in EC (2013), the Commission Services are of the view that while OELs and DNELs may co-exist, and in some circumstances may apply simultaneously to some work activities, in principle the lowest level should be complied with by the employer. Where the DNEL is lower than the OEL, compliance with DNEL is expected on the basis that the employer has obtained new scientific information which indicated that the OEL does not provide the appropriate level of protection. On this basis, it is strongly recommended that this OEL setting process takes into account the possibility to set a harmonised OEL in line with the DNEL of 0.4ppm (0.5 mg/m^3); this would solve an important issue regarding **risk communication** to workers as to what constitutes a "safe threshold" for formaldehyde.

9.3 Justification for Risk Management Action on an EU-wide basis

Formaldehyde is a high production volume chemical which will be assessed under the Evaluation Procedure under REACH.

As part of this study, information on emissions and emissions control was obtained from sites across the EU. The data obtained indicates that there is variability in risk management practices across MS, as evidenced by variations in OELs. There are also variations in risk management approaches amongst different sites within a given sector, as evidenced by

"outliers" in emissions data from different sites and differences in the production and emissions control technology in place. It is, therefore, appropriate that any risk management action is taken on an EU-wide basis.

It is important that the identified RMOs are implemented at the EU level for the following reasons:

- an occupational exposure limit (OEL) value for formaldehyde does not currently exist at the European level – it is important that EU citizens enjoy an *adequate level of protection*, regardless of the country in which they work in line with the *principle of equal treatment*;
- there are national OEL values in the vast majority of EU countries, with these varying from 0.1ppm to 2ppm. A harmonised OEL value will ensure fair competition between operators and further harmonisation of the internal market; and
- the vast majority of the national OELs are inconsistent with the DNEL for formaldehyde. While it is certainly the case that DNELs are not primarily intended to serve a regulatory role within OSH regulations, numerical difference between both values will, in practice, lead to confusion for employees and employers; and
- taking into account the global and international nature of the WBP market, it is the case that for economic and competitive purposes, action is justified on an EU-wide basis. Non-EU manufacturers must not be allowed to place WBP on the EU market, which are restricted for EU manufacturers; hence the recommendation for REACH restrictions to be introduced as the most appropriate risk management approach (rather than authorisation).

Finally, as noted in the REACH Regulation (preamble);

- it is important that chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment;
- the efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from MS to MS; and
- a high level of human health and environmental protection should be ensured in the approximation of legislation on substances, with the goal of achieving sustainable development.

In concluding, EC (2013) states that "*before considering the inclusion of a substance in the candidate list, an assessment of the best risk management option under REACH is performed … and no automatic link is assumed between the classification of a substance as a CMR and its inclusion in the candidate list*". This study has considered the RMOs available for dealing with concerns relating to formaldehyde and concludes *inter alia* that restrictions are the most appropriate RMOs for WBP on the basis that proper implementation and enforcement of RMMs will not be possible under Authorisation, in particular, due to issue of imports.

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ANNEX 1. COST-BENEFIT ANALYSIS OF PROPOSED RMOS FOR WORKERS

See Separate document.

ANNEX 2. COST-BENEFIT ANALYSIS OF PROPOSED RMOS FOR CONSUMERS

See separate document.