THIS DOCUMENT HAS BEEN PREPARED ACCORDING TO THE PROVISIONS OF ARTICLE 136(3) “TRANSITIONAL MEASURES REGARDING EXISTING SUBSTANCES” OF REACH (REGULATION (EC) 1907/2006). IT IS NOT A PROPOSAL FOR A RESTRICTION ALTHOUGH THE FORMAT IS THE SAME

ANNEX XV TRANSITIONAL DOSSIER

SUBMITTED BY: **UK COMPETENT AUTHORITY**
DATE: 28th November 2008

SUBSTANCE NAME: **STYRENE**
IUPAC NAME: STYRENE
EC NUMBER: 202-851-5
CAS NUMBER: 100-42-5

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A. PROPOSAL

A.1 Proposed restriction(s)

No restrictions are proposed for the occupational and consumer uses for styrene covered in this transitional dossier. Risk management measures for the occupational setting are described in section A.2.3. Options to address the concerns identified for consumer use are described in section A.2.4. Justification for the proposals is given in section A.2

A.1.1 The identity of the substance(s)

Substance name: Styrene
IUPAC name: Styrene
EC Number: 202-851-5
CAS Number: 100-42-5

A.2 Background to the transitional dossier

The hazards and risks associated with styrene have been evaluated and agreed under the Existing Substances Regulations (ESR) (793/93/EEC). The human health risk assessment report (RAR) was agreed by the Technical Committee for New and Existing Substances (TCNES) in 2008 and underwent independent peer review by the Scientific Committee on Health and Environmental Risks (SCHER) at its meeting of 6 May 2008.

Under the ESR, when a conclusion (iii) was assigned a risk reduction strategy was developed. A conclusion (iii) denotes that further risk management measures are required to control the risk. As ESR has been repealed by REACH (Registration, Evaluation and Authorisation of Chemicals), an Annex XV Restriction document has to be developed for this transitional substance. The Annex XV report for styrene does not re-evaluate any conclusions about the hazardous properties of styrene. This Annex XV report **only** examines those human health scenarios that were assigned a conclusion (iii) in the RAR in 2008. This Annex XV report **will not** revisit any other conclusions made in the RAR.

A.2.1 Human Health

The RAR concluded that:

1. Workers

There is a need for reducing the risks (conclusion iii) from styrene because of the following human health effects:

- acute toxicity (CNS depression), skin, eye and respiratory tract irritation, effects on the ear and colour vision discrimination following repeated exposure and developmental toxicity for GRP (glass-reinforced plastic);
- effects on the ear following repeated exposure and developmental toxicity for the production of UP-styrene resins;
- developmental toxicity in relation to the production of styrene butadiene rubber (SRB) and styrene-butadiene latex (SBL).

2. Consumers

There is a need for reducing the risks (conclusion iii) from styrene because of the following human health effects:

- acute toxicity (CNS depression), skin, eye and respiratory tract irritation, effects on the ear and colour vision discrimination following repeated exposure and developmental toxicity for boat-building;
- eye and respiratory tract irritation, effects on the ear and colour vision discrimination following repeated exposure and developmental toxicity for the use of styrene-containing liquid resins;
- developmental toxicity for the use of styrene-based paste resins.

3. Man via the environment

There are no human health effects that lead to a conclusion (iii) for man via the environment. Therefore, no further risk management activity under REACH is required.

4. Combined exposure

There are no human health concerns that lead to a conclusion (iii) for combined exposure. Therefore, no further risk management activity under REACH is required.

A.2.2 Environment

The environmental RAR for styrene was agreed in 2002. There are no concerns for the environment that lead to a conclusion (iii). Therefore, there are no outstanding hazards or risks for the environment that need to be considered in this Annex XV report.

A.2.3 Proposed risk management measures for occupational uses

The following measures are recommended to manage the risks identified for the occupational use scenarios covered in this transitional dossier:

EU-wide measures

- Establish an OEL for styrene.

- Establish a biological monitoring “benchmark”.

Manufacture of UP-styrene resins and styrene butadiene rubber and styrene butadiene latex (SBR/SBL)

- Voluntary implementation of good practice ahead of REACH

Glass-Reinforced Plastic (GRP) manufacture

- Registration of styrene under REACH to provide better information to help decide on the most appropriate targeted action

A.2.4 Proposed risk management measures for consumer uses

The following measures are recommended to manage the risks identified for the consumer use scenarios covered in this transitional dossier:

Consumer boat building

- Action at a national level to address the risks identified in this transitional dossier.

Consumer use of styrene-based liquid resins for small-scale repair

- Registration of styrene under REACH to provide better information to help decide on the most appropriate targeted action.

Consumer use of styrene-based resin pastes for small-scale repair

- Registration of styrene under REACH to provide better information to help decide on the most appropriate targeted action.

A.3 Summary of the justification

A.3.1 Identified hazard and risk

The risk characterisation for the manufacture of UP-styrene resins indicated that the Reasonable Worst Case (RWC) 8-hour TWA inhalation exposure value is too high. The RWC short-term inhalation exposure value is also slightly too high. However, typical inhalation exposure values and dermal exposure values are below the relevant DNEL values and are therefore judged to be acceptable. This indicates that the risk management measures currently applied are adequate to address concerns for systemic toxicity providing they are properly implemented and maintained. In this situation, it is not considered necessary to look at additional risk management measures to control the risks that have been identified but to consider whether there are any barriers to effective implementation of current risk management measures. The risk characterisation also indicated a need for workers to wear suitable gloves and goggles where there is the potential for direct contact with styrene to prevent irritation.

A similar situation exists for the manufacture of styrene butadiene rubber (SBR) and styrene butadiene latex (SBL). For this use, only the RWC 8-hour TWA inhalation exposure values are slightly above the DNEL. All other exposure values are below relevant DNELs. As with the manufacture of UP-styrene resins it is not considered necessary to identify additional risk management measures to control the risks that have been identified but to consider whether there are any barriers to effective implementation of current risk management measures. For the reasons outlined above, the use of suitable gloves and suitable eye protection are also recommended in this use scenario where there is the potential for direct contact with styrene.

The risk characterisation for glass-reinforced plastic (GRP) manufacture and the use of UP-styrene resins has identified that additional measures are required to reduce both RWC and typical short-term and 8-hour TWA exposure values to the level of the DNEL. Further work is needed to identify the range of control measures that will secure adequate control of airborne styrene in all occupational situations where styrene-based resins are used. In relation to dermal exposure RWC dermal exposures are marginally above the dermal DNEL for systemic toxicity but typical dermal exposure values are below the DNEL. The current risk management measure to control dermal exposure is the use of gloves. This assessment suggests that gloves are an adequate measure to address concerns for systemic toxicity but that the measure needs to be implemented and monitored more thoroughly and consistently. In addition to the use of suitable gloves, the use of chemical goggles should also be required for situations where there is the potential for direct contact with styrene containing resins.

In relation to consumer use scenarios, the estimated RWC inhalation and dermal exposure values for boat building projects exceed the relevant DNEL values. It is not clear what range of control measures would be available to, or used by a consumer undertaking a boat building project. It cannot be assumed that a consumer will work in a well-ventilated area or that a consumer will wear gloves or eye protection whilst working on the project. Given that it will be necessary to implement a range of risk management measures to ensure adequate control in GRP workshops, it seems unlikely that the concerns identified for consumers carrying out the same type of process can easily be remedied.

For consumer use of liquid resins for repair tasks, a comparison of estimated RWC inhalation and dermal exposure values for a product estimated to contain 40% styrene with the relevant DNELs gives risk characterisation ratios (RCRs) greater than one. Exposures are therefore not adequately controlled for this use scenario. There is also a need to address concerns relating to skin and eye irritation from direct contact with liquid resins.

For the use of resin pastes, for a product assumed to contain 12% styrene, estimated inhalation values are below the relevant DNEL values. Hence, no additional risk management measures need to be applied to control airborne exposure. Although RWC dermal exposure estimates exceed the DNEL for systemic toxicity, the level of contamination that has been assumed is rarely likely to occur. Typical dermal exposure estimates are below the dermal DNEL for systemic toxicity indicating that current use is acceptable. In relation to concerns for skin and eye irritation, the assessment indicated that additional risk management measures (the use of suitable gloves and goggles) would only be required where the resin product contains 12.5% or more styrene. On this basis, providing a resin paste contains no more than 12% styrene, there is no need to implement specific risk management measures. There will be a need to implement risk management measures for the use of resin pastes containing greater than 12% styrene. Since this assessment is based on typical exposures it is preferable to use a 10% cut off to indicate the need for additional risk management measures.

A.3.2 Justification that action is required at community-wide basis

Community wide action is justified on the basis that styrene is traded and used throughout the EU. As such, consistent measures need to be implemented across the EU to ensure a "level playing field" is maintained and that consistent standards of control are implemented in all Member States.

In the case of consumer boat building, this activity seems to be confined to a few Member States. In this case, it is more appropriate for the concerns to be addressed at the national level.

A.3.3 Justification that the proposed risk management measures are the most appropriate measures

A.3.3.1 EU-wide measures

In section B.9.1.2 it is identified that although many EU Member States have national occupational exposure limits (OELs) in place for styrene there is a wide difference in the values. This means that there are differing standards of control that can be applied in different Member States. In order to remedy this situation it is recommended that the European Commission initiates activity to set an EU-wide OEL. An EU limit will affect all workplaces where styrene is used, not just those sectors covered in this transitional dossier.

It is also recommended that consideration be given to the establishment of an EU-wide biological monitoring "benchmark". Styrene has the potential to cause systemic toxicity because of dermal uptake and it is likely that RPE will need to be used in certain situations to control worker exposure.

A.3.3.2 Manufacture of UP-styrene resins and SBR/SBL

The data in this transitional dossier suggest that the risk management measures described in section B.9.3 and B 9.4 have the potential to secure adequate control for the manufacture of UP-styrene resins and SBR/SBL respectively. The information that has been received suggests that these measures are typical for these sectors. It is therefore recommended that the quickest route to secure adequate control where this is not already in place is by the voluntary adoption of good practice measures ahead of the provision of exposure scenarios under REACH. The UK considers that good practice for maintenance activities in plants manufacturing UP-styrene resins and SBR/SBL should include a permit-to-work system where there is a need to enter blending or mixing vessels to ensure that the vessels are suitably decontaminated before they are accessed. Also to mitigate the identified hazards of skin and eye irritation, good practice should include the use of suitable gloves and eye protection in situations where there is the potential for direct contact with styrene or products containing unbound styrene monomer at a concentration of 12.5% or more. It is expected that any good practice measures that are agreed in advance of the registration of styrene under REACH will be included in exposure scenarios that are drafted as part of the registration package.

A.3.3.3 GRP manufacture

REACH appears to be the most practical way to identify and implement suitable control measures to secure adequate control of styrene for all uses of styrene-based resins. In order to comply with the requirement to register, suppliers of styrene will have to assess exposure for all identified uses of styrene and prepare exposure scenarios that describe appropriate risk management measures. Member State Competent Authorities (MSCAs) have the opportunity to check the DNELs that have been identified and the risk management measures that are described in exposure scenarios through substance evaluation. Industry has indicated to the UK Competent Authority that the Styrene REACH Consortium intends to submit a registration dossier for styrene by 1 December 2010. The timings for registration and dissemination of information along the supply chain indicate that within 3 years (by December 2011) downstream users should be taking steps to comply with the risk management measures described in an exposure scenario. The Enforcement Forum established under REACH provides a mechanism for an EU-wide inspection and enforcement project to examine implementation of the RMMs described in exposure scenarios. Regulators have the power to prosecute downstream users who fail to implement RMMs correctly. It is therefore proposed that regulators should allow industry to prepare registration dossiers for styrene and allow downstream users time to implement these measures. After 1 December 2011, styrene should be considered a priority for substance evaluation and there should be a programme of inspection to ensure that downstream users are implementing the RMMs in exposure scenarios correctly. Enforcement action should be considered where employers fail to comply with REACH. The need for additional targeted regulatory action can be considered once substance evaluation and the inspection programme have been completed.

A.3.3.4 Consumer boat building

This dossier has indicated that the risks to consumers who choose to build boats using GRP may be at least as great as the risks identified for workers manufacturing GRP articles using open moulding methods. Since the exposure assessment is informed by measured data for open moulding in the workplace rather than modelled data, and since the RCRs are so high, it seems unlikely that any additional information that may be obtained during the preparation of an exposure scenario will change the conclusion that the risks to consumers using styrene-based resins to build boats are unacceptable. Given that consumer boat building using styrene based resins appears to occur in only a small number of Member States, it is recommended that action is taken at a national level to address the risks. It is noted that any action to restrict the supply of styrene-based liquid resins for small scale consumer use, either as an outcome of the registration of styrene under REACH or as a specific restriction imposed by Member States will also restrict the supply of such resins for consumer boat building.

A.3.3.5 Consumer use of styrene-based liquid resins for small scale repair

For liquid resins, registration of styrene under REACH has two possible outcomes for consumer use scenarios. The chemical safety report (CSR) may confirm the view that the risks to consumers are unacceptable (i.e. the risk characterisation ratio (RCR) is greater than 1). Howevr, the exposure values underpinning this conclusion are based on very conservative assumptions. It is therefore possible that the registration dossier could

provide evidence that consumer use of certain types of styrene-based liquid resin products is acceptable (i.e. RCR < 1). It is not possible to predict in advance what the outcome of registration may be. Industry has indicated to the UK Competent Authority that the Styrene REACH Consortium intends to submit a registration dossier for styrene by 1 December 2010. If the supply of styrene-based liquid resin products continues after registration, it is expected that Member States will regard styrene as a priority for substance evaluation to confirm that this consumer use is acceptable. Substance evaluation could begin on 1 December 2011 and a decision on the adequacy of risk management measures proposed for consumers could be reached by 1 December 2012. If it is concluded that the measures being proposed in the exposure scenario are inadequate, it is expected that Member States will wish to initiate restrictions proceedings. By waiting for registration of styrene under REACH, Member States will be able to use the information in the registration dossier to inform decisions on the need for further action. If restrictions are required, Member States will be able to identify measures that are proportionate to the risks. REACH therefore appears to be an appropriate mechanism to address the concerns that have been identified for consumer use of styrene-based liquid resins.

A.3.3.6 Consumer use of styrene-based resin pastes for small scale repair

Registration of styrene under REACH has two possible outcomes for consumer use of resin pastes. The CSR could confirm the view that consumer use of styrene-based resin pastes is only acceptable where the styrene content is kept at 10% or below. However, the exposure values underpinning this conclusion are based on very conservative assumptions. It is therefore possible that the CSR could provide evidence to allow registrants to increase the maximum permitted styrene content in resin pastes sold for consumer use. It is not possible to predict in advance what the outcome of registration may be. Industry has indicated to the UK Competent Authority that the Styrene REACH Consortium intends to submit a registration dossier for styrene by 1 December 2010. As with liquid resin products, it is expected that Member States will identify styrene as a priority for substance evaluation to confirm the conditions under which acceptable use has been demonstrated. REACH therefore appears to be an appropriate mechanism to address the concerns that have been identified for consumer use of styrene-based resin pastes.

A.3.3.7 Restriction

On the basis that typical exposures for the manufacture of UP-styrene resins and the manufacture of SBR/SBL are at an acceptable level, restrictions are not considered appropriate for these use scenarios.

Four restrictions have been identified in this dossier that have the potential to reduce occupational exposure to styrene during the manufacture of GRP articles. These are:

- restrict the occupational use of styrene-based resins;
- restrict the use of UP-styrene resins for hand lay-up and spray-up;
- restrict the use of UP-styrene resins in open workshops;
- introduce a licensing scheme for companies wishing to use styrene based resins.

One restriction has been identified that has the potential to reduce consumer exposure to styrene. This is to:

- restrict sale of all styrene-based liquid resins, and resin pastes containing more than 10% styrene.

At this time, the UK Competent Authority does not have sufficient information about exposures across all GRP fabrication processes to formulate an appropriate restriction proposal that will be technically feasible and proportionate to the risks. Article 1 states that the purpose of REACH is "to ensure a high level of protection for human health and the environment". While this assessment has identified risks to health arising from the use of styrene-based resins to manufacture fibre reinforced composites (FRCs), it is not clear that alternative monomers or materials will automatically carry lower risks to human health or to the environment. The UK Competent Authority currently does not have enough process specific information for the different GRP fabrication processes to develop a restriction focussed on the use of specific RMMs. One key barrier is that it is not possible at present to identify which measures will be required to achieve the levels of control indicated by the DNEL values. There are also concerns about the possible disproportionate imposition of costs to smaller companies for all of the identified restriction options; technical difficulties with moving to alternative types of resin or alternative materials; technical difficulties with the adoption of enclosed moulding methods and possibly technical difficulties with a requirement to install ventilated booths for open moulding. Of the options identified here, the most workable, though also the most costly, seems to be the introduction of a licensing scheme. However, under REACH licensing (authorisation) is only reserved for substances of very high concern and it may therefore not be a proportionate measure for styrene. A licensing scheme will also be burdensome for national authorities to implement and may divert scarce resources away from other activities.

It has not been possible to conduct a proper evaluation of all of the risks to human health and the environment associated with the restriction identified for consumer use. However, based on the information that is currently available it is not clear that such a restriction will automatically result in lower risks to humans and the environment. One outcome of this restriction may be the creation of additional potentially non-recyclable waste where customers find they are unable to obtain suitable products to repair damaged articles. It is noted that the risk assessment from which the need for a restriction has been judged is based on modelled data that incorporates several conservative assumptions about the airborne levels that will arise during use and the likely level of skin contamination. It is therefore not clear if the restriction that has been identified will be a proportionate measure to address the risks to consumers.

For these reasons, restrictions on occupational and consumer use of styrene-based resins do not seem to be the most effective options at this time to limit the risks that have been identified.

B. INFORMATION ON HAZARD AND RISK

B.1 Identity of the substance(s) and physical and chemical properties

B.1.1 Name and other identifiers of the substance(s)

Chemical Name:	Styrene
EC Number:	100-42-5
CAS Number:	220-851-5
IUPAC Name:	Styrene
Common Names:	Cinnamene, Ethenyl benzene, Phenylethene, Phenylethylene and Vinylbenzene
Molecular Formula:	C_8H_8
Structural Formula:	$C_6H_5CH=CH_2$
Molecular Weight	104.15

B.1.2 Composition of the substance(s)

The purity of Styrene, as stated in the section 1.2 of the Risk Assessment Report (RAR) varies from 99.7% to greater than 99.9% w/w (EU, 2008). The impurities, which vary with the plant and production method, comprise some or all of the following (as % w/w):

Ethylbenzene	<0.1%
Isopropylbenzene (cumene)	<0.1%
2-Phenylpropene	<0.1%
Water	<0.025%
Phenyl acetate	<0.02%
p-Xylene	<0.06%
m-Xylene	<0.001%

The only additive stated in the RAR was 4-tert-butylpyrocatechol (4-tert-butylbenzene-1, 2-diol), which is added as a polymerisation inhibitor at <0.006 – 0.01% w/w.

B.1.3 Physico-chemical properties

Table B.1: Summary of physico-chemical properties of styrene from section 1.3 of the RAR (EU, 2008)

Property	**IUCLID section**	**Value**
Physical state at 20 C and 101.3 KPa	3.1	Colourless to slightly yellow volatile liquid with pungent odour (odour threshold of 0.15ppm)
Melting / freezing point	3.2	-30.6 °C
Boiling point	3.3	145-146°C (at 1 atmosphere)
Density	3.4 density	0.906 g/cm^3 at 20°C
Vapour pressure	3.6	5 mmHg (667 Pa) at 20°C
Surface tension	3.10	No value identified
Water solubility	3.8	300 mg/l at 20°C
Partition coefficient n-octanol/water (log value)	3.7 partition coefficient	3.02
Flash point	3.11	31 °C (open cup)
Flammability	3.13	1.1 – 6.1 (as % of air)
Explosive properties	3.14	Not explosive on basis of structure and oxygen balance calculations Heavy vapour may burn explosively if ignited in enclosed area
Auto flammability	3.12	490 °C
Vapour Density (air =1)		3.6

Conversion factors are 1 mg/m^3 = 0.23 ppm; 1 ppm = 4.33 mg/m^3

B.1.4 Justification for grouping

Not relevant for this proposal

B.2 Manufacture and uses

B.2.1 Manufacture and import of a substance

The manufacture of styrene is detailed in sections 2.1 and 2.2 of the RAR (EU, 2008)

B.2.2 Uses

The uses of styrene are presented in section 2.3 of the RAR (EU, 2008). For human exposure the following scenarios were considered in the RAR.

Table B.2: Scenarios considered within the RAR (EU, 2008)

Scenario	User Exposed	Conclusion
Manufacture of Monomer	Worker	(ii)
Manufacture of Polystyrene	Worker	(ii)
Manufacture of UP-Styrene resin	***Worker***	***(iii)***
Manufacture of SBR and SBL	***Worker***	***(iii)***
Manufacture of GRP	***Worker***	***(iii)***
Use of polymeric materials releasing free monomer	Consumer	(ii)
Other sources of continuous exposure (e.g. food packaging and chewing gum)	Consumer	(ii)
Sporadic emissions from laying new carpets	Consumer	(ii)
Use of Styrene-containing resins (liquid & paste)	***Consumer***	***(iii)***
Boat building	***Consumer***	***(iii)***

Conclusion (iii) indicates that 'there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account'. Only those scenarios for which a conclusion (iii) was reached in the RAR, highlighted in bold italic, are considered further within this transitional dossier.

B.2.3 Uses advised against by the registrants

Styrene has not yet been registered under REACH therefore no uses have been advised against by the registrants.

B.2.4 Description of targeting

This transitional dossier considers risk management measures to address the risks to human health identified for the use scenarios for which a conclusion (iii) was reached in the RAR. The RAR did not identify any risk to the environment for styrene.

B.3 Classification and labelling

B.3.1 Classification in Annex I of Directive 67/548/EEC

Styrene is classified as a dangerous substance within the meaning of Directive 67/548/EEC and is listed in Annex I of this Directive, being assigned risk and safety phrases:

R10:	Flammable
Xn; R20:	Harmful by Inhalation
Xi; R36/38:	Irritating to eyes and skin
S2:	Keep out of reach of children
S23:	Do not breathe gas/fumes/vapour/spray.

A specific concentration limit of 12.5% has been assigned to styrene with respect to classification with Xn; R20-36/38.

B.3.2 Classification agreed in the RAR

For human health the following classification and labelling was agreed by the Technical Committee on Classification & Labelling at their meeting in September 2007:

R10:	Flammable
Xn; R20:	Harmful by Inhalation
Xi; R36/38/37:	Irritating to eyes, skin and respiratory system
Xn; R48/20:	Danger of serious damage to health by prolonged exposure via inhalation

No agreement could be reached in relation to classification for developmental toxicity [Repr Cat 2; R61/Repr Cat 3; R63/not classified]. Since the TC C&L is no longer operational, any further discussion on classification and labelling for styrene will fall within the remit of the Risk Assessment Committee (RAC). The purpose of this transitional dossier is to consider the risk management measures necessary to address use scenarios for which conclusion (iii) was reached in the RAR. It is not the intention for this transitional dossier to make any proposals for classification and labelling for styrene. The risk management measures that are identified in this transitional dossier take account of all identified hazards for styrene not just those endpoints where classification has been assigned.

B.3.3 Classification in classification and labelling inventory/Industry's self classification(s) and labelling

Not applicable for a transitional substance

B.4 Environmental fate properties

The risk characterisation for environmental effects was completed in 2002. No environmental scenarios obtained a conclusion (iii) in the RAR (EU, 2002) and so environmental fate properties are not considered in this transitional dossier.

B.5 Human health hazard assessment

Information under this heading is taken from the RAR for styrene (EU, 2008).

B.5.1 Toxicokinetics

A summary of the toxicokinetics of styrene is given in section 4.1.2.1.5 in the RAR (EU, 2008).

B.5.2 Acute toxicity

A summary of the acute toxicity of styrene is given in section 4.1.2.2.3 in the RAR (EU, 2008).

B.5.3 Irritation

A summary of the irritation of styrene is given in section 4.1.2.3.4 in the RAR (EU, 2008).

B.5.4 Corrosivity

A summary of the corrosivity of styrene is given in section 4.1.2.4 in the RAR (EU, 2008).

B.5.5 Sensitisation

A summary of the sensitisation of styrene is given in section 4.1.2.5.3 in the RAR (EU, 2008).

B.5.6 Repeated dose toxicity

A summary of the effects of repeated exposure to styrene is given in section 4.1.2.6.3 in the RAR (EU, 2008).

B.5.7 Mutagenicity

A summary of the genotoxicity of styrene is given in section 4.1.2.7.4 in the RAR (EU, 2008).

B.5.8 Carcinogenicity

A summary of the carcinogenicity of styrene is given in section 4.1.2.8.3 in the RAR (EU, 2008).

B.5.9 Toxicity for reproduction

A summary of the effects on reproduction of styrene is given in section 4.1.2.9.4 in the RAR (EU, 2008).

B.5.10 Other effects

No other effects were separately reported in the RAR (EU, 2008).

B.5.11 Derivation of DNEL(s)/DMEL(s) or other quantitative or qualitative measure for dose response

The purpose of this transitional dossier is to develop risk reduction strategies for exposure situations for which conclusion (iii) was reached in the RAR (EU, 2008).

Therefore, DNELs have only been calculated for the health endpoints and routes of exposure that are relevant to the exposure scenarios of concern identified in the RAR.

B.5.11.1 Overview of dose descriptors

The human health endpoints for which concerns have been identified in the RAR are:

- acute toxicity (CNS depression)
- skin, eye and respiratory tract irritation
- effects on colour vision discrimination following repeated exposure
- effects on hearing (ototoxicity) following repeated exposure
- developmental toxicity

The dose descriptors that were identified in the RAR for these endpoints are summarised in table B.3 below. In relation to skin and eye irritation as a result of direct contact with liquid styrene, the available data do not provide sufficient information to characterise the dose-response relationship for this effect. It is therefore not possible to derive a DNEL or DMEL for this endpoint. In accordance with the REACH Chemical Safety Assessment (CSA) guidance (Chapter R8, P122 and Part E, table E 3.1) the irritant potency, as indicated by the assigned R-phrases R36 (irritating to the eyes) and R38 (irritating to the skin) will be used to identify suitable risk management measures. This will be considered further in the risk characterisation.

Table B.3: Dose descriptors identified in the RAR for endpoints of concern

Endpoint	**Quantitative dose descriptor or other information on potency**		**Associated relevant effect**	**Remarks on the study**
	Local effect	**Systemic effect**		
Acute toxicity				
Inhalation		NOAEC 100 ppm (7-hour)	CNS depression	Human volunteer data
Irritation/corrosivity				
Eye Respiratory tract	NOAEC 216 ppm (1-hour)		Eye and respiratory tract irritation from airborne vapour	Human volunteer data
Repeated dose toxicity (sub-acute/sub-chronic/chronic)				
Inhalation (human)		NOAEC 50 ppm (8-hour TWA)	Effects on colour vision discrimination	Obtained from studies in workers using tests specifically designed to evaluate colour vision.
Inhalation (animal)		NOAEC 500 ppm	Effects on hearing (ototoxicity)	4 week study in the rat, exposure for 6 hours per day, 5 days per week.
Developmental toxicity				
Inhalation		NOAEC 150 ppm		2-generation study in the rat, exposure 6 hours per day, 7 days per week.

B.5.11.2 Exposure situations for which risk reduction strategies are required

In the RAR, conclusion (iii) was identified for the following exposure situations:

Workers: Manufacture of UP-styrene resins
Manufacture of styrene-butadiene rubber and latex
Manufacture of GRP articles and use of UP-styrene resins

The pattern of exposure for these uses includes short-term peak exposure by the inhalation and dermal routes and long-term repeated exposure by the inhalation and dermal routes. In the case of short-term peak dermal exposure, there are no measured or modelled data from which to characterise this type of exposure therefore the potential for systemic toxicity to arise following dermal exposure will be assessed by comparison to the long-term dermal DNEL. As indicated previously, it is not possible to derive a DNEL/DMEL for local irritation. Appropriate risk management measures will be identified based on assigned R-phrases.

The following worker DNELs have been calculated:

Worker-DNEL short-term for inhalation route
Worker-DNEL long-term for inhalation route
Worker-DNEL long-term for dermal route

Consumers: Use of styrene containing liquid resins and pastes
Consumer boat-building using GRP

The consumer exposure scenarios for which risk reduction measures are required relate to do-it-yourself (DIY) activities. Inhalation and dermal exposures during such tasks will generally fit a pattern of repeated short-term peaks and longer-term inhalation and dermal exposure during the day on which the task is undertaken. There is the potential for longer-term repeated inhalation and dermal exposure where a DIY project e.g. boat-building takes place over several weeks. In the case of short-term peak dermal exposure, since there are no measured or modelled data from which to characterise this type of exposure the potential for systemic toxicity to arise following dermal exposure will be assessed by comparison to a long-term dermal DNEL. As for workers, risk management measures for local dermal effects will be identified using assigned R-phrases.

The following consumer DNELs have been calculated:

Consumer-DNEL short-term for inhalation route
Consumer-DNEL long-term for inhalation route
Consumer-DNEL long-term for dermal route

Man via the environment: No concerns were identified

B.5.11.3 Worker-DNEL short-term inhalation route

Peak airborne exposure to styrene vapour causes both local and systemic effects. It is therefore necessary to calculate DNELs for both types of effect to determine which will be the critical health endpoint for the risk assessment of short-term exposure.

B.5.11.3.1 DNEL based on local effects (eye and respiratory tract irritation from the vapour)

The dose descriptor is the NOAEC of 216 ppm obtained from human volunteers exposed for 1 hour. Irritation is a concentration specific effect, it is therefore not necessary to modify the dose descriptor to take account of differences in breathing rates between volunteers at rest and active workers. It is also not necessary to modify the dose descriptor to take account of the difference in dose that will be obtained from the 1-hour exposure of the volunteers and the 15-minute reference period for the short-term DNEL. The starting point is therefore 216 ppm.

Table B.4: Assessment factors and DNEL calculation for worker-DNEL short-term inhalation local effects

Uncertainties	AF	Justification
Interspecies differences	-	The starting point is obtained from human data so it is not necessary to apply a factor to take account of interspecies differences.
Intraspecies differences	3	There are no data to quantify variability in susceptibility to the irritant effects of styrene in the human population. Since irritant effects relate to the concentration at the target site it is not necessary to apply a factor to take account of toxicokinetic differences. In relation to toxicodynamic differences, the IPCS recommends a factor of 3.16 to account for differences within the human population (IPCS, 2005). Although it is generally accepted that smaller factors can be adopted for worker populations because the very young, the very old and those in poor health are excluded, the irritancy of styrene vapour has been investigated in only a small number of volunteers and hence a factor of 3 will be used to take account of toxicodynamic differences in the worker population.
Differences in duration of exposure	1	It is not necessary to apply a factor to take account of duration of exposure.
Dose response and endpoint specific/severity issues	1	The starting point is a NOAEC. In this study, volunteers exposed to 100 ppm for 1 hour did not report irritation but when the exposure period was extended to 7 hours, mild and transient eye irritation was reported. There were no reports of irritation in volunteers exposed to 216 ppm for 1

		hour and hence it was concluded in the RAR that the irritation reported by volunteers exposed to 100 ppm for 7 hours may have been due to eye dryness rather than primary irritation. At 375 ppm, 4 out of 9 volunteers reported mild eye irritation and all reported nasal irritation. These findings indicate that the dose-response relationship for irritation is not steep. A factor to take account of uncertainties in the NOAEC is therefore not justified.
Quality of database	1	The quality of the database for this endpoint is adequate. A range of concentrations and exposure durations were tested in the key study. The results were internally consistent and were supported by results obtained in two separate but small scale human volunteer studies. It is therefore not necessary to apply a factor to take account of deficiencies in the quality of the data.
Overall assessment factor: 3		
Endpoint specific DNEL: 216/3 = 72 ppm		

B.5.11.3.2 DNEL based on systemic effects (CNS depression)

The dose descriptor is the NOAEC of 100 ppm obtained from human volunteers exposed for 7 hours. CNS depression is a dose-dependent effect. It is therefore necessary to adjust the NOAEC by a factor of 0.67 to take account of the different doses that will be received due to differences in breathing rates between volunteers at rest and workers engaged in light activity (CSA guidance, Chapter R8, section 8.4.2, Ad 4, page 26).

100 x 0.67 = 67 ppm (7 hours)

Since the short-term inhalation DNEL has a 15 minute reference period it is also necessary to convert the 7-hour NOAEC to an equivalent dose that would be inhaled over a 15 minute period. This is done using the modified Haber's rule $c^n t = k$ (CSA guidance, Chapter R8, Appendix R8-8, page 108) where 'c' is the concentration, 't' is the exposure time, 'n' is a regression coefficient and 'k' is a constant. It is not possible to determine an appropriate value for 'n' from the available data, therefore the default value of 3 to extrapolate from a longer to shorter exposure period will be used.

$\sqrt[3]{(67^3 \times 7 \times 4)} = 203$ ppm (15 minutes)

The corrected starting point is 203 ppm (15 minutes)

Table B.5: Assessment factors and DNEL calculation for worker DNEL short-term inhalation systemic effects

Uncertainties	AF	Justification
Interspecies differences	-	The starting point is obtained from human data so it is not necessary to apply a factor to take account of interspecies differences.
Intraspecies differences	5	There are no data to quantify variability in susceptibility to the CNS depressant effects of styrene in workers. In the

		absence of substance specific data the default factor of 5 will be used to take account of differences in susceptibility between workers for the CNS depressant effects of styrene.
Differences in duration of exposure	1	It is not necessary to apply a factor to take account of duration of exposure.
Dose response and endpoint specific/severity issues	1	The starting point is a NOAEC. Minor impairments in neurobehavioural test performances were reported for volunteers exposed to concentrations of around 200 ppm for 1 hour. These data support the conclusion that 100 ppm can be regarded as a NOAEC for a 7-hour exposure and suggest that the dose-response relationship for CNS depression is not steep. A factor to take account of uncertainties in the NOAEC is therefore not justified.
Quality of database	1	The quality of the database for this endpoint is adequate. The key study is a human volunteer study the results of which show a dose-related trend for increasing severity with increasing dose. The results of the key study are supported by data from several additional human volunteer studies conducted by separate groups of researchers. This consistency provides confidence in the reliability of these studies. It is therefore not necessary to apply a factor to take account of deficiencies in the quality of the data.
Overall assessment factor: 5		
Endpoint specific DNEL: 203/5 = 41 ppm		

B.5.11.3.3 Selection of worker-DNEL short-term inhalation

A DNEL of 72 ppm was calculated for eye and respiratory tract irritation compared to a DNEL of 41 ppm for CNS depression. CNS depression is therefore identified as the critical health effect for the risk assessment of short-term exposure.

The worker DNEL short-term inhalation route is 41 ppm (15-minute reference period).

B.5.11.4 Worker-DNEL long-term inhalation route

The RAR concluded that long-term repeated exposure to styrene has the potential to cause effects on colour vision discrimination, ototoxicity and developmental toxicity. A dose descriptor for effects on colour vision discrimination has been identified from studies on workers conducted specifically to look at colour vision. The available human data relating to ototoxicity and developmental toxicity do not provide sufficient information to allow human dose descriptors to be identified for these endpoints. Dose descriptors for these endpoints have been identified from animal data. Since the dose-response relationship and evidence base for each endpoint is different it is not clear which is the critical endpoint for risk assessment of long-term repeated exposure. It will therefore be necessary to calculate separate endpoint specific DNELs for each effect to identify the critical long-term DNEL.

B.5.11.4.1 Endpoint specific DNEL for effects on colour vision

There is an extensive body of data in the RAR on the effects of exposure to styrene on colour vision discrimination obtained from studies using tests specifically designed to examine this endpoint. A NOAEC of 50 ppm (8-hr TWA) was identified. Since this dose descriptor was obtained from studies of workers it is not necessary to modify the dose descriptor. The starting point is therefore 50 ppm.

Table B.6: Assessment factors and DNEL calculation for worker DNEL long-term inhalation for effects on colour vision

Uncertainties	**AF**	**Justification**
Interspecies differences	-	The starting point is obtained from human data so it is not necessary to apply a factor to take account of interspecies differences.
Intraspecies differences	3	There are no data to quantify variability in susceptibility to the effects of long-term exposure to styrene in workers. Since the dose descriptor reflects findings from a number of studies covering in total hundreds of workers from several nationalities the data already addresses some sources of human variability and hence a factor of 3 has been selected to take account of the remaining intraspecies variability within the worker population.
Differences in duration of exposure	1	It is not necessary to apply a factor to take account of duration of exposure because the data relate to long-term workplace exposure.
Dose response and endpoint specific/severity issues	1	The extensive database for this endpoint encompasses a range of exposure conditions allowing information on the exposure-response relationship and severity to be obtained. The RAR concluded that no changes in colour vision discrimination would be expected with 8-hour TWA exposures below 20 ppm. At 50 ppm, although slight changes were detected in tests, the effects were reversible, the individuals concerned were not aware of any deficit and there was no indication that performance was affected in jobs requiring good colour discrimination. The data at higher levels of exposure was not considered to be sufficiently robust to reliably characterise the scale and nature of the effect. On this basis and given that the effects are reversible, it is not considered necessary to apply an assessment factor to take account of uncertainties in the dose-response relationship.
Quality of database	1	Since the database for this endpoint includes rigorous and well-reported studies, it is not considered necessary to apply an assessment factor to take account of uncertainties arising from poor quality information.
Overall assessment factor: 3		

Endpoint specific DNEL: 50/3 = 17 ppm

B.5.11.4.2 Endpoint specific DNEL for ototoxicity

Studies have been conducted in workers and in laboratory animals to investigate the potential for exposure to styrene to have an adverse effect on hearing. Limited evidence was obtained for styrene-induced hearing loss in workers but due to co-exposure to noise and other solvents in these studies it was not possible to establish a clear dose-response relationship. There is clear evidence from studies in laboratory animals that styrene has a specific adverse effect on hearing. The effect is characterised by an elevation of hearing thresholds across particular frequencies and is the result of irreversible damage within the ear. This occurs because styrene selectively destroys hair cells in the cochlea possibly because of an effect on the membranous organisation of these cells. It is assumed that the effects seen in animals are of relevance for humans. Studies in rats have indicated that hearing loss occurs within a few days of the start of exposure and although it does not increase in severity with continued exposure, the initial effect is irreversible. A NOAEC of 500 ppm was identified in the RAR and this will be used as the starting point for the derivation of DNELs for ototoxicity.

Since animals were exposed for 6 hour per day whereas workers may be exposed for up to 8 hours per day it is necessary to adjust the starting point for workers by a factor of 0.75 to take account of differences in the dose that will be obtained over the daily exposure period. It is also necessary to adjust the starting point for workers by a factor of 0.67 to take account of differences in inhalation rates between animals at rest and humans involved in light activity.

The corrected starting point is therefore:

500 ppm x 0.75 x 0.67 = 251 ppm (8-hours)

Table B.7: Assessment factors and DNEL calculation for worker DNEL long-term inhalation for ototoxicity

Uncertainties	AF	Justification
Interspecies differences	2.5	The dose descriptor was obtained from an inhalation study and is being used to derive an inhalation DNEL. It is therefore not necessary to apply an allometric scaling factor to take account of differences in basal metabolic rates between animals and humans. There are no data for styrene to quantify other differences between animals and humans that could affect interspecies extrapolation. On this basis the default factor of 2.5 to account for other species differences will be applied.
Intraspecies differences	5	There are no data to quantify variability in susceptibility to the effects of long-term exposure to styrene in the human population. The default factor of 5 for workers will therefore be used to take account of intraspecies variability.
Differences in	1	The dose descriptor was obtained from a 4 week study.

duration of exposure		Although the DNEL is to be used to assess long-term repeated exposure there is evidence to suggest that the ototoxic effects of styrene occur within a week of initial exposure and do not progress in severity with further exposure. On this basis, the duration of this study is adequate for the endpoint being studied and it is not necessary to apply a factor to take account of differences in duration of exposure.
Dose response and endpoint specific/severity issues	1	Several studies have been conducted in the rat to investigate ototoxicity. The studies encompass a range of concentrations and durations of exposure and provide reliable information on the dose-response relationship and severity of effect. The effect is characterised by an elevation of hearing thresholds and is the result of irreversible damage within the ear. A NOAEC of 500 ppm has been obtained in the key study. At higher exposure levels, hearing thresholds were increased and the level of increase correlated with dose. Minor shifts of 1-3 dB were reported in rats exposed to around 600 ppm increasing to threshold shifts of 35 – 40 dB at concentrations of 800 – 1000 ppm. On this basis the NOAEC is considered to be reliable and, given that the dose-response relationship does not appear to be excessively steep around the NOAEC, it is considered that it is not necessary to apply an additional factor to take account of uncertainties in the dose-response relationship.
Quality of database	1	The findings from the key study are supported by findings from several additional studies conducted to modern regulatory standards by separate groups of researchers. On this basis the quality of the database is not considered to contribute uncertainty and it is therefore not necessary to apply an additional factor.
Overall assessment factor: 12.5		
Endpoint specific DNEL: 251/12.5 = 20 ppm (8-hours)		

B.5.11.4.3 Endpoint specific DNEL for developmental toxicity

A NOAEC of 150 ppm has been identified for developmental toxicity in a 2 -generation reproductive toxicity study in which rats were exposed for 6 hours per day, 7 days per week. Since animals were exposed for 6 hours per day, whereas workers may be exposed for up to 8 hours per day, it is necessary to adjust the starting point by a factor of 0.75. To take account of the fact that animals were exposed for 7 days whereas the working week is assumed to be 5 days duration, the starting point will be adjusted by a factor of 7/5 (1.4). It is also necessary to adjust the starting point for workers by a factor of 0.67 to take account of differences in inhalation rates between animals at rest and humans undertaking light activity.

The corrected starting point is therefore:

150 ppm x 0.75 x 1.4 x 0.67 = 106 ppm (8-hours)

Table B.8: Assessment factors and DNEL calculation for worker DNEL long-term inhalation for developmental toxicity

Uncertainties	AF	Justification
Interspecies differences	2.5	The dose descriptor is obtained from an inhalation study and is being used to derive an inhalation DNEL. It is therefore not necessary to apply an allometric scaling factor to take account of differences in basal metabolic rates between animals and humans. There are no data for styrene to quantify other differences between animals and humans that could affect interspecies extrapolation. A default factor of 2.5 to account for other species differences will be applied.
Intraspecies differences	5	There are no data to quantify variability in susceptibility to the effects of long-term exposure to styrene in workers. The default factor of 5 for workers will therefore be used to take account of intraspecies variability.
Differences in duration of exposure	1	The dose descriptor was obtained from a 2-generation study in the rat. It is therefore not necessary to apply a factor to take account of differences in duration of exposure.
Dose response and endpoint specific/severity issues	2	At the NOAEC of 150 ppm there was a minor decrease (up to 10%) in pre-weaning body weight only in F_2 generation rats. This was not considered sufficient to warrant lowering the NOAEC but a factor of 2 is applied to take account of this.
Quality of database	1	The key study was conducted to modern regulatory standards and was adequately reported. The findings are supported by results from other studies conducted to modern regulatory standards. On this basis the quality of the database is not considered to contribute uncertainty and it is therefore not necessary to apply an additional factor.
Overall assessment factor: 25		
Endpoint specific DNEL: 106/25 = 4 ppm (8-hour)		

B.5.11.4.4 Selection of worker-DNEL long-term inhalation

The most sensitive endpoint-specific DNEL is that for developmental toxicity. There are no reasons to assume that this endpoint is not relevant for workers so the endpoint specific DNEL for developmental toxicity is identified as the worker-DNEL long-term inhalation.

The worker DNEL long-term inhalation route is 4 ppm (8-hr TWA).

B.5.11.5 Worker-DNEL long-term dermal route

Styrene has the potential to be absorbed across the skin and there is the potential for adverse systemic effects to arise as a result of skin exposure. No studies have been undertaken by the dermal route to characterise the dose-response relationship for systemic effects therefore it will be necessary to obtain a long-term dermal DNEL by route-to-route extrapolation. Since developmental toxicity has been identified as the critical health endpoint for long-term inhalation exposure, this endpoint will also be the critical endpoint for long-term dermal exposure. The NOAEC for developmental toxicity identified from a 2-generation study in the rat was 150 ppm. During this study there was a period of oral dosing. PBPK modelling was used to identify an oral dose that would give rise to equivalent blood concentrations to those achieved from the inhalation concentration. The equivalent oral dose for the 150 ppm concentration was 120 mg/kg/day. An oral dose of 120 mg/kg/day will therefore be used as the starting point to derive a DNEL for repeated dermal exposure.

It is necessary to convert this oral dose to an equivalent dermal dose. The RAR concludes that there is 100 % absorption of styrene from the gastrointestinal tract but in humans only 2 % of a dermal dose of liquid styrene is likely to be absorbed. The corrected dermal NOAEL is therefore:

120 x 100/2 = 6000 mg/kg/day

Table B.9: Assessment factors and DNEL calculation for worker DNEL long-term dermal systemic effects

Uncertainties	AF	Justification
Interspecies differences	10	The starting point is an oral dose descriptor from a rat study. It is therefore necessary to include an allometric scaling factor of 4 to take account of differences in basal metabolic rates between rats and humans. There are no data for styrene to quantify other differences between animals and humans that could affect extrapolation. On this basis a default factor of 2.5 will be applied to account for other interspecies differences giving an overall assessment factor of 10.
Intraspecies differences	5	There are no data to quantify variability in susceptibility to the effects of long-term exposure to styrene in the human population. The default factor of 5 for workers will therefore be used to take account of intraspecies variability.
Differences in duration of exposure	1	The dose descriptor was obtained from a 2-generation study in the rat. It is therefore not necessary to apply a factor to take account of differences in duration of exposure.
Dose response and endpoint specific/severity	2	At the NOAEC of 150 ppm there was a minor decrease (up to 10%) in pre-weaning body weight only in F_2 generation rats. This was not considered sufficient to

issues		warrant lowering the NOAEC but a factor of 2 is applied to take account of this.
Quality of database	1	The key study was conducted to modern regulatory standards and was adequately reported. The findings are supported by results from other studies conducted to modern regulatory standards. On this basis the quality of the database is not considered to contribute uncertainty and it is therefore not necessary to apply an additional factor.
Overall assessment factor: 100		
Endpoint specific DNEL: 6000/100 = 60 mg/kg/day		

The worker DNEL long-term dermal route for systemic effects is 60 mg/kg/day.

This DNEL does not address the potential for local irritation. The risk characterisation will consider whether specific risk management measures are necessary to protect against local effects.

B.5.11.6 Consumer-DNEL short-term for inhalation route

Since CNS depression has been identified as the critical health endpoint for short-term worker inhalation exposure this will also be the critical health endpoint for short-term consumer inhalation exposure. The dose descriptor is the NOAEC of 100 ppm obtained from human volunteers exposed for 7 hours. CNS depression is a dose-dependent effect. Since the consumer exposure scenarios of concern relate to DIY tasks, consumer exposure will be under conditions of light activity. It is therefore necessary to adjust the NOAEC by a factor of 0.67 to take account of the different doses that will be received due to differences in breathing rates between volunteers at rest and consumers engaged in light activity.

100 x 0.67 = 67 ppm (7-hours)

Since the short-term inhalation DNEL has a 15-minute reference period it is also necessary to convert the 7-hour NOAEC to an equivalent dose that would be inhaled over a 15 minute period. This is done using the modified Haber's rule $c^n t = k$ (TGD, Chapter R8, Appendix R8-8, page 108). It is not possible to determine an appropriate value for 'n' from the available data, therefore the default value of 3 to extrapolate from a longer to shorter exposure period will be used.

$\sqrt[3]{(67^3 \times 7 \times 4)} = 203$ ppm (15 minutes)

The corrected starting point is 203 ppm (15 minutes)

Table B.10: Assessment factors and DNEL calculation for consumer DNEL short-term inhalation

Uncertainties	**AF**	**Justification**
Interspecies	-	The starting point is obtained from human data so it is not

differences		necessary to apply a factor to take account of interspecies differences.
Intraspecies differences	10	There are no data to quantify variability in susceptibility to the CNS depressant effects of styrene in the general population. In the absence of substance specific data the default factor of 10 (general population) will be used to take account of differences in susceptibility between consumers for the CNS depressant effects of styrene.
Differences in duration of exposure	1	It is not necessary to apply a factor to take account of duration of exposure.
Dose response and endpoint specific/severity issues	1	The starting point is a NOAEC. Minor impairments in neurobehavioural test performances were reported for volunteers exposed to concentrations of around 200 ppm for 1 hour. These data support the conclusion that 100 ppm can be regarded as a NOAEC for a 7-hour exposure and suggest that the dose-response relationship for CNS depression is not steep. A factor to take account of uncertainties in the NOAEC is therefore not justified.
Quality of database	1	The quality of the database for this endpoint is adequate. The key study is a human volunteer study the results of which show a dose-related trend for increasing severity with increasing dose. The results of the key study are supported by data from several additional human volunteer studies conducted by separate groups of researchers. This consistency provides confidence in the reliability of these studies. It is therefore not necessary to apply a factor to take account of deficiencies in the quality of the data.
Overall assessment factor: 10		
Endpoint specific DNEL: 203/10 = 20 ppm (15 minutes)		

The consumer DNEL short-term inhalation route is 20 ppm (15-minute reference period).

B.5.11.7 Consumer-DNEL long-term for inhalation route

The consumer-DNEL long-term inhalation is being used to assess exposures during DIY tasks. These tasks may take place for varying periods of time depending on the task and may be carried out once for a small repair task or over several days for a large project such as boatbuilding. No continuous (24-hour) exposure scenarios have been identified as a concern for consumers. In the RAR it was suggested that a consumer building their own boat may spend up to 8 hours in one day on the project therefore an 8-hour reference period will be used for the consumer-DNEL long-term for the inhalation route. It is assumed that a consumer will spend 2 days at a time (i.e. a weekend) on their project.

Since developmental toxicity has been identified as the critical health endpoint for long-term worker exposure, the consumer DNEL for long-term inhalation exposure will be based on this endpoint. A NOAEC of 150 ppm has been identified for developmental toxicity in a 2 -generation reproductive toxicity study in which rats were exposed for 6

hours per day, 7 days per week. Since animals were exposed for 6 hours per day, whereas a reference period of 8 hours has been adopted for consumers it is necessary to adjust the starting point by a factor of 0.75. It is assumed that a consumer will spend up to 2 days at a time on a large DIY project. It is therefore necessary to adjust the starting point by a factor of 7/2 (3.5) to take account of the fact that animals were exposed for 7 days per week whereas consumer exposure is only expected to occur on 2 days per week.

The corrected starting point is therefore:

150 ppm x 0.75 x 3.5 = 394 ppm (8-hour)

Table B.11: Assessment factors and DNEL calculation for consumer DNEL long-term inhalation

Uncertainties	**AF**	**Justification**
Interspecies differences	2.5	The dose descriptor is obtained from an inhalation study it is therefore not necessary to apply an allometric scaling factor to take account of differences in basal metabolic rates between animals and humans. There are no data for styrene to quantify other differences between animals and humans that could affect interspecies extrapolation. On this basis the default factor of 2.5 to account for other species differences will be applied.
Intraspecies differences	10	It is necessary to apply a factor to take account of variability in the human population. There are no data to quantify variability in susceptibility to the effects of long-term exposure to styrene in the human population. A default factor of 10 for consumers will therefore be used.
Differences in duration of exposure	1	The dose descriptor was obtained from a 2-generation study in the rat. It is therefore not necessary to apply a factor to take account of differences in duration of exposure.
Dose response and endpoint specific/severity issues	2	At the NOAEC of 150 ppm there was a minor decrease (up to 10%) in pre-weaning body weight only in F_2 generation rats. This was not considered sufficient to warrant lowering the NOAEC but a factor of 2 is applied to take account of this minor uncertainty.
Quality of database	1	The key study was conducted to modern regulatory standards and was adequately reported. The findings are supported by results from other studies conducted to modern regulatory standards. On this basis the quality of the database is not considered to contribute uncertainty and it is therefore not necessary to apply an additional factor.
Overall assessment factor: 50		
Endpoint-specific DNEL: 394/50 = 8 ppm (8-hour) (rounding to the nearest whole number)		

The consumer DNEL long-term inhalation route is 8 ppm (8-hour TWA).

B.5.11.8 Consumer-DNEL long-term for dermal route

Styrene has the potential to be absorbed across the skin and there is the potential for adverse systemic effects to arise as a result of skin exposure. No studies have been undertaken by the dermal route to characterise the dose-response relationship for systemic effects therefore it will be necessary to obtain a long-term dermal DNEL by extrapolation. Since developmental toxicity has been identified as the critical health endpoint for long-term inhalation exposure, this endpoint will also be the critical endpoint for long-term dermal exposure. The NOAEC for developmental toxicity identified from a 2-generation study in the rat was 150 ppm. During this study there was a period of oral dosing. PBPK modelling was used to identify an oral dose that would give rise to equivalent blood concentrations to those achieved from the inhalation concentration. The equivalent oral dose for the 150 ppm concentration was 120 mg/kg/day. An oral dose of 120 mg/kg/day will therefore be used as the starting point to derive a DNEL for repeated dermal exposure.

It is necessary to convert this oral dose to an equivalent dermal dose. The RAR concludes that there is 100 % absorption of styrene from the gastrointestinal tract but in humans only 2 % of a dermal dose of liquid styrene is likely to be absorbed. The corrected dermal NOAEL is therefore:

120 x 100/2 = 6000 mg/kg/day

Table B.12: Assessment factors and DNEL calculation for worker DNEL long-term dermal systemic effects

Uncertainties	AF	Justification
Interspecies differences	10	The starting point is an oral dose descriptor from a rat study. It is therefore necessary to include an allometric scaling factor of 4 to take account of differences in basal metabolic rates between rats and humans. There are no data for styrene to quantify other differences between animals and humans that could affect extrapolation. On this basis a default factor of 2.5 will be applied to account for other interspecies differences giving an overall assessment factor of 10.
Intraspecies differences	10	There are no data to quantify variability in susceptibility to the effects of long-term exposure to styrene in the human population. The default factor of 10 for the general population will therefore be used to take account of intraspecies variability in the consumer population.
Differences in duration of exposure	1	The dose descriptor was obtained from a 2-generation study in the rat. It is therefore not necessary to apply a factor to take account of differences in duration of exposure.
Dose response and endpoint specific/severity	2	At the NOAEC of 150 ppm there was a minor decrease (up to 10%) in pre-weaning body weight only in F_2 generation rats. This was not considered sufficient to

issues		warrant lowering the NOAEC but a factor of 2 is applied to take account of this.
Quality of database	1	The key study was conducted to modern regulatory standards and was adequately reported. The findings are supported by results from other studies conducted to modern regulatory standards. On this basis the quality of the database is not considered to contribute uncertainty and it is therefore not necessary to apply an additional factor.
Overall assessment factor: 200		
Endpoint specific DNEL: 6000/200 = 30 mg/kg/day		

The consumer DNEL long-term dermal route for systemic effects is 30 mg/kg/day.

This DNEL does not address the potential for local irritation. The risk characterisation will consider whether specific risk management measures are necessary to protect against local effects.

B.5.11.9 Summary of critical DNELs

Table B.13: Summary of Critical DNEL values

	Worker	**Consumer**
DNEL short-term inhalation	41 ppm (15-minute TWA)	20 ppm (15 minute TWA)
DNEL long-term inhalation	4 ppm (8-hour TWA)	8 ppm (8-hour TWA)
DNEL long-term dermal	60 mg/kg/day	30 mg/kg/day

B.6 Human health hazard assessment of physico-chemical properties

No concerns for human health were identified in the RAR relating to the physico-chemical properties of styrene (EU, 2008).

B.7 Environmental hazard assessment

This section is not relevant for this transitional dossier which addresses the concerns for human health identified in the RAR. The risk characterisation for environmental effects of styrene did not identify any concerns (EU, 2002).

B.8 PBT and vPvB assessment

B.8.1 Assessment of PBT/vPvB properties – Comparison with criteria of Annex XIII

Not considered to be a PBT in the RAR (EU, 2008)

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

The total number of persons exposed to styrene in the EU is not accurately known. However, in 2004 an enlarged EU styrene industry survey was carried out (CEFIC – APME, 2004). This showed that there were 247 producers and 17,500 converters involved in the styrene industry, employing about 440,000 people. Of these about 250,000 were employed directly in the styrene industry and 190,000 were employed indirectly. The ratio of workers employed in producers:converters is 1:8.

The occupational exposure scenarios for which a conclusion (iii) was reached in the RAR (EU, 20008) are:

- manufacture of UP-styrene resins
- manufacture of SBR and SBL
- manufacture of GRP

Of these, the scenario giving rise to the highest exposures is the manufacture of GRP products. This sector consists mainly of small and medium sized enterprises (SMEs). The manufacturing methods that tend to be used require workers to handle resins directly and in some companies there is little or no effective control.

Consumer exposure scenarios for which a conclusion (iii) was reached in the RAR are:

- consumer boat-building
- consumer user of styrene-containing liquid and paste resins

Of these, boat-building is a very minor use. The use of UP-styrene resins for small scale repair of car body work and boats, or as wood filler, is the predominant consumer use.

B.9.1.1 Summary of the existing legal requirements

B.9.1.1.1 Environmental Legislation

Environmental legislation related to styrene, processes in which it occurs and emission controls are briefly outlined below.

The IPPC Directive stipulates measures for the prevention and reduction of pollution (Directive 96/61/EC). Nowadays all production plants for UP-styrene resins are operated under this directive. In the Polymer BREF (**B**AT (Best Available Techniques) **Ref**erence

Document (European Commission, 2006) that is issued within the framework of the IPPC directive there is general information on techniques that can be used to minimise emissions of air pollutants and dust during polymer production. In addition, for emulsion SBR, a number of techniques are listed, along with an indication of their relative cost and efficiency, which could help reduce airborne levels and hence occupational exposure. Examples include monitoring of flanges, pumps and seals; preventative maintenance; updating seals, valves and gaskets; and closed loop sampling. Within the UK the IPPC Directive is enacted as the Pollution Prevention and Control (England and Wales) Regulations 2000 SI 1973 and guidance is available covering Best Available Techniques (BAT) and Best Available Techniques Not Entailing Excessive Cost (BATNEEC) (DEFRA, 2005).

Emissions to the aquatic environment are covered by the EU Groundwater Directive (80/68/EEC). Styrene is included as a List I substance, under the Groundwater Directive (80/68/EEC) and as such must be prevented from reaching groundwater. The substance may be disposed of to the ground, under a permit, but must not reach groundwater. Within the UK there are Environmental Quality Standards (EQS), as annual average concentrations, for assessing pollution in controlled waters. The EQS for styrene in freshwater is 50 µg/l and the Maximum Allowable Concentration is 500 µg/l.

B.9.1.1.2 Workplace Legislation

The key pieces of EU legislation that govern workplace health and safety are the Framework Directive (89/391/EEC) and its daughter directives including the Chemical Agents Directive (98/24/EC) (CAD). The Framework Directive outlines general principles for the management of workplace health and safety for all workplace hazards. CAD describes specific measures to be taken in relation to the control of chemical hazards. It requires employers to assess the risks to worker health and safety posed by chemical agents in the workplace and to take the necessary preventative measures to minimise those risks by:

- substitution of a hazardous process or substance with a process or substance which presents no or lower hazards to workers;
- designing work processes and engineering controls to minimise the release of a hazardous chemical agent;
- applying collective protection measures at the source of the risk e.g. adequate ventilation and appropriate organisational measures;
- where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment.

Employers should always, by preference, try to prevent exposure. Where it is not possible to do this, they must control exposure adequately by all routes. The Directive outlines a priority order (as above) in which risk management measures should be applied.

B.9.1.1.3 Occupational Exposure Limit Values

The European Union has developed a programme for protection of workers against risks from dangerous substances. Its objectives are:

- to prevent or limit the exposure of workers to dangerous substances at workplaces; and,
- to protect the workers that are likely to be exposed to these substances.

Setting occupational exposure limits is an essential part of this strategy, which is endorsed under the following directives:

- Council Framework Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work;
- Council Directive 98/24/EC on the protection of the health and safety of the workers from the risks relating to chemical agents at work (the "Chemical Agents Directive");
- Commission Directive 2000/39/EC establishing a first list of Indicative Occupational Exposure Limit Values (IOELVs) (for 63 agents);
- Commission Directive 2006/15/EC establishing a second list of Indicative Occupational Exposure Limit Values (IOELVs) (for 33 agents);
- Council Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (the Carcinogens and Mutagens Directive).

The Scientific Committee on Occupational Exposure Limits (SCOEL) provides scientific advice to the European Commission to underpin regulatory proposals on exposure limits for chemicals in the workplace. Its mandate is to examine available information on toxicological and other relevant properties of chemical agents, evaluate the relationship between the health effects of the agents and the level of occupational exposure, and where possible recommend values for occupational exposure limits which it believes will protect workers from chemical risks. SCOEL may recommend OELs, which can be supplemented by further notations and information such as routes of absorption, as:

- eight-hour time-weighted average (8hr-TWA) limits;
- short-term exposure limits (STELs); and/or
- biological limit values (BLVs).

SCOEL aims to derive health-based occupational exposure limits (OELs) that can be recommended when the available scientific data suggest that a clear threshold value can be identified for the adverse effects of the substance in question. For some adverse effects (in particular carcinogenicity, respiratory sensitisation and genotoxicity), according to current knowledge, limits cannot be identified for these endpoints. In these cases, SCOEL can recommend a pragmatic OEL, at levels that are considered to be a sufficiently low risk.

The European Commission uses the scientific advice from SCOEL to make proposals for EU-wide OELs. Limits based solely on scientific considerations are considered as adaptations to technical progress, and are incorporated into proposals for Commission Directives within the framework of CAD and are indicative. Limits that take account also of socio-economic and technical feasibility factors are included in proposals for Council directives under either CAD or the Carcinogens and Mutagens Directive and are binding. The European Commission has not established an OEL for styrene. However, national OELs have been established for this substance in most Member States (see table B.14). Data are from the RAR (EU, 2008) with additional information from CEFIC (CEFIC,

2008a) and the GESTIS International limit values database (BGIA website, 2008). In two cases the values differ between the CEFIC and BGIA sources (Austria and Spain), and the lower values from BGIA are quoted in table B.14.

Table B.14: National Occupational Exposure Limits for Styrene

Country	8-hour TWA (ppm)	STEL (ppm)
Austria	20	80 (15 min)
Belgium	50	100 (15 min)
Canada – Quebec	50	100
Czech Republic	47	234
Denmark	25	25
Finland	20	100 (15 min)
France	50	---
Germany	20	40 (15 or 30 min)
Hungary	~12 (given as 50 mg/m^3)	~12 (given as 50 mg/m^3)
Italy	50	100 (15 min)
Japan	50	--
Luxembourg	20	40 (30 min)
Netherlands	25	50 (15 min)
Norway	25	37.5 (15 min)
Poland	~12 (given as 50 mg/m^3)	~50 (given as 200 mg/m^3)
Spain	20	40 (15 min)
Sweden	20 (10*)	50 (15 min)
Switzerland	50	40
United Kingdom	100	250 (15 min)
USA OSHA	100	200
USA ACGIH	20	40
USA NIOSH	50	100

*When new facilities are planned, or old ones altered they should be designed to meet an 8-hour TWA of 10 ppm (Swedish Work Environment Authority, 2002)

In July 1993, the various European styrene-based resin producing and using industries drew up a voluntary Code of Practice to encourage the industry to work to an occupational exposure limit of 50 ppm 8-hour TWA.

B.9.1.2 Summary of effectiveness of the implemented risk management measures

B.9.1.2.1 Environmental Legislation

The RAR did not identify any concerns for environmental release. It is therefore considered that the current risk management measures for the environment are effective providing they are correctly implemented.

B.9.1.2.2 Workplace Legislation

The principles for managing the risks from chemical agents outlined in CAD can be effective providing employers know the standards of control that they need to achieve. Employers regularly rely on OELs or other benchmarks, where available, to signify this level of control. Providing that the OEL or other benchmark is based on good data it can be an effective risk management tool.

In the case of styrene, there are marked differences between the OELs established in different Member States. This reflects the different historical development of OEL setting programmes across the EU and the different times at which Member States have reviewed national OELs for styrene. An OEL is only effective as a risk management tool if it is based on up-to-date information. The findings from the ESR risk assessment have not been taken into account in the limit values in every Member State and hence, employers in some Member States will be relying on OELs based on out of date information. This will mean that although employers are doing what they believe is necessary to comply with the CAD, the control measures that they implement may not be adequate. Rather than leave it to individual Member States to revise their national OELs for styrene it is recommended that the European Commission should establish an EU-wide OEL for this substance to ensure harmonisation between Member States.

B.9.2 Manufacturing

Occupational exposure during the manufacture of styrene is detailed in Section 4.1.1.1.2 of the RAR (EU, 2008). No concerns were identified for this scenario in the RAR and hence it is not discussed further in this transitional dossier.

B.9.3 Use 1: Occupational Exposure during Manufacture of UP-styrene resin

B.9.3.1 Introduction

There are seven major producers of UP-styrene resin in the EU who each operate several sites. All seven are members of CEFIC and are organized into the UP Resin Group of Plastics*Europe*. They represent about 90% of the total volume produced in the EU, which is approximately 700,000 tonnes per annum according to the latest statistics (2008). There are also about 20 smaller producers of UP-styrene resins who typically have one operational plant and are located amongst most of the EU countries. Production capacities per site vary from 10,000 to 60,000 tonnes per annum (CEFIC, 2008e)

The number of workers exposed to styrene during the manufacture of UP-styrene resins can be estimated, based on the assumption that each production plant runs a full continuous shift system with four shifts each consisting of about 5 operators (CEFIC, 2008b). Hence for the 58 production facilities given below approximately 1200 workers could be exposed to styrene.

Data on the distribution of sites for the production and conversion of UP-styrene resins are available from the CEFIC-APME survey summary table, and are given in table B.15

below. These data represent production and converter sites, and hence in many cases more than one site will be owned by a single producer.

Table B.15: Number of Production and Converter sites around Europe for UP-styrene resin, including the total number of people employed (CEFIC-APME, 2004)

Country	Number of Production Sites (number employed)	Number of Converter* Sites (number employed)
Austria	2 (406)	0 (0)
Belgium	0 (1)	17 (354)
Czech Republic	2 (528)	49 (1,914)
Denmark	0 (1)	0 (0)
Finland	2 (406)	0 (0)
France	5 (1,013)	107 (2,268)
Germany	5 (1,013)	70 (2,127)
Greece	2 (488)	0 (0)
Hungary	1 (266)	15 (590)
Iceland	0 (1)	0 (0)
Ireland	0 (1)	0 (0)
Italy	11 (2,676)	104 (3,096)
Luxembourg	0 (1)	0 (0)
Malta	0 (1)	0 (0)
Netherlands	1 (203)	60 (1,276)
Norway	1 (203)	0 (0)
Poland	5 (1,318)	90 (3,551)
Portugal	2 (488)	0 (0)
Slovakia	1 (266)	0 (0)
Spain	7 (1,703)	20 (595)
Sweden	0 (1)	0 (0)
Switzerland	2 (406)	0 (0)
UK	9 (1,823)	93 (1,985)
TOTAL	58 (13,207)	625 (17,757)

*Converters cover downstream modification and use.

Most polyester resins are formed by the reaction of a mixture of unreactive and reactive (saturated and unsaturated) dibasic acids, often phthalic acid and maleic acid respectively, with a dihydric alcohol such as ethylene glycol at 160 – 200^{o}C and under vacuum in a largely enclosed system (CEFIC, 2008b).

The highly viscous polymer, which is produced during the poly-condensation process, is then dissolved in styrene in a blender at temperatures around 80 °C. In the blender or in a mixing vessel, other ingredients, such as thixotropic agents, UV stabilisers, inhibitors, etc. can also be added. The blenders and mixing vessels are closed vessels, which operate under an atmosphere of inert gas. In modern installations the adding of ingredients is frequently done by means of programmable metering pumps, so the blenders and the mixing vessels are no longer opened during the normal production process. In some installations the formulation ingredients are still added manually, and during this process LEV is in operation on the vessel. This LEV keeps the vessel under a slight negative pressure as long as it is opened, so that styrene vapour cannot escape from the vessel into the surrounding workplace atmosphere (CEFIC, 2008e)

In the rare case that blenders or mixing vessels have to be cleaned, they are drained completely, rinsed with styrene or glycol and blown dry over a number of days. The composition of the atmosphere inside the vessel (e.g. oxygen level, carbon dioxide level) is then checked. Only when the atmosphere inside the vessel is found to be safe may an operator enter the vessel under strict conditions and wearing appropriate breathing protection equipment. Under these circumstances exposure to styrene is not the main issue, rather the safety associated with entering confined spaces (CEFIC, 2008e), and a permit-to-work system should be implemented to minimise all the risks associated with working in confined spaces.

From the final mixing vessel the UP-styrene resin is usually pumped to bulk storage tanks, from where it is either pumped to a road tanker for bulk transport or pumped to a filling line for drumming off into 200 – 250 litres metal drums or 1 tonne IBC containers. Although it differs from producer to producer, as an average approx. 50 % of the resin volume is sold in drums / IBCs and 50 % is supplied in bulk. This means that the drum filling lines are operated daily for several hours (CEFIC 2008e).

Modern drum filling lines are usually highly automated installations that can operate to a large extent without the actual presence of an operator. The filling lines are equipped with exhaust ventilation so styrene vapour escaping from the drums during filling will not enter the work area. They are also normally situated in buildings that are constructed in such a way that natural ventilation ensures that styrene vapours cannot accumulate in the vicinity of the filling line. Industrial heavy duty gloves are used by the operators as a standard, whilst thermal resistant gloves are worn when handling hot resin samples. RPE is normally available and used in situations where high styrene concentrations can be expected (maintenance or equipment failure situations) (CEFIC, 2008e). No further information has been provided on the type of gloves or RPE used.

Liquid resins now usually contain 30 - 45 % of styrene monomer, with the level dependent on the proposed use.

B.9.3.2 Exposure Values from the RAR

Few measured data were available in the RAR (EU, 2008) to characterise short and long term exposure during the manufacture of UP-styrene resins. At one site, personal exposures measured during drumming-off ranged between 2-6 ppm (8-hour TWA). At another site, personal monitoring in the main resin producing room and in the resin formulating plant indicated that exposure to airborne styrene is less than 1.0 ppm (8-hour TWA).

As there was only a small amount of real sampling data EASE was used to estimate long-term exposure (at the blender and during drumming off), short-term exposure (during drumming off) and dermal exposure.

B.9.3.3 Data obtained since the RAR was finalised

CEFIC have confirmed that information in the RAR is still adequate to describe exposure during UP-styrene resin manufacturing (CEFIC, 2008e), so these values will be used in this transitional dossier.

B.9.3.4 Exposure values used for risk characterisation

Table B.16: Values for inhalation exposure data for manufacture of UP- styrene resins used for risk characterisation

Inhalation exposures	RWC exposures ppm (mg/m^3)	Typical exposures ppm (mg/m^3)	Source
Long-term (8-hour TWA)	20 (86.6)	3 (13)	Industry/ EASE
Short-term (15-min)	50 (216.5)	9 (39)	EASE

Conversion factor: 1 ppm = 4.33 mg/m^3
RWC – Reasonable worst case

Table B.17: Values for dermal exposure for manufacture of UP- styrene resins used for risk characterisation

Dermal exposures	RWC exposures mg/ cm^2/d (surface area exposed cm^2)	RWC exposures mg/kg bw/d*	Typical exposures mg/ cm^2/d (surface area exposed in cm^2)	Typical exposures mg/kg bw/d*	Source
Long-term	0.4 (210)	1.2	0.04 (210)	0.12	EASE

* human body weight has been assumed to be 70 kg, as used in the RAR (EU, 2008)

B.9.4 Use 2: Occupational Exposure during Manufacture of Styrene Butadiene Rubber and Latex

B.9.4.1 Introduction

SBL is a colloidal aqueous emulsion (containing 20-35% styrene) that can be used either directly e.g. in adhesives, paper coatings and foams or converted to SBR using coagulation, removal and drying to isolate the rubber fraction from the latex. SBR (containing from 23 - 40% styrene depending upon the grade) is mainly used in the production of tyres but also for producing insulation, moulded rubber goods, footwear and for use in nanocomposites (Sadhu and Bhowmick, 2004).

The enlarged EU styrene industry survey (CEFIC-APME, 2004) covered the manufacture and conversion of SBR/SBL and the summary data are given below.

Table B.18: Number of Production and Converter facilities around Europe for SBR / SBL, including the total number of people employed.

Country	SBR		SBL
	Number of Production Sites (numbers employed)	Number of Converter* Sites (numbers employed)	Number of Production Sites (numbers employed)
Austria	0 (0)	0 (0)	1 (67)
Belgium	1 (115)	17 (354)	1 (67)
Czech Republic	1 (250)	49 (1,914)	0 (0)
Finland	0 (0)	0 (0)	4 (266)
France	3 (423)	107 (2,268)	3 (199)
Germany	2 (307)	70 (2,127)	5 (332)
Hungary	0 (0)	15 (590)	0 (0)
Italy	3 (600)	104 (3,096)	4 (319)
Netherlands	1 (192)	60 (1,276)	0 (0)
Poland	1 (250)	90 (3,551)	1 (88)
Spain	1 (139)	20 (595)	2 (160)
Sweden	0 (0)	0 (0)	2 (133)
UK	3 (423)	93 (1,985)	4 (266)
TOTAL	16 (2,700)	625 (17,757)	27 (1,901)

*Converters cover downstream modification and use.

A typical large producer of SBL within the EU produces about 400,000 dmt per annum. For each site, a typical large production site produces about 130,000 dmt (dry metric tonnes) of SBL, whilst a small one produces about 25,000 dmt per annum. The main companies producing SBL are members of the European Polymer Dispersion and Latex Association (EPDLA).

Whilst the number of people employed (directly & indirectly) in the manufacture of SBR / SBL is about 4,600, the number of workers exposed to styrene during the manufacture of SBR/SBL is approximately 850 based on each of the 43 production plants running a full continuous shift system with four shifts each consisting of 5 operators (CEFIC, 2008b).

SBR is produced by manufacturing companies throughout the EU in closed systems using 25% styrene and 75% butadiene, although there may be slight variations in the percentage of each substance used depending on customer specifications.

In a polymerisation plant, both the styrene and the butadiene are copolymerised in a continuous polymerisation process initiated by a hydroperoxide catalyst. The polymerisation is terminated by the addition of sodium polysulphide or sodium dimethyl dithiocarbamate. During polymerisation, which occurs under slight pressure, the conversion of monomers to copolymer in most cases does not exceed 72 %, so the latex flowing off from the reactor contains unbound monomers. These monomers are removed by degasification under vacuum to produce SBL (e.g. butadiene can be removed with a

compressor and styrene by vacuum steam distillation in the monomer recovery area). Both polymerisation and degasification steps are carried out in closed systems and production halls are equipped with supply ventilation and workers wear antistatic working clothing. The SBL can then be used directly for some purposes, or the rubber (SBR) can be isolated from the latex by coagulation, removal and drying.

B.9.4.2 Exposure Values from the RAR

A number of measured data were available to characterise 8-hour TWA exposures. However, the data were all obtained at one site, and so may not be representative for all sites.

Table B.19: Values for inhalation exposure for manufacture of SBR / SBL used for risk characterisation

Inhalation exposures	RWC exposures ppm (mg/m^3)	Typical exposures ppm (mg/m^3)	Source
Long-term (8-hour TWA)	5 (21.7)	1 (4.3)	Industry
Short-term (15-min)	15 (65)	1 (4.3)	EASE

Conversion factor: 1 ppm = 4.33 mg/m^3

Table B.20: Values for dermal exposure for manufacture of SBR / SBL used for risk characterisation

Dermal exposures	RWC exposures mg/ cm^2/d (surface area exposed cm^2)	RWC exposures mg/kg bw/d*	Typical exposures mg/ cm^2/d (surface area exposed in cm^2)	Typical exposures mg/kg bw/d*	Source
Long-term	0.1 (420)	0.60	0.1 (210)	0.3	EASE

* human body weight has been assumed to be 70 kg, as used in the RAR (EU, 2008)

B.9.4.3 Data obtained since the RAR was finalised

One Member State has provided information on the two main processes that take place in a coagulation plant, namely coagulation of latex and drying of the synthetic rubber. The description indicated that these steps are carried out mostly in open systems, so each piece of equipment e.g. coagulation tanks, expanders, expellers are equipped with local exhaust ventilation. The production hall is equipped with "supply ventilation". The off-gases from local exhaust ventilation units and from dryers (containing trace amounts of hydrocarbons – mostly styrene monomer) are disposed of in the REGENOX® catalytic afterburning unit. The workers always wear protective work clothing. As butadiene is the more volatile compound (compared to styrene) it is more likely to be present in the atmosphere outside the polymerisation reactors, whilst as styrene is less volatile than butadiene it is expected to remain at higher concentrations in synthetic rubber than butadiene after the latex degasification. It is unclear whether this description is representative for SBR manufacturers in other Member States. Monitoring data for this plant are presented in Table B.21.

Table B.21: Results of measurements of levels of styrene in the air of a coagulation plant within a synthetic rubber manufacturing facility, expressed as 8-hour TWA

Year	Total no. of analyses	No. of analyses where substance was not detected	Highest determined level (mg/m^3)*
2006	25	5	8.70
2004	16	16	< 5

*The limit of detection (LOD) for the method was 5 mg/m^3, but no further details are available on how the sampling was carried out.

From the description, the UK CA deduces that the potential for inhalation exposure to butadiene is greater in the polymerisation plant. For styrene the potential inhalation exposure is greater in the coagulation plant, with the level of exposure being enhanced as the equipment used in the coagulation plant is not closed.

Data have been provided (CEFIC, 2008f) from four different companies manufacturing SBR/SBL in the EU, on the processes and control measures in place during the production of SBL dispersions containing about 50% polymer in water.

Table B.22: Key stages and control features being used during manufacture of SBR / SBL (CEFIC, 2008f)

Stage	**Controls measures**
Styrene storage	Storage tanks kept at low temperature (around 10°C)
Transfer of Styrene	Styrene is pumped from its source into storage tanks/reaction vessels via pipe systems
Production System	Batch production used for polymerisation. Reaction vessels are closed systems with automated feeds and appropriate low emission valves etc to prevent diffuse emissions. • Reaction pressure vessel has safety relief venting externally to the production buildings, with vent gases incinerated before release • Pipelines to unload styrene are equipped with pumps with double seals
Purification/concentration/recovery of unreacted styrene	In degassing / steam stripper, steam is used to removal volatile residual organics including unwanted monomer which are condensed and separated in a closed decanting system located outside the production building. This increases the solid content of the aqueous dispersion to about 50% styrene, and the organic layer is used as fuel for the thermal oxidisers.
Cooling of latex	This occurs in vacuum coolers where the temperature is reduced from 100°C to 40°C prior to filtration to remove the polymer agglomeration.
Venting of Gases	Vent gases from the pressures reactor, residual monomer and off-gases removed by stripping etc are vented to thermal oxidisers for incineration and heat may be recovered by steam generation
Cleaning/ Reconditioning	Non-routine activities controlled by Permit-to-Work. Procedures include discharge of waste water from reconditioning

	[styrene value of 3.28 mg/m^3 (40 minutes)] and cleaning chiller [static measurement for styrene of 8.7 mg/m^3].

The information provided (CEFIC, 2008f) indicates that contact with the styrene resin is limited to:

- product sampling - not done on the polymerisation unit. Laboratory analysis and associated sample preparation carried out under fume-hoods which are periodically evaluated;
- connection/disconnection of pipelines;
- cleaning and inspection of the partial condenser (which occurs twice a year);
- cleaning the tanks (for small tanks the tanks are emptied, solids removed and then steamed, with air circulation to remove residual hydrocarbons. For larger tanks, permit-to-work systems operate and air samples are monitored for hazardous substances before anyone is allowed to enter, and respirators are worn when opening the tank. For large styrene tanks self-contained breathing apparatus is used in the initial stage of cleaning);
- maintenance. During maintenance:
    - sampling is carried out near vessel openings during opening/cleaning;
    - biological monitoring (determination of mandelic acid and phenylglyoxylic acid in end-of-shift urine) of maintenance workers is undertaken.

New monitoring data have recently been provided, via CEFIC (CEFIC, 2008f) from three of these four companies mentioned above, encompassing about 10 plants and different Member States. The data are collated below.

Table B.23: New monitoring data showing exposure to styrene during the different stages of the manufacture of SBR / SBL process (CEFIC, 2008f)

Task / Location	Duration	Styrene (in ppm) *	Total number samples taken	Number of Workers exposed	Comments
Manufacturing Plant (1)	8-hour TWA	< 0.0007 – 0.88	10	-	2003- Sept 2008 Personal air sampling gave < 0.0032 – 3.8 mg/m^3
Manufacturing Plant (2)		< 0.009 – 0.74	-	-	Sampling values of < 0.04 to 3.2 mg/m³
Manufacturing Plant (3)		< 0.23 – 1.43	108	-	Sampling values of < 1.0 to 6.2 mg/m³
Manufacturing Plant (4)	8-hour TWA	< 0.005 – 0.006	63	-	Production exposure across 15 work tasks, 2007. Personal sampling gave < 0.02 – 0.026 ppm
Pipe connections / disconnections (unloading styrene from a barge)	4 minutes	0.6	1	30	
	6 minutes	0.4	1	30	

Pipe Connections (sampling)	40 minutes	0.8	1	30	
	40 minutes	0.8	1	30	
Completing unloading cycle from barge	240 minutes	< LOD of 0.02	2	30	
	197	0.2	1	30	
Operator in SBL plant	8-hour TWA	0.09 - 0.15	100 (Approx)	30	
	8-hour TWA	0.02 – 0.1	5	20	
	8-hour TWA	0.02	7	20	
	8-hour TWA	0.02 – 0.04	4	20	
		< LOD of 1.2	67	-	2004-06. Sampling values gave < LOD of 5 mg/m^3
Operator in Coagulation plant		< LOD of 1.2 – 2.0	25	-	5 samples below LOD of 5 mg/m^3 others in range < 5 – 8.70 mg/m^3
		< LOD of 1.2	16	-	Sampling gave values < LOD of 5 mg/m^3, 2004
Cleaning of Stripping Vessel	8-hour TWA	< LOD of 0.05	90	20	
	60 minutes	0.01 – 0.1	8	20	
QA lab	8-hour TWA	0.1	2	2	
Maintenance		0.01 - 0.57			Exposure during engineering, over 10 years with 95% confidence limits
	8-hour TWA	0.01	17	5	
	8-hour TWA	0.01 ppm	1	5	
	8-hour TWA	< 0.02 ppm	31		2007. Personal sampling.
General		0.01 – 3.14 ppm			All samples (from sampling, cleaning & maintenance, June 2007- June 2008

* where date have been presented in mg/m^3 they have been converted using the conversion factor: 1 ppm = 4.33 mg/m^3 and LOD is the limit of detection.

A summary of 8-hour TWA data obtained from four SBR production sites in 2001 and 2005-2008 have also been provided, although no further details are available on the methodology used for the sampling (CEFIC, 2008g).

Table B.24: 8-hour TWA data from four SBR production sites for 2001 and 2005-2008 (CEFIC, 2008g)

Data Range	Number of Samples				
	2001	2005	2006	2007	2008
< 1.0 ppm	14	13	140	319	30
1.0 - < 2.0 ppm	1	-	-	-	2
2.0 - < 3.0 ppm	1	-	-	-	1
< 3.0 – 50 ppm	-	-	-	-	-

B.9.4.4 Exposure values for risk characterisation

The additional inhalation data provided appear to support the long-term (8-hour TWA) inhalation exposures values used for risk characterisation. However, for the short-term inhalation exposures there are some data to suggest that the RWC exposure from EASE may be slightly high, although the typical exposures seem to be similar. No additional dermal data have been provided. On this basis, the values for risk characterisation remain unchanged.

Table B.25: Values for inhalation exposure for manufacture of SBR / SBL taken forward for risk characterisation

Inhalation exposures	RWC exposures ppm (mg/m^3)	Typical exposures ppm (mg/m^3)	Source
Long-term (8-hour TWA)	5 (21.7)	1 (4.3)	Industry
Short-term (15-min)	15 (65)	1 (4.3)	EASE

Conversion factor: 1 ppm = 4.33 mg/m^3

Table B.26: Values for dermal exposure for manufacture of SBR / SBL taken forward for risk characterisation

Dermal exposures	RWC exposures mg/ cm^2/d (surface area exposed cm^2)	RWC exposures mg/kg bw/d*	Typical exposures mg/ cm^2/d (surface area exposed in cm^2)	Typical exposures mg/kg bw/d*	Source
Long-term	0.1 (420)	0.60	0.1 (210)	0.3	EASE

* human body weight has been assumed to be 70 kg, as used in the RAR (EU, 2008)

B.9.5 Use 3: Occupational Exposure during Manufacturing of Glass Reinforced-Plastic (GRP)

B.9.5.1 Introduction

GRP is a type of fibre reinforced plastic (FRP). FRPs are composite materials consisting of a polymer resin matrix reinforced by a fibrous material. The fibres are usually fibreglass, carbon or aramid and the polymer resin is usually based on polyester, vinylester or an epoxy chemosetting plastic. In the case of GRP, the polymer resin is based on an unsaturated polyester (UP) dissolved in styrene which also acts as the cross-linking agent during curing.

GRP is a strong lightweight material which is durable, resistant to a wide range of chemicals and has good electrical insulating properties. This means that it has a wide variety of applications including:

- marine applications (boats, yachts, kayaks);
- applications in the automotive and transport industries (vehicle body parts, technical parts, structural components for buses and trains, insulated container panels for refrigerated transport);
- applications for building and construction (façade elements, roofing, architectural features where light weight is necessary);
- sanitary ware (e.g. baths and shower cubicles);
- industrial uses (storage tanks and pipelines for corrosive liquids, pipes for exhaust gases of waste incinerators);
- applications in the energy sector (wind turbine blades and housing for wind turbine generators) and
- applications in the telecommunications sector (owing to radiofrequency permeability GRP can be used to shroud the visual appearance of telecommunications antennae and to make radar domes).

UP resins without fibre reinforcement may also be used to make rain gutters, drainage channels, pipes for effluent water, buttons, the resins are present in polyester paints and are used in resin pastes for car body and boat repairs.

It has been estimated that the total volume of composite materials produced using UP-styrene resins in the EU is around 1.2 million tonnes per annum (CEFIC, 2008b). Due to the nature of the GRP industry, the majority of fabrication companies are small and medium sized enterprises employing between one and a few hundred employees. CEFIC estimate that there are currently between 7,000 and 10,000 companies manufacturing GRP articles in the EU. Depending on the size of the company, between 1 and 20 employees may potentially be exposed to styrene at each company leading to an estimated 35,000 to 200,000 workers potentially exposed to styrene.

A variety of processes are used to fabricate GRP articles (described below). Open mould applications account for around 60% of resins supplied and include hand lay-up, spray-up, filament winding and casting operations. Closed moulding applications account for most of the remaining volume of resin supplied for occupational use and include resin transfer moulding (RTM) and vacuum infusion, continuous lamination, sheet and bulk moulding compound (SMC/BMC) production and moulding, pultrusion and sewer relining. Specialised applications account for around 5% of the resins supplied. The following table from good practice guidance prepared by the German Chemical Industries Statutory Accident Insurance Association (BG, 1999) describes different processing methods for UP-styrene resins.

Table B.27: Processing methods for UP-styrene resins

Processing Reactive Resins				
Fibre reinforced			**Non-fibre reinforced**	
1. Manual Process –partly large scale use with open laminates	**2. Partially mechanised process-discontinuous,**	**3. Mechanical, predominantly automated continuous process**	**4. Moulding process**	**5. Painting / surface treatment**
1.1Hand lamination	2.1 BMC manufacture -small and medium batch	3.1. Manufacture of -tiling -tracks	4.1 Button manufacture	5.1 Application of polyester paints -coating.
1.2 Fibre spraying	2.2. Injection moulding BMC	3.2 SMC manufacture	4.2 Manufacture of UP-resin concrete - Aggloarmor - imitation stone	5.2 Application of fillers containing styrene
1.3 Winding using rovings, mats, tissue, hand laying.	2.3. Moulding SMC, BMC	3.3. BMC manufacture - large batch	4.3 Furniture applications-embedding	
1.4. Injection process	2.4 Wet moulding	3.4 Profile drawing	4.4. Filler manufacture	
1.5. Finishing coatings	2.5 Winding using predominantly rovings -parallel winding -cross winding 2.6 Centrifugal process 2.7 Preform manufacture	3.5 Continuous winding process		
Abbreviations BMC and SMC refer to resins processed in a hot-press moulding process (semi-finished products)				

BMC = Bulk moulding compounds
SMC = Sheet moulding compound
Aggloarmor = imitation marble

The main source of exposure to styrene during the manufacture of GRP articles and the use of styrene based resins is evaporation of styrene during the application (dynamic phase) and curing (static) stages. During the dynamic phase, the resin or gelcoat is sprayed or brushed onto the mould and the lamination rolled out. The surface of the resin is constantly being refreshed and this leads to the highest emissions of styrene. The static phase begins when the moulding is left to cure. Generally resins that are formulated for spray application contain a higher percentage of styrene to reduce viscosity.

Resin suppliers have developed resins that have lower styrene emissions during use. There are two types. Low styrene emission (LSE) resins contain vapour suppressants which form a film over the resin surface once the moulding is left to cure. Film forming additives are only effective during the static phase when the surface is undisturbed. Low styrene content (LSC) resins are formulated with a lower percentage of styrene. These

create lower emissions during the dynamic and static phases. It is also possible to purchase LSC resins that include film forming agents.

LSE and LSC resins are available for laminating. It is not possible to include film forming agents in gelcoats because the film could impair the bond between the gelcoat and the subsequent lamination. However, LSC gelcoats are available. Topcoats are sometimes applied as the last layer on a cured laminate to give a resin-rich and tack free inner surface finish. Topcoat resins can contain film forming agents and may also be formulated with low styrene content. Data from good practice guidance produced by industry illustrates the differing percentage losses of styrene during the different manufacturing processes.

Table B.28: Typical percentage of styrene loss with different processing techniques (CEFIC, 2008a)

Process	**Styrene loss %**
Gelcoat spray	10-14
Spray-up, non LSE resin	7-10
Gelcoat, brush	6-8
Filament winding	5-7
Hand lay-up, non LSE resin	4-6
Spray-up, LSE/LSC resin	4-6
Topcoat, spray	4-5
Topcoat, brush	3-4
Hand Lay-up, LSE/LSC resin	3-4
Pultrusion	1-3
Polymer concrete etc	1-3
Continuous lamination	1-2
SMC/BMC manufacturing	1-2
SMC/BMC processing	1-2
Closed processes (RTM/RTM light/ infusion)	<1

In addition to exposure to styrene vapour, there is also the potential for exposure of the skin and eyes to styrene as a result of direct contact with resins during manual fabrication tasks.

B.9.5.2 Exposure values from the RAR

A reasonably large quantity of measured 8-hour TWA exposure data was available to characterise occupational exposure to styrene in the GRP industry. However, much of this data lacked sufficient contextual information to enable comparisons to be made between exposure levels in different studies and under different risk management regimes. Since the job/task which usually leads to the highest level of exposure is hand lay-up/lamination, this was used to determine the RWC and typical exposures for all types of GRP fabrication. The exposure values used for risk characterisation in the RAR are summarised in tables B.29 and B.30 below:

The 8-hour TWA values used for risk characterisation of inhalation exposure in the RAR were based on published data obtained between 1990 and 1996, HSE data obtained between 1997 and 2002 and data from the CEFIC pilot study for a harmonised

monitoring programme gathered in 2002/2003. Short term exposure values were based on data from Kolstad *et al*, (2005) data from HSE's NEDB and modelled exposure data from EASE. The risk characterisation for dermal exposure was based on data gathered for the Riskofderm project.

Table B.29: Values for inhalation exposure for manufacture of GRP articles used for the risk characterisation in the RAR.

Inhalation exposures	**RWC exposures ppm (mg/m^3)**	**Typical exposures ppm (mg/m^3)**	**Source**
Long-term (8-hour TWA)	100 (433)	40 (173)	Industry /HSE/ Kolstad *et al*
Short-term (15-min)	180 (779)	60 (260)	Kolstad *et al* /HSE /EASE*

Conversion factor: 1 ppm = 4.33 mg/m^3
RWC = reasonable worst case
* exposure predicted for hand lay-up, assuming wide dispersive use, direct handling and dilution ventilation

Table B.30: Values for dermal exposure for manufacture of GRP articles used for the risk characterisation in the RAR.

Dermal exposures	**RWC exposures $mg/cm^2/d$ (surface area exposed cm^2)**	**RWC exposures mg/kg/d***	**Typical exposures $mg/cm^2/d$ (surface area exposed cm^2)**	**Typical exposures mg/kg/d***	**Source**
Long-term	8 (820)	93.7	1.2 (820)	14.1	Riskofderm**

*Based on a 70kg adult
**Riskofderm project results available at: http://annhyg.oxfordjournals.org/cgi/content/full/50/5/469#TBL6

Industry considers that the exposure values presented in the RAR give a good overall view of the exposure situation as it was until approximately 2000. However, the data may not reflect recent changes due to improvements in working practices that industry have been implementing over the last few years. It should also be noted that the figures used for risk characterisation in the RAR relate to one type of fabrication process, hand lay-up/lamination. Based on the percentage loss figures above and with reference to the process specific exposure data provided by CEFIC for the RAR and reproduced below, it is likely that alternative GRP fabrication processes (e.g. closed moulding processes such as RTM and vacuum infusion and machine moulding processes such as filament winding and pultrusion) are likely to be associated with a lower potential for exposure than is suggested by the exposure values used for risk characterisation in the RAR.

B.9.5.2.1 Exposure Data provided by CEFIC for the RAR

The following occupational exposure data were received from CEFIC during drafting of the RAR. These data were collated by CEFIC and the following tables (reproduced directly from their report) were produced to summarise exposures across the range of activities using GRP. All of the exposure values are in ppm and were taken using a variety of methods. They were taken over different time periods and may not all represent 8-hour TWAs. The report provided the following conclusions:

- open mould operations show the highest exposure of workers to styrene with gel coating being the activity with the highest exposure. The wealth of data on open mould operations show that keeping the workers exposure below the specified MAC value has proved to be very difficult.

- conversely in all data coming from closed mould injection operations the styrene concentration stays well below the MAC value.

- SMC/BMC operations also typically show a high variation in styrene concentrations. The highest values are obtained during SMC moulding when SMC sheets are laid in the press, essentially the "open mould" part of the operation.

Table B.31: Hand Lay Up

Country	N	Min (ppm)	Max (ppm)	Average (ppm)	50%ile (ppm)	90%ile (ppm)
Austria	19	2.6	52.1	17.1	8.6	37.3
Belgium	3	4.9	41.2	24.4	*	*
Denmark	156	0.3	282.7	31.9	19	73.6
France	1500	0.2	313.8	45.2	36.3	101
Germany	1171				18	61
Italy	1030			55.4	38.6	
Netherlands	48	4	111	31	22	68
UK	255	1	374	35	23	90

N – number of samples * Insufficient data

Table B.32: Spray Up

Country	N	Min (ppm)	Max (ppm)	Average (ppm)	50%ile (ppm)	90%ile (ppm)
Austria	1	11.7	11.7	11.7	*	*
Belgium	23	0.7	84.5	18.9	10.6	47.6
Denmark	3	49.1	186.9	105.9	*	*
France	458	2.3	380.1	43.6	41.7	98
Italy	166			31.3	19.2	
Netherlands	76	2	374	46	30	94
UK	1	45	45		*	*

N – number of samples * Insufficient data

Table B.33: Gel Coating

Country	N	Min (ppm)	Max (ppm)	Average (ppm)	50%ile (ppm)	90%ile (ppm)
Austria	4	8.2	13.7	11.5	*	*
Belgium	2	9.9	50.5	30.2	*	*
Denmark	36	3	133.2	28.8	19.6	60.8
France	259	0.1	193.2	31.3	21.7	85
Germany	67				10.7	47.9
Netherlands	12	9.2	100	47.3	34.9	98
UK	2	26	45	35.5	*	*

N – number of samples * Insufficient data

Table B.34: RTM

Country	N	Min (ppm)	Max (ppm)	Average (ppm)	50%ile (ppm)	90%ile (ppm)
Denmark	33	0.5	49.1	3.8	1.8	5.7
Sweden	1	0.5	0.5		*	*
UK	19	1	98	16.3	8	27.8

N – number of samples * Insufficient data

Table B.35: SMC/BMC Production

Country	N	Min (ppm)	Max (ppm)	Average (ppm)	50%ile (ppm)	90%ile (ppm)
Austria	1	12.9	12.9	12.9	*	*
Belgium	1	2.6	2.6			
Germany	77				17.1	38.3
UK	84	1	122	27	18	62.4

N – number of samples * Insufficient data

Table B.36: SMC/BMC Moulding

Country	N	Min (ppm)	Max (ppm)	Average (ppm)	50%ile (ppm)	90%ile (ppm)
Austria	5	8.9	16.9	21.1	11.9	15.3
Belgium	3	6.3	56.1	28.5	*	*
France	432	0.9	290.9	44.4	33.8	102
UK	38	1	100	15	10	35.8

N – number of samples * Insufficient data

Table B.37: Filament Winding

Country	N	Min (ppm)	Max (ppm)	Average (ppm)	50%ile (ppm)	90%ile (ppm)
Denmark	3	10.3	19.6	15.8	*	*
Italy	71			20.1	11.1	
Netherlands	20	2.1	31.0	10.3	6.4	21.6

N – number of samples * Insufficient data

Table B.38: Pultrusion

Country	N	Min (ppm)	Max (ppm)	Average (ppm)	50%ile (ppm)	90%ile (ppm)
Denmark	20	0.2	5.8	1.6	0.8	4.1
Italy	71			20.1	11.1	
UK	23	1	68	11	7	19

N – number of samples

There are over 12,000 results in total from across most EU Member States. They generally date back over the last ten years (the French data were from 1987 to 2001). The samples were collected using a variety of methods and sampling times and the results may not all represent 8-hour TWAs. It is therefore not possible to be confident about the quality of all the data. In addition, the data were sent to CEFIC in many different forms, some summarised and some as individual data points. In addition, to produce the above tables they had to make assumptions about the data, and in some cases generate figures for their calculations.

These data in these tables for RTM, SMC/BMC production and moulding, filament winding and pultrusion (tables B.34-B.38) support the view that lower exposures are likely for these processes compared with hand lay-up, spray up and gelcoating (tables B.31-B.33). Modern resin moulding techniques are clearly helping to drive down exposures, but older open moulding techniques are still in extensive use across the EU. These open moulding processes result in higher exposures.

B.9.5.2.2 Data from CEFIC Pilot Study for a Harmonised Monitoring Programme provided for the RAR

In 2002, CEFIC set up a pilot study to test a proposed harmonised monitoring programme for occupational exposure to styrene in the GRP industry. The pilot study took place in seven EU countries: Belgium and the Netherlands, Denmark, Finland, France, Italy and the UK. In each country the main resin supplier was asked to distribute 50 ‘do-it-yourself’ sampling kits among 15 – 25 of their customers. Each ‘styrene sampling kit’, consisted of a 3M badge, an instruction leaflet for the worker on how to use the badge, a task registration form and a return envelope. All of the returned badges were collected and sent to the same laboratory for analysis. The study was carried out between December 2002 and April 2003.

78% of the 88 companies that received sampling kits participated in the study and 76% of the 300 sampling kits were returned. The report indicates that the duration of the

measurements ranged from 400 minutes to 600 minutes, with an average sampling time of 480 minutes, therefore the results below will be assumed to be representative of 8-hour TWAs. Table B.39 gives the sampling results from this study. As has been seen in the other industry data presented, rolling and hand lamination gives rise to the highest exposures, closely followed by other open mould tasks.

Table B.39: CEFIC data on styrene concentration in breathing zone by job category

Job category	Styrene concentration in breathing zone (8-hour TWA)			
	Number of samples	Min (ppm)	Max (ppm)	Median (ppm)
Gel coating	10	6.2	78	33
Spray up	17	8.3	126	44
Rolling/ Hand laminating	61	1.6	167	47
Filament winding	2	42	121	
Variable – open mould	63	2.3	112	35
Finishing	8	1.1	50	27
Injection	9	3	18	10
Cold press	4	7.8	31	15
SMC/BMC moulding	4	0.7	25	21
Variable – closed mould	5	6.2	19	9
SMC/BMC production	5	14.3	25	20
variable- other	26	0.5	44	18
Unknown	4	4	45	20
TOTAL	**218**	**0.5**	**167**	**30**

B.9.5.3 Data obtained since the RAR was finalised

B.9.5.3.1 Inhalation

Three reports have been published that provide additional information beyond that available in the RAR.

One report is available that provides a comparison between exposures during open and closed moulding of boat hulls at a boat manufacturer in the USA (Valladares *et al*, 2005). The open mould plant produced mainly larger boats of 24 feet or more and it was common for several individuals to work on a single boat at the same time. Gelcoats were sprayed within an enclosed and ventilated booth. A barrier coat (containing styrene as a major component) was also applied. Boat hulls were then moved to the factory floor for spray lamination. Separate workers rolled out the lamination. Although the plant was ventilated, the ventilation was not working effectively at the time of the survey. The exposure values obtain during this survey can therefore be considered to represent RWC exposures. The report indicated that workers wore respirators while moulding, applying gel coat and applying spray core. The policy at this workplace was for the mandatory use of RPE (which the report stated was appropriate and properly face fit tested) in areas where there was a potential for exposure to styrene at levels near to above 50 ppm. Employees were also required to wear safety glasses in production areas. Few details were provided on the types of resins in use but the report indicated that the resin contained 32.25% styrene. Mean personal 8-hour TWA values of around 30 ppm were measured for gelcoaters, 53 ppm for gunners (spraying resin and fibre), 77 ppm for rollers and 46 ppm for sprayers (applying spray core).

The closed moulding plant used an injection moulding method referred to as Virtual Engineered Composites (VEC). Moulds were located inside semi-enclosed, ventilated booths. Gelcoat was sprayed manually onto the lower half of the mould. This involved one worker, and the ventilation system in the booth automatically turned on to a high airflow setting during the task. Once the gelcoat had partially cured, the glass mat was laid out, the mould closed and resin injected under pressure. The report stated that employees regularly wore respirators during gelcoating but not for other tasks. An 8-hour TWA value of around 8 ppm was recorded for sprayers (carrying out gelcoating) at the closed moulding plant and 0.8 ppm for operators (placing glass fibre mats and operating the moulds).

Since the predominant source of exposure to styrene for sprayers at the closed moulding plant was gelcoating, the authors calculated the potential short term exposures that may arise during this task. Assuming that each hull takes 15 minutes to gelcoat, 6 hulls are coated per day and the exposure for the remainder of the day is at a similar level to that of the operators, short-term exposures of around 35-40 ppm can be estimated for gelcoating.

This study supports the view that the use of closed moulding processes has the potential to significantly reduce 8-hour TWA exposure values because they limit evaporation into the workroom of styrene during the laminating and curing stages. The study also indicates that even where closed moulding processes are adopted there is a need to consider potential short-term exposures during tasks (e.g. gelcoating) that are not enclosed.

Carlo *et al* (2007) presented the results of a week long survey to investigate exposure to styrene and noise at a small yacht maker in Florida using both open and closed moulding processes. The aim of the survey was to quantify exposures during moulding and to evaluate the effectiveness of the engineering controls that were in place. The company manufactured yachts from 37 to 50 feet in length with an output of around 1 yacht per week. It employs around 170 staff of whom fewer than 20 are directly exposed to styrene. With the exception of gelcoating, tasks requiring the use of styrene resins were performed in an open workshop. Gelcoating was performed in a semi-enclosed spray booth fitted with a ventilation system designed to pull 35,000 cubic feet per minute of air. Gelcoated parts were left to cure in the booth for around 30 minutes before being moved to the open workshop.

Lamination of larger parts was done manually using low-flow pressure-fed perforated rollers fitted with long handles to apply resins and roll-out between laminations. This maximised the distance between the workpiece and the operator's breathing zone. Smaller parts, e.g. hatch covers and water tanks, were produced using an enclosed moulding process (vacuum infusion moulding) in which a flexible plastic sheet is used to form the upper surface of the mould and resins are pulled through the glass fibre matting under reduced pressure.

For ventilation, the main workshop relied on the exhaust fans in the gelcoating booth and a similar fan situated in a grinding booth on the opposite side of the workshop. At the time of the survey, the large roller doors to the workshop were kept open. Pedestal fans were used in the workshop to push contaminated air away from workers during hand

lamination tasks. Smoke tubes revealed that the air in the workshop was well mixed but was not moving in the direction intended by the general ventilation system.

All production workers wore tyvek overalls and safety glasses. Laminators wore impermeable gloves (not further described) during lamination but gloves were not consistently worn for other tasks. Although RPE was available its use was not mandatory for any task. Some laminators were seen to be wearing particulate masks (models Moldex 2400, North 7130, 3M 8000).

Table B.40: Styrene content of products used at this workplace (Carlo *et al*, 2007)

Product description	Application	% styrene
General purpose resin	Roller	35
General purpose resin	Hand Lay-up	35
ASCC vinyl ester	Roller	34.1
Tooling	Roller	34.1
Casting resin	Hand lay-up	35
Gelcoat-lite camel	Spray	27
Gelcoat-lite Ivory	Spray	28
PG-9 putty	Hand	16
SprayCore (polycore)	Spray	29
Deck bonding putty	Hand	26
Styrene	Spray	100
Duratec-All varieties	Spray	21
Liner putty	Hand	14
Tooling gel	Spray	37
Dion vinyl ester resin	Hand	45
Hexion infusion	Infusion	42.5
Dion vinyl ester resin	Infusion	45

Table B.41: Examples of quantities of resin used for a 48 ft yacht (Carlo *et al*, 2007)

Part	lbs. of resin
Hull	
Skin	324.7
Lamination 2	707
Lamination 3	450.8
Lamination 4	434.7
Lamination 5	559.4
Sub total	**2476.6**
IGU	
Skin	238.3
Lamination 2	453.1
Lamination 3	286.1
Bond wood	167.4
Sub total	**1144.9**
Deck	
Skin	300.8
Lamination 2	632.5
Deck bubble 1 & 2	497.8
Lamination 3	460.4
Sub-total	**1891.5**
Headliner	
Skin & Lamination 2	303.2

Lamination 3	425
Sub total	**728.2**
Grand total	**6241.2**

Long-term personal and background samples (duration of sampling was not reported so it is not possible to determine if the values represent 8-hour TWAs) were taken using pumped sampling onto charcoal sorbent tubes with GC FID analysis. The limit of detection for the analytical procedure was 0.33 ppm and the limit of quantitation was 2.93 ppm. In addition, electrochemical direct reading instruments were used for real time monitoring to identify jobs/tasks contributing the most to worker exposure.

Table B.42: Personal and area sample statistical results for styrene vapour (Carlo *et al*, 2007).

Sample type	Job title	Geometric mean (ppm)	Geometric standard deviation	Lower 95% confidence limit (ppm)	Upper 95% confidence limit (ppm)	n
Area	Eastern gelcoat booth	7.92	1.39	4.66	13.45	4
Area	Western gelcoat booth	6.63	1.12	5.51	7.98	4
Area	Tooling area	1.91	1.35	1.19	3.07	4
Area	Closed-mould area	5.67	1.2	4.22	7.6	4
Area	Small part lamination area	6.46	1.27	4.39	9.51	4
Area	Large part lamination area	6.57	1.23	4.75	9.1	4
Area	Grinding booth	7.06	1.23	5.07	9.84	4
Personal	Gelcoat	13.65	1.22	9.97	18.68	4
Personal	Gelcoat assistant	4.27	1.68	1.87	9.76	4
Personal	Gelcoat supervisor	10.15	1.18	7.81	13.17	4
Personal	Grinding/cutting	5.15	1.24	4.31	6.15	8
Personal	Hull laminator	13.01	1.28	11.03	15.35	11
Personal	Infusion	7.34	1.39	4.33	12.45	4
Personal	Infusion small parts supervisor	7.04	1.26	4.87	10.16	4
Personal	Large part laminator	13.51	1.43	11.75	15.52	28
Personal	Putty and cutting	6.66	1.12	5.07	8.77	3
Personal	Small parts laminator	11.55	1.28	9.39	14.2	8
Personal	Tooling	2.58	1.96	1.68	3.96	12

Although some measures were taken in this workshop to reduce worker exposure to styrene, in many cases the measures that were in place were not being used correctly. The authors considered that the relatively low exposures measured during lamination were due to the combination of general ventilation, overhead doors being open and the use of low-flow pressure-fed rollers to apply resins. It was noted that lamination of some difficult to reach areas of hulls required workers to lean into the moulds and this could have given rise to short-term high levels of exposure that are not reflected in these long-term sampling results. This study demonstrates that although closed moulding has the

potential to markedly reduce long-term worker exposure values, this is only effective where it is segregated from open moulding processes.

A study has also been published that looked at trends in exposure to styrene during the manufacture of GRP articles in Europe for the period 1966 – 2002 (van Rooij *et al*, 2008). They based their analyses on published reports, national databases (from Germany – MEGA, the UK – NEDB, Norway – EXPO and Denmark) and data provided by CEFIC. It is likely that much of this data was also presented in the RAR. Most of the data derive from Nordic countries, Germany, France and the UK. Little data was available for Spain, Portugal and eastern European countries. In terms of processes, most data had been gathered from companies using open mould techniques (94%) with only 2% from companies using closed mould techniques. The remaining 4% related to other techniques or there was insufficient information to identify which type of process was being used.

For open moulding, mean concentrations measured in the breathing zone during the 1970's and 1980's ranged up to 150 ppm compared to mean concentrations of 12 – 48 ppm (8-hour TWA) for the 1990's and up to 2002. Average mandelic acid concentrations in post shift urine between 1976 and 1990 ranged between 300 and 1700 mg/g creatinine whereas the highest mean value post 1990 was 600 mg/g creatinine and many were below 300 mg/g creatinine. Mean airborne concentrations measured in the breathing zone during closed moulding operations in from 1990 onwards ranged from 2 – 21 ppm (8-hour TWA). Biological monitoring data were not reported for closed moulding.

A temporal trend analysis indicated the average annual decline in breathing zone concentrations measured for open moulding was 5.3% for the period 1966-1990 compared with an annual decline of only 0.4% after 1990. The average annual decline noted in biological monitoring results was even steeper at 8.9% and there seemed to be a greater decline in air measurements in companies that also recorded biological monitoring data. Owing to the nature of the reports from which the data were obtained it was not possible to link these reductions in exposure levels to the implementation of specific control measures though the introduction of LSE resins in the 1970's and 1980's may have contributed to the decline in measured exposures. The authors did not have sufficient information on conditions at the various workplaces to comment on the small reductions observed for exposures in open moulding after 1990. It is possible that the levels that are found in the more recent studies are approaching the minimum that can be achieved using LSE/LSC resins.

B.9.5.3.2 Dermal

No additional dermal exposure data are available.

B.9.5.4 Current risk management measures

In order to determine whether the exposure values used for risk characterisation in the RAR are still relevant, it is necessary to consider whether the styrene resin formulations in use and the risk management measures that were in place at the time the data in the RAR were gathered are relevant for modern GRP workshops.

Using information contained in recent UK Health and Safety Executive (HSE) inspection reports it is possible to gain an indication of the risk management measures that can be found in some modern workshops and the corresponding levels of exposure that were measured on the day of the visit. It should be noted that the nature of inspection visits means that the reports will often relate to situations in which control is poor. It should also be noted that production may not have been at the maximum capacity for the workshop on the days when measurements were taken and hence the sampling data may not necessarily reflect the highest exposure levels that could be experienced with the control measures that were witnessed.

For the period 2005 – 2008 there are reports for 12 visits. The workshops visited were generally small scale enterprises employing between 1 and 34 workers for production work and manufacturing small and medium sized articles including bathroom fittings and smaller leisure boats. The risk management measures that were in place at each site were patchy. In several cases all fabrication tasks were carried out in a single workroom and resins were stored and mixed in the same workroom. Several workplaces relied on general ventilation provided by opening factory doors, in some cases pedestal fans were provided to help airflow but this was not common. LEV was generally inadequate or not used. Although RPE was usually available it was not necessarily appropriate for the task (for example at one workplace, GRP workers were seen to be wearing ori-nasal RPE fitted with FFP1 filters which is inappropriate to control exposure to solvents) and was not necessarily properly fit tested or maintained. Gloves were generally provided but were not always of the most suitable type and were not properly maintained. The styrene content of the resins in use was not always reported but where this information was provided, styrene content ranged from around 30 -50%. One report noted that the resin in use was of the LSE type. The 8-hour TWA values in these reports are summarised in table B.43 below. We have no information to indicate how representative this information is for other Member States.

Table B.43: NEDB data for 2005 – 2008

Activity	Year	No. of Samples	8-hour TWA (ppm)			
			Range	Arithmetic Mean	Median	90th percentile
	2005	24	2.7 – 113*	40	32.4	93
	2006	6	6 – 28.9	15	12.2	
	2007	14	2.5 – 53.5	17.4	15	38.5
	2008	11	3.8 – 63.4	16	8.6	58.1

*This value is likely to be an overestimate. The sample was collected over 59 minutes and extrapolated to an 8-hr TWA value on the assumption that the exposure level was at the same level for 8 hours. Samples collected over a longer duration at this workplace (173-205 minutes) revealed concentrations ranging from 10.1 – 49.3 ppm.

Good practice guidelines have been produced for GRP manufacture by both industry and regulatory authorities. Guidance is available on the website of the trade association Plastics*Europe* (http://www.plasticseurope.org). The following risk management measures are recommended:

- use closed moulding processes where possible;

- use low styrene emission and low styrene content resins where possible;
- store resins in separate, well ventilated storerooms with adequate bunding to contain leaks;
- resins and gelcoats should be dispensed from storage drums using dip pumps and stored in lidded containers;
- waste for disposal should be stored outside in closed containers or in a separate well ventilated room if outdoor storage is not possible;
- avoid overspray and spills during spraying/lamination;
- ensure the working areas are kept clean. Contamination of the working area can be minimised with the use of disposable paper or solvent resistant films on tables and floors which is changed on a daily basis or after a severe spill;
- remove spills as soon as possible;
- wear appropriate safety clothing such as gloves, coveralls and goggles;
- regular monitoring of airborne levels;
- maintain workshop temperatures between 18 to 25^{o}C for optimal resin performance;

Industry considers that general ventilation will only be suitable for small scale fabrication and that in most cases carefully designed LEV taking into account the layout of the workshop and size and shape of the articles being made should be in place. The guidance provides examples of the types of LEV that could be considered and advice on how to calculate the general ventilation capacity that may be required based on the size of the workshop, the amount of resin used and the estimated percentage evaporation of styrene during use.

Where RPE is used it should be carefully selected. The most recent version of the guidance (April 2008) indicates that half face masks with active carbon cartridge reduce exposure to styrene by only 25-30% (also these masks may be less effective where other solvents are in use e.g. acetone, methylene chloride) whereas a “ventilation assisted” full face mask will provide a reduction in exposure of around 80%.

Advice on controlling exposure to styrene during GRP manufacture has also been published by the German Chemical Industries Statutory Accident Insurance Association (BG, 1999). The following measures were recommended:

- the use of automated/enclosed processes, but this may not be technically feasible for complex shapes or practical for large parts such as boat hulls and where items are produced in short production runs;
- the use of LSE/LSC resins;
- the use of photo-hardening resins. These contain a light-initiator enabling the surface of the laminate to be cured immediately on completion of the moulding creating a skin that will reduce emissions while the rest of the moulding cures;
- wrapping with film (wrapping process);
- processing semi-finished products, intermediate stages;
- injection moulding;
- the installation of spray stations, spraying booths (fibre spraying, gel-coat spraying);
- the use of local exhaust ventilation at the workplace; and
- process area ventilation.

This German document provides illustrations of ventilation systems with the potential to limit exposure to styrene during hand lay-up and spray-up and case studies demonstrating the efficacy of effective ventilation and describes case studies where substantial reductions in airborne styrene levels were achieved by the introduction of ventilation systems. In two cases, the installation of ventilated booths for open lamination tasks was able to reduce styrene levels in the workers breathing zone to levels of 9 and 7 ppm respectively, representing an almost 10 fold reduction from previous levels. In another case study an airborne concentration of 4.6 ppm was achieved by the introduction of a targeted laminar air flow at a temperature around 5ºC lower than the ambient temperature within the workshop. In a fourth case study, airborne styrene concentrations were more than halved by replacing hand lamination with closed moulds and the use of general ventilation.

Measures recommended by the Norwegian Labour Authority in its good practice guidance developed to help businesses achieve compliance with an 8-hour TWA limit of 25 ppm include the following (Norwegian Labour Inspection Authority, 2004):

- production premises must normally be arranged in such a way that moulding, assembly and storage of raw materials are done in separate rooms. A separate mixing area should be available to mix polyester, hardener and accelerator;
- gloves and safety glasses must be worn for mixing;
- mechanical ventilation must be present in all production premises which should provide sufficient clean air to comply with national OELs. Newly installed ventilation should provide sufficient clean air to reduce exposures substantially below national OELs;
- hand lay-up and spray up of large articles should be done in ventilated spray booths or cubicles. The guidance provides advice on suitable designs for spray booths;
- easily accessed areas in work premises should be cleaned of resin residues daily, harder to reach areas should be cleaned monthly;
- RPE, either air fed or filter type, must be used when spraying large quantities of polyester resin and may be necessary for other processes.

These general measures are also referred to in a Swedish document discussing measures that would be needed to comply with a limit of 10 ppm (8-hr TWA). This document suggests that laminated objects should be allowed to cure in a restricted access area (e.g. ventilated booth) segregated from the main workroom.

Based on a comparison of the control measures described in HSE inspection reports with the measures that are recommended in good practice guidance it is clear that the standard of control in some GRP workshops is poor. If the measures described in good practice guidance were implemented it is likely that substantial reductions in exposure would be achieved. Unfortunately, there are no data to confirm the levels that could be attained in workshops which implement most or all of the good practice measures described above.

B.9.5.5 Exposure values used for risk characterisation

Styrene based resins are used in a variety of fabrication processes. Some of these processes have a greater potential for exposure than others owing to the way the resins

are handled and the need in some cases for workers to work in close proximity to workpieces. The values used for risk characterisation in the RAR were obtained for hand lay-up/lamination which is one of the fabrication processes with the greatest potential for exposure. Separate assessments were not performed for alternative fabrication processes because few exposure data were available for these processes. The additional information that has been obtained since the RAR was finalised suggests that the exposure values used in the RAR are still valid for open moulding. These data may overestimate exposures for machine fabrication processes and enclosed moulding processes that give rise to lower styrene emissions but there is still insufficient information to allow process specific assessments to be made. Comparing the risk management measures seen in workplaces inspected by HSE with the measures described in good practice guidance from industry and Scandinavian authorities for GRP fabrication indicates that good practice is not universally followed and that reductions in levels of exposure could be achieved by improving working practices and enforcing such practices across the sector. Subsequent sections of this report will consider the extent to which exposures need to be reduced to bring levels below the DNEL and the measures that could be implemented to achieve these reductions.

B.9.6 Use 4: Consumer Use of UP-Styrene Resin for Boat-building

B.9.6.1 Introduction

Information received from Member States during the preparation of the RAR, indicated that in several EU countries (including Sweden, Finland and the Netherlands) consumers (amateurs) build their own boats. No measured or modelled exposure data were available for amateur boat building so the risk assessment was based on the assumption that the exposures of amateur boat-builders would be similar to those of professional boat-builders using open moulding methods.

B.9.6.2 Exposure values in the RAR

The exposure assessment presented in the RAR was based on construction of a small boat 4.6 m long, 1.83 m beam and 0.2 – 1.2 m draft requiring one layer of gelcoat and 3 layers of glass fibre. The following exposure values for hand lay-up in the workplace were used in the RAR to assess consumer exposure.

- Reasonable worst case (RWC) inhalation short-term = 180 ppm
- RWC inhalation 8-hour TWA = 100 ppm
- RWC dermal exposure = 93.7 mg/kg/day (based on a body weight of 70 kg)

B.9.6.3 Data obtained since the RAR was finalised

For the transitional dossier, the UK contacted industry and Member States for additional information to update this assessment. The only Member State that identified products available for amateurs to build boats was Sweden. The Norwegian authorities also indicated availability of products for consumer boat building. No new measured or modelled exposure data were available. Information received from CEFIC indicated that consumers rarely choose to build their own boats completely. The most likely objects that

a consumer may choose to build would be smaller boats such as kayaks or rowing boats in the 8 - 18 feet range (approximately 2.5 – 6 metres), wake boards or surf boards. It is more likely that a consumer would buy a new boat or refurbish a second-hand boat. This view is supported by information provided from the Norwegian CA obtained by informal consultation with amateur boat-builders. Although the Norwegian contact suggested that a consumer may choose to build a boat up to 40 feet (approx 13 metres) in length, this is likely to be a very rare event. On this basis, the exposure values obtained in the RAR are considered to be valid for this scenario.

B.9.6.4 Current risk management measures

It is not clear what risk management measures would be adopted by an amateur boat-builder. There is uncertainty about the type of workroom that would be used and the level of ventilation that would be available. There is also uncertainty about whether or not a consumer would use PPE and, if it was used, whether it would be used and maintained correctly. In relation to the type of workroom and level of ventilation, the assessment in the RAR assumed that construction would take place in a poorly ventilated outbuilding or shed with inward leakage of fresh air via badly fitting doors and windows being the only source of ventilation. Based on the information that has been received, these assumptions are still valid. In relation to the use of PPE, CEFIC indicate that suppliers of UP-styrene resins for consumer use will often include gloves and "standard" respiratory protection with the packs. However, no information is available on the types of gloves and RPE that is provided and it cannot be assumed that an amateur boat-builder would use and maintain the PPE correctly. It is therefore not possible to conclude that provision of PPE to consumers will have the potential to reduce exposure. It must therefore be assumed that no risk management measures are in place.

B.9.6.5 Exposure values used for risk characterisation

No new information has been received that warrant a change in the exposure values obtained for this scenario in the RAR. Therefore the risk assessment in this transitional dossier will be based on the exposure values in the RAR (see tables B.29 and B.30). It will be assumed that no risk management measures are in place.

B.9.7 Uses 5+6 Consumer Use of Styrene Resins (Liquid & Paste)

B.9.7.1 Introduction

It is estimated that less than 0.1 % of the total market volume of UP-styrene resins (i.e. maximum 550 tonnes per year) reaches the consumer market (CEFIC, 2008b). Resins for consumer use are available as liquids and as resin pastes. The products are sold both through Do-it-Yourself (DIY) stores and through specialist trade suppliers or sub-distributors, although it is also possible for consumers to purchase styrene-containing resins via the internet. For example, one of the largest DIY shops in Norway sells styrene resins, containing 40-50% styrene, in pack sizes of up to 10 kg, on the internet (Norwegian Authorities, 2008). This supplier provides Safety Data Sheets on their home page, but does not give information on the supply of PPE with the products (CEFIC, 2008b).

B.9.7.1.1 Liquid Resins

Liquid resins are used mainly for boat and car repair; the resin is used in a glass reinforced laminate. Product data suggest that the level of styrene in liquid resins may vary from 25 – 50% styrene (internet 1, 2008). The higher levels of styrene are more likely to be found in vinyl-ester styrene polymers, where it is needed to ensure that the viscosity is appropriate for the process, but these resins are expensive and used for the top segment of the market by professional users. The lower levels of styrene are likely to produce less effective resins due to reduced styrene cross-linking and poor surface quality (personal communication, 2008). Typically liquid resins are generally supplied as LSE resins, containing a styrene level of 30 – 40% with an average styrene level of 35% (personal communication, 2008).

A resin kit contains a tin of UP-styrene resin, a catalyst and a piece of glass fibre. Specialist outlets which supply professional users may provide pack sizes of liquid resin up to 40 kg to consumers, whilst in other cases consumers may buy smaller liquid resin packs (250 ml up to 5 litre cans). Usually the kits contain 1 to 5 kg of UP-styrene resin and are supplied via a sub-distributor, but larger amounts may be purchased from the internet (e.g. a kit containing 4 x 5 litre of resin (internet 2, 2008)) or by consumers approaching a GRP workshop.

Kits are generally supplied with instructions for the safe use of the UP-styrene resin and the other constituents of the kit. Often kits also contain (protective) safety gloves and simple (standard) respirators, equipped with an active carbon cartridge (CEFIC, 2008e) though this is not always the case. As no further information has been provided on the specific types of gloves and respirators supplied in the kit, the UK CA has been unable to confirm that the correct use of them would ensure the safe handling of the resin. In one pack four pairs of gloves are provided with 1 litre of liquid resin, suggesting that one application of resin might use about 250 ml of the liquid product (density 1.1 g/cm^3) (internet 1, 2008). In addition information may be available from the suppliers or distributors etc on the internet.

Application is likely to be by hand, using a brush for the liquid resin. The use of these kits has been estimated to be for no more than a few hours per year in the RAR (EU, 2008) based on the assumption that repair tasks are only likely to be carried out on a few days per year.

B.9.7.1.2 Resin Pastes

Resin pastes are used predominantly for car repairs, although some can be formulated specifically for household repairs such as wood filling. A paste formulation typically contains 10 – 18 % of UP-styrene resin (EU, 2008; CEFIC, 2008e) blended with inert fillers and plasticisers to turn it into a paste-like formulation, and hence they have a greater density, around 1.8 g/cm^3. There is some evidence to suggest higher styrene concentrations (up to 35%) may occur occasionally (MSDS, 2001 & MSDS, 2006).

As these kits are formulated for high speed curing, the amount of formulated paste per kit is limited to a maximum of approximately 3 kg / 1.85 litre cans. Most consumer kits containing polyester resin paste and hardener vary in volume between 60 and 600 ml,

with the commonest size being around 250 ml / 250 grams per tin. These kits also contain instructions for safe use.

Application is likely to be by hand, using a spatula/spreading knife for the paste, and the maximum frequency of exposure is likely to be 1-3 hours per day, according to the RAR (EU, 2008), with the amount depending on the task and tools used.

B.9.7.2 Exposure Values for Risk Characterisation

Although the exposure scenario from the small scale use of liquid resin is likely to be similar to that for polyester resin repair paste, the higher styrene content in the liquid resin may give rise to higher exposures.

It is unclear how many consumers use styrene-containing liquid or paste resins, but they are unlikely to do so on a frequent basis. Exposures are therefore considered per event. Both paste and liquid resins are probably applied by hand using a knife or plastic spreading tool (for resin paste) or a brush (for liquid resin). Information on how to use the liquid/paste resins safely, and any PPE required, may be provided with the product, although the provision and / or use of PPE with the product cannot be assumed.

The exposure data used for risk characterisation in the RAR came from worst case calculations supplied by industry and were based on the following assumptions / parameters (EU, 2008).

Table B.44: Key parameters / assumptions used in calculation of consumer exposure to liquid and paste resins with the RAR (EU, 2008)

Parameter	***Symbol***	***Liquid resin***	***Resin paste***	***Comments***
Product per event	q	550g	250 ml / 450g	Assumption of 500 g use per event for a liquid resin based on a standard 500 ml "consumer" pack in the UK. Assumption of 450 g use per event for a resin paste based on a standard 250 ml "consumer" pack in the UK.
Density of product		1.1 g/cm^3	1.8 g/cm^3	
Weight fraction of Styrene	W_f	0.4	0.12	In the RAR it was assumed that a liquid resin formulation for a consumer may contain up to 40% styrene. In the RAR it was assumed that a resin paste formulation will typically contain around 12% styrene. Data obtained since the RAR was finalised suggests that resin paste formulations for consumers may contain a higher percentage. The implications of this assumption will be taken into account in the risk characterisation.
% Styrene volatilising during exposure	R	7.5	5.0	Values based on laboratory studies of emissions to air during hand-lay up (liquid resins) or the use of a resin paste containing 12% styrene.
Volume of air surrounding user	V_f	65 m^3	65 m^3	In the RAR, it was assumed that the typical volume of a garage is 35m^3 and the volume of an enclosed car is 9 m^3. Hence, the airspace available for styrene to evaporate into is 26 m^3. It was assumed that the level of ventilation in the garage allows 1 air change per hour. Hence, the total volume of air into which styrene may evaporate during the repair task is 52 m^3. The UK Competent Authority notes

				that a default ventilation rate of 1.5 air changes per hour is recommended for a typical garage in fact sheets prepared to support the CONSEXPO model (Bremmer *et al.* 2006). This value is considered to be more reliable than the value used in the RAR and will therefore be used for this transitional dossier. If this value is used, the total volume of air into which styrene may evaporate is 65 m^3.
Ventilation rate of adult		1.3 m^3/h	1.3 m^3/h	US EPA default for painting work
Thickness of layer of product in contact with skin	T_{der}	0.1 cm	0.1 cm	
Surface area of exposed skin	S_{der}	280 cm^2	280 cm^2	Estimate for the surface area of all fingers on both hands from EC Algorithm (mentioned in RAR (EU, 2008)) The UK Competent Authority considers this value is very conservative. It is expected that if all of the fingers on both hands became contaminated with paste resin, it would obstruct effective working and the consumer would attempt to clean their hands before proceeding. Hence, a surface area of 280 cm^2 is never likely to be fully in contact with styrene in paste resin.
% Styrene evaporating from product		10	10	It was estimated in the RAR that 10% of styrene in a liquid resin or resin paste would evaporate when in contact with the skin and would not be available for absorption.

Additional information has been provided (CEFIC, 2008e) on how the resins are used.

B.9.7.2.1 Liquid Resin

The resin is usually processed by hand lamination. Typically the consumer weighs approximately 500 grams of resin in a mixing container, adds an adequate amount of catalyst and laminates the resin as desired. Such a laminating operation takes between 10 and 15 minutes. Then the next batch is prepared and processed in the same way; this is repeated until the repair is completed.

The time the resin is used per day can vary between 15 minutes and a few hours depending on the object the consumer is going to build/repair. Work could be done indoors depending on the parts being built / repaired and facilities available.

UP-styrene resin producers provide extensive information about the safe use of UP-styrene resins to their downstream users (CEFIC, 2008e). However, they do not have control over how this information, on the safe use of UP-styrene resins, is communicated to the end user (consumer). Information for the consumer is provided on the packaging of the product, for example, details of how to use the product (in words and symbols), its level of styrene and the required hazard labels and risk phrases (Flammable, Harmful by Inhalation and Irritating to Eyes and Skin). For the products reviewed, the safety phrases given included ‘Use only in well-ventilated areas’ but did not indicate any need for gloves, respiratory nor eye protection, although a filling knife or spatula was provided to aid application and this could help limit dermal contact with the product.

Inhalation and dermal exposures for liquid resins were calculated in the RAR using the EU Technical Guidance Algorithms as outlined below. The scenario is filling dented bodywork in a car within a closed garage.

Inhalation

The average concentration of styrene in air can be calculated using the following equation:

$C_{air} = q \times W_f \times R \times V_r^{-1}$

Where: C_{air} is the average concentration of styrene in air
q is the amount of product used per event
W_f is the weight fraction of styrene in the product
R is the fraction of styrene that volatilises during the event
V_f is the volume of air surrounding the user

Referring to the parameters in table B.44,

$C_{air} = 550 \times 0.4 \times 0.075/65$
$C_{air} = 254$ mg/m^3 (converts to 59 ppm)

Table B.45: Calculated inhalation exposure values for styrene during consumer use of liquid resins

INHALATION EXPOSURES **Scenario**	**Concentration of styrene in air ppm (mg/m^3)**
Liquid Resin Kit	59 (254)

Dermal exposure

To calculate dermal exposure it is necessary to determine the average concentration of styrene in the product and the amount of product that may potentially be in contact with the skin.

The average concentration of styrene in a liquid resin (C_{der}) can be calculated using the equation:

C_{der} = product density x W_f
where: W_f is the weight fraction of styrene in the product.

The average concentration of styrene on the skin is then given by $C_{der} \times T_{der} \times S_{der}$
where: C_{der} is the average concentration of styrene in the product
T_{der} is the thickness of the layer of product in contact with the skin
S_{der} is the surface area of the skin potentially exposed.

Referring to the parameters in table B.44,

$C_{der} = 1.1 \times 0.40 = 0.44$ g/cm^3

Therefore the average concentration on the skin is 0.44 x 0.1 x 280 = 12.3 g/event

Since 10% of styrene in the resin will evaporate and will therefore not be available for uptake, only 90% of what is in contact with the skin will be available for uptake. The amount of the substance on the skin available for uptake is therefore 12.3 x 0.9 = 11.1 g/event.

Table B.46: Calculated dermal exposure for styrene during consumer use of liquid resins

DERMAL EXPOSURES **Scenario**	**Amount for uptake on skin (g/event i.e. over 1 hr)**	**Amount for uptake on skin (mg/kg bw /d)**
Liquid Resin Kit	11.1	158.6

The amount for uptake from skin, as mg /kg bw/d is based on a use of 1 hour (i.e. 1 event) per day and a human body weight of 70 kg

B.9.7.2.2 Resin paste

Typically an amount of resin paste between 50 and 200 grams is applied on a mixing plate, an adequate amount of hardener (usually a paste like formulation) is added and the two constituents are mixed with a spatula. The mixture obtained is quickly applied to a dented car body for filling dents etc. The mixture quickly hardens in 10 to 15 minutes and can be sanded afterwards. This operation is repeated as often as desired.

According to CEFIC, their members who are UP-styrene resin producers provide extensive information about the safe use of UP-styrene resins to their downstream users. However, they do not have control how this information about the safe use of UP-styrene resins is communicated to the end user (consumer). Information for the consumer is provided on the packaging of the product. For the products reviewed, the safety phrases given included 'Use only in well-ventilated areas' but did not indicate any need for gloves, respiratory nor eye protection, although a filling knife or spatula was provided to aid application and this could help limit dermal contact with the product.

Inhalation and dermal exposures for liquid resins were calculated in the RAR as outlined below. The scenario is filling dented bodywork in a car within a closed garage.

Inhalation

The average concentration of styrene in air can be calculated using the following equation:

$C_{air} = q \times W_f \times R \times V_r^{-1}$

Where: C_{air} is the average concentration of styrene in air
q is the amount of product used per event
W_f is the weight fraction of styrene in the product
R is the fraction of styrene that volatilises during the event
V_f is the volume of air surrounding the user

Referring to the parameters in table B.44,

C_{air} = 450 x 0.12 x 0.05/65
C_{air} = 41.5 mg/m^3 (converts to 10 ppm)

Table B.47: Calculated inhalation exposure values for styrene during consumer use of resin pastes

INHALATION EXPOSURES **Scenario**	**Concentration of styrene in air ppm (mg/m^3)**
Car Body Filler Paste	10 (41.5)

Dermal exposure

To calculate dermal exposure it is necessary to determine the average concentration of styrene in the product and the amount of product that may potentially be in contact with the skin.

The average concentration of styrene in a liquid resin (C_{der}) can be calculated using the equation:

C_{der} = product density x W_f
where: W_f is the weight fraction of styrene in the product.

The average concentration of styrene on the skin is then given by C_{der} x T_{der} x S_{der}
where: C_{der} is the average concentration of styrene in the product
T_{der} is the thickness of the layer of product in contact with the skin
S_{der} is the surface area of the skin potentially exposed.

Referring to the parameters in table B.44,

C_{der} = 1.8 x 0.12 = 0.22 g/cm^3

Therefore the average concentration on the skin is 0.22 x 0.1 x 280 = 6.2 g/event

Since 10% of styrene in the resin will evaporate and will therefore not be available for uptake, only 90% of what is in contact with the skin will be available for uptake. The amount of the substance on the skin available for uptake is therefore 6.2 x 0.9 = 5.5 g/event.

The UK Competent Authority considers this is a RWC estimate for dermal exposure. The calculation assumes skin contact of all four fingers on both hands occurs because of accidental spillage. Since the product is a thick paste, if the container were to be knocked over, the product is unlikely to spread away from the container and hence this level of contamination is unlikely to occur in practice. The product is normally handled with a filling knife or plastic spreading tool provided in consumer kits. On this basis, an alternative value for dermal exposure of 1.7 g/event was accepted in the RAR to indicate typical exposure.

Table B.48: Calculated dermal exposure for styrene during consumer use of resin pastes

DERMAL EXPOSURES Scenario		Amount for uptake on skin (g/event i.e. over 1 hr)	Amount for uptake on skin (mg/kg bw/d)
Car Body Filler Paste	RWC	5.5	78.6
	typical	1.7	24.3

The amount for uptake from skin, as mg /kg bw/d is based on a use of 1 hour (i.e. 1 event) per day and a human body weight of 70 kg

B.9.8 Other sources (for example natural sources)

Not relevant for this proposal

B.9.9 [Summary of] environmental exposure assessment

Not relevant for this proposal

B.9.10 Combined human exposure assessment

No concerns were identified from the human risk assessment in the RAR (EU, 2008)

B.10 Risk characterisation

The risk characterisation approach taken in this transitional dossier follows the model outlined in the CSA guidance. Exposure values are compared to the calculated DNEL values to derive a risk characterisation ratio (RCR) according to the formula:

Exposure value/DNEL = RCR

In accordance with the REACH regulation Annex I, para 6.4 which states that:

"For any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the lifecycle of the substance that results from manufacture or identified uses, if:

- the exposure levels estimated in Section 6.2 do not exceed the appropriate DNEL or the PNEC, as determined in sections 1 and 3, respectively, and,

- the likelihood and severity of an event occurring due to the physicochemical properties of the substance as determined in section 2 is negligible."

control of exposure will be regarded as adequate where the RCR is equal to or less than 1.

The following DNEL values have been calculated for systemic toxicity endpoints for workers and consumers.

Table B.49: Summary of critical DNEL values

	Worker	**Consumer**
DNEL short-term inhalation	41 ppm (15-minute TWA)	20 ppm (15 minute TWA)
DNEL long-term inhalation	4 ppm (8-hour TWA)	8 ppm (8-hour TWA)
DNEL long-term dermal	60 mg/kg/day	30 mg/kg/day

The RAR also identified a concern for skin and eye irritation. DNELs are not available for these endpoints. The use of appropriate gloves and eye protection is recommended in any situation where there is a potential for direct contact with products containing styrene.

The following exposure values have been obtained for the use scenarios covered by this transitional dossier.

Table B.50: Summary of exposure values used in the risk characterisation

Scenario	**Inhalation**				**Dermal**	
	Reasonable Worst Case (RWC) Exposure in ppm		**Typical Exposure in ppm**		**Reasonable Worst Case (RWC) Exposure in mg/ kg */ d**	**Typical Exposure in mg/ kg*/ d**
	Long-term (8 h TWA)	**Short-term (15 min)**	**Long-term (8 h TWA)**	**Short-term (15 min)**	**Long-term (8 h)**	**Long-term (8 h)**
Manufacture of UP-styrene resins	20	50	3	9	1.2	0.12
Manufacture of SBR / SBL	5	15	1	1	0.6	0.3
Manufacture of GRP	100	180	40	60	93.7	14.1
Consumer Boat Building	100	180	-	-	93.7	-
Consumer use of liquid resin	9	59	-	-	158.6	-
Consumer use of resin paste	1.5	10	-	-	78.6	24.3

* based on human body weight of 70 kg, as used in the RAR

B.10.1 Human health

B.10.1.1 Use 1: Occupational Exposure during Manufacture of UP-styrene resins

Risk Characterisation Ratios (RCRs) have been determined based on RWC and typical exposures during the manufacture of UP-styrene resins. Short-term RWC and typical inhalation exposure values for the manufacture of UP-styrene resins are derived from EASE. Long-term RWC and typical inhalation exposure values derive from measured data and EASE. RWC and typical dermal exposure values are derived from EASE.

Table B.51: Risk Characterisation Ratios for RWC exposures during manufacture of UP-styrene resins

REASONABLE WORST CASE EXPOSURES	15 min short term	8-hour TWA
RCR for inhalation	50 / 41 = **1.2**	20 / 4 = **5**
RCR for dermal	---	1.2 / 60 = 0.02
RCR for combined exposure	---	5 + 0.02 = **5.02**

Table B.52: Risk Characterisation Ratios for typical exposures during manufacture of UP-styrene resins

TYPICAL EXPOSURES	15 min short term	8-hour TWA
RCR for inhalation	9 / 41 = 0.2	3 / 4 = 0.75
RCR for dermal	---	0.12 / 60 = 0.002
RCR for combined exposure	---	0.75 + 0.002 = 0.752

When RWC inhalation exposure values are compared with short-term and long-term DNEL values the RCR values are greater than one, indicating that risks are not adequately controlled. Of greatest concern is the 8-hour inhalation exposure value. Short-term exposure values are only marginally above the DNEL. These RWC exposure values derive from an EASE assessment that assumed no LEV was in place during a drumming off task. Information on current risk management measures obtained for this transitional dossier indicates that LEV will be in place and hence these RWC values are likely to overestimate exposure.

When typical exposures are compared to the DNEL values the RCR values are less than one. This indicates that the current control measures as described in section B.9.3 are adequate to control the risks from inhalation. In the light of this assessment it is most appropriate to look at measures that will secure implementation of good practice across this sector rather than consider changes to substances or manufacturing processes.

Both RWC and typical dermal exposure values are below the DNEL and hence current risk management measures (use of gloves) are adequate to address concerns for systemic toxicity. The qualitative risk assessment approach outlined in the chemical safety assessment guidance Part E (table E 3.1) indicates that use of suitable gloves is an appropriate risk management measure for a skin irritant that is assigned the R-phrase R38

(Irritating to skin) therefore no additional measures are required for the dermal route. The R-phrase R36 (Irritating to eyes) has been assigned to styrene. Using the qualitative risk assessment approach referred to above, an appropriate risk management measure for this hazard is the use of chemical goggles. This measure should be included in good practice recommendations for situations where there is the potential for direct eye contact with styrene.

B.10.1.2 Use 2: Occupational Exposure during Manufacture of Styrene Butadiene Rubber and Latex

RCRs have been determined based on RWC and typical exposures for production of SBR and SBL. Short-term RWC and typical inhalation exposure values for the manufacture of SBR/SBL are derived from EASE. Long-term RWC and typical inhalation exposure values derive from measured data provided by industry. RWC and typical dermal exposure values are derived from EASE.

Table B.53: Risk Characterisation Ratios for reasonable worst case exposures during manufacture of SBR / SBL

REASONABLE WORST CASE EXPOSURES	15 min short term	8-hour TWA
RCR for inhalation	15 / 41 = 0.37	5 / 4 = **1.25**
RCR for dermal	---	0.6 / 60 = 0.01
RCR for combined exposure	---	1.25 + 0.01 = **1.26**

Table B.54: Risk Characterisation Ratios for typical exposures during manufacture of SBR / SBL

TYPICAL EXPOSURES	15 min short term	8h TWA
RCR for inhalation	1 / 41 = 0.02	1 /4 = 0.25
RCR for dermal	---	0.3 / 60 = 0.01
RCR for combined exposure	---	0.25 + 0.01 = 0.26

Although the RWC short-term inhalation exposure value is below the short-term DNEL, when the RWC 8-hour TWA inhalation exposure value is compared with the long-term DNEL the RCR is greater than one. This indicates that control of airborne exposure under RWC conditions is not adequate. These RWC exposure values derive from measured data and hence reflect situations that have occurred in the workplace. When typical 8-hour TWA inhalation exposures are compared to the long-term DNEL value the RCR is less than one. This indicates that the current control measures as described in section B.9.4 are adequate, when correctly implemented, to control the risks from inhalation. In the light of this assessment it is most appropriate to look at measures that will secure implementation of good practice across this sector rather than consider changes to substances or manufacturing processes.

Both RWC and typical dermal exposure values are below the DNEL and hence there is no need to implement additional risk management measures to address concerns for systemic toxicity. The qualitative risk assessment approach outlined in the chemical safety assessment guidance Part E (table E 3.1) indicates that use of suitable gloves is an appropriate risk management measure for a skin irritant that is assigned the R-phrase R38 (Irritating to skin). The R-phrase R36 (Irritating to eyes) has been assigned to styrene. An appropriate risk management measure for this hazard is the use of chemical goggles. The use of suitable gloves and goggles should be included in good practice recommendations for situations where there is the potential for direct eye contact with styrene.

B.10.1.3 Use 3: Occupational Exposure during Manufacturing of Glass Reinforced-Plastic (GRP)

RCRs have been determined based on RWC and typical exposures. Short-term RWC and typical inhalation exposure values for the manufacture of GRP and the use of styrene based resins derived from published data, HSE inspection reports and EASE. Long-term RWC and typical inhalation exposure values derive from published data, measured data provided by industry and HSE inspection reports. RWC and typical dermal exposure values are derived from the Riskofderm project.

Table B.55: Risk Characterisation Ratios for reasonable worst case exposures during manufacture of GRP

REASONABLE WORST CASE EXPOSURES	15 min short term (ppm)	8-hour TWA (ppm)
RCR for inhalation	**180 / 41 = 4.4**	**100 / 4 = 25**
RCR for dermal	---	**93.7 / 60 = 1.6**
RCR for combined exposure	---	**25 + 1.6 = 26.6**

Table B.56: Risk Characterisation Ratios for typical exposures during manufacture of GRP

TYPICAL EXPOSURES	15 min short term (ppm)	8-hour TWA (ppm)
RCR for inhalation	**60 / 41 = 1.5**	**40 / 4 = 10**
RCR for dermal	---	14.1 / 60 = 0.2
RCR for combined exposure	---	**10 + 0.2 = 10.2**

The comparison of RWC and typical inhalation exposure values for both reference periods with the relevant DNELs reveals RCRs greater than one therefore control of airborne exposure is not adequate for this use scenario. These RWC and typical exposure values derive from measured data and hence reflect situations that occur in the workplace. Although RWC exposures clearly derive from workplaces where control

measures have been implemented ineffectively, the fact that typical exposure values also exceed the DNEL calls into question whether adequate control can be achieved by improving implementation of current controls. Referring to the case studies described in the German good practice document (see section B.9.5.4) it is clear that installation of effective ventilation has the potential to secure significant reductions in exposure. However, it is not clear if this measure alone will be sufficient. Further work needs to be done to identify a range of control measures that would secure adequate control of airborne styrene in all situations where styrene-based resins are used.

RWC dermal exposures are marginally above the dermal DNEL for systemic toxicity but typical dermal exposure values are below the DNEL. The current risk management measure to control dermal exposure is the use of gloves. This assessment suggests that gloves are an adequate measure to address concerns for systemic toxicity but that the measure needs to be implemented/enforced more thoroughly. The qualitative risk assessment approach outlined in the chemical safety assessment guidance Part E (table E 3.1) indicates that use of suitable gloves is an appropriate risk management measure for a skin irritant that is assigned the R-phrase R38 (Irritating to skin). The R-phrase R36 (Irritating to eyes) has been assigned to styrene. An appropriate risk management measure for this hazard is the use of chemical goggles. In addition to the use of suitable gloves, the use of chemical goggles should also be required for situations where there is the potential for direct contact with styrene containing resins.

B.10.1.4 Use 4: Consumer Use of UP-Styrene Resin for Boat-building

For boat-building by consumers the following RCR values have been calculated. No measured exposure data were available. Exposures for this use scenario were therefore estimated using the RWC exposure values obtained for hand lamination.

Table B.57: Risk Characterisation Ratios for exposure during consumer boat-building

	15 min short term (ppm)	8-hour TWA (ppm)
RCR for inhalation	**180 / 20 = 9**	**100 / 8 = 12.5**
RCR for dermal	---	**93.7 / 30 = 3.1**
RCR for combined exposure	---	**12.5 + 3.1 = 15.6**

The comparison of RWC inhalation exposure values for both reference periods with the relevant DNELs reveals RCRs greater than one therefore control of airborne exposure is not adequate for this use scenario. Since it is not clear what range of control measures would be available to/used by a consumer undertaking a boat-building project, it is not possible to determine whether there is any scope for reducing these exposure values. Options to secure adequate control for consumers building boats will be considered further in section E.

RWC dermal exposures exceed the dermal DNEL for systemic toxicity. It is not clear what risk management measures are currently implemented by consumers to control dermal exposure. It is possible that a consumer would choose to wear gloves for a boat building project where the consumer was handling sticky resins and fibre glass because skin contamination with these agents would be uncomfortable. However, it cannot be assumed that a consumer will always choose to wear gloves. Also if a consumer does use gloves, it cannot be assumed that the consumer will use an appropriate type of glove or that the gloves will be properly maintained. Therefore, although the use of appropriate gloves is an acceptable measure to manage the risks from skin contact with styrene in the workplace, this is not a suitable measure for consumers. In relation to the identified hazard of eye irritation, it is proposed that the use of suitable goggles will be an adequate risk management measure for the workplace. Since it cannot be assumed that a consumer will comply with a requirement to wear suitable eye protection this is not an adequate measure for consumers. Other options to manage the risks for consumers will be considered in section E.

B.10.1.5 Use 5: Consumer Use of Liquid Resins

B.10.1.5.1 Inhalation

The inhalation values that were calculated are expressed as 1-hour TWAs since this relates to the time a consumer might typically spend using styrene based resins for repair tasks on one day. However, the DNEL values that have been calculated for consumers are expressed as a 15-minute TWA for short-term exposure and an 8-hour TWA for long-term exposure. The critical health effects on which the DNEL values are based are dose-dependent effects, i.e. the total dose obtained during a particular period of exposure will determine the severity of the effect. It is therefore not valid to make a direct comparison between a 1-hour exposure value and a DNEL relating to a different time period because this does not take account of the dose that will be attained during the relevant periods of exposure. In order to assess exposures received during repair tasks it is necessary to consider what exposure may be attained over periods of 15 minutes and 8 hours and compare these values with the relevant DNELs.

For short-term exposure, if it is assumed that the 1-hour TWA exposure of 59 ppm for a repair task using liquid resins occurs under steady state conditions, the average exposure during any 15-minute period will also be 59 ppm. On this basis it is assumed that the 15-minute TWA exposure value for small repair tasks using liquid resins is 59 ppm.

For long-term exposure, the DNEL is expressed as an 8-hour TWA. However, the repair task will only take 1 hour. Calculation methods to convert exposures over different time periods into 8-hour TWA values have been published in HSE's EH40 guidance document (HSE, 2005). Using this approach, and assuming that there is no further exposure to styrene on the day a repair task is performed, a 1-hour exposure to 59 ppm equates to an 8-hour TWA of:

$$\frac{(59 \times 1) + (0 \times 7)}{8} = 7.4 \text{ ppm.}$$

Hence, in summary for liquid resin,

- the 15 minute TWA = 59 ppm
- the 8 hour TWA = 7.4 ppm

B.10.1.5.2 Dermal

A dermal exposure value of 159 mg/kg bodyweight was calculated in section B.9.7.2 for the use of liquid resins.

B.10.1.5.3 Risk Characterisation Ratios

The exposure values for consumer exposure to styrene resins have been estimated using modelling algorithms described in the technical guidance document to support ESR. The assessment assumes the products are used in an unventilated room/garage and that no measures are taken to prevent skin contact.

Table B.58: Risk Characterisation Ratios for exposures during consumer use of styrene-containing liquid resins

LIQUID RESINS	15 min short term	8-hour TWA
RCR for inhalation	59 / 20 = **2.95**	7.4 / 8 = 0.92
RCR for dermal	---	159 / 30 = **5.3**
RCR for combined exposure	---	0.92 + 5.3 = **6.22**

For liquid resins, although the RWC long-term inhalation exposure value is below the long-term DNEL, when the short-term exposure value is compared with the short-term DNEL the RCR is greater than one. This pattern is not surprising given that the exposure assessment is based on a task duration of 1 hour. This indicates that control of airborne exposure under RWC conditions is not adequate. The exposure values were calculated on the assumption that the resin was used in an unventilated garage/room. It cannot be assumed that a consumer would implement any specific control measures (e.g. opening windows or doors) to limit airborne exposure during use. It is also not clear whether this measure would be sufficient in all situations where liquid resins will be used for repair tasks. Options to secure adequate control for consumers using liquid resins will be considered further in section E.

RWC dermal exposures during the use of liquid resins also exceed the dermal DNEL for systemic toxicity. It is not clear what risk management measures are currently implemented by consumers to control dermal exposure, and it cannot be assumed that consumers would necessarily wear gloves for a small scale repair. Also if a consumer does use gloves, it cannot be assumed that the consumer will use an appropriate type of glove or that the gloves will be properly maintained. Therefore, although the use of appropriate gloves is an acceptable measure to manage the risks from skin contact with styrene in the workplace, this is not a suitable measure for consumers. In relation to the identified hazard of eye irritation, it is proposed that the use of suitable goggles will be an adequate risk management measure for the workplace. Since it cannot be assumed that a

consumer will comply with a requirement to wear suitable eye protection this is not an adequate measure for consumers. Other options to manage the risks for consumers will be considered in section E.

B.10.1.6 Use 6: Consumer Use of Resin Pastes

B.10.1.6.1 Inhalation

Following the arguments outlined above, it is assumed that the 15-minute TWA exposure value for small repair tasks using resin pastes is 10 ppm. A 1-hour exposure to 10 ppm during a repair task using resin pastes equates to an 8-hour TWA of:

$$\frac{(10x1) + (0x7)}{8} = 1.25 \text{ ppm.}$$

Hence, in summary for resin paste,

- the 15 minute TWA = 10 ppm
- the 8 hour TWA = 1.25 ppm

B.10.1.6.2 Dermal

A RWC dermal exposure value of 78.6 mg/kg bodyweight was calculated in section B.9.7.2 for the use of resin pastes.

A typical dermal exposure value of 24.3 mg/kg bodyweight was calculated in section B.9.7.2 for the use of resin pastes.

B.10.1.6.3 Risk Characterisation Ratios

Table B.59: Risk Characterisation Ratios for exposures during consumer use of styrene-containing resin pastes

RESIN PASTES	15 min short term	8-hour TWA
RCR for inhalation	10 / 20 = 0.5	1.25 / 8 = 0.16
RCR for dermal	---	78.6 / 30 = **2.62** (RWC) 24.3 / 30 = 0.81 (typical)
RCR for combined exposure	---	0.16 + 2.62 = **2.78** (RWC) 0.16 + 0.81 = 0.97 (typical)

For resin pastes, a comparison of RWC inhalation exposure values for both reference periods with the relevant DNELs reveals RCRs less than one therefore control of airborne exposure is adequate for this use scenario and no additional measures need to be implemented.

RWC dermal exposures during the use of resin pastes exceed the dermal DNEL for systemic toxicity. The RWC dermal exposure value was calculated on the assumption that the entire surface of the fingers of both hands could be contaminated with the paste in the event of an accidental spill. Given that resin pastes are thick and sticky, and that consumer kits include a spreading tool, it is very unlikely that this level of contamination will arise during normal use. If the hands did become heavily contaminated, it is probable that the consumer would choose to clean their hands before continuing work owing to the sticky nature of uncured resin pastes. A typical dermal exposure value of 1.7 g/event was also agreed in the RAR. If this value is used, the RCR is < 1 indicating adequate control. On this basis, it can be concluded that there is no need to implement additional risk management measures to address concerns for systemic toxicity during normal use of resin pastes. This assessment is based on the assumption that the resin paste contains 12% styrene. Given that typical exposures for a resin product containing 12% styrene give a RCR close to 1, this suggests that there will be a need to implement additional risk management measures for resin pastes containing more than 12% styrene. Since this assessment is based on typical exposures it is preferable to use a 10% cut off to indicate the need for additional risk management measures.

In relation to the potential skin and eye irritancy of styrene, the qualitative risk assessment approach outlined in the chemical safety assessment guidance Part E (table E 3.1) indicates that use of suitable gloves and suitable eye protection are appropriate risk management measures for the workplace. As indicated above these measures are not suitable for consumers. However, in considering the need for these risk management measures, the chemical safety assessment guidance Part E (section E 3.4.2, page 17) states that where specific concentration limits have been assigned to a substance in relation to hazard classification, these can be used to inform decisions on the need for risk management measures. The specific concentration limit currently assigned to styrene in Annex I of the Dangerous Substances Directive for the endpoints of acute toxicity and skin and eye irritancy is 12.5%, i.e. a preparation containing styrene must be assigned the R-phrases R20-36/38 if the concentration of styrene is 12.5% or more. This suggests that it is only necessary to use suitable gloves and goggles when using resin pastes containing 12.5% or more styrene.

In summary, RWC exposure values for the use of styrene-based resin pastes indicate the risks are not acceptable for this use. However, RWC exposure values are based on very conservative assumptions about the level of contamination that could arise during use. The UK Competent Authority does not consider these assumptions to be realistic. Under typical use conditions, there is no need to implement additional control measures for consumer use of resin pastes containing 10% or less styrene.

B.10.2 Environment

Not relevant for this proposal

B.11 Summary of hazard and risk

The risk characterisation for the manufacture of UP-styrene resins indicates that the RWC 8-hour TWA inhalation exposure value is too high. The RWC short-term inhalation exposure value is also slightly too high. However, typical inhalation exposure values and

dermal exposure values are below the relevant DNEL values and are therefore judged to be acceptable. This indicates that the risk management measures currently applied are adequate to address concerns for systemic toxicity providing they are properly implemented and maintained correctly. In this situation it is not considered necessary to look at additional risk management measures to control the risks that have been identified but to consider whether there are any barriers to effective implementation of current risk management measures. The risk characterisation also indicates a need for workers to wear suitable gloves and goggles where there is the potential for direct contact with styrene to prevent irritation. These issues will be considered further in section E.

A similar situation exists for the manufacture of SBR and SBL. For this use, only the RWC 8-hour TWA inhalation exposure values are slightly above the DNEL. All other exposure values are below relevant DNELs. As with the manufacture of UP-styrene resins it is not considered necessary to identify additional risk management measures to control the risks that have been identified but to consider whether there are any barriers to effective implementation of current risk management measures. For the reasons outlined above, the use of suitable gloves and suitable eye protection are also recommended in this use scenario where there is the potential for direct contact with styrene. This will be discussed further in section E.

The risk characterisation for GRP manufacture and the use of UP-styrene resins has identified that additional measures are required to reduce both RWC and typical short-term and 8-hour TWA exposure values to the level of the DNEL. Further work is needed to identify the range of control measures that will secure adequate control of airborne styrene in all occupational situations where styrene-based resins are used. In relation to dermal exposure RWC dermal exposures are marginally above the dermal DNEL for systemic toxicity but typical dermal exposure values are below the DNEL. The current risk management measure to control dermal exposure is the use of gloves. This assessment suggests that gloves are an adequate measure to address concerns for systemic toxicity but that the measure needs to be implemented and maintained more thoroughly. In addition to the use of suitable gloves, the use of chemical goggles should also be required for situations where there is the potential for direct contact with styrene containing resins.

In relation to consumer use scenarios, the estimated RWC inhalation and dermal exposure values for a boat building project exceed the relevant DNEL values. It is not clear what range of control measures would be available to or used by a consumer undertaking a boat building project. It cannot be assumed that a consumer will work in a well-ventilated area or that a consumer will wear gloves or eye protection whilst working on the project. Given that it will be necessary to implement a range of risk management measures to ensure adequate control in GRP workshops, it seems unlikely that the concerns identified for consumers can easily be remedied. Options to secure adequate control for consumers building boats will be considered further in section E.

For consumer use of liquid resins for repair tasks, a comparison of estimated RWC inhalation and dermal exposure values for a product estimated to contain 40% styrene with the relevant DNELs gives RCRs > 1. Exposures are therefore not adequately controlled for this use scenario. There is also a need to address concerns relating to skin and eye irritation from direct contact with liquid resins. Options to secure adequate control will be considered further in section E.

For the use of resin pastes, for a product assumed to contain 12% styrene, estimated inhalation values are below the relevant DNEL values. Hence, no additional risk management measures need to be applied to control airborne exposure. Although RWC dermal exposure estimates exceed the DNEL for systemic toxicity, the level of contamination that has been assumed is rarely likely to occur. Typical dermal exposure estimates are below the dermal DNEL for systemic toxicity indicating that for a resin paste containing 12% or less styrene, current use is acceptable. In relation to concerns for skin and eye irritation, the assessment indicated that additional risk management measures (the use of suitable gloves and goggles) would only be required where the resin product contains 12.5% or more styrene. On this basis, providing a resin paste contains no more than 12% styrene, there is no need to implement specific risk management measures. Since acceptable risks have been identified on the basis of typical exposure values, it is preferable to take a cut off of 10% styrene for a requirement to implement additional risk management measures.

Options to implement the additional risk management measures that this assessment indicates will be needed, to bring exposure values below the level of the DNEL, are discussed in section E.

C. AVAILABLE INFORMATION ON ALTERNATIVES

This section considers alternative resins and fabrication processes that have the potential to reduce exposure to styrene in the manufacture of GRP articles.

C.1 Identification of possible alternative substances and techniques

C.1.1 Use 1: Manufacture of UP-styrene resin

Styrene is a cost-effective monomer that has good technical characteristics and can be used for a wide variety of applications. The potential to substitute styrene with an alternative monomer will depend on the application for which the resin will be used. Alternatives monomers have been investigated and are discussed in section C.1.3.1 (Seigberg, 2006). Difficulties identified with some alternative monomers include too high a viscosity, unfavourable curing characteristics and production of unpleasant odours in the workplace. In the view of the UK Competent Authority it is likely to be very difficult to find a single alternative substance that would allow the final manufactured products to have the full range of properties that enable them to be used in the extensive variety of products for which they are currently used e.g. lightweight components for cars/weight to make them more fuel-efficient, provide insulation to boilers to cut energy losses and provide structural sound and hygiene packaging (SIRC, 2008). To replace all styrene in UP-styrene resins (about 300,000 tpa styrene) would also require a significant tonnage of the alternative substance, and as such its hazard and risk profile would need to be well-studied (with corresponding costs) to ensure safety and confidence that any alternative was better overall as compared to styrene.

In addition to alternatives to either replace or partially replace styrene in the manufacture of UP- styrene resins, work has been carried out to investigate the use of additives to reduce the level of styrene emissions. It is believed that in many cases LSE and LSC products are already being used for this purpose.

C.1.2 Use 2: Manufacture of Styrene Butadiene Rubber and Latex

Alternatives for styrene in the manufacture of SBR/SBL could not be identified by the UK Competent Authority. This is probably due to a lack of alternative substances that provide the same range of properties in the final manufactured products that enable them to be used in the extensive variety of products for which they are currently used.

C.1.3 Use 3: GRP manufacture and use of UP-Styrene resins

In the case of GRP manufacture and the use of UP-styrene resins, the following options for substitution are available.

- substitution of a styrene-based resin with a resin based on an alternative substance may be possible in some cases;

- LSE/ LSC resins may help to reduce exposures where companies are not already using such products;
- it may be possible to move from open mould to closed mould processes for GRP manufacture but there may be technical difficulties owing to awkward shapes for some items;
- it may be possible to modify the risk management measures that are in place around existing fabrication processes;
- it may be possible to automate the process.

C.1.3.1 Substitute styrene-based resins with resins based on alternative monomers

The applicability of various alternative monomers to specific use scenarios is dependent upon their material properties, the technical functionality and price relative to that of the styrene liquid/paste resin. The information that has been obtained by the UK so far is summarised in table C.1 below.

Table C.1: Possible alternative monomers to styrene

Alternative	Area of Use
Acrylates / Methacrylates	Acrylate / methacrylate monomers can be used to replace styrene where high clarity resins are required (personal communication, 2008).
Polyurethane resins	Cannot be used to replace styrene in polyester resins used by consumers e.g. for hand lay-up / spraying, but are alternatives for occupational injection moulding and foaming insulation (personal communication, 2008).
Epoxy resins	Can be used as an alternative in boat building, and are occasionally used by consumers (CEFIC, 2008e). Generally used where high strength and adhesion are required, and may be combined with carbon fibre or glass fibre. However, there is concern over the risk of skin allergy.
Methylstyrene	a-methylstyrene can be used instead of styrene in resins for moulding parts of high mechanical and thermal grade, whilst m-/p-methylstyrene have lower peak temperatures during polymerisation and stress-free curing but give worse mechanical properties
Diallyl phthalate	Resins based on this monomer require elevated temperatures to cure and so are not suitable for consumer use. These resins are used in the workplace for compounding at high temperatures (personal communication, 2008)
Powder filler	Could be used by consumers for small scale repairs on building materials e.g. wood or stone (MSDS, 2008)

It is important to note that to replace all styrene in UP-styrene resins (about 300,000 tpa styrene) would require a significant amount of the alternative substance. As such the hazard and risk profile would need to be well-studied (with corresponding costs) to ensure safety and confidence that any alternative was better overall compared to styrene. There is, of course, the option to select different alternatives for different resin uses but widening the product portfolio and producing smaller amounts of different resins for specific uses may have production cost implications and may give a more confusing range of products for downstream users.

C.1.3.2 Use of Low Styrene Emission (LSE) and Low Styrene Content (LSC) resins

The use of LSE and LSC resins has the potential to reduce styrene emissions during GRP manufacture. LSE resins contain additives such as paraffin waxes that form films on top of the styrene resin. The film has the potential to reduce evaporation during curing (by about 50% compared to the standard styrene resins). However, the additives are unable to form an effective film during the lay-up process and become less effective if the layer is disturbed e.g. by air currents from ventilation. Film forming agents cannot be included where dicyclopentadiene has been used to lower the percentage of styrene required in the resin formulation and can cause problems with adhesion between laminations. This is resolvable via the use of an adhesion enhancer (Siegberg, 2006).

LSC resins are formulated with a lower styrene content but the formulation may include alternative monomers to retain the technical characteristics of the resin.

As indicated in section B.9.5, such resins first appeared in the 1970s. It is expected that some GRP fabricators will already use LSE and LSC resins and it is possible that all resins now supplied have been formulated in some way to lower styrene emissions during use. Further information is required to confirm how widely LSE/LSC resins are used by GRP fabricators.

LSE and LSC resins are available to consumers and are equally easy to use and are about the same cost as traditional formulations. Further information is required to confirm how widely LSE/LSC resins are used by consumers.

Table C.2: Substances that may be included in resin formulations to enable the styrene content to be reduced

Alternative	Area of Use
Dicyclopentadiene	DCPD is not an alternative monomer to styrene in UP-resins although its use as a builder in resins can reduce the amount of styrene (from 35% to about 30-32%) into which the polymer is dissolved (personal communication, 2008). The resin can then be used in much the same way as styrene resins and gel coats, although, it tends to be used without reinforcement and is most commonly used in reactive injection moulding (RIM) (Norwegian Authorities, 2008)
Vinyl esters	Vinyl esters can be used as part of the polymer, in combination with epoxy and methacrylate esters, that are dissolved into styrene. It is expensive and currently used by professionals to manufacture articles where production costs are of lesser concern e.g. the manufacture of luxury yachts (personal communication, 2008).
Acrylates / Methacrylates	Acrylate / methacrylate monomers can also be included in styrene containing formulations to allow a lower styrene content (Costin and Bailey, 2005).

C.1.3.3 Use an alternative material to GRP to manufacture articles

In some cases it may be possible to substitute GRP for another material. In the time frame for preparing this transitional dossier it has not been possible to identify alternative

materials that could be used to make all of the different articles that are currently made using GRP. Some examples include the use of ceramics or cast iron for bathroom fittings, metal alloys for vehicle body panels and steel, aluminium or wood for boats. This is an area that will need to be looked at in more detail if restrictions are proposed on the use of styrene to manufacture GRP articles.

C.1.3.4 Replacement of open mould process with a closed mould process

One option to reduce exposure to styrene is to alter the fabrication process that is used. The type of article that is being made will determine the fabrication processes that can be substituted. For articles that are currently produced using hand lay-up and spray up it may be possible to substitute an enclosed laminating process. Good practice guidance from Norway suggests that the adoption of vacuum injection has the potential to reduce styrene emissions by up to 75-98% compared to spray lamination (Norwegian Labour Inspection Authority, 2004). Note that many enclosed moulding methods still require gelcoats to be applied manually to open moulds, hence the substitution of an enclosed moulding process will only address exposures during lamination. Data presented in section B.9.5.3 indicated that substantial short-term exposures can occur during open gelcoating. Unless tasks requiring application of resins to open moulds are segregated from the enclosed moulding process, the full potential for enclosed moulding to reduce styrene levels will not be realised.

The most commonly used enclosed processes are resin transfer moulding (RTM) and vacuum infusion. The RTM process uses a sealed mould. The glass fibre matting is placed in the previously gelcoated lower half of the mould. The upper half of the mould is then sealed onto the lower half and resin is fed in from one side of the mould using pressure or vacuum injection. Surplus resin is removed from the opposite side. The workpiece is not removed from the mould until curing is complete. This method has the advantage that there is minimal worker exposure to resins during infusion. There is no requirement for resins to be manually applied to the glass fibre mats, nor to roll out trapped air bubbles. Also styrene that would normally evaporate during open curing is reacted within the polymer matrix. Hence, only small amounts of styrene vapour are still present when the workpiece is removed from the mould. Moulds for RTM are more expensive than open moulds but the quality of the product is more consistent and the time to produce each article is less, hence this can be cost effective for long production runs. LePree (*undated*) suggests a production run of at least 150 000 parts per year is required to cover the costs of RTM tools. The UK Competent Authority considers that this anecdotal information will need to be verified before it can be used in an assessment of the costs of introducing RTM. There are limitations in the types of shapes that are suitable for RTM, e.g. lipped articles cannot be constructed using this method.

The vacuum infusion technique relies on plastic sheeting or a light semi-flexible outer mould to form the upper surface of the mould. It is less costly to implement than RTM and can be retrofitted to an existing open process. There is greater flexibility in the size/shape of article that can be moulded, however, where plastic sheeting is used to form the upper half of the mould this usually has to be replaced after a single use. A description of the use of plastic sheeting for vacuum infusion in a company specialising in the construction of sailing yachts from 15 to 40 meters in size is provided by Richez (2000). As with RTM, fibre matting is placed onto the previously gelcoated mould and is held in place along with any reinforcing struts with a contact adhesive. Plastic sheeting

equipped with a network of pipes is connected to a vacuum pump and a separate network supplying resin is then laid over the surface of and sealed to the mould. Resin infusion takes place under reduced pressure and the article is left to cure. As with RTM, in some cases it may be necessary to adapt the design of the workpiece.

C.1.3.5 Carry out open moulding tasks in enclosed ventilated booths

If it is not possible to substitute an enclosed moulding process, it may be possible to carry out an open moulding task in a ventilated booth. BG (1999) provides examples of booth design that may be suitable for different types of article. Siegberg (2006) also discusses the use of ventilated booths and improvements that can be made to ventilation systems in open workshops. Saamanen (1998) notes that where fixed LEV is used in open workshops, large airflow rates and many exhaust openings are required to keep exposures below 20 ppm. Without some segregation of open moulding tasks from the general workroom it may therefore be difficult to achieve the reductions in styrene exposure that are indicated by this transitional dossier. Where ventilated booths are used it is expected that people working inside the booth will need to wear suitable air-supplied RPE for the task.

C.1.3.6 Automate the process

Automating the gelcoating and laminating stages is another option. An automated form of RTM is the Virtual Engineered Composites (VEC) process described by Berenberg (2003). The computer-controlled resin injection process features a manufacturing cell that comprises two matched composite moulds situated between two fluid-filled pressure vessels. Each mould floats on a fluid (usually water) that forms a tight seal over the vessels. It reduces the time required for lamination and can achieve reductions in styrene emissions by around 90% when compared with open moulding. In addition, the process has been adapted to replace the gelcoat layer with a thin, thermoformed plastic shell that is bonded to the fibreglass laminate during the VEC moulding process. Berenberg refers to the use of VEC for the manufacture of small boats and baths/shower cubicles. Since the VEC process does not require the use of steel or aluminium moulds (which are generally required for RTM) it is said to be less costly (LePree, *undated*).

One wind blade manufacturer has introduced robotics in the form of laser-guided, automated glass lay-up to improve the quality and manufacturing efficiency for windmill blades (Gardiner, 2008). However, automating a process is not always an effective solution. Another wind blade manufacturing company quoted in this article had evaluated the costs and technical limitations of automated tape laying (ATL) and automated fibre placement (AFP) and thought that automation was only now progressing to a point where this company could consider them viable. For this company, barriers to the use of ATL and AFP were the size of machine required for wind turbine blades and the complex geometry of jet propellor blades.

C.1.4 Use 4: Consumer boat building

For amateur boatbuilding it may be possible to:

- substitute a styrene based resin with a resin based on an alternative monomer;

- use an alternative boatbuilding material

The issues surrounding the availability of alternative resins for amateur boat-builders will be similar to those identified for GRP manufacture.

Possible alternative materials for an amateur boat-builder are discussed at http://www.osmanardali.com/boatbuilder.htm. These include:

- wood/epoxy;
- steel;
- aluminium and;
- ferrocement.

Of these, the simplest materials to work with are wood/epoxy. Several internet sites have been identified that will supply kits for amateurs to build wood/epoxy boats. Specialist expertise is required to build boats using steel, aluminium or ferrocement.

The availability of these alternative boatbuilding materials, costs, human health and environmental risks and technical issues will be considered further in an Annex XV restriction dossier if community wide restrictions are to be proposed for this scenario.

C.1.5 Use 5: Alternatives to styrene-based liquid resins for consumer use

The issues associated with the use of alternative monomers have been discussed above. It is noted that although high tonnages of alternative monomers may be required to substitute styrene in resins produced for occupational use, given the relatively small-scale of supply to the consumer market (up to approximately 550 tpa of which liquid resins are only a part), alternative substances available at lower tonnages could be viable options. However, selecting different alternatives for small/different resin uses could widen the product portfolio, increase production costs and may give a more confusing range of products for the consumer. It is also uncertain whether larger producers of styrene would support the development of alternatives for such a small part of their European market.

C.1.6 Use 6: Alternatives to styrene-based resin pastes for consumer use

Some alternatives for styrene in resin pastes are available for consumer use. These have not been considered further in this transitional dossier because the risk characterisation has identified that typical exposures from the use of resin pastes formulated with up to 10% styrene are acceptable. Section E will consider measures to ensure that resin paste formulations supplied to the consumer market contain no more than 10% styrene.

C.2 Availability of alternatives

Industry considers that at present a move to resins based on an alternative monomer to styrene is impractical for large-scale occupational uses because alternative monomers are not available in sufficient quantities (personal communication, 2008). The UK Competent Authority does not have information on the timescale that would be required for

producers of alternative monomers to scale-up production to meet the demand for occupational use. Given that the EU market for consumer use of liquid/paste resins is small (about 550 tpa), any change from styrene-based resins to alternatives for consumer use is expected to have a limited impact on the consumption of any specific alternative. The UK Competent Authority does not have information at present to confirm whether alternative monomers are available in sufficient quantities to allow substitution for styrene in consumer products.

No issues are seen with respect to the availability of the equipment required to make the technical adaptations to the process described above. Issues relating to cost are discussed in section C.5. In the time available for preparation of this transitional dossier, the UK Competent Authority has not been able to investigate the availability of alternative materials to GRP for all of the different articles that are currently made using GRP.

C.3/C.4 Human health and environmental risks related to alternatives

It has not been possible to conduct a detailed evaluation of the human health and environmental risks for all potential alternative substances and processes within the timescale for preparation of this transitional dossier. Where restrictions are proposed the human health and environmental risks of alternatives will be considered as part of the Annex XV restriction dossier.

C.5 Technical and economical feasibility of alternatives

C.5.1 Alternative substances to replace or partially replace styrene in styrene-based resins

Issues relating to the technical feasibility of substituting styrene with an alternative monomer are discussed below. It has not been possible to obtain information on the economic feasibility of substitution with these monomers within the time frame for preparation of this transitional dossier. This information will be required for a comprehensive evaluation of potential alternatives to styrene.

Methylacrylates
Multifunctional acrylate and methacrylate monomers can by used as additives in unsaturated polyester resins to lower styrene emissions or as replacement for styrene. The methacrylate resins have higher flexural strength and slightly greater hardness with the advantage of lower cost, but have a slightly higher viscosity and cure more slowly with a lower peak exotherm temperature (Costin & Bailey, 2005). Whilst an advantage when high clarity resins are required, the difficulties with slower curing mean it is harder for untrained consumers to carry the process out effectively, so a UP-methacrylate resin would normally be used by a professional user with detailed instruction (personal communication, 2008). The effect of changes in the lengths of fatty acid methacrylates on the properties of the resin have been studied (Scala *et al*, 2004).

Polyurethane resins
Polyurethane resins are suitable for injection moulding and can be used in foam insulation, but are not appropriate for the consumer use scenarios for which UP-styrene

resins are used. They are more expensive than polyester resins, but costs can be offset by the faster cycle times and shorter oven cure times, and they give a higher tensile strength and impact, although a lower stiffness which can be partially addressed by optimising the use of fibreglass reinforcement (TSE Industries, 2008).

Dicyclopentadiene

DCPD is not an alternative monomer to styrene in UP-resins although its use as a alternative builder in the resin (e.g. instead of maleic acid or phthalic acid) can reduce the amount of styrene (from 35% to about 30-32%) into which the polymer needs to be dissolved (personal communication, 2008). The DCPD modified resin has a lower viscosity but can be used in much the same way as UP-styrene resins and gel coats, although, it tends to be used without reinforcement and is most commonly used in reactive injection moulding (RIM) (Norwegian Competent Authority, 2008). RIM is an enclosed moulding process in which low viscosity resins are injected into the mould under slightly elevated pressure. DCPD is produced from oil refineries, so its availability is dependent on the market demand for oil.

Vinyl esters

Vinyl esters can be used as part of the polymer, in combination with epoxy and methacrylate esters dissolved into styrene. The resin has high mechanical and corrosion resistance properties but is more expensive and hence used by professionals for the top segment of the market e.g. luxury yachts (personal communication, 2008).

Epoxy resins

Epoxy resins have a very low shrinkage, higher adhesion to many materials, higher chemical resistance and are up to 50% more durable and less brittle compared to polyester resins. They can be combined with carbon fibre or glass fibre (internet 1, 2008). As a result, they are already available in Norway for consumer use as an alternative to styrene-based resins (Norwegian Competent Authority, 2008). However there is concern over the risk of skin allergy from epoxy resins.

Methylstyrene

Methylstyrene is a possible alternative to styrene in polyester resins. Alpha-methylstyrene is relatively cheap alternative to styrene, copolymerises well and produces mould parts of high mechanical and thermal grade. Meta / para-methylstyrene has lower peak temperature during polymerisation and stress-free curing but gives worse mechanical properties for the resulting resin. Whilst methylstyrene is available at large tonnage volumes, its reactivity with the polymer is lower compared to styrene so that more effort is required to cure the resin, making it less appropriate for consumer use (personal communication, 2008).

Diallyl phthalate

Diallyl phthalate has low volatility compared to styrene so is suitable for compression moulding and parts that need good electrical, thermal and mechanical characteristics. However, it is only suitable for hot curing (around 160^{o}C) and the higher temperature could lead to enhanced level of styrene emissions to the atmosphere. Hence it is only suitable for occupational use, and not for consumer use because it cannot be cured at room temperature (personal communication, 2008).

C.5.2 Alternative manufacturing processes and the inclusion of additional control measures around existing processes

In terms of the technical feasibility of replacing an open moulding process with an enclosed or automated moulding process, one key consideration is the shape of the article being produced. For example, it will be difficult to use an enclosed mould for a lipped article. Depending on the requirements of the finished article, it may not always be possible to adapt the design to enable the article to be made using an enclosed or automated moulding process. There are also size constraints. For example it is impractical to consider enclosed moulding for large boat hulls. It is therefore not clear if it will always be technically feasible for GRP workshops to replace an open moulding process with an enclosed or automated moulding process. Where substitution is not possible it may be possible to use ventilated booths to segregate an open moulding process from the main workshop.

The use of enclosed or automated moulding processes or ventilated booths could impose considerable costs on GRP fabricators. In relation to the use of an enclosed or automated moulding process there will be costs to introduce enclosed moulding tools, not only for the tools themselves but also to train the workforce in correct usage and it is likely that there will be increased maintenance costs. These costs may in part be offset by the faster turnover allowed by enclosed moulding and a greater consistency in the finished product. However, as indicated above, this benefit will only be gained where there are large production runs. Enclosed or automated moulding may be too costly for a workshop whose main business is small production runs of custom designed items. In this situation, it will be more appropriate to look at segregating open lamination using ventilated booths. Depending on the size of the article that is produced, there may be considerable costs to design and install a suitable system.

It has not been possible to make quantitative estimates of the costs involved within the time frame for preparing this transitional dossier.

C.6 Other information on alternatives

None obtained.

D. JUSTIFICATION FOR ACTION ON A COMMUNITY-WIDE BASIS

Styrene is used throughout the EU. Information obtained for this transitional dossier indicates that sites manufacturing UP-styrene resins, SBR/SBL and sites manufacturing articles using styrene-based resins are located in every Member State.

In relation to consumer uses, it is expected that styrene-based resins for small-scale repairs are supplied to the consumer market in every Member State. However, consumer boat-building using GRP appears to be a rare event and one that may take place in a only a few Member States. When Member States were approached for information on consumer boat building, only Sweden, the UK (and Norway) identified that products were available in their countries for this use.

D.1 Considerations related to human health and environmental risks

With the exception of consumer boat building, the occupational and consumer uses for styrene that are discussed in this transitional dossier take place in all Member States. Therefore, the risks to human health arising from these uses are a matter of concern for all Member States. In this situation, to ensure consistency in the approaches adopted across the EU and to avoid duplication of effort it is most appropriate to consider measures at the EU level to tackle these risks.

In the case of consumer boat building, this use appears to be limited to a few Member States. It will therefore be more appropriate for action to be taken at a national level to address the risks.

No environmental risks were identified in the RAR therefore environmental risks relating to the use of styrene have not been considered in this transitional dossier

D.2 Considerations related to internal market

There is a need to act on a Community-wide basis due to the fact that styrene is a traded good. Goods must be allowed to flow freely between EU Member States. It is thus not appropriate for one Member State on its own to restrict placing on the market or use of styrene (unless styrene was used in only one Member State on a very local and small basis, in which case other means than EU wide legislation may be more appropriate).

The reason for proposing EU-wide measures to control the manufacture of UP-styrene resins, SBR/SBL and articles using styrene-based resins at sites stems from the need to avoid trade and competition distortions, which could occur within the EU under regulations imposed at a national level. Proposing measures to control the manufacture of styrene at community level ensures a “level playing field” such that the burden on enterprises from any legislative requirements does not result in them becoming less competitive in the internal market, as compared to the case if national level measures are taken.

D.3 Other considerations

National occupational exposure limits (OELs) are in force in most Member States but the values are widely different owing to the different historical development of national OELs in Member States. This difference in regulatory exposure standards could lead to differences in the levels of control that can be enforced across the EU. It is therefore considered that swift action needs to be taken on a community wide basis to harmonise OELs to ensure a consistent level of control is enforceable across the EU.

D.4 Summary

Community wide action is justified on the basis that styrene is traded and used throughout the EU. As such, consistent measures need to be implemented across the EU to ensure a “level playing field” is maintained and that consistent standards of control are implemented in all Member States.

E. IDENTIFICATION OF THE MOST APPROPRIATE COMMUNITY-WIDE MEASURE

The aim of this transitional dossier is to identify suitable risk management measures to control the identified risks for the uses of styrene for which conclusion (iii) was reached in the RAR. Since different options are available to manage risks in the occupational setting compared to those available for consumers, occupational risk management measures and consumer risk management measures will be considered separately. To distinguish between sections discussing measures for the occupational setting and measures for the consumer section the sections will be numbered E(occ) for occupational and E(cons) for consumers.

RISK MANAGEMENT MEASURES FOR THE OCCUPATIONAL SETTING

E(occ).1 Identification and description of risk management options

This section considers generic risk management options for the following occupational scenarios:

- manufacture of UP-styrene resins;
- manufacture of SBR and SBL;
- manufacture of GRP and use of styrene-based resins.

It does not aim to specify the sets of control measures that may be needed for specific workplaces.

E(occ).1.1 Risk to be addressed – the baseline

The risk characterisation for the manufacture of UP-styrene resins indicated that the RWC 8-hour TWA inhalation exposure value is too high. The RWC short-term inhalation exposure value is also slightly too high. However, typical inhalation exposure values and dermal exposure values are below the relevant DNEL values and are therefore judged to be acceptable. This indicates that the risk management measures currently applied are adequate to address concerns for systemic toxicity providing they are properly implemented and maintained correctly. In this situation it is not considered necessary to look at additional risk management measures to control the risks that have been identified but to consider whether there are any barriers to effective implementation of current risk management measures. The risk characterisation also indicated a need for workers to wear suitable gloves and goggles where there is the potential for direct contact with styrene to prevent irritation.

A similar situation exists for the manufacture of SBR and SBL. For this use, only the RWC 8-hour TWA inhalation exposure values are slightly above the DNEL. All other exposure values are below relevant DNELs. As with the manufacture of UP-styrene resins it is not considered necessary to identify additional risk management measures to control the risks that have been identified but to consider whether there are any barriers to

effective implementation of current risk management measures. For the reasons outlined above, the use of suitable gloves and suitable eye protection are also recommended in this use scenario where there is the potential for direct contact with styrene.

The risk characterisation for GRP manufacture and the use of UP-styrene resins has identified that additional measures are required to reduce both RWC and typical short-term and 8-hour TWA exposure values to the level of the DNEL. Further work is needed to identify the range of control measures that will secure adequate control of airborne styrene in all occupational situations where styrene-based resins are used. In relation to dermal exposure RWC dermal exposures are marginally above the dermal DNEL for systemic toxicity but typical dermal exposure values are below the DNEL. The current risk management measure to control dermal exposure is the use of gloves. This assessment suggests that gloves are an adequate measure to address concerns for systemic toxicity but that the measure needs to be implemented and maintained more thoroughly and consistently. In addition to the use of suitable gloves, the use of chemical goggles should also be required for situations where there is the potential for direct contact with styrene containing resins.

Options to implement the additional risk management measures that this assessment indicates will be needed to bring exposure values below the level of the DNEL are discussed below.

E(occ).1.2 Other Community-wide risk management options than restriction

The following risk management options have the potential to reduce exposure to styrene:

- introduce an EU OEL;
- introduce a biological monitoring guidance value;
- implementation of risk management measures (RMMs) following registration of styrene under REACH;
- implementation and maintenance of good practice.

E(occ).1.3 Options for restrictions

On the basis that typical exposures for the manufacture of UP-styrene resins and the manufacture of SBR/SBL are at an acceptable level, restrictions are not being considered for these scenarios. In the case of GRP manufacture, the following options for restriction have the potential to reduce exposure:

- restrict the occupational use of styrene-based resins;
- restrict the use of UP-styrene resins for hand lay-up and spray-up;
- restrict the use of UP-styrene resins in open workshops;
- introduce a licensing scheme for companies wishing to use styrene based resins.

An option not considered here is to restrict the amount of styrene present in resins supplied for occupational use. As indicated earlier in this dossier, LSE/LSC resins are widely available and resins manufacturers have explored the limits of what can be

achieved in terms of reducing the styrene content whilst maintaining the technical properties of the resins. Since LSE and LSC resins are already in use, the UK Competent Authority believes that a restriction to limit the level of styrene in resins has a limited potential to secure further reductions in exposures. However, the use of resins containing the lowest styrene content that is necessary to achieve the required technical properties should be considered as one element of good practice where styrene-based resins are used.

E(occ).2 Comparison of instruments: restriction(s) vs. other Community-wide risk management options

This section compares the potential for a formal restriction under REACH to address the concerns identified in this transitional dossier compared with other risk management options short of restriction.

E(occ)*.2.1 Effectiveness*

E(occ).2.1.1 Risk reduction capacity

E(occ).2.1.1.1 Restriction under REACH

Under REACH, Member States can introduce restrictions when there is an unacceptable risk to human health or the environment and the risk needs to be addressed on a Community-wide basis. This transitional dossier has identified that the current risk management measures in place for GRP fabrication are not adequate. Four options for restrictions have been identified in section E(occ).1.3. Each of these options has the potential to reduce exposure to styrene. However, from the information currently available to the UK Competent Authority it is not possible to identify which option or options will be the most effective at reducing the overall risks to human health and the environment.

A restriction that prohibited all use of styrene in the manufacture of fibre-reinforced composites (FRCs) would force manufacturers to move to resins based on alternative monomers or to consider alternative materials. It has not been possible to evaluate the risks that alternative monomers pose to health and the environment in the time available. However, it is known that some alternative monomers do present risks to health. For example, there are concerns for skin sensitisation with epoxy resins. A move to alternative materials may also carry risks for health. It has not been possible to carry out a comprehensive evaluation of all possible alternatives for the many uses for GRP. Referring to the alternative materials identified in section C.1.3.3., the use of wood instead of GRP for building boats will result in a greater number of people being exposed to wood dusts, many of which have been identified as a potential cause of occupational asthma. Adverse health effects are also associated with metal casting and the welding that would be required to manufacture for example vehicle body panels or boats using metals. Any restriction that required manufacturers to move away from the use of styrene-based resins will need to consider all of the potential health risks from alternative monomers and alternative materials.

In terms of risks to the environment, it is noted that no risks were identified for styrene in the ESR RAR for the environment (EU, 2002). Any restriction that required manufacturers to move away from the use of styrene-based resins will need to consider the potential risks to the environment from alternative monomers and alternative materials.

As well as direct effects on the environment, there may be indirect effects. FRCs are seen as a strong and lightweight alternative to metal. Where FRCs are used to manufacture body panels in lorries, caravans, trains or aircraft fuselages they can bring about a reduction in the weight of the vehicle which means that the vehicle uses less fuel and produces lower emissions. FRCs are also being hailed as a cost effective alternative to concrete for civil engineering projects. In 2008, FRCs were used to build a road bridge in Germany (http://www.plasticseurope.org/Content/Default.asp?PageID=1420). In the UK in 2006, a farm access bridge made of FRC was installed across a busy motorway (http://news.bbc.co.uk/2/hi/uk_news/england/lancashire/6748401.stm). In both cases, the use of FRCs allowed the bridge installation to take place more quickly and the bridges are expected to have a longer life span and require less maintenance than a conventional concrete bridge. Any decision that will limit the availability of FRCs needs to consider the broader environmental impacts that this may have.

In the light of this, restrictions that dictate the RMMs that are in place where styrene-based resins are used e.g. to restrict the use of land-lay up/spray-up or to restrict the use of styrene in open workshops may seem to be a more appropriate route. However, it is not clear from the information currently available which GRP fabrication processes should be targeted by such a restriction. For example, a restriction that prohibited hand-lay up or spray up on the basis that these fabrication processes are associated with the highest exposures may reduce human exposure to styrene. However, there may still be adverse environmental impacts. The replacement of open moulding processes with enclosed processes will reduce the emissions of styrene to air because more of the styrene in the resin will cure into the article. It will also avoid the contamination of the workroom that can occur with splashing and overspray during manual moulding and there will be no need to clean brushes, rollers and spray guns. However, there may be additional generation of wastes with for example the vacuum infusion technique since it may be necessary to replace the plastic sheeting used as the upper surface of the mould after each lamination. There will also be a need to clean the infusion equipment after use. It has not been possible to quantify the different environmental impacts associated with different GRP fabrication processes within the timescale for preparing this transitional dossier. It is therefore not possible to identify which fabrication process has the lowest environmental impacts.

An option to prohibit the use of styrene in open workshops would not only target open lamination but could also target machine moulding processes. Additional exposure data needs to be obtained to determine if human exposures during machine moulding are sufficiently high to warrant the imposition of restrictions. It is not clear whether a restriction to prohibit the use of styrene in open workshops would have any environmental impacts. It is not clear whether a licensing scheme would have any adverse impacts on human health or the environment.

Overall, based on the information that is available in this transitional dossier, there is no clear evidence that a restriction will automatically reduce the overall risks to human health or the environment and for some options, the overall risks may increase.

E(occ).2.1.1.2 Occupational Exposure Limits

An occupational exposure limit (OEL) is not a prevention measure in itself but is a useful tool to set a benchmark standard of control for industry to achieve. An OEL also enables employers to assess the significance of measured exposure data and, should employees become ill, allows the employer to demonstrate that an adequate control regime was in place. Within the EU it is possible to set health-based limits and pragmatic limits. In order to set a health-based limit is necessary to have good data to indicate the critical health effects and dose-response relationships for each effect. Pragmatic limits may be set where there is uncertainty about the dose-response relationship for one or more critical health effects but there is a need to limit exposure. In the case of styrene, based on RWC exposure values there is a need to limit 8-hour TWA inhalation exposure values for all the occupational scenarios considered in this transitional dossier. There is also a need to limit short-term inhalation exposure values during the manufacture and use of UP-styrene resins.

OELs can be set for both reference periods and once an OEL has been set by a regulatory body, it has the potential to be used as a legal instrument to force employers to control exposures to the level of the OEL. If it is properly complied with, an OEL offers one possible route to secure adequate control for styrene. As indicated in section B.9.1.1.3, although OELs for styrene are in place in most Member States, the limit values are not necessarily based on up-to-date information. An OEL that does not take account of all relevant hazard information is not an effective risk management tool even if it is effectively enforced. It is therefore recommended that an EU-wide OEL should be established under the Chemical Agents Directive (CAD) to ensure the limit values in each Member State are based on current information and that there is consistency across the EU.

E(occ).2.1.1.3 Biological Monitoring

Biological monitoring is a useful tool for assessing individual worker exposure, particularly where there is the potential for dermal exposure and uptake or where respiratory protective equipment (RPE) is used to control exposure to airborne substances. The introduction of a biological monitoring benchmark for styrene will provide an indicator against which an employer can judge the exposures received by an individual worker. Biological monitoring data can also be used to demonstrate that an adequate level of control has been maintained.

In the case of styrene, there is the potential for dermal exposure to contribute to the systemic body burden and RPE is used as a control measure for GRP manufacturing. Biological monitoring methods are available and biological monitoring “benchmarks” have already been established in certain Member States e.g. Germany and Finland. It is considered that the introduction of a biological monitoring “benchmark” across the EU as an adjunct to an EU OEL would provide a useful additional risk management tool.

E(occ).2.1.1.4 Implementation of RMMs following registration of styrene under REACH

REACH requires companies that manufacture and/or import substances into the EU in quantities greater than 1 tonne per annum to register them with the European Chemicals Agency (ECHA). The act of registration requires companies to submit a dossier of information to ECHA, the amount and type of information increases with increasing tonnage.

Styrene is a high tonnage chemical, manufactured in quantities of > 1000 tpa. The registration package for styrene should therefore include a technical dossier and a chemical safety report. Since styrene meets the criteria for classification as dangerous, the chemical safety report will include an exposure assessment and descriptions of exposure scenarios for all identified uses. Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends to control, exposures to humans and the environment. The exposure scenarios must include the appropriate risk management measures (RMMs) and operational conditions (OCs) that, when properly implemented, should ensure that the risks from the uses of the substance are adequately controlled. In this case, adequate is defined as control to a level of exposure that does not exceed the DNEL.

Exposure scenarios should be developed to cover all “identified uses” which are the manufacturers’ or importers’ own uses, and uses that are made known to the manufacturer or importer by his downstream users and which the manufacturer or importer includes in his assessment. For styrene, this will include all of the uses identified in the RAR as being of concern. One issue for this transitional dossier is that the risk characterisation for GRP manufacture is based on data for hand lamination. This fabrication process is expected to give rise to exposure levels which may be unrealistically high for machine moulding processes or enclosed moulding processes. Based on current data it is not possible to conduct process specific risk characterisations for individual fabrication processes. In this situation, and given that the UK Competent Authority has limited information on current risk management measures for machine fabrication processes, it is difficult to determine the range of additional risk management measures that may be appropriate for all types of GRP fabrication process. In developing exposure scenarios, industry will need to consider each fabrication process and will develop a series of risk management measures that are relevant for each process. Exposure scenarios will be annexed to the safety data sheets that will be supplied to downstream users and distributors. REACH therefore provides an effective mechanism to identify relevant risk management measures for individual fabrication processes and to communicate this information to the relevant workplaces.

In relation to the timing for registration, companies that pre-register the chemicals they supply have the opportunity to take advantage of extended deadlines for registration. Industry has indicated to the UK Competent Authority that the Styrene REACH Consortium intends to submit a registration dossier for styrene by 1 December 2010. It is therefore anticipated that by 1 December 2010, companies that supply styrene will have described exposure scenarios for all identified uses, including the uses that are covered in this transitional dossier. Exposure scenarios will therefore have started to filter to downstream users in just over 2 years. Once a user has received the extended safety data sheet they have a maximum of 12 months to implement the measures described in the extended safety data sheet (Article 39.1). This suggests that all users of styrene should be

in possession of information on appropriate risk management measures for their use and should have taken steps to implement appropriate measures within 3 years.

Regulators have the opportunity to oversee this process through the mechanism of substance evaluation. Substance evaluation will include consideration of the DNEL values derived by registrants, the exposure assessment that the registrant has made and the risk management measures that are proposed in the exposure scenarios. Member States can propose substances for evaluation if there are grounds to consider that the substance presents a risk to human health or to the environment. A substance proposed for evaluation will be included on the Community Rolling Action Plan. The first draft action plan will be published by the Agency on 1 December 2011 and it will be updated annually on 28 February thereafter. It is not clear whether substance evaluation can begin ahead of the inclusion of a substance on the action plan but it is anticipated that if no restrictions are being considered by Member States under REACH, styrene could be considered a priority for substance evaluation by Member States. A Member State has 12 months to reach a decision. Assuming substance evaluation for styrene started on 1 December 2011, a decision on whether the exposure scenarios were adequate to control the risks identified in this transitional dossier would be made by 1 December 2012. If it was concluded that the measures proposed in an exposure scenario were inadequate the Member State conducting the evaluation could either request additional information to confirm that control was adequate or would have a sound basis from which to propose targeted restrictions.

On this basis, it is proposed that the implementation of REACH will be an effective mechanism to identify suitable RMMs that are specific to each of the use scenarios described in this transitional dossier. Furthermore the RMMs described in exposure scenarios will be specific for the different GRP fabrication processes that are in use.

E(occ).2.1.1.5 Implementation and maintenance of good practice

Under ESR, one risk management option was voluntary adoption by industry of a code of good practice. On the basis that the RMMs and OCs described in the exposure scenarios that will be prepared for styrene under REACH will describe good practice for each use, assuming that these RMMs and OCs are followed properly, a voluntary agreement may not be any more effective than REACH in terms of reducing exposures. However, a voluntary agreement may enable good practice measures to be implemented in advance of the timescale for implementation of measures under REACH. Based on the information provided for this transitional dossier, it is expected that good practice will follow the process description given in B.9.3 and B.9.4. The UK also considers that good practice for maintenance activities in plants manufacturing UP-styrene resins and SBR/SBL will include a permit-to-work system where there is a need to enter blending or mixing vessels to ensure that the vessels are suitably decontaminated before they are accessed. To mitigate the identified hazards of skin and eye irritation, good practice should also include the use of suitable gloves and eye protection in situations where there is the potential for direct contact with styrene or products containing unbound styrene monomer at a concentration of 12.5% or more. It is expected that any good practice measures that are agreed in advance of the registration of styrene under REACH will be included in exposure scenarios that are drafted as part of the registration package.

In relation to the manufacture of UP-styrene resins and SBR/SBL, these sectors are characterised by larger companies, most of whom are members of the umbrella trade association CEFIC. Within CEFIC the UP Resin Group members represent 90% of the UP-styrene resin manufactured within the EU, whilst the European Polymer Dispersion and Latex Association (EPDLA) members represent the majority of SBR/SBL produced in the EU and hence CEFIC could help further develop good practice for UP-styrene resin and SBR/SBL manufacturers.

Implementation of good practice measures ahead of the registration of styrene under REACH is not seen as a viable option to secure adequate control for GRP manufacture. The data available for this transitional dossier do not provide sufficient information to identify the range of control measures that will be required to achieve the necessary levels of control. Therefore, while various documents indicating good practice measures are available, it is not clear whether the measures proposed within these documents are sufficient. An additional barrier for this sector is the lack of a clear channel to disseminate good practice guidance and the likely varying levels of expertise in risk management. This sector is characterised by a large number of small and medium sized enterprises who may or may not be members of a trade association. It is difficult to see how good practice guidance could be effectively communicated to the majority of GRP fabricators in the EU by another mechanism than the Safety Data Sheet route used by REACH. On this basis, implementation of good practice ahead of REACH within the GRP manufacturing sector will not be considered further.

E(occ).2.1.2 Proportionality

E(occ).2.1.2.1 Restriction under REACH

It is not possible to determine whether any of the restriction options identified in section E.1.3 will be proportionate. An assessment of the proportionality of a restriction will need to consider whether the restriction is economically feasibility (i.e the costs to comply with the restriction are in proportion to risks). It has not been possible to conduct any economic evaluation of the measures suggested in this dossier in the time available.

It has also not been possible to assess the technical feasibility of any of the proposed restriction options. An assessment of technical feasibility will need to consider the technical suitability of alternative monomers and materials. In terms of the technical feasibility of replacing an open moulding process with a closed moulding process, the main consideration is the shape of the article being produced. Depending on the requirements of the finished article, it may not always be possible to adapt the design to enable the article to be made using an enclosed moulding process. The greatest technical feasibility issues with the requirement to carry out open moulding processes in an enclosed booth will arise where large articles such as boat hulls are being manufactured. It has not been possible to investigate the availability of booths large enough to accommodate the various sizes of boat hull that may be manufactured within the time scale for producing this transitional dossier nor to consider other technical issues that might be encountered in fitting such booths into GRP workshops. Although, it is expected that it will be possible to resolve any technical difficulties associated with the use of ventilated booths for open moulding, the costs may be prohibitive for some GRP manufacturers.

It is expected that the costs of a licensing scheme will have the greatest impact on smaller companies who may not have the resources to deal with the additional paperwork. A licensing scheme will also be burdensome for national authorities in Member States to administer. Licensing is usually reserved for work activities with the highest level of risk. It may therefore not be a proportionate measure for styrene.

E(occ).2.1.2.2 Occupational Exposure Limits

Depending on the measures already in place at a particular workplace, the potential costs to implement the control measures needed to achieve an OEL may include the costs of installing, maintaining and running local exhaust ventilation (LEV), remodelling facilities to improve containment and RPE. A value for an OEL for styrene has not yet been identified. In the case of the manufacture of UP-styrene resins and the manufacture of SBR/SBL, typical exposures are below the level of the DNEL. It is therefore expected that the costs to comply with an OEL will be modest for the majority of companies. Further discussions with industry will be required to identify the costs once the level of an OEL has been decided.

In the case of GRP manufacture, it is likely that many companies, particularly those that use open moulding and have high exposures as a consequence, will face high costs to implement the additional control measures that they are likely to need. In order to derive a suitable assessment of the likely costs of improved control measures, it will be necessary to consult with industry to determine the nature of the additional controls required and the costs associated with implementing these measures.

E(occ).2.1.2.3 Biological Monitoring

The introduction of a biological monitoring "benchmark" is not a formal legislative measure so there will be no legal requirement for an employer to "comply" with the value. However, there will be costs associated with the setting up of a biological monitoring programme and subsequent running of such a programme. Also where the results indicate control is not adequate there may be a need to implement additional controls. Consultation with industry will be required to establish the costs for different sizes of company to set up biological monitoring programmes and any additional costs that might arise from the need to implement additional controls.

E(occ).2.1.2.4 Implementation of RMMs following registration of styrene under REACH

This is a current piece of legislation and industry must comply with the various elements of REACH as they are implemented. By recommending this option no additional costs beyond those required to comply with REACH are being imposed.

E(occ).2.1.2.5 Implementation and maintenance of good practice

If the requirements of the framework directive and daughter directives are being followed correctly then workplaces should follow good practice as a matter of routine. Good practice in relation to the manufacture of UP-styrene resins and the manufacture of SBR/SBL can be defined as the set of control measures required to achieve the "typical"

exposure levels identified in section B. Where companies already follow good practice it is expected that any additional costs will be modest.

E(occ).2.2 Practicality: implementability, enforceability, manageability

E(occ).2.2.1 Restriction under REACH

It has not been possible to conduct an evaluation of the practicality of any of the restriction options identified in section E.1.3 within the time available for preparation of this transitional dossier. It is noted that operating a licensing scheme will be resource intensive for national authorities in Member States and that this may divert scarce resources away from other regulatory activities.

E(occ).2.2.2 Occupational Exposure Limits

The introduction of an OEL requires that it be achievable (i.e. there is potential for exposure reduction within reasonable cost) and that concentrations of styrene are measurable in air. Styrene can be measured in air and an OEL (if of the same order of magnitude as the DNEL) could also be measured. Methods for sampling styrene in air have been described (MDHS 80 and MDHS 96). Depending on the sampling time and analytical methods used, the limits of detection range from 0.005 ppm – 0.1 ppm.

In relation to achievability, given that comparatively low exposure values have been reported for the manufacture of UP-styrene resins and SBR/SBL, it is expected that there will be no technical barriers to achieving compliance with an OEL (if of the same order of magnitude as the DNEL) for these sectors. There may be technical barriers for GRP fabricators and other users of styrene-based resins. This will need to be explored during deliberations around the value of an OEL.

Issues relating to costs of compliance have been considered in section E.2.1.2.2.

A regulatory mechanism is in place to agree and implement an EU-wide OEL. EU-wide limits have been established under CAD and the Carcinogens and Mutagens Directive. It is expected that the same process will be used to establish an EU-wide OEL for styrene.

Once an EU-wide limit is in place, the workplaces to which the OEL will apply should be familiar with workplace health and safety legislation and should understand what steps need to be taken to manage compliance with an OEL or have access to a suitably qualified advisor. On the basis that styrene in air can be measured over a range of concentrations it is considered that an OEL will be a practical measure to implement.

On this basis, it is considered that the introduction of an EU-wide OEL will be a practical risk management measure for styrene.

E(occ).2.2.3 Biological Monitoring

For a biological monitoring “benchmark” to be a practical risk management tool there has to be an available method to measure the substance of interest. In addition, the preferred method of biological monitoring is via a non-invasive technique (e.g. urine or breath).

Biological monitoring has been used for over 30 years to assess exposure to styrene. Most biological monitoring is based on the analysis of the metabolites mandelic acid and phenylglyoxylic acid in urine although styrene has also been measured in blood, urine and breath. The ACGIH have established a biological exposure index (BEI) of 400 mg mandelic acid plus phenylglyoxylic acid/g creatinine in end of shift urine samples after exposure to 20 ppm styrene. The BEI also has a 'NS' notation to show the metabolites are not specific to styrene (can also come from e.g. ethylbenzene). The document supporting the BEI also gives a value of 300 mg/g for mandelic acid alone. Biological monitoring guidance values have also been established in some EU countries. The Deutsche Forschungsgemeinschaft (DFG) has a *Biologishe Arbeitsstoftoleranzwerte* (BAT) of 600 mg mandelic acid plus phenylglyoxylic acid/g creatinine in end of shift urine samples after exposure to 20 ppm styrene. The Finish Institute of Occupational Health has a guidance value for the sum of mandelic and phenylglyoxylic acids of 1.2 mmol/L (approx 140 mg/g) in samples collected pre-shift at the end of the week. During pregnancy this is reduced to 0.3 µmol/L, corresponding to an exposure at 10% of the Finnish occupational exposure limit (20 ppm, 8-hour TWA). Thus biological monitoring is a practical option.

On the basis that metabolites of styrene can be measured in urine over a range of concentrations and that biological monitoring is already used in workplace risk management strategies for styrene it is considered that a biological monitoring "benchmark" would be of practical use. Although participation in a biological monitoring programme would be voluntary on the part of the worker, experience in the UK with workers in the manufacturing sector has shown that they are generally willing to participate in such programmes. The introduction of biological monitoring programmes should therefore be manageable.

E(occ).2.2.4 Implementation of RMMs following registration of styrene under REACH

The work that manufacturers/importers have to carry out is outlined in the legislation and is being further clarified by guidance documents. Although this area will be new for industry and will require specialist input, it should be practicable for them to follow. Since the process for developing exposure scenarios allows for downstream users to contribute, the advice contained within the exposure scenario should be practicable and the measures should be manageable.

Under REACH it will normally be a contravention of Article 37(5) for downstream users not to follow the conditions set down in the exposure scenarios unless these are not appropriate or the downstream user has taken other action provided for by Article 37. It is therefore suggested that after December 2011, the end of the period by which companies should have implemented the necessary RMMs, there is an EU-wide programme of inspection. This can be proposed via the REACH Enforcement Forum. If this occurs in parallel with substance evaluation it will enable Member States to determine whether the measures described in exposure scenarios are being implemented correctly. If the inspection programme finds that the measures in exposure scenarios are not being followed this will provide evidence to inform subsequent regulatory activity which may take the form of prosecutions under REACH or the development of targeted restrictions.

E(occ).2.2.5 Implementation and maintenance of good practice

Good practice in relation to the manufacture of UP-styrene resins and the manufacture of SBR/SBL can be defined as the set of control measures required to achieve the “typical” exposure levels identified in section B. On the basis that typical exposure levels for an industrial sector reflect the most prevalent control regimes within the sector, the measures required to implement good practice should be practical and manageable for all companies. In relation to enforcement, if a company has not implemented sufficient control measures to comply with good practice, they are not taking effective measures to minimise worker exposure and are therefore not complying with the requirements of CAD. CAD is enacted into national legislation in each Member State and it is expected that mechanisms will be in place in each Member State to enforce it. Once styrene has been registered under REACH, good practice as described in exposure scenarios for the manufacture of UP-styrene resins and SBR/SBL can be enforced under REACH.

E(occ).2.3 Monitorability

E(occ).2.3.1 Restriction under REACH

REACH requires each Member State to devise and implement a suitable enforcement regime for REACH. This includes enforcement of restrictions. An inspection programme will allow regulators to monitor whether the terms of a restriction are being adhered to and identify areas where additional enforcement action may be necessary.

E(occ).2.3.2 Occupational Exposure Limits

Employers are required to keep records of measurements taken to determine levels of airborne contaminants in the workplace. The successful implementation of an OEL can be monitored by such records demonstrating that levels of airborne contaminants have been kept within the OEL.

E(occ).2.3.3 Biological Monitoring

Employers are required to keep the results from biological monitoring programmes. The successful implementation of a biological monitoring guidance value will be monitored by such records demonstrating that worker exposures have been kept within the biological monitoring guidance value.

E(occ).2.3.4 Implementation of RMMs following registration of styrene under REACH

REACH requires each Member State to devise and implement a suitable enforcement regime for REACH. This includes enforcement of registration and whether downstream users are correctly following the advice given within the exposure scenario. An inspection programme will allow regulators to monitor whether exposure scenarios are being implemented correctly and identify areas where additional action is necessary.

E(occ).2.3.5 Implementation and maintenance of good practice

Monitoring the implementation of good practice will require an inspection programme. Comparatively few sites around Europe are engaged in the manufacture of styrene-based resins and the manufacture of SBR/SBL and hence relatively few visits will be necessary.

E(occ).2.4 Overall assessment against the three criteria

E(occ).2.4.1 Restriction under REACH

On the basis that typical exposures for the manufacture of UP-styrene resins and the manufacture of SBR/SBL are at an acceptable level, restrictions are not considered appropriate for these use scenarios. At this time, the UK Competent Authority does not have sufficient information about exposures across all GRP fabrication processes to formulate an appropriate restriction proposal that will be technically feasible and proportionate to the risks. Article 1 states that the purpose of REACH is "to ensure a high level of protection for human health and the environment". While this assessment has identified risks to health arising form the use of styrene-based resins to manufacture FRCs, it is not clear that alternative monomers or materials will automatically carry lower risks to human health or to the environment. The UK Competent Authority currently does not have enough process specific information for the different GRP fabrication processes to develop a restriction focussed on the use of specific RMMs. One key barrier is that it is not possible at present to identify which measures will be required to achieve the levels of control indicated by the DNEL values. Although a licensing scheme provides the most flexibility in terms of the RMMs that individual workshops may implement, it may not be an appropriate measure for styrene under REACH. It will be burdensome for national authorities to implement and may divert scarce resources away from other activities. On this basis, a restriction on occupational use of styrene does not seem to be a practicable option at present.

E(occ).2.4.2 Occupational Exposure Limits

There are few barriers to the establishment of an OEL for styrene. Methods are available to measure styrene in air across a range of concentrations and there are sufficient data to allow a health-based limit to be set. OELs are familiar risk management tools. Employers and their risk management advisors should understand the steps they need to take to comply with an OEL. Given the variability in the values of OELs for styrene across the EU, it is considered that in harmonisation between Member States is an essential step towards ensuring consistent standards of risk management across the EU. The level at which an OEL will be set is not known at this time. No major barriers are envisaged for the manufacturers of UP-styrene resins or SBR/SBL to comply with an OEL. However, depending on the value that is adopted there could be technical barriers for users of styrene-based resins to achieve the necessary levels of control. It is therefore recommended that the European Commission considers establishing an OEL for styrene.

E(occ).2.4.3 Biological Monitoring

Biological monitoring is a useful risk management tool. Non-invasive methods are available and are already used by industry to monitor exposure to styrene. Although it is

not possible to link biological levels directly to markers of ill health for all health endpoints of concern, it is nevertheless possible to determine the level of urinary metabolites that will correspond to an 8-hr exposure at the level of an OEL or the level of the DNEL. Where there are concerns for systemic toxicity because of dermal uptake or RPE is used to control worker exposure, biological monitoring can be used to demonstrate that the body burdens for individual workers are maintained within acceptable levels. Biological monitoring will therefore be a useful adjunct to other control measures to verify that individual worker exposure is being adequately controlled.

E(occ).2.4.4 Implementation of RMMs following registration of styrene under REACH

REACH appears to be the most practical way to identify and implement suitable control measures to secure reductions in exposure to styrene across the range of uses covered in this transitional dossier. It provides a legislative framework for the identification and implementation of appropriate control measures across all sectors and there are penalties for non compliance at all levels of the supply chain. In order to comply with the requirement to register, suppliers of styrene will have to assess exposure for all identified uses of styrene, including the uses identified in this transitional dossier. Suppliers must also prepare exposure scenarios that describe the risk management measures that are necessary for each use to ensure exposures are at or below the level of the DNEL. Member State Competent Authorities have the opportunity to check the DNELs that have been identified and the risk management measures that are described in exposure scenarios through substance evaluation.

The timings for registration and dissemination of information along the supply chain indicate that within 3 years (by December 2011) downstream users should be taking steps to comply with the risk management measures described in an exposure scenario. The Enforcement Forum established under REACH provides a mechanism for EU-wide inspection and enforcement project of the implementation of the RMMs described in exposure scenarios. Regulators have the power to prosecute downstream users who fail to implement RMMs correctly. It is therefore proposed that regulators should allow industry to prepare registration dossiers for styrene and allow downstream users time to implement these measures. After 1 December 2011, styrene should be considered a priority for substance evaluation and there should be a programme of inspection to ensure that downstream users are implementing the RMMs in exposure scenarios correctly. Enforcement action should be considered where employers fail to comply with REACH. The need for additional targeted regulatory action can be considered once substance evaluation and the inspection programme have been completed.

E(occ).2.4.5 Implementation and enforcement of good practice

It is suggested that voluntary implementation of good practice by manufacturers of UP-styrene resins and SBR/SBL may be a quicker route than REACH to improve control in these sectors where improvement is necessary. This is not seen as an effective approach for GRP workshops.

E(occ).2.5 Risk management measures proposed for styrene

To summarise, the following measures are recommended for the occupational use scenarios covered in this transitional dossier:

E(occ).2.5.1 EU-wide measures

In section B.9.1.1.3 it is identified that although many EU Member States have national OELs in place for styrene there is a wide difference in the values. This means that there are differing standards of control in different Member States. In order to remedy this situation it is recommended that the European Commission initiates activity to set an EU-wide OEL. An EU limit will affect all workplaces where styrene is used, not just those sectors covered in this transitional dossier.

It is also recommended that consideration be given to the establishment of an EU-wide biological monitoring "benchmark". Styrene has the potential to cause systemic toxicity because of dermal uptake and it is likely that RPE will need to be used in certain situations to control worker exposure.

E(occ).2.5.2 Manufacture of UP-styrene resins and SBR/SBL

The data in this transitional dossier suggest that the risk management measures described in section B.9.3 and B9.4 have the potential to secure adequate control for the manufacture of UP-styrene resins and SBR/SBL respectively. The information that has been received suggests that these measures are typical for these sectors. It is therefore recommended that the quickest route to secure adequate control where this is not already in place is by the voluntary adoption of good practice measures ahead of the provision of exposure scenarios under REACH. The UK considers that good practice for maintenance activities in plants manufacturing UP-styrene resins and SBR/SBL should include a permit-to-work system where there is a need to enter blending or mixing vessels to ensure that the vessels are suitably decontaminated before they are accessed. Also to mitigate the identified hazards of skin and eye irritation, good practice should include the use of suitable gloves and eye protection in situations where there is the potential for direct contact with styrene or products containing unbound styrene monomer at a concentration of 12.5% or more. It is expected that any good practice measures that are agreed in advance of the registration of styrene under REACH will be included in exposure scenarios that are drafted as part of the registration package.

E(occ).2.5.3 GRP manufacture

REACH appears to be the most practical way to identify and implement suitable control measures to secure adequate control of styrene for all uses of styrene-based resins. In order to comply with the requirement to register, suppliers of styrene will have to assess exposure for all identified uses of styrene and prepare exposure scenarios that describe appropriate risk management measures. Member State Competent Authorities have the opportunity to check the DNELs that have been identified and the risk management measures that are described in exposure scenarios through substance evaluation. The timings for registration and dissemination of information along the supply chain indicate that within 3 years (by December 2011) downstream users should be taking steps to comply with the risk management measures described in an exposure scenario. The

Enforcement Forum established under REACH provides a mechanism for EU-wide inspection and enforcement of the implementation of the RMMs described in exposure scenarios. Regulators have the power to prosecute downstream users who fail to implement RMMs correctly. It is therefore proposed that regulators should allow industry to prepare registration dossiers for styrene and allow downstream users time to implement these measures. After 1 December 2011, styrene should be considered a priority for substance evaluation and there should be a programme of inspection to ensure that downstream users are implementing the RMMs in exposure scenarios correctly. Enforcement action should be considered where employers fail to comply with REACH. The need for additional targeted regulatory action can be considered once substance evaluation and the inspection programme have been completed.

E(occ).3 Comparison of restrictions options

Section E.2 identified that a restriction was not an appropriate risk management option for styrene at this time. Options to restrict occupational use of styrene will therefore not be considered further.

E(occ).4 Main assumptions used and decisions made during analysis

The assumptions used and decisions made in the analysis for the occupational setting are described within the text.

E(occ).5 The proposed risk management measure(s) and summary of the justifications

E(occ).5.1 Risk management measures proposed for occupational uses of styrene

The following measures are recommended to manage the risks identified for the occupational use scenarios covered in this transitional dossier:

E(occ).5.1.1 EU-wide measures

- Establish an OEL for styrene.
- Establish a biological monitoring “benchmark”.

E(occ).5.1.2 Manufacture of UP-styrene resins and SBR/SBL

- Voluntary implementation of good practice ahead of REACH

E(occ).5.1.3 GRP manufacture

- Implementation of RMMs following registration of styrene under REACH

E(occ).5.2 Justification

E(occ).5.2.1 EU-wide measures

In section B.9.1.2 it is identified that although many EU Member States have national OELs in place for styrene there is a wide difference in the values. This means that there are differing standards of control that can be enforced in different Member States. In order to remedy this situation it is recommended that the European Commission initiates activity to set an EU-wide OEL. An EU limit will affect all workplaces where styrene is used, not just those sectors covered in this transitional dossier.

It is also recommended that consideration be given to the establishment of an EU-wide biological monitoring "benchmark". Styrene has the potential to cause systemic toxicity because of dermal uptake and it is likely that RPE will need to be used in certain situations to control worker exposure.

E(occ).5.2.2 Manufacture of UP-styrene resins and SBR/SBL

The data in this transitional dossier suggest that the risk management measures described in section B.9.3 and B 9.4 have the potential to secure adequate control for the manufacture of UP-styrene resins and SBR/SBL respectively. The information that has been received suggests that these measures are typical for these sectors. It is therefore recommended that the quickest route to secure adequate control where this is not already in place is by the voluntary adoption of good practice measures ahead of the provision of exposure scenarios under REACH. The UK Competent Authority considers that good practice for maintenance activities in plants manufacturing UP-styrene resins and SBR/SBL should include a permit-to-work system where there is a need to enter blending or mixing vessels to ensure that the vessels are suitably decontaminated before they are accessed. Also to mitigate the identified hazards of skin and eye irritation, good practice should include the use of suitable gloves and eye protection in situations where there is the potential for direct contact with styrene or products containing unbound styrene monomer at a concentration of 12.5% or more. It is expected that any good practice measures that are agreed in advance of the registration of styrene under REACH will be included in exposure scenarios that are drafted as part of the registration package.

E(occ).2.5.3 GRP manufacture

REACH appears to be the most practical way to identify and implement suitable control measures to secure adequate control of styrene for all uses of styrene-based resins. In order to comply with the requirement to register, suppliers of styrene will have to assess exposure for all identified uses of styrene and prepare exposure scenarios that describe appropriate risk management measures. Member State Competent Authorities have the opportunity to check the DNELs that have been identified and the risk management measures that are described in exposure scenarios through substance evaluation. Industry has indicated to the UK Competent Authority that the Styrene REACH Consortium intends to submit a registration dossier for styrene by 1 December 2010. The timings for registration and dissemination of information along the supply chain indicate that within 3 years (by December 2011) downstream users should be taking steps to comply with the risk management measures described in an exposure scenario. The Enforcement Forum established under REACH provides a mechanism for an EU-wide inspection and

enforcement project to examine implementation of the RMMs described in exposure scenarios. Regulators have the power to prosecute downstream users who fail to implement RMMs correctly. It is therefore proposed that regulators should allow industry to prepare registration dossiers for styrene and allow downstream users time to implement these measures. After 1 December 2011, styrene should be considered a priority for substance evaluation and there should be a programme of inspection to ensure that downstream users are implementing the RMMs in exposure scenarios correctly. Enforcement action should be considered where employers fail to comply with REACH. The need for additional targeted regulatory action can be considered once substance evaluation and the inspection programme have been completed.

E(occ).2.5.4 Restriction

On the basis that typical exposures for the manufacture of UP-styrene resins and the manufacture of SBR/SBL are at an acceptable level, restrictions are not considered appropriate for these use scenarios.

Four restrictions have been identified in this dossier that have the potential to reduce occupational exposure to styrene during the manufacture of GRP articles. These are:

- restrict the occupational use of styrene-based resins;
- restrict the use of UP-styrene resins for hand lay-up and spray-up;
- restrict the use of UP-styrene resins in open workshops;
- introduce a licensing scheme for companies wishing to use styrene based resins.

At this time, the UK Competent Authority does not have sufficient information about exposures across all GRP fabrication processes to formulate an appropriate restriction proposal that will be technically feasible and proportionate to the risks. Article 1 states that the purpose of REACH is “to ensure a high level of protection for human health and the environment”. While this assessment has identified risks to health arising form the use of styrene-based resins to manufacture FRCs, it is not clear that alternative monomers or materials will automatically carry lower risks to human health or to the environment. The UK Competent Authority currently does not have enough process specific information for the different GRP fabrication processes to develop a restriction focussed on the use of specific RMMs. One key barrier is that it is not possible at present to identify which measures will be required to achieve the levels of control indicated by the DNEL values. There are also concerns about the possible disproportionate imposition of costs to smaller companies for all of the identified restriction options; technical difficulties with moving to alternative types of resin or alternative materials; technical difficulties with the adoption of enclosed moulding methods and possibly technical difficulties with a requirement to install ventilated booths for open moulding. Of the options identified here, the most workable, though also the most costly, seems to be the introduction of a licensing scheme. However, under REACH licensing (authorisation) is only reserved for substances of very high concern and it may therefore not be an appropriate measure for styrene. A licensing scheme will also be burdensome for national authorities to implement and may divert scarce resources away from other activities.

On this basis, a restriction on occupational use of styrene does not seem to be the most effective option to limit the risks that have been identified.

RISK MANAGEMENT MEASURES FOR CONSUMERS

E(cons).1 Identification and description of risk management options

This section considers risk management options for the following consumer use scenarios:

- consumer boat building;
- consumer user of styrene-based liquid resins;
- consumer use of styrene-based paste resins.

It has been identified that consumer boat-building using GRP only appears to take place to a limited extent in a few Member States. When Member States were approached for information on consumer boat building, the only Member State that identified products available for amateurs to build boats was Sweden. The Norwegian authorities also indicated availability of products for consumer boat building. Since consumer boat building is likely to be a rare event and may be limited to a few Member States, it will be most appropriate for action to be taken at a national level to address the concerns identified for this use scenario. Specific measures to address the risks to consumers building GRP boats will therefore not be considered in this transitional dossier.

E(cons).1.1 Risk to be addressed – the baseline

In relation to consumer use scenarios, the estimated RWC inhalation and dermal exposure values for larger scale DIY projects such as boat building exceed the relevant DNEL values. It is not clear what range of control measures would be available to or used by a consumer undertaking a boat-building project. It cannot be assumed that a consumer will work in a well-ventilated area or that a consumer will wear gloves or eye protection whilst working on the project. Given that it will be necessary to implement a range of risk management measures to ensure adequate control in GRP workshops, it seems unlikely that the concerns identified for consumers carrying out the same type of process can easily be remedied by measures short of restriction.

For consumer use of liquid resins for repair tasks, a comparison of estimated RWC inhalation and dermal exposure values for a product estimated to contain 40% styrene with the relevant DNELs gives RCRs greater than one. Exposures are therefore not adequately controlled for this use scenario. There is also a need to address concerns relating to skin and eye irritation from direct contact with liquid resins. It is noted that these conclusions are based on conservative assumptions about the airborne levels that will arise during use and the likely level of skin contamination.

For the use of resin pastes, for a product assumed to contain 12% styrene, estimated inhalation values are below the relevant DNEL values. Hence, no additional risk management measures need to be applied to control airborne exposure. Although RWC dermal exposure estimates exceed the DNEL for systemic toxicity, the level of contamination that has been assumed is rarely likely to occur. Typical dermal exposure estimates are below the dermal DNEL for systemic toxicity indicating that current use is acceptable. In relation to concerns for skin and eye irritation, the assessment indicated that additional risk management measures (the use of suitable gloves and goggles) would

only be required where the resin product contains 12.5% or more styrene. On this basis, providing a resin paste contains no more than 12% styrene, there is no need to implement specific risk management measures. There will be a need to implement risk management measures for the use of resin pastes containing greater than 12% styrene. Since this assessment is based on typical exposures, it is preferable to use a 10% cut off to indicate the need for additional risk management measures. It is noted that these conclusions are based on conservative assumptions about the airborne levels that will arise during use and the likely level of skin contamination.

The following sections consider options to manage the risks that have been identified and possible barriers to their effective implementation.

E(cons).1.2 Other Community-wide risk management options than restriction

The following risk management options have the potential to address the concerns that have been identified:

- changes to the type of products supplied to the consumer market as a result of registration of styrene under REACH;
- voluntary agreement with industry.

E(cons).1.3 Options for restrictions

Since this assessment has identified that the risks to consumers using styrene-based resin pastes containing up to 10% styrene are acceptable, restrictions will not be considered for this type of product. For all other types of styrene-based liquid resin and resin paste the impacts of the following restrictions will be considered:

- restrict consumer use of styrene-based liquid resins;
- restrict consumer use of styrene-based resin pastes containing more than 10% styrene;
- restrict the sale of styrene-based resins to consumers to small pack sizes only;
- restrict the level of styrene in liquid resins and resin pastes to as low as is practicable for the resin to deliver its technical functionality.

E(cons).2 Comparison of instruments: restriction(s) vs. other Community-wide risk management options

This section compares the potential for a formal restriction under REACH to address the concerns identified in this transitional dossier compared with other risk management options short of restriction.

E(cons).2.1 Effectiveness

E(cons).2.1.1 Risk reduction capacity

E(cons).2.1.1.1 Restriction under REACH

A restriction on consumer use of all styrene-based liquid resins and resin pastes containing more than 10% styrene will eliminate all the risks to consumers that have been identified in this dossier. Consumers may look at other materials. For small repair tasks consumers may decide that the repair can be carried out using a resin paste containing 10% or less styrene. They may consider alternative product types or they may choose to dispose of the damaged article. It has not been possible to evaluate the health hazards of all alternative products or materials within the timeframe for preparing this transitional dossier. This should be considered if an Annex XV restriction dossier is prepared for consumer use. The evaluation should take into account the fact that it may be possible to substitute current liquid resin and resin paste products with styrene based resin pastes containing no more than 10% styrene. Where this is possible, this assessment indicates the risks to human health will be acceptable.

Limiting the pack size supplied to consumers is unlikely to address the concerns identified for small-scale repairs. The risk assessment is based on the assumption that a consumer will spend 1 hour carrying out repair tasks with a liquid resin or resin paste. If pack sizes are reduced, the most likely consumer response will be to purchase multiple packs to obtain sufficient for the repair task which may prolong the time taken to complete the task and potentially increase exposure. This option will therefore not be an effective measure.

The final option that has been identified is to restrict the level of styrene in liquid resins and resin pastes to as low as is practicable to maintain technical functionality. It has already been identified that the use of resin pastes containing 10% or less styrene is acceptable. It is not clear if this will be an adequate measure for liquid resins. The current risk assessment for liquid resins assumes a styrene content of 40%. This is high compared to some resin formulations that are available. The minimum level of styrene required for a liquid resin to maintain technical functionality is 22% (personal communication, 2008). If this were the maximum permitted level of styrene in a liquid resin formulation the following exposure values can be estimated using the calculation approach described in section B.9.7.2.

Inhalation

The average concentration of styrene in air can be calculated using the following equation:

$C_{air} = q \times W_f \times R \times V_r^{-1}$

Where: C_{air} is the average concentration of styrene in air
q is the amount of product used per event
W_f is the weight fraction of styrene in the product
R is the fraction of styrene that volatilises during the event
V_f is the volume of air surrounding the user

Referring to the parameters in table B.44,

C_{air} = 550 x 0.22 x 0.075/65
C_{air} = 139.6 mg/m^3 (converts to 32 ppm) (1-hour TWA)

DNEL values are available for 15-minute and 8-hour reference periods. As described in section B.10.1.5 it is necessary to consider the exposures that would be attained from the use of this product during a 15-minute period and what the equivalent 8-hour TWA exposure value would be.

For short-term exposure, if it is assumed that the 1-hour TWA exposure of 32 ppm for a repair task using liquid resins occurs under steady state conditions, the average exposure during any 15-minute period will also be 32 ppm. On this basis it is assumed that the 15-minute TWA exposure value for small repair tasks using liquid resins containing 22% styrene is 32 ppm.

For long-term exposure, the DNEL is expressed as an 8-hour TWA. However, the repair task will only take 1 hour. Calculation methods to convert exposures over different time periods into 8-hour TWA values have been published in HSE's EH40 guidance document (HSE, 2005). Using this approach, and assuming that there is no further exposure to styrene on the day a repair task is performed, a 1-hour exposure to 32 ppm equates to an 8-hour TWA of:

$$\frac{(32 \times 1) + (0 \times 7)}{8} = 4 \text{ ppm.}$$

Hence, in summary for a liquid resin containing 22% styrene,

- the 15 minute TWA = 32 ppm
- the 8 hour TWA = 4 ppm

Table E.1: Calculated inhalation exposure values for styrene during consumer use of liquid resins

INHALATION EXPOSURES **Scenario**	**Concentration of styrene in air ppm (mg/m^3)**	**15 minute TWA (ppm)**	**8-hour TWA (ppm)**
Liquid Resin Kit	32 (139.6)	32	4

Dermal exposure

To calculate dermal exposure it is necessary to determine the average concentration of styrene in the product and the amount of product that may potentially be in contact with the skin.

The average concentration of styrene in a liquid resin (C_{der}) can be calculated using the equation:

C_{der} = product density x W_f

where: W_f is the weight fraction of styrene in the product.

The average concentration of styrene on the skin is then given by C_{der} x T_{der} x S_{der}
where: C_{der} is the average concentration of styrene in the product
T_{der} is the thickness of the layer of product in contact with the skin
S_{der} is the surface area of the skin potentially exposed.

Referring to the parameters in table B.44,

C_{der} = 1.1 x 0.22 = 0.242 g/cm^3

Therefore the average concentration on the skin is 0.242 x 0.1 x 280 = 6.8 g/event

Since 10% of styrene in the resin will evaporate and will therefore not be available for uptake, only 90% of what is in contact with the skin will be available for uptake. The amount of the substance on the skin available for uptake is therefore 12.3 x 0.9 = 6.1 g/event.

Table E.2: Calculated dermal exposure for styrene during consumer use of liquid resins

DERMAL EXPOSURES **Scenario**	**Amount for uptake on skin (g/event i.e. over 1 hr)**	**Amount for uptake on skin (mg/kg bw /d)**
Liquid Resin Kit	6.1	87.1

The amount for uptake from skin, as mg /kg bw/d is based on a use of 1 hour (i.e. 1 event) per day and a human body weight of 70 kg

Risk characterisation ratios for a liquid resin containing 22% styrene

Table E.3: Risk Characterisation Ratios for exposures during consumer use of styrene-containing liquid resins

LIQUID RESINS	15 min short term	8-hour TWA
RCR for inhalation	32 / 20 = **1.6**	4 / 8 = 0.5
RCR for dermal	---	87.1 / 30 = **2.9**
RCR for combined exposure	---	0.5 + 2.9 = **3.4**

The calculation shows that RWC short-term inhalation exposure values and dermal exposure values exceed the relevant DNELs even when the styrene content of the resin is reduced to the minimum required to maintain technical functionality. It is therefore concluded that it will not be possible to reduce the styrene content of liquid resins sufficiently to ensure that such products can be used safely by consumers.

On this basis, the only effective restriction that could be introduced is to restrict consumer use of all styrene-based liquid resins and resin pastes containing more that 10% styrene.

No significant risk to the environment from the consumer use of styrene resins has been identified in the RAR (EU, 2008). It has not been possible to carry out an adequate assessment of the environmental impacts relating to restrictions on consumer use of styrene-based resins within the time available for the preparation of this transitional dossier. This should be considered if an Annex XV restriction dossier is prepared for consumer use. It is noted that material compatibility is one issue for deciding the type of product to use for a repair. If a restriction prevented consumers from obtaining products that allowed them to carry out minor repairs to certain items, this could require consumers to discard damaged objects that they might otherwise have repaired. It is not clear whether it will be possible to recycle such articles and hence this has the potential to create additional potentially non-recyclable waste. This may have an adverse impact on the environment. This should also be considered in any proposal to restrict consumer use of styrene-based resins for small-scale repair

E(cons).2.1.1.2 Changes to the type of products supplied to the consumer market as a result of registration of styrene under REACH

REACH will require companies that manufacture and/or import chemicals above one tonne per annum into the EU to register them with the European Chemicals Agency. For substances like styrene that are manufactured / imported at levels above 10 tonnes per annum per manufacturer/importer and are classified as hazardous, a chemical safety report (CSR) is required as part of the registration dossier. This CSR must include exposure scenarios for all 'identified uses', including consumer uses, and should identify appropriate operational conditions (OCs) and risk management measures (RMMs) to ensure that the risks from the substance are adequately controlled. In the case of consumer products, it cannot be assumed that a consumer will comply with instructions requiring them to use a product in a particular way or to wear PPE when using the product. Hence, the OCs and RMMs that will be relevant for consumers will relate to measures that a supplier can take in terms of the formulation that is sold, the packaging for the product and the amount that can be dispensed per use.

In the case of consumer products there are two possible outcomes to substance registration. The first outcome is that the registrant demonstrates the risks to a consumer are acceptable i.e. the risk characterisation ratio (RCR) < 1. If it is necessary to formulate a product in a particular way or sell the product in a particular type of packaging to minimise consumer exposure this will be identified. The second outcome is that the registrant is unable to demonstrate that the risks to a consumer are acceptable i.e. the RCRs are greater than 1. In this case, the registrant will not be able to support this use in their registration package. It is assumed that once the deadline for registration has passed, a registrant will cease supply for any uses that are not supported in the registration package. If no further action is taken, this will result in a gradual decline in the availability of such products until remaining stocks in the supply chain have been used up.

This transitional dossier has identified concerns relating to consumer use of all types of liquid resins and for the use of resin pastes containing more than 10% styrene. If no further information is obtained it seems likely that registrants will not be able to support these uses under REACH. It is noted that the exposure assessment for consumer use in this transitional dossier is based on very conservative assumptions about the levels of airborne exposure and skin contamination that may occur during use. Work by registrants

to develop exposure scenarios may allow the exposure assessment to be refined. It is not possible to predict in advance what the outcome of registration may be.

Thinking about the timescale for registration, industry has indicated to the UK Competent Authority that it intends to submit a registration dossier for styrene by 1 December 2010. If the decision was taken to wait for REACH to address the concerns identified for consumer uses, there may be no action taken before 1 December 2010. After this time, registrants may have evidence to confirm that the risks for certain consumer uses are acceptable or they may choose not to support particular consumer uses. Where consumer use is not supported it is assumed that this will result in the removal of these products from the supply chain. As indicated for occupational uses in section E.2.1.1.4 above, regulators have the opportunity to oversee risk assessments for consumer use through the mechanism of substance evaluation. A substance proposed for evaluation will be included on the Community Rolling Action Plan. The first draft action plan will be published by the Agency on 1 December 2011 and it will be updated annually on 28 February thereafter. Assuming substance evaluation for styrene started on 1 December 2011, a decision on whether the risk management measures identified for consumers were adequate to control the risks identified in this transitional dossier would be made by 1 December 2012. If it was concluded that the measures proposed in an exposure scenario were inadequate the Member State conducting the evaluation would have a sound basis from which to propose targeted restrictions.

It is therefore suggested that waiting for styrene to be registered under REACH is a viable option to address the concerns that have been identified for consumers. It will allow suppliers the opportunity to identify the range product types for which the risks to consumers will be acceptable (RCR < 1). Information contained in registration dossiers will also provide Member States with better data to inform decisions about the need for further regulatory action. However, there may be a minimum 2-year delay before any action would be initiated by registrants to address unacceptable uses and a minimum 3-year delay before further regulatory action could be initiated.

E(cons).2.1.1.3 Voluntary agreement with industry

Businesses sometimes jointly agree on action, called a ‘voluntary agreement’, in pursuit of stated objectives which goes beyond the requirements of the law. The regulator may be involved in monitoring progress, especially when regulatory action would have to be taken if the voluntary agreement failed to deliver the required improvement.

For the consumer use of styrene-based liquid and paste resins there are number of RMMs that might form part of a voluntary industry agreement to help reduce consumer exposure to styrene during the use of liquid and paste resins. These are:

- reformulate styrene-based liquid resins and resin pastes to reduce styrene emissions during use;
- change the pack design to limit consumer exposure during use;
- provide information e.g. hazard warnings on packages and instructions for use;
- provide the correct PPE in the product package (i.e. gloves and respirator).

The following sections consider the potential for each of these measures to reduce consumer exposure:

E(cons).2.1.1.3.1 Reformulate styrene-based liquid resins and resin pastes to reduce styrene emissions during use

The extent to which the use of LSE and LSC resins would reduce exposures for consumers is unclear. LSE resins, i.e. resins that contain film-forming agents are currently available to consumers but it is unclear whether inclusion of film forming agents will have an impact on consumer exposure. As identified in section B.9.5.1, the film forming agents in these resins are only effective at reducing exposure during the curing stage. Unlike a workplace where a worker is likely to have additional tasks to complete in the workroom while a lamination cures, a consumer may well go elsewhere. It therefore seems that the inclusion of vapour suppressants has a limited potential to reduce consumer exposure.

Provision of LSC resins offers a greater potential to reduce consumer exposure. It has been identified in section E(cons) 2.1.1.1. that, based on current assumptions, it will not be possible to reformulate styrene-based liquid resins to contain a sufficiently low quantity of styrene. For resin pastes, the risk characterisation based on typical exposures indicated that there were no concerns for human health for resin pastes containing up to 10% styrene. It is assumed that this is at or above the minimum styrene content necessary for functionality based on products currently on the market. A voluntary agreement to limit the styrene content to a level of around 10% would therefore appear to be an effective measure to reduce the risks that have been identified for this type of product.

E(cons).2.1.1.3.2 Change the pack design to limit consumer exposure during use

Styrene-based resins need to be blended with a hardening agent immediately before application. A consumer will need to have choice about the amount that is dispensed to ensure that a suitable amount of resin is blended for each repair. The most likely consequence of restricting the amount that can be dispensed at any one time will be to prolong the time taken for larger repair tasks, since several applications may need to be made. This may increase rather than decrease the overall exposure for the task. On this basis changing pack design to limit the amount that can be dispensed per use is not an effective risk management measure.

E(cons).2.1.1.3.3 Provide information e.g. hazard warnings on packages and instructions for use.

Instructions should provide a minimum level of information on the product, its application method and rate and ‘good practice’ in relation to handling, storage, use and disposal. Even though such information is provided to consumers, the effectiveness of this as a risk management measure will ultimately depend upon the consumer being prepared to read the information, be able to understand it and be willing to follow the instructions. Since it cannot be assumed that a consumer will comply with product information, it is not possible to conclude that more effective provision of instructions on safe use will be an effective risk management measure.

E(cons).2.1.1.3.4 Provide the correct PPE in the product package (i.e. gloves and respirator).

Although PPE is considered a viable option for risk management in the workplace, it is not appropriate to rely on correct use of PPE for consumers. A requirement for suppliers to provide the correct PPE in product packs will address the potential for consumers to select the wrong type of PPE when faced with a situation in which they consider PPE is necessary. However, there is no guarantee that consumers would use the measures supplied in the correct manner for them to be effective.

E(cons).2.1.1.3.5 Summary

It has not been possible to identify any effective measures that could be applied to liquid resins to reduce the risks to consumers. For resin pastes, the only effective measure is for voluntary action to limit the styrene content to a level of around 10%.

E(cons).2.1.2 Proportionality

E(cons).2.1.2.1 Restriction under REACH

A restriction on consumer use of all styrene-based liquid resins, and resin pastes containing more than 10% styrene is expected to have a limited economic impact on larger EU manufacturers since consumer products account for around 0.1% of the total EU market for styrene-based resins. However, the restriction may have a greater impact on smaller companies and particularly those with a large portfolio of consumer products. Costs will be incurred due to the loss of markets for liquid resin products and the need to reformulate resin paste products to comply with the terms of the restriction. An assessment of the costs that will be incurred if a restriction is implemented has not been undertaken for this transitional dossier, but such an assessment will need to be made if a restriction proposal is drafted.

It has not been possible to explore issues relating to the technical feasibility of this restriction within the time available for preparing this transitional dossier. For repair tasks this assessment will need to consider the material compatibility of alternative product types including reformulated resin pastes across the range of repair tasks for which current styrene based liquid-resin and resin paste products are used.

It is noted that the consumer exposure assessment for repair tasks by consumers in this transitional dossier is based on very conservative assumptions about the levels of airborne exposure and skin contamination that may occur during use. Work by registrants to develop exposure scenarios to support registration may allow the exposure assessment to be refined. Preparation of exposure scenarios may identify that the risks for certain product types are lower than the risks identified here. In this case, a restriction may prove to be disproportionate for certain product types.

E(cons).2.1.2.2 Changes to the type of products supplied to the consumer market as a result of registration of styrene under REACH

REACH is a current piece of legislation and industry must comply with the various elements of REACH as they are implemented. By recommending this option no additional costs beyond those required to comply with REACH are being imposed.

If no restrictions are imposed on consumer uses of styrene ahead of registration, it is expected that this substance will be considered a priority for substance evaluation. Member States will then be able to use the data in the registration dossier to inform decisions about the need for further regulatory action. Whereas there are concerns that restrictions based on current information may not be proportionate to the risks, it is expected that the data in registration dossiers will provide a much sounder basis to identify proportionate measures to address risks to consumers.

E(cons).2.1.2.3 Voluntary agreement with industry

The costs involved in establishing a voluntary industry agreement and monitoring it are unknown. There would also be a number of additional costs involved in implementing the various stages that this agreement would need to address, in order to ensure the safe use of styrene-containing liquid and paste resins by consumers i.e.:

- research costs to develop resins containing the minimal styrene content necessary for technical functionality, and redesign pack sizes and delivery systems;
- develop standardised clear information and instructions;
- provision of PPE that provides adequate protection and is simple enough for consumers to use correctly.

It is not possible to determine whether the costs to do this may outweigh the benefits of maintaining a small market position for styrene-containing liquid and paste resins for consumer user.

E(cons).2.2 Practicality: implementability, enforceability, manageability

E(cons).2.2.1 Restriction under REACH

The only effective restriction that has been identified will require supply of all styrene-based liquid resins, and resin pastes containing more than 10% styrene to cease. This can be implemented through the supply chain by:

- requirements on suppliers and importers of styrene to not supply this chemical for inclusion in certain types of consumer product,
- requirements on suppliers and importers of styrene based resins to cease supply of certain product types to the consumer market and;
- requirements on retailers removing certain product types from sale.

It is possible that a consumer may try to obtain supplies for repairs from a nearby GRP workshop or may try to purchase styrene-based resins from non-EU manufacturers. Consideration will need to be given in an Annex XV restriction dossier to how these avenues of supply could effectively be prevented. In the case of consumer import this is likely to require the involvement of customs authorities.

Legislative mechanisms are in place to enforce implementation within the supply chain in the EU. It may be hard to stop GRP workshops supplying styrene-based resins to consumers if consumers use this route to obtain supplies. It is also possible that a

consumer may chose to purchase styrene-based resins from non-EU manufacturers through the internet. If importation under these circumstances is to be prevented, enforcement action by an appropriate authority may be required.

E(cons).2.2.2 Changes to the type of products supplied to the consumer market as a result of registration of styrene under REACH

The work that manufacturers/importers have to carry out is outlined in the legislation and is being further clarified by guidance documents. Although this area will be new for industry and will require specialist input to develop exposure scenarios and show that they do not pose an unacceptable risk, it should be practicable for them to do so.

Legislative measures are in place to allow regulatory authorities to enforce duties on suppliers under REACH. Once registration of styrene has been completed, Member States will be able to examine the conclusions reached in relation to consumer use through the mechanism of substance evaluation. If this reveals that the changes registrants propose do not adequately address the risks to consumer health, Member States will have better data to inform decisions about subsequent regulatory action. It is likely that this will take the form of a restriction under REACH.

E(cons).2.2.3 Voluntary agreement with Industry

In relation to the supply of styrene-based resins for repair tasks, it may be possible to establish a voluntary agreement to limit the styrene content in products with some manufacturers. However, given the conservative assumptions on which this assessment is based, it could be difficult to gain agreement with suppliers who are not convinced that their products pose a risk to consumers and wish to continue to supply products with higher styrene content because they provide better technical characteristics. On this basis, a voluntary agreement may not be practical to implement. Since there are no legal requirements to force companies to comply with a voluntary agreement is will not be possible to enforce this measure. On this basis a voluntary agreement to limit the styrene content in resins may not be a sufficient measure.

E(cons).2.3 Monitorability

E(cons).2.3.1 Restriction under REACH

Monitoring of supply for consumer use may require regulators to gather information from suppliers and from retail outlets on the range of products that are supplied for consumer use. It will be harder to monitor supply to consumers by GRP workshops and consumer imports.

E(cons).2.3.2 Changes to the type of products supplied to the consumer market as a result of registration of styrene under REACH

REACH requires each Member State to devise and implement a suitable enforcement regime for REACH. This includes enforcement of whether manufacturers/importers have registered the substances, how they are used in the occupational setting and the consumer uses for which they are being supplied. Monitoring of supply for consumer use may

require regulators to gather information from suppliers and from retail outlets on the range of products that are supplied for particular tasks.

E(cons).2.3.3 Voluntary agreement with Industry

It is not clear how a voluntary agreement would be monitored. Regulators could request that resins manufacturers provided information on the products that they supply. Information could also be sought from retailers. However, it would not be possible to require such information to be provided and therefore monitoring this voluntary agreement could be difficult.

E(cons).2.4 Overall assessment against the three criteria

E(cons).2.4.1 Restriction under REACH

It has not been possible to conduct a proper evaluation of all of the risks to human health and the environment associated with a restriction on consumer use of all types of styrene-based liquid resins, and resin pastes containing more than 10% styrene. However, based on the information that is currently available it is not clear that such a restriction will automatically result in lower risks to humans and the environment. One outcome of this restriction may be the creation of additional potentially non-recyclable waste where customers find they are unable to obtain suitable products to repair damaged articles. It is noted that the risk assessment from which the need for a restriction has been judged is based on conservative assumptions about about the airborne levels that will arise during use and the likely level of skin contamination. It is therefore not clear if the restriction that has been identified will be a proportionate measure to address the risks to consumers. On this basis, it is concluded that a restriction is not the most appropriate measure to reduce the risks to consumers from the use of all styrene-based liquid resins, and resin pastes containing more than 10% styrene at this time.

E(cons).2.4.2 Changes to the type of products supplied to the consumer market as a result of registration of styrene under REACH

REACH appears to be a practicable way to deal with styrene risk reduction. It has the potential to provide information that consumer uses are acceptable and to identify consumer uses that are not acceptable. It provides a legislative framework for Member States to evaluate the measures proposed by registrants in their registration dossiers and will enable Member States to identify proportionate regulatory action to address consumers uses that pose an unacceptable risk. However, the timescale for registration of styrene under REACH is such that there could be a minimum of 2 years before any action may be taken and a minimum of 3 years before further regulatory action could be initiated.

E(cons).2.4.3 Voluntary agreement with Industry

A voluntary agreement does not seem to be a suitable measure to address the concerns that have been identified for consumer use of liquid resins and resin pastes. The only effective risk management measure appears to be to cease supply of styrene-based liquid resins and reformulate resin pastes to contain a maximum of 10% styrene. Given that this

conclusion derives from a risk assessment that is based on conservative assumptions it is possible that registration of styrene under REACH will provide a more refined assessment that will demonstrate that additional products can be used. On this basis, a voluntary agreement ahead of REACH may not be a proportionate measure for industry. In this situation there are concerns about the willingness of all parties to agree and hence this may not be an effective measure.

E(cons).3 Comparison of restrictions options

Section E.2 identified that a restriction was not an appropriate risk management option for styrene at this time. Options to restrict occupational use of styrene will therefore not be considered further.

E(cons).4 Main assumptions used and decisions made during analysis

The assumptions used and decisions made in the analysis for consumer uses are described within the text. The main assumption for the analysis for consumer use is that consumers do not apply any specific risk management measures when using styrene-based resin products.

E(cons).5 The proposed risk management measure(s) and summary of the justifications

E(cons).5.1 Risk management measures proposed for consumer uses

The following measures are recommended to address the concerns identified for consumer use of styrene-based liquid resins and resin pastes containing more than 10% styrene.

E(cons).5.1.1 Consumer boat building

- Action at a national level to address the risks identified in this transitional dossier.

E(cons).5.1.2 Consumer use of styrene-based liquid resins for small scale repair

- Registration of styrene under REACH to provide better information to help decide on the most appropriate targeted action.

E(cons).5.1.3 Consumer use of styrene-based resins pastes for small scale repair

- Registration of styrene under REACH to provide better information to help decide on the most appropriate targeted action.

E(cons).5.2 Justification

E(cons).5.2.1 Consumer boat building

This dossier has indicated that the risks to consumers who choose to build boats using GRP may be at least as great as the risks identified for workers manufacturing GRP articles using open moulding methods. The exposure assessment is informed by measured data for open moulding in the workplace rather than modelled data. Since the RCRs are so high, it seems unlikely that any additional information that may be obtained during the preparation of an exposure scenario will change the conclusion that the risks to consumers using styrene-based resins to build boats are unacceptable. Given that consumer boat building using styrene-based resins appears to occur in only a small number of Member States, it is recommended that action be taken at a national level to address the risks. It is noted that any action to restrict the supply of styrene-based liquid resins for small-scale consumer use, either as an outcome of the registration of styrene under REACH or as a specific restriction imposed by Member States will also restrict the supply of such resins for consumer boat building.

E(cons).5.2.2 Consumer use of styrene-based liquid resins for small-scale repair

For liquid resins, registration of styrene under REACH has two possible outcomes for consumer use scenarios. The chemical safety report (CSR) may confirm the view that the risks to consumers are unacceptable (i.e. the risk characterisation ratio (RCR) is greater than 1). Howevr, the exposure values underpinning this conclusion are based on very conservative assumptions. It is therefore possible that the registration dossier could provide evidence that consumer use of certain types of styrene-based liquid resin products is acceptable (i.e. RCR < 1). It is not possible to predict in advance what the outcome of registration may be. Industry has indicated to the UK Competent Authority that the Styrene REACH Consortium intends to submit a registration dossier for styrene by 1 December 2010. If the supply of styrene-based liquid resin products continues after registration, it is expected that Member States will regard styrene as a priority for substance evaluation to confirm that this consumer use is acceptable. Substance evaluation could begin on 1 December 2011 and a decision on the adequacy of risk management measures proposed for consumers could be reached by 1 December 2012. If it is concluded that the measures being proposed in the exposure scenario are inadequate, it is expected that Member States will wish to initiate restrictions proceedings. By waiting for registration of styrene under REACH, Member States will be able to use the information in the registration dossier to inform decisions on the need for further action. If restrictions are required, Member States will be able to identify measures that are proportionate to the risks. REACH therefore appears to be an appropriate mechanism to address the concerns that have been identified for consumer use of styrene-based liquid resins.

E(cons).5.2.3 Consumer use of styrene-based resin pastes for small-scale repair

Registration of styrene under REACH has two possible outcomes for consumer use of resin pastes. The CSR could confirm the view that consumer use of styrene-based resin pastes is only acceptable where the styrene content is kept at 10% or below. However, the exposure values underpinning this conclusion are based on very conservative assumptions. It is therefore possible that the CSR could provide evidence to allow registrants to increase the maximum permitted styrene content in resin pastes sold for consumer use. It is not possible to predict in advance what the outcome of registration may be. Industry has indicated to the UK Competent Authority that the Styrene REACH

Consortium intends to submit a registration dossier for styrene by 1 December 2010. As with liquid resin products, it is expected that Member States will identify styrene as a priority for substance evaluation to confirm the conditions under which acceptable use has been demonstrated. REACH therefore appears to be an appropriate mechanism to address the concerns that have been identified for consumer use of styrene-based resin pastes.

E(cons).5.2.4 Restriction under REACH

It has not been possible to conduct a proper evaluation of all of the risks to human health and the environment associated with a restriction on consumer use of all types of styrene-based liquid resins, and resin pastes containing more than 10% styrene. However, based on the information that is currently available it is not clear that such a restriction will automatically result in lower risks to humans and the environment. One outcome of this restriction may be the creation of additional potentially non-recyclable waste where customers find they are unable to obtain suitable products to repair damaged articles. It is noted that the risk assessment from which the need for a restriction has been judged is based on conservative assumptions about about the airborne levels that will arise during use and the likely level of skin contamination. It is therefore not clear if the restriction that has been identified will be a proportionate measure to address the risks to consumers. On this basis, it is concluded that a restriction is not the most appropriate measure to reduce the risks to consumers from the use of all styrene-based liquid resins, and resin pastes containing more than 10% styrene at this time.

F. SOCIO-ECONOMIC ASSESSMENT OF PROPOSED RESTRICTION(S)

A socio-economic assessment has not been conducted because no restrictions are proposed.

F.1 Human health and environmental impacts

F.1.1 Human health impacts

F.1.2 Environmental impacts

F.2 Economic impacts

F.3 Social impacts

F.4 Wider economic impacts

F.5 Distributional impacts

F.6 Main assumptions used and decisions made during analysis

F.7 Uncertainties

F.8 Summary of the benefits and costs

G. STAKEHOLDER CONSULTATION

Trade Associations

British Marine Federation (BMF)
CEFIC including the Styrenics Sector Group, the UP Resins Group & European Polymer Dispersion and Latex Association (EDPLA)

Industry

Industries were not generally contacted directly, but the following were covered by the CEFIC responses received.

- Members of the Styrenics Sector Group:
  - BASF AG
  - Bayer Material Science
  - Dow Chemical
  - Ineos
  - Lyondell Basell
  - Polimeri (subsidiary of Eni)
  - Repsol ypf
  - Shell Chemicals
  - Total Petrochemicals
- UP-styrene resin manufacturers/suppliers
  - Ashland Chemical
  - Cray Valley
  - DSM Composite Resins
  - Polynt SpA
  - Reichhold Srl
  - Scott Bader Company Ltd
  - SIR Industriale SpA

Additional Contacts
U-POL

Member States

All MSs were sent a questionnaire seeking information related to the five scenarios of interest (manufacture of UP-styrene resins, manufacture of SBR/SBL, manufacture of GRP, consumer boat-building and consumer use of liquid resins/pastes)

H. OTHER INFORMATION

No other information is included in this transitional dossier

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GLOSSARY

ACGIH	American Conference of Governmental Industrial Hygienists
AF	Assessment Factor
AFP	Automated Fibre Winding
APME	Association of Plastics Manufacturers in Europe
ATL	Automated Tape Laying
BAT	Best Available Techniques
BAT	Biologishe Arbeitsstoff-Toleranz-Werte
BATNEEC	Best Available Techniques Not Entailing Excessive Cost
BEI	Biological Exposure Index
BGIA	Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (Institute for Occupational Safety)
BLV	Biological Limit Values
BMC	Bulk Moulding Compound
BMF	British Marine Federation
BPF	British Plastics Federation
BREF	BAT Reference Document
CA	Competent Authority
CAD	Chemical Agents Directive (98/24/EC)
CEFIC	European Chemical Industry Council
C & L	Classification and Labelling
CNS	Central Nervous System
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
dB	Decibels
DCDB	Dicyclopentadiene
DFG	Deutsche Forschungsgemeinschaft
DIY	Do-It-Yourself
DMEL	Derived Minimal Effect Level
dmt	Dry Metric Tonne
DNEL	Derived No Effect Level
DU	Downstream User
EASE	Estimation and Assessment of Substance Exposure
EC	European Community
ECHA	European Chemicals Agency
EEC	European Economic Community
EPA	Environment Protection Agency
EPDLA	European Polymer Dispersion and Latex Association
EQS	Environmental Quality Standard
EU	European Union
EUCIA	European Composites Industry Association
EXPO	EXPOsure database at National Institute of Occupational Health in Norway
FFP1	Face Filter Protection 1
FID	Flame Ionisation Detector
FRC	Fibre Reinforced Composite
FRP	Fibre Reinforced Plastic
GC	Gas Chromatography
GESTIS	GESTIS-Substance Database maintained by BGIA

GRP	Glass Reinforced Plastic
HSE	Health & Safety Executive
IBC	Intermediate Bulk Container
IOELV	Indicative Occupational Exposure Limit Value
IPCS	International Programme on Chemical Safety
IPPC	Integrated Pollution Prevention Control
LEV	Local Exhaust Ventilation
LOD	Limit of Detection
LSC	Low Styrene Content
LSE	Low Styrene Emission
MAC	Maximum Acceptable Concentration
MDHS	Method for Determination of Hazardous Substances
MEGA	Messdaten zur Exposition gegenüber Gefahrstoffen am Arbeitsplatz (Measurement data relating to workplace exposure to hazardous substances) - the chemical workplace exposure database of the Institute for Occupational Safety (BIA) of the German Berufsgenossenschaften (BG) (statutory accident institutions for insurance and prevention).
MSCA	Member State Competent Authority
MSDS	Material Safety Data Sheet
NEDB	National Exposure DataBase at HSE in UK
NIOSH	National Institute for Occupational Safety and Health
NOAEC	No Adverse Effect Concentration
OEL	Occupational Exposure Limit
OC	Operational Control
OSHA	Occupational Safety and Health Administration
PBPK	Physiologically-based Pharmacokinetic Modelling
PBT	Persistent, Bioaccumulative and Toxic substance
PNEC	Predicted No Effect Concentration
PPE	Personal Protective Equipment
ppm	Parts per million
QA	Quality Assurance
RAC	Risk Assessment Committee (within ECHA)
RAR	Risk Assessment Report
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC No. 1907/2006)
Repr. Cat x	Reproductive Toxicant Category x
RIM	Reactive Injection Moulding
RMM	Risk Management Measure
RPE	Respiratory Protective Equipment
RTM	Resin Transfer Moulding
RWC	Reasonable Worst Case
SBL	Styrene Butadiene Latex
SBR	Styrene Butadiene Rubber
SCHER	Scientific Committee on Health and Environmental Risks
SCOEL	Scientific Committee on Occupational Exposure Limits
SEAC	Socio-Economic Analysis Committee (within ECHA)
SIRC	Styrene Industry Research Council
SMC	Sheet Moulding Compound

SME	Small Medium Enterprise
SSA	Ship-builders and Ship-repairers Association
STEL	Short-term Exposure Limits
TC	Technical Committee
TGD	Technical Guidance Document
TWA	Time-Weighted Average
UK	United Kingdom
UP	Unsaturated Polyester
USA	United States of America
UV	Ultraviolet
VEC	Virtual Engineered Composites
vPvB	Very Persistent and Very Bioaccumulative substance