Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Response to comments document (RCOM)

to the opinions on the Annex XV dossier proposing restrictions on

Dimethylfumarate (DMFu)

ECHA/RAC/RES-O-0000001305-83-04/S2

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Dimethylfumarate (DMFu)

EC number: 210-849-0

CAS number: 624-49-7

16 March 2011

General comments

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
68	N	2010/12/20 14:47	/ / Norway MSCA		The Climate and Pollution Agency (Member State Competent Authority for REACH in Norway) supports the proposed regulation of Dimethylfumarate (DMFu) in products. We want to emphasise that the content of DMFu in products shall apply to individual articles, parts thereof or materials as it is important due to the sensitisation properties of DFMu. For a user it is important that the concentration in any part of an article do not exceed the 0.1 % as this may cause sensitisation. Therefore the concentration limit needs to be for any part of a complex article. A concentration limit for example in a furniture as a whole will not be sufficient as it will give the possibility for smaller parts of the furniture to contain much higher amount. Such smaller parts that contain higher amount DMFu can pose a risk for sensitisation. To secure this important point, we suggest that the proposed text about the "individual articles, part and material" in the footnote is included in the ordinary text. One way of including this could be by changing point 1 and 2 as follow: " 1. Shall not be used in articles or parts thereof in concentration greater than 0.1 mg/kg. 2. Articles or parts thereof containing dimethylfumarate …" Another point to consider is the need of an	Concerning the wording of the entry, the French CA maintains its initial proposal, based on its position on the definition of "article	Noted and agreed that "parts of" articles need mentioning. Labelling was	Noted

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					additional labelling phrase on articles that contain less than 0.1 mg/kg DMFu. An example of a useful phrase is EUH208; "Contains (name of sensitizing substance). May produce an allergic reaction.". This labeling is important to consumers who have had an allergic reaction on DMFu as they will be able to avoid products with low concentrations of DMFu. As regards the mentioning of DMFu in "Chinese fat cookies", we have noticed that in some of the MSDS for this substance the following is written about the use: Often used for food and feeds mildew preventive.	Noted	discussed but is not deemed to be a feasible option as concentrations below 0.1 mg/kg can not be measured.	
63	N	2010/12/20 11:53	/ / Sweden MSCA		One important piece of information concerning DMFu is how many Member States that have been affected by DMFu-related cases of dermatitis. We have noted that the dossier currently only considers cases reported in the scientific literature, and would like to point out that this approach will underestimate the occurrence of cases in the EU. The Swedish Chemicals Agency has first-hand information from one Swedish hospital (Akademiska Sjukhuset, Uppsala) that they have diagnosed 2 cases of dermatitis linked to DMFu in chairs imported from China. There are also similar cases reported from Malmö University Hospital (Universitetssjukhuset i Malmö), which also reports results from patch testing of 556 persons with 0.1% DMFu during 2009. DMFu-induced dermatitis was confirmed in 1.1% of these persons.		Noted.	Noted. This information was known to us and we have used it to support the proposal additionally

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					Thus, DMFu has been a problem also in Sweden, and we therefore fully support the French restriction proposal.	Noted		
62	N	2010/12/20 10:47	/ / Ireland MSCA	(A) (B), (C), (E), (F), (G)	The Irish Competent Authority (IECA) would like to thank the French CA (FRCA) for the work it has undertaken to prepare this Annex XV dossier to propose a restriction on dimethylfumarate in articles. In general, we support the principle that a permanent EU restriction on DMFu should be introduced to address the risk to human health associated with import articles treated with DMFu. We would also like to contribute the following comments and observations in relation to the Annex XV restriction dossier for DMFu under the specified headings: A. Suggested restriction A.1 Limit value – unit: During the review of Annex XVII to the REACH Regulation carried out in 2008-2009, some of the limit values were changed to % (w/w) for consistency. In light of this, we would like to suggest that consideration is given, as to how the new limit value unit (mg/kg) correlates with this approach. A.2 IUPAC Name: We suggest inclusion of the substance's IUPAC name: Dimethyl (E)-butenedioate in the first column with 'dimethylfumarate' listed as the trade name.	Noted The unit expressed in mg/kg is based on the available analytical methods for the measurement of DMFu in products Noted. This has been done in the first version of the background	Noted. The choice of unit has been discussed in RAC, and our understanding is that it suffices to use the proposed unit of mg/kg. Thus, we agree with DS. Noted and included by DS. The opinion does not include an	Noted Noted IUPAC name was included in later drafts. Done

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					A.3 Asterisk statement: It is noted that due to the format of Annex XVII it will not be possible for an asterisk to reside on the 'conditions of restrictions' column title and therefore this information must be incorporated into the entry text.	document.	'asterisk sentence' any more.	
					A.4 Wording: If the limit is to be applied to the entire article and/or each individual part of the article, we would suggest using the following amendments to paragraph 1 and 2: "1. Shall not be used in articles, or parts thereof, in concentration greater than 0.1 mg/kg. 2. Articles, or parts thereof, containing dimethylfumarate in concentration greater than 0.1 mg/kg shall not be placed on the market"	Concerning the wording of the entry, the French CA maintains its initial proposal, based on its position on the definition of "article"	A reworded text, in line with the Irish suggestion, is proposed in the opinion.	Several versions of the wording were proposed in the earlier drafts. A reworded text, in line with the Irish suggestion, is proposed in the draft opinion.
					A.5 Wider scope: Pg. 57 of the dossier states that Decision 2009/251/EC "requires the same conditions of restriction as this proposal". We suggest that this is slightly contradictory to the statement on page 13 which states that "the scope of the REACH restriction may be slightly wider than the one of EU Decision 2009/251/EC as the Decision focuses on products which are intended for consumers".		It is noted that the scope has indeed been widened somewhat, but we do not find the Background document (BD) contradictory.	The Commission will decide about the final wording. Noted
					A.6 Definition of placing on the market (PoM): There is no definition of placing on the market in the General Product Safety Directive (GPSD). The Irish National Consumer Agency has informed us that the term 'placing on the market' is commonly understood within the context of Community legislation as the first making		Noted.	Noted

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					available of a product on the Community market. The definition also covers imports. However, the definition of placing on the market under REACH covered the first transfer into the Community market and all subsequent transfers. We see this as a significant difference between Decision 2009/251/EC and any potential restriction under REACH. We also believe it provides greater protection therefore supporting the justification for restriction on a community wide basis. Therefore we suggest it may be useful to include this point in Section A.2.2 (pg. 13) of the dossier for completeness.	Noted		
					A.7 Tonnage of DMFu imported into IT: We believe the gap in information surrounding the tonnage of DMFu imported into IT is significant in this dossier. We would like to suggest that further clarification is sought as to how this high tonnage of DMFu is being used in IT.	ECHA requested the information from the Italian CA concerning the Italian usage of DMFu as agreed in the 1st Rapporteurs' dialogue. The Italian response indicates that the Italian usage should appear as zero.	The question was clarified with IT, who explained that the tonnage really should be zero for Italy.	The question was clarified with IT and the tonnage used in IT is zero in the latest versions.
					A.8 EU Origin of products mentioned in RAPEX notifications: Table 17, on pg. 19 of the dossier, lists the countries of origin which were identified for the products mentioned in the	Most of notifications concern shoes and clothing.	There are 8 notifications where the country of origin is an EU	Noted

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					RAPEX notifications. In our opinion, it would have been useful if the dossier included clarification on what type of products are coming from these countries and especially those from EU countries IT, PT, BE and DE to allow us to understand the significance of this information. A.9 Other EU legislation: We would like to suggest that the dossier would have benefited from inclusion of a section which discusses the aims of the current proposal in comparison with other EU legislation. For example, • On page 22 of the dossier it is stated that a high level of DMFu was found in wooden toys. In our opinion, it would have been beneficial for the dossier to comment on whether the Toy Safety Directive would address this risk. • While we appreciate that the proposed revision of the Biocidal Products Directive (BPD) have not been agreed, we suggest it would have been beneficial if the dossier had discussed the possible likely implications the proposed revision of the BPD would have with respect to articles treated with unauthorised biocidal products.	Noted. Storage and transport conditions of toys are taken into account in the Directive 2009/48/EC on the safety of toys, published after the submission of annex XV dossier: "Importers shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise, its compliance with the requirements set out in Article 10 (Essential safety	MS. In 7 cases it concerns shoes (3 from Italy, and one each from Spain, Germany, Belgium, and Portugal). There is also one case from Italy concerning jeans. Noted. The relation with the Biocide Directive (BPD) has been addressed earlier.	Noted Text has been added to the background document.

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						requirements) and Annex II (particular safety requirements)"		
					A.10 Mixtures containing DMFu: Pg. 58 of the dossier states "no data related to non-biocidal mixtures containing DMFu has been collected and no consumer exposure, due to non-biocidal mixtures containing DMFu has been reported". Based on the information gap relating to the large quantity of DMFu imported into IT, we are of the opinion that there is insufficient data to support this statement. We feel it is important to first understand what this quantity of DMFu imported into IT is being used for. It could be for non-biocidal mixtures containing DMFu.	ECHA requested the information from the Italian CA concerning the Italian usage of DMFu as agreed in the 1st Rapporteurs' Dialogue. The Italian response indicates that the Italian usage should appear as zero.	Agree with DS.	
					A.11 Sachets containing DMFu: We are of the opinion that the use of DMFu in sachets should be interpreted as the use of a mixture in a container, rather than meeting the definition of an article under REACH. It is important that the wording of the restriction entry ensures that there is no ambiguity as to whether such products are restricted or not. A.12 Authorisation as risk management option: Pg. 58 of the dossier discusses the use of Authorisation to address risk however it is noted that this would not cover imported articles treated with DMFu. We suggest that a statement to this effect should be included in the dossier to illustrate	Noted. We do not have the same interpretation: sachets containing DMFu should be considered as articles rather than mixtures. Noted. This has been done in the first version of the background document (section	According to the REACH guidance, sachets may be viewed both as articles and mixtures. In either case, the use as a biocide will be restricted, either under the current restriction proposal or under BPD. This is taken care	Sachets can be viewed in different ways but if viewed as a mixture, they are banned anyway in accordance with Biocides Directive. Noted

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					why restriction and not authorisation is the most appropriate risk management instrument under REACH. B – Information on hazard and risk B.1 Risk characterisation approach: Section B.5.11 of the dossier states "...that sensitisation is considered as a threshold effect. However, skin sensitisation may also be considered, by some experts, as a non-threshold effect and in practice it may be very difficult to set up a DNEL for this effect". The dossier also states that a DNEL for skin sensitisation could not be identified for DMFu, and that in such cases the approach to managing the risk should be to reduce/avoid contact with the substance as far as possible. For this reason, the dossier sets the limit based on the limit of quantification of the analytical method (0.1 mg/kg). While we generally agree with the approach taken in the dossier for risk characterisation, we have the following comments: • We agree that it is difficult to identify a DNEL for sensitisation. However, in our opinion it would be better to clarify that skin sensitisation is considered a threshold effect (ref Ch R.8 of Guidance on information requirements and chemical safety assessment), but that the available data for DMFu does not allow the derivation of a threshold dose and therefore no DNEL can be derived.	E.1.3 of BD1 - revision n.5) Noted. The point that skin sensitization is considered a threshold effect is very complex and some experts do not share this opinion. Indeed, sensitization effects depend on the sensitivity and	of in the revised BD. We agree with the threshold, and that no DNEL can be set, but we agree with DS that the proposed threshold (based on elicitation data) can be assumed not to lead to sensitisation.	

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						immune system of each person (allergic potential), as mentioned in the dossier, and the "threshold" would change for each person.		
					• We agree that the available data for DMFu does not allow the derivation of a DNEL and that in such cases sensitisation can be considered a non-threshold effect and the risk characterisation approach should be to avoid/reduce exposure to DMFu. However, the dossier states that "0.1 mg/kg (0.00001% w/w) seems to be protective". If a DNEL cannot be derived, then it is suggested that identification of a "protective dose" is not appropriate.	This proposed value is based on analytical data and we confirm its reliability by available toxicological data, in order to conclude that the value is not completely irrelevant for health issue. Consequently, the concentration of 0.1 mg/kg seems to be protective as no health effects have been reported at this level. The term "protective dose" is not used in the dossier.		
					B.2 Justification for Grouping: The Annex XV dossier states that grouping is not relevant for	The sentence "several	No active use of the homologues as	

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					this dossier. However, the available human hazard data indicates that sensitisation may be due to cross-reacting chemicals. Furthermore, the dossier indicates that several homologues to DMFu may have the same health effects as those demonstrated by DMFu. This information would suggest that grouping may be relevant for DMFu and its homologues yet no justification is provided in the dossier as to why such a grouping is considered not relevant in this case.	homologues to DMFu may have the same health effects as those demonstrated by DMFu" is an hypothesis without certainties. Indeed, we didn't collect data on homologues for this dossier, thus, we couldn't conclude on the relevance of grouping. This point was not the issue for the restriction dossier but could be assessed in further works.	biocides has been identified. The grouping is addressed in the opinion.	
					C – Information on alternatives C.1 Risk assessment not available: The dossier suggests possible alternative substances such as quarternary ammonium compounds, PHMB and triclosan, which are all substances on the review programme for BPD. However, the dossier concluded that it is not possible to recommend such alternatives unless a risk assessment is performed, to prove that the use of these substances does not pose a human health risk. For this reason, no valid alternatives are proposed. We believe further explanation for not proposing valid alternatives should be included in the dossier.	Noted. Evaluation of possible alternatives pertaining PT-9 of BPD is ongoing as mentioned in section C.2.1 of BD1-revision n.5: a total of 41 substances are currently being or will be evaluated, the last reports are expected by May	We have used all available information on alternatives. The authorisation process of biocidal products under BPD will ensure that only safe and approved biocides (not causing concerns for humans or the	Only **Available** information is required on alternatives. A question concerning alternatives was asked in public consultation and a consulting company was contacted but no useful information turned out.

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						2012, possibly followed by Annex I inclusion.	environment) can be used in Europe in the future.	
					C.2 Limited information: We believe that not enough information is contained in Section C on alternatives. We feel that because no concrete alternatives are identified it is not possible to assess the risks associated with them. We believe it is therefore difficult to assess their availability and feasibility, for example. In addition, based on the limited information in Section C we also do not believe the dossier should make the following statements: • "before using alternatives (such as the ones which are proposed in Section C)…"(pg. 13) • "no problem related to technical feasibility is foreseen as the alternatives are already available and authorised in Europe" (pg. 53) • "given the availability of alternatives.." (pg. 59) • "There does not seem to be any technical difficulty to replace DMFu" (pg. 59) • "The level of administrative burden for the actors concerned is not expected to be high as alternatives exist and are expected to be technically and economically feasible" (pg. 67)	Noted. As mentioned before evaluation of possible alternatives pertaining PT-9 of BPD is ongoing. Noted. We do not expect technical problem as substances should be used by impregnation of the textile or the leather. However with respect to the potential alternative where temperature and humidity are physically controlled, some technical difficulties may be	See comment to C1	

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						expected in order to keep these parameters well under control in certain circumstances (e.g. long-range transport), as mentioned in section C.2.4 of BD1-revision n.5.	See comment to C1	
					C.3 Risk assessment by actors: Pg. 13 of the dossier states "before using alternatives (such as the ones which are proposed in Section C) actors will have to make sure that they do not pose any health or environmental risk and that they comply with the applicable regulation". In our opinion some form of risk assessment of representative alternative substances should be included in the dossier to assist possible stakeholders in carrying out their own assessment of alternatives.	Noted. As mentioned before evaluation of possible alternatives pertaining PT-9 of BPD is ongoing.	See comment to C1	
					C.4 Non-DMFu containing articles: The opening statement of this section states (Page 51): "First, it should be highlighted that many articles on the market do not contain DMFu, implying that adding DMFu to articles is not the only existing method for preserving them from humidity and mould and also implying that many actors already use other techniques." We suggest it would have been beneficial if the dossier had included information to support this statement.	Noted	Noted	

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					C.3 Economic feasibility: The dossier concludes that substitution of DMFu is economically feasible on the basis that alternatives are available and widely used. However, we believe that in order to conclude that substitution is economically feasible, it would be necessary for the dossier to provide information on the risks and costs of at least one suitable alternative. If no alternative can be recommended then we envisage that there will be costs associated with assessing alternatives and these costs may be incurred by European producers or passed along the supply chain to European importers or consumers. We feel this additional cost should have been investigated further in the dossier. C.4 Non-substance alternatives: The dossier states that physical controls should be 'prioritised' (p.54). However, there is limited consideration of non-substance alternatives. Further information on physical controls and their costs would be valuable, especially given the human health risks associated with the listed possible alternative substances. C.5 Replacement of word 'mandatory': The conclusion on pg. 54 states that because of the potential human health and environmental effects of using potential alternatives, it is mandatory to perform a risk assessment before using these alternative substances. We would like to suggest that the word 'mandatory' is replaced with the	Noted. As mentioned before evaluation of possible alternatives pertaining PT-9 of BPD is ongoing. There is therefore no suitable alternative for the moment. Substances should be used by impregnation of the textile or the leather and additional costs are not expected (except the price of the substance itself). The dossier submitted contains all the data collected during the instruction Agree. This has been done in the first version of the background document	See comment to C1 The text is revised.	

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					word 'recommended'. E – Why a restriction is the most appropriate EU-wide measure E.1 Analytical method: While it is preferable to have a standardized analytical method available before the restriction enters into force, this should not prevent the restriction inclusion in Annex XVII as the dossier indicates that there are methods available for measuring DMFu concentrations in products. E.2 Limit of quantification: Pg. 36 contains a graph which presents the LOQ of the different analytical methods to measure DMFu in products and of the NOELs derived from the available tox studies. It is stated that "the concentration of 0.1 mg/kg corresponding to the lowest reliable limit of quantification of available methods for the measurement of DMFu in products". This suggests that it is possible to reliably quantify presence of DMFu down to the proposed 0.1mg/kg limit using analytical methods listed in Table 15. However on pg. 65 of the dossier it is stated: "some work is ongoing at the EU level in the CEN TC/309 "Footwear" - WG2 "Footwear and environmental aspects". The objective of this work is the standardisation of a method to measure DMFu concentration in leather and fabrics. The method uses liquid-liquid extraction and GC-MS analysis. Its limit of detection is 0.1 mg/kg and its limit of quantification is of 0.3 mg/kg". If CEN are currently working on developing a method for	Noted Noted. As the limit of detection is 0.1 mg/kg, this limit seems sufficient to ensure that an article complies with the restriction proposal: ban of an article where DMFu is detected.	Noted. Noted. The limit has been chosen based on an pragmatic consideration of analytical issues and patch test data. We support using the 0.1 mg/kg limit.	Noted

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					detecting DMFu in articles with a LOQ of 0.3mg/kg, we would question whether it is more appropriate to use the limit of quantification proposed for this new CEN standard of 0.3 mg/kg rather than a value of 0.1 mg/kg. By setting the limit as 0.1% we could end up with a situation where the limit value is too low for the agreed CEN standard to quantify, requiring a new CEN standard to be created to measure DMFu down to 0.1mg/kg.			
					E.3 Enforcement authorities: Pg. 14 of the dossier states "It is consistent with legal requirements already in place and no additional effort is expected from the actors to implement and from the authorities to enforce the restriction". In the context of enforcement authorities, under Decision 2009/251/EC this would be under the remit of national authorities responsible for the GPSD. These may not be the same authorities with responsibilities under REACH. Therefore a considerable amount of additional effort would be required of (non-GPSD) national authorities taking on this new restriction under REACH. We feel this point should be reflected in the dossier.	Noted. This enforcement issue should be discussed by Member State Competent Authorities and, if needed, by the Forum.	The point in the dossier is, that no significant additional resources will be needed for enforcement, regardless of which authority spends them.	The point in the dossier is, that no significant additional resources will be needed for enforcement, regardless of which authority spends them.
					E.4 Enforcement of restriction: If documentary evidence (e.g. safety data sheets/supply chain lists/certificates of compliance from suppliers etc.) does not clarify whether or not DMFu with a concentration limit of 0.1mg/kg is 1) being used in articles being produced in the EU or 2) contained in articles imported from outside the	Noted	Noted.	Noted and suggested in later versions.

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					EU, then an enforcement inspector would need to sample the articles and test them.. We suggest that specific information about sample preparation and testing could be contained in the FAQs on the Restriction pages of the ECHA website. F – Socio-economic assessment of the proposed restriction F.1 Socio-economic assessment: Pg. 71 of the Annex XV dossier states "based on this information it does not seem appropriate to more precisely assess the socio-economic impacts of the proposed restriction as they are not expected to be significantly higher than the ones of the baseline situation". We suggest that this statement may be too generalized and not enough information is provided in Section F. F.2 Socio-economic analysis baseline: The baseline selected for this analysis (EU Decision 2009/251/EC and assumed renewal thereof) is problematic. Using the temporary decision as baseline effectively bypasses the requirement for a socio-economic assessment. Given that there was no impact assessment conducted to support the introduction of the temporary decision there is the possibility that this restriction could be introduced without assessment of socio-economic impacts at any stage in the process. SEA guidance states that the purpose of the SEA is to consider 'all relevant impacts of imposing a restriction compared to its continued use' (p.20). It is important that SEAC would not set a precedent for this approach. If it is	Noted. More information is given in section F of the 1st version of the background document Agreed. The 1st version of the background document will take into account a baseline scenario in which the temporary ban would not be renewed.	Noted.	More information is given in the Background document, as suggested, including new baseline scenario.

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					not considered proportionate to revise the baseline in this case, I would strongly recommend that concerns about the baseline should be recorded so that this approach is not adopted in future dossiers. G – Consultation G.1 Consultation with Industry representatives: Pg. 78 of the Annex XV dossier lists 5 industry federations which were contacted in order to obtain information. In our opinion, it would have been beneficial if federations spanning the whole Community had been consulted also, so as to achieve a more Community-wide representation.	Noted. As mentioned in section G.3 of BD1 the European Consumers' Organisation, the BEUC, which represents more than 40 national consumer organisations from some thirty European countries, has been contacted by e-mail.	Noted.	
56	N	2010/12/16 11:47	/ / Denmark MSCA		Denmark supports the restriction of the use of DMFu in concentration greater than 0.1 mg/kg in articles produced and placed on the market. DMFu has serious allergenic potential and the use of DMFu should therefore be restricted in all products placed on the market. Denmark supports the proposed restriction under the REACH Regulation to make the temporary ban permanent	Noted.	Noted.	

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38	N	2010/09/21 14:29	/ / Germany MSCA		Comment of the German CA: We support the proposal for a restriction of dimethylfumarate (DMFu) in articles and are of the opinion that the proposed option for Risk Management measures and the toxicological assessment are adequate. Furthermore, we support the suggestion that specific information on sampling and preparation and a compilation of analytical methods for DMFu in articles should be made available on the restriction pages of the ECHA website or on a COM website. The risk assessment in the restriction dossier relies on numerous case reports describing dermal (and in one case also respiratory) reactions after contact to DMFu containing articles and subsequent patch tests with article components and with DMFu. No systemic exposure has been calculated, as irritation and sensitisation do not depend on systemic exposure. Instead, data on DMFu contents in consumer articles have been compiled with a special emphasis on the case reports and consumer sensitisation associated with different consumer articles has been documented. This approach seems sensible for a qualitative demonstration of exposure and causality in the present restriction proposal. The efforts undertaken by the French Competent Authority are highly appreciated. Nevertheless, some indecisiveness should be clarified:			

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					- The Advice of the Forum on the enforceability of the proposed restriction (from July 16th, 2010) should be taken into account (in the following Forum proposals are put in quotion marks): "The wording of the entry should be clarified." The sentence -The limit value should normally relate to individual articles, parts or materials that a complex article consists of- needs some interpretation. What is considered to be normal in this case? Why does it only relate to complex articles? We propose to change the wording and to incorporate it into the entry text. 1. Shall not be used in articles and any parts thereof in concentration greater than 0.1 mg/kg. The analytical results of each sample from one article should be compared to the limit of 0.1 mg/kg. 2. Articles or any parts thereof containing dimethylfumarate in concentration greater than 0.1 mg/kg shall not be placed on the market. The analytical results of each sample from one article should be compared to the limit of 0.1 mg/kg. "It has to be decided if the second hand market should be excluded or not." "A guide for sampling and sample preparation is needed." In the sampling guide it has to be clarified that in some cases concentrations are higher in depth than on the surface, in other cases it is the contrary. "A standardized analytical method should be	Concerning the wording of the entry, the French CA maintains its initial proposal, based on its position on the definition of "article".	We agree with the comment and we have proposed a revised wording along this line in the opinion.	**Wording:** We agree with the proposal of the wording and will recommend it in the SEAC opinion in a slightly different form, but essentially keeping the meaning (both about "parts" and "samples". **Guide for sampling:** We agree that a guide for sampling would help in the enforcement and will recommend it. **Standardised analytical method**: We agree that a standardised

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					available before the restriction enters into force. It should be clarified if different methods should be used for various materials." "Potentially high testing costs, e.g. for a sofa requiring a large number of samples are brought forward by the Forum. However, this is in the nature of things and we do not see a possibility to avoid these costs nor enforcement problems resulting from purchase or storage of large articles. - The degree of risk reduction achieved with the proposed restriction will depend on information of the different actors in the supply chain and other enforcement activities. According to the Dossier it is unclear if EU Decision 2009/251/EC has shown an effect so far. There are some facts mentioned in the Dossier which give reason to the suspicion that there are problems with the enforcement of the Decision as well as with the enforcement of the BPD provisions. For example there is still a high number of RAPEX notifications for products originating from non-EU countries and even from EU Member States. During the consultation period of the Dossier one industrial entity (nationality not mentioned) even declared that it does import DMFu and sells it as a preservative to the textile industry, which is illegal according to the BPD. However, a permanent restriction in Annex XVII of the REACH Regulation should result in a higher level of awareness between industry actors. In summary we expect a reduction of the identified risk, but	Noted	Noted Since it is not known when products have actually been put on the market, it is not clear to us whether RAPEX notifications concern "new violations" or products put on the market before the temporary ban entered into force.	analytical method would help in the enforcement and recommend it. **Compliance with EU decision 2009/251/EC:** We agree with the statement that the effects of the above mentioned decision are unclear so far. However, it should be noted that RAPEX notifications are not a full proof that the decision is not effective, since the reports might well concern articles, which were on the market prior to its stepping into force. One might even argue, that RAPEX notifications prove,

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					recommend to simultaneously strengthen enforcement activities. - DMFu may be incorporated in little sachets that are in contact with articles. Our interpretation is that the use of DMFu in the sachets has to be considered as use of a mixture in a container and the import of such a mixture is already prohibited by the BPD. The latter is true as long as DMFu is used as a biocide. Only if DMFu would be used for non-biocidal purposes in the sachets this use would be legal, even after adoption of the proposed restriction. - There is few information available on use, potential production and import of DMFu in the EU. However, there are 34 preregistrations of the substance in spite of the already existing time-limited restriction. There might be unknown (non-biocidal) uses of DMFu which do not imply incorporation of the substance in articles. In view of these facts it is proposed to re-evaluate the necessity of an extended restriction as soon as more information on DMFu becomes available via the registration process. - We suggest a better separation of induction and elicitation processes in the wording. E.g. the documented NOAELs and LOAELs refer to patch test elicitation reactions and they do not give information on the induction dose.	We have the same interpretation. DMFu has not been identified for other use than biocidal purpose. Noted The observed dermatitis correspond to the elicitation phase. Actually, the induction phase cannot be characterised because it can be	We agree. Very limited information has been obtained from the pre-registrations, but so far there is no indication of non-biocidal uses of DMFu. We agree with both the comment and the response. We have corrected the terminology and the descriptions in the opinion and BD.	that the decision is being enforced. **Non biocidal use of DMF:** We agree **Pre-registrations:** The development with registrations of DMFu is being closely monitored by ECHA.

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						asymptomatic. It occurs between the time when the person is in contact with the contaminated furniture/shoe and the time when effects are observed. The NOAEL/LOAEL are determined after patch tests, corresponding to a re-challenge, and estimate the dose inducing the challenge but the dose provoking the induction phase cannot be identified, especially based on these publications.		
34	N	2010/09/20 16:26	/ / United Kingdom MSCA	(A) (B) (C) (E) (F)	We appreciate the work that has been put into preparing this Annex XV dossier. We agree that there is a problem with imported goods contaminated with DMFu and that EU-wide regulatory action is required to prevent this activity. We suggest that additional information on the reasons for the continuing notifications to RAPEX would help support justification for making the temporary restriction permanent. If the temporary	The reasons for non compliance and thus RAPEX notifications are not known.	More information on the notifications would be helpful, but we realise it will be difficult to get it. Since it is not known when products have actually been put on the market, it is	**Compliance with EU decision 2009/251/EC:** We agree with the statement that the effects of the above mentioned decision are unclear so far. However, it should be noted that RAPEX

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					restriction has not been fully effective, it may be useful to consider if adjustments can be made to the restriction to improve its effectiveness before it is brought into REACH. It would also be useful to have further information on the scale of the problem to help assess the proportionality of the proposal.	All member states have been contacted in order to obtain information on the cases of dermatitis linked to DMFu. The document already compiles all the available information.	not clear to us whether RAPEX notifications concern "new violations" or products put on the market before the temporary ban entered into force. We are not sure "adjustments" are needed. We also feel that there is no further info on "scale" to be obtained. We have even used info on insurance cases in the UK as indicative info on the scale.	notifications are not a full proof that the decision is not effective, since the reports might well concern articles, which were on the market prior to its stepping into force. One might even argue, that RAPEX notifications prove, that the decision is being enforced.
					It would have been useful to discuss the impact that the proposed EU Biocidal Products Directive may have on the import of articles treated with biocides that are not approved for use in the EU.	At the time of the elaboration of the dossier, the new regulation for biocides was not available. Consequently it was not possible to discuss its impacts.	We agree with the DS response.	The future development of the biocides regulation is still unclear, both regarding the timing and the extended scope. The timing is definitely such, that a time gap of 3 to 5

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								years could exist, if no restriction is in force of the day of the new regulation coming into force (transitional measures, Art. 81 of the proposed regulation). Regarding the scope, the position of the council is that restrictions for articles treated with biocides should be less severe than for biocidal products themselves. During SEAC 8 we discussed the question only existing legislation should be taken into account
					It would be helpful to provide justification for the choice of baseline to assess the socio-economic impact of the proposal. In our opinion there is not enough information in the socio-economic assessment (SEA) to properly evaluate the	Noted. This has been done in the first version of the background document.	A new baseline is indeed discussed in BD.	**The baseline** proposed here, with the temporary restriction expired is considered BD. For

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					economic impacts of the restriction. We suggest that it may be useful to consider an alternative baseline in which the temporary restriction has expired. The "status quo" baseline will need to include future legislative changes such as the revision to the Biocidal products legislation (entry into force for the proposed EU Biocidal Products Regulation is anticipated for Jan 2013).			including the revision to the Biocidal products legislation, see response above.
26	Y	2010/08/27 15:17	Germany / Company /	(A) (B) (H)	DMFu may also be formed as a technical impurity during synthesis of other substances. Such substances may contain amounts of DMFu in the order of magnitude of some ppm.	Noted. Should be discussed in the Committees. As the restriction proposal relates to the articles, it may be interesting to know amounts of DMFu remaining in articles after using substances which contain DMFu as a technical impurity in order to assess the relevance of changing the scope at this stage.	We agree with the DS response. We have tried to get more information on this, with the assistance of ECHA. However, we consider that regardless of the route in which DMFu comes into an article, the proposed scope and limit should apply.	We consider that regardless of the route in which DMFu comes into an article, the proposed limit should apply.
21	N	2010/08/12 17:26	Belgium / International NGO / European	(A) (C) (F)	The comments that follow are from the perspective of socio-economic assessment. EEB may wish to provide additional comment from other perspectives (e.g. risk assessment).			

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			Environmental Bureau		1. The restriction seems to be described appropriately. Use of the word 'Articles' is appropriate – though seen largely as a problem linked to the application of DMFu on furniture, DMFu has been used more widely (e.g. on clothing, toys, etc.), so it is good that the restriction is more generally applicable (particularly as DMFu is resistant to washing (Section B2.2.3)). It is also appropriate that it is not aimed solely at protection of consumers (as in EU Decision 2009/251/EC). The justification for a limit of 0.1mg/kg (applying to any part of a product) looks reasonable on grounds of effect and monitorability.	1. Noted.	The support is noted.	
					2. Effects of DMFu on health, as a result of the uses targeted under the proposed restriction, are clear, as is the need to avoid them.	2. Noted	The support is noted.	
					3. Alternatives to DMFu are available and are already in use. There are thus no issues of economic or technical feasibility to consider. The consideration of alternatives to DMFu highlights a problem that is likely to come up repeatedly – that little is known about the risks of the main chemical alternatives. The conclusion on the use of alternatives is as follows (Section C3):… based on the available data, the previously mentioned human health and environmental effects related to the substances indicated by IFTH cannot be ignored. It is thus mandatory to perform a risk assessment before using these substances as potential alternatives to DMFu. On a more general	3. Noted. About the word "mandatory", indeed, it should be "recommended". It will be replaced in the 1st version of the background document.	All potential alternative PT9-biocides are assessed during 2010-2012 under BPD. We have high-lighted the need for info on actual alternatives when the public consultation started, but no information was received.	

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					perspective, in the frame of this restriction proposal, it is advised to identify alternative substances pertaining to the Product-type 9 'Fibre, leather, rubber and polymerised materials preservatives' which comply with the biocidal regulation and to perform a health and environmental risk assessment before producing and placing on the market articles which contain them. Also, as a general rule, control of physical parameters (such as humidity rate and temperature) and use of chemical substances which do not persist on the consumer article should be prioritized. I am not sufficiently familiar with the legislation more generally to know what is meant by the use of the 'mandatory' in the second sentence ('mandatory' to me means something that legally has to be done, I am not sure if it is used in this sense here, or whether it is used in the sense of something that would be desirable to do). However, the subsequent recommendations given in the paragraph are sound and I support the view that control of physical parameters or the use of non-persistent chemical treatments is to be preferred. 4. A thorough SEA has not been undertaken because of the effects of EU Decision 2009/251/EC – the restriction will simply make this decision permanent. The logic of not examining a counter-scenario to the current position seems incorrect: from an economic	4. Agreed. The 1st version of the background document will take into account a baseline scenario in	There is indeed a new baseline discussed in BD.	4 The SEA has been elaborated in the background document, although it is not a fully monetised cost-

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					perspective a scenario which considered use of DMFu could have been considered as it cannot be assumed that the current decision preventing use of DMFu will remain in place. However, the evidence given on health effects and the ready availability of alternatives seems quite sufficient to justify the restriction. That said, I do have concerns about possible effects of some of the alternatives. There are some potentially important co-benefits that are not mentioned, for example, a reduction in health effects on workers in poorly regulated countries. Although worker protection is not the focus of the restriction proposal it is important to know what additional benefits or burdens a restriction (or authorisation) may lead to. 5. It would be useful to see the economic arguments brought together at some point, as was done in the lead in jewellery dossier.	which the temporary ban would not be renewed. This baseline scenario will be further discussed. Concerning the workers, the additional benefits of their protection will also be added. This will be done in section F in the 1st version of the background document.	 Noted.	benefit-analysis. Thanks for pointing out the co-benefits, we will consider how to include them. Also see DS response. See DS response.
20	N	2010/07/16 17:23	Germany / Company / BCH Brühl - Chemikalien Handel GmbH		We do not import DMFu. Our business will not be affected by the restriction of DMFu and its inclusion into Annex XVII of REACH.	Noted.	Noted.	

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Specific comments

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34	N	2010/09/20 16:26	/ / United Kingdom MSCA	(A) (B) (C) (E) (F)	A) Suggested restriction Assuming this restriction is the most effective way to address this issue, we consider that the proposed limit of 0.1% is pragmatic based on the toxicological evidence and limits of detection for the available analytical techniques. To ensure consistent implementation of the restriction, it will be necessary to adopt a standard analytical method and establish a schedule describing the way monitoring should be performed (e.g. what proportion of a consignment of imported goods should be sampled and how many samples should be taken from each item etc.). B) Information on hazard and risk B.1.3 (Physicochemical properties) Please could clarification be provided with respect to the statement that DMFu is a (VOC). The justification at the bottom of page 16 is not clear and the source document for the information (ISO, 2005) is not included in the reference list. It may be better to refer to an existing regulatory definition such as the one in the Solvents Emissions Directive (1999/13/EC) where VOCs are defined as organic compounds with a vapour pressure of 0.01 kPa or more at 25°C. If available, it would be useful to have information on volatility at body temperature since this could	A) Noted. Noted. Vapour pressure of DMFu is 510 Pa at 25°C: it is superior to 10 Pa at 25°C according to the definition of a VOC of the Solvents Emissions Directive (1999/13/EC). This will be included in the 1st version of the background	Noted. The indicated information would indeed be helpful, but not a prerequisite for this restriction. Noted.	A) We agree that a standardised analytical method would help in the enforcement and recommend it.

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					be relevant to the rate of release of the substance from treated articles during use. B.2 (Manufacture and uses) In addition to the biocidal use which is the subject of the restriction, the dossier refers to pharmaceutical uses, use as a laboratory agent and an apparent food use (Chinese high fat cakes). For clarity, it would be helpful to state all uses that are known (and if possible the tonnages supplied for these uses) and the technical function that DMFu is providing for each of these uses in an introduction to this section. A search of the list of pre-registered substances indicates that the envisaged date for registration of DMFu is 30.11.2010. Did any of the pre-registrants contacted indicate what registration deadline applied to them and are there any plans to interrogate any registrations made by 30.11.2010 to fill data gaps in this proposal? This could be done before RAC and SEAC have to finalise their opinions. B.2.1 (Manufacture, import and export) Where information has been obtained from a consultation (e.g. information in tables 4 and 5) it would be helpful to give the date that the consultation was carried out to put the information into context. It is not possible to get an indication of the scale of the problem from the numbers of RAPEX notifications in table 6. It would be useful to know what proportion of imports these notifications	document. No more information than that is presented in the report. Consultation has been carry out between May and August 2009.	More information would be helpful, but we understand that the info is not easily available. With the assistance of ECHA, we are trying to get more info from the pre-registrations, although at present we are not very hopeful that we will get any useful information. Noted. It would indeed be helpful if more information could be obtained from	The development with registrations of DMFu is being closely monitored by ECHA. All pre-registrants have been contacted but no conclusive response was obtained. No registration is expected in the forthcoming deadline for substances over 1000 t. We agree that the number of RAPEX notifications does not give an indication of

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					represent, whether the notifications represent single product units or batches of stock (covering multiple product units) and what triggered the notifications (regulatory monitoring or adverse consumer reactions). It would be particularly useful to identify the triggers for notifications made after the introduction of the temporary restriction because this will help assess the likely effectiveness of the proposal. The concentrations of DMFu that have been measured in articles are very variable and it is not clear what conclusions should be drawn from these data other than DMFu may be present at varying concentrations in mainly leather and textile articles. It would be helpful to have a view on how representative these measurements are (e.g. what proportion of imports were sampled and how were test samples selected?) for articles sprayed with DMFu or packaged with sachets containing DMFu. The first line on p 24 concludes that DMFu is present in a huge variety of articles. This suggests that many different types of articles could potentially be affected whereas the evidence points to leather and textile articles being the main concern with wooden toys as an exception. This gives a more accurate picture. If there is evidence that other article types may be contaminated this should be included. B.2.2.3 (Stability of DMFu in articles) The information presented in this section does not		the RAPEX notifications. However, there is very limited information in the RAPEX database. We had thought that additional information on how DMFu has been used would be obtained from the public consultation, but no such information was submitted.	the scale of the problem. We consider that the reports of adverse effects from 8 (9) countries, combined with the UK court decision to give compensations to 1600 affected consumers (additional 3000 cases are being processed) mentioned in the BD give an indication of the scale of the problem all over Europe.

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					provide a good picture of the residence time and rates of migration/leaching/evaporation of DMFu. More information on the experimental conditions and scope of observations would help to interpret the data. For example, to understand the stability of DMFu in articles it is important to know the conditions of storage and the treatments the article has undergone. It would be useful to have more information on the data linking fibre type and retention of DMFu reported in the Affset study. B.5 (Human health hazard assessment) Evidence to support DMFu's irritation and sensitisation potential is provided by animal data. Limited information on some other end-points is also included. Overall, insufficient information from the animal studies is presented to enable an informed evaluation of the hazards associated with this substance. In particular, the following points are noted: B.5.3.1. (Skin irritation) Some of the cited information was taken from 'Micromedex' (Datec and Lavoisier, 2010), which is a database for medical professionals to access evidence-based clinical information. Without access to this database, it is not possible to make a judgement on the reliability of the data. Additional, somewhat contradictory, information was taken from CCTV (National Coordination Committee for Toxicovigilance, 2009), but no additional details were provided in the CCTV document, and it did not cite a reference. A	For the references: Datec and Lavoisier (2010) and CCTV (2009) we do not have more available information. We agree that the reliability of these data are consequently quite low.	We agree that the information on the "stability" of DMFu in articles is rather contradictory. Noted. DS has indicated the reliability of the studies in BD.	

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					published study was also cited. No information on study protocols or irritation scores was given. More information needs to be provided in the Annex XV dossier to fully evaluate these data. B.5.3.2. (Eye irritation) DMFu was reported to be very irritant for the eyes based on the 'Micromedex' citation, but as no further information was provided, it was not possible fully to evaluate this end-point. More information needs to be provided in the Annex XV dossier B.5.5.1. (Skin sensitisation) A guinea pig maximisation test (GPMT) was reported in a published journal. The concentration administered was 0.3%, but it was not stated if this was for the intradermal induction, the topical induction, or the challenge. DMFu was concluded to be a moderate sensitiser, although only 3/9 (33%) animals gave a positive response, and so in this assay the substance was only just above the cut-off (30%) for classification as a sensitiser under Directive 67/548/EEC and CLP. More information on the test protocol and the reaction scores in test and control animals should be included. The other cited studies provide information on cross-sensitisation with esters of maleic acid. Please could you confirm if the substance tested in these studies was the (Z)-isomer (dimethyl maleate). B.5.5.2. (Respiratory sensitisation)	We do not have more available information. We agree that the reliability of these data are consequently quite low because cannot be confirmed. Some details have been added in the 1st version of the background document. Yes, the substance tested in these studies was the (Z)-isomer (dimethyl maleate)	Noted. More information has been added.	

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					The limited information comes from unconfirmed case reports of respiratory symptoms that were associated with dermal exposure. As the number of cases is not reported, but appears to be small, and some of the evidence appears to be anecdotal, it is not possible to establish a causal link between DMFu and respiratory sensitisation from the information provided. B.5.6.2.2 (Repeated dose toxicity dermal route) Most of the data on the hazards associated with exposure to DMFu are taken from human case studies. Several reports have linked exposure to DMFu to sensitisation and/or acute irritant responses. Some reports also describe cross-sensitisation reactions to acrylates and isomers/homologues of DMFu. The dossier should be specific about the patch test method employed to investigate responses in the negative controls: were they intended to induce and elicit sensitisation or just to elicit responses? In the descriptions of the human case reports, it is frequently reported that DMFu 'induced positive reactions' in individuals who had presented with dermatitis. To be accurate, this should state 'elicited', since sensitisation in the individuals has already been induced, and the purpose of patch tests in these subjects is to determine a causal relationship between DMFu exposure and the elicitation of a response. B.5.11. (Derivation of DNEL/DMEL)	We agree that the link between DMFu and respiratory sensitisation cannot be clearly established. Therefore, the sentence has been changed. We have not this information in the publications, but if they were intended to elicit sensitisation, we can assume they covered the induction of sensitisation. Agreed.	Noted. Noted.	

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					The two phases in the development of sensitisation, induction and elicitation, are usually considered to be threshold phenomena. However, for each allergen, these thresholds are not absolute values and are subject to many factors, including: dose of substance per unit of area; the sensitisation potency of the substance; the vehicle matrix; exposure conditions such as duration, occlusion; and individual variation amongst populations. In particular, there is large variability in the elicitation threshold between individuals, as it is not an inherent property of an allergen but is, rather, a consequence of the severity of the induction regime. Therefore, derivation of a DNEL/DMEL for skin sensitisation can be complex. The animal study reported in the dossier (a GPMT) does not enable an estimation of potency or dose response. The proposed threshold for the restriction has thus been determined from human data. The threshold of 0.1 mg/kg was originally chosen for inclusion in Decision 2009/251/EC based on the study by Rantanen et al., (2008), being 1/10 of the lowest observed concentration that produced a dermal reaction in the most sensitive patient (section G.4, page 81). At that time the 2009 studies by Mercader, Giménez-Arnau, Lammintausta and Susitaival were not available. Review of these publications shows that they generally give NOAEL values that are consistent with that of Rantanen; in particular, a NOAEL of			

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					0.1 mg/kg was identified in the publication of Lammintausta, in which the largest number of individuals (37) was investigated. In none of the available studies was there a positive reaction to 0.1 mg/kg DMFu in sensitised individuals or in control subjects. On page 13 (A.2.3, effectiveness in reducing the identified risks), it is acknowledged that the 'risk of sensitisation cannot be completely excluded as, by definition, even a very small quantity of substance can induce sensitisation.' Usually the amount of substance needed to induce sensitisation is greater than the amount required to elicit a response in an individual who is already sensitised. From the human data presented there were no cases of elicitation of sensitisation or irritation at a DMFu concentration of 0.1 mg/kg, and so a threshold of this concentration would be predicted to also be protective against induction for the majority of the population. The proposed limit of 0.1 mg/kg is therefore a pragmatic one, predicated on both the toxicological data and the limit of quantification of the available analytical methods (since DMFu cannot be detected in articles below this concentration and so enforcement of a lower threshold would be problematic). To be precise in the intended aim of the restriction, the conclusion on page 35 should state that 'the concentration of 0.1 mg/kg seems to be protective against induction of sensitisation in naïve	Agreed. The proposed sentence has been added in the 1st version of the	The support is noted. Noted.	

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					individuals and elicitation in those already sensitised to DMFu, and against irritation based on the available toxicological data'. This conclusion should also be reflected in section A. B.9 (Exposure assessment) A quantitative exposure assessment has not been performed for DMFu. Where measured exposure data are not available, it may be possible to generate quantitative data using exposure estimation tools. For example, CONSEXPO could be used to estimate potential inhalation exposure and dermal exposure as a result of migration of DMFu from articles or sachets. Generating quantitative exposure values would allow a more robust, quantitative risk characterisation to be performed. This will help to establish the scale of risk. Since it is not possible to obtain useful exposure estimates from the case reports cited in section B9, we suggest that it would be clearer to include these studies with the health effects evaluation. B.9.1.2 (Summary of the effectiveness of implemented measures) In our opinion, there are too many uncertainties in numbers of reported cases of skin sensitisation to use this as a basis from which to assess the success of the restriction. It would be useful to have information on the monitoring and enforcement activities being carried out in relation to the current restriction and the reasons for any non-compliance. It may be useful to gather information	background document. Noted. Case reports cited in section B.9 describe sources of exposure and will not be removed.	Because of limited and sometimes conflicting information, it will be difficult to use modelling. We are not sure how modelling could help us. More information would be helpful, but we have to proceed with the available information.	

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					from importers/retailers about the actions they are taking to comply. B.9.3.2.2.7 (Consumer exposure – other) It is suggested that that DMFu may be found in certain Chinese foods. Do we know if DMFu is present as an ingredient or because the foods were imported in containers treated with DMFu? If the latter, we need to understand if this use for DMFu could be a source for harmful levels of DMFu in articles and what action may be required to address this. B.10.1.1 (Risk characterisation – Human health) The hazard data do not provide sufficient information to conclude that DMFu is a moderate or strong sensitiser and these statements could be misleading. Where reactions are elicited in persons already sensitised this could be a reflection of the individual's sensitivity rather than the potency of the sensitiser. C) Information on alternatives It would be helpful to consider the health effects of isomers/homologues and whether DMFu can readily be substituted with an isomer/homologue (e.g. dimethyl maleate) with the same health concerns in case there is the possibility for the restriction to replace one problem with another.	Noted. The publication cited gives no more information. We agree that the employed terms could be misleading as they do not reflect sensitisation potency. Consequently, they have been removed.	We would also appreciate more information on this topic, but we realize that there may not be any further information available. We agree. The homologues might have similar biocidal activities as DMFu, but as there is no single indication that they have been used for this purpose, they will not be considered further	

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					Several alternative substances have been suggested but the information on the hazards and costs for these alternatives is limited. More information on hazard and exposure is needed to properly assess the human health and environmental risks that could arise from substitution. More information on the availability and costs of alternatives is needed to assess economic feasibility. The conclusion on page 54 states that, because of the potential human health and environmental effects of using the potential alternatives, it is mandatory to perform a risk assessment before using these alternative substances. How will this be monitored and enforced given that imported goods will be treated outside the EU? E) Why a restriction is the most appropriate EU-wide measure E1.3 (Other Community-wide risk management options) To help justify the restriction that has been proposed, it would be useful to provide a more detailed discussion of the various legislative options that are currently available (and are planned) and the reasons why these measures are not suitable to address this concern. The second paragraph suggests that the ongoing notifications to RAPEX are due to non compliance with the temporary restriction. This is used to support the conclusion that voluntary action would	Noted. About the word "mandatory", indeed, it should be "recommended". It will be replaced in the 1st version of the background document.	in this restriction. All potential PT9-alternatives are being assessed under the BPD. We hoped to get more information on the biocides actually used, after the use of DMFu was banned, from the public consultation. Unfortunately, we did not get such information. We do not think there is sufficient basis to judge the degree of	The question about alternatives was included in the public consultation but it produced no results. E1.3 By planned legislative options we understand the proposal of the new Biocides regulation. The future development of the Biocides regulation is still unclear, both regarding the timing and the extended scope. The timing is definitely such, that a time gap of 3 to 5

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					not be adequate to address the identified risks. If non-compliance is the reason for ongoing notifications to RAPEX, is there the possibility for similar non-compliance issues to arise with the permanent restriction and if so, what steps will be required to address non-compliance?		compliance of the present temporary ban.	years could exist, if no restriction is in force of the day of the new regulation coming into force (transitional measures, Art. 81 of the proposed regulation). Regarding the scope, the position of the council is, that restrictions for articles treated with biocides should be less severe than for biocidal products themselves. During SEAC 8 we discussed the question and the representative of the Commission affirmed, that only existing legislation should be taken into account It should be noted that RAPEX notifications are not a full proof that the decision is not

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								effective, since the reports might well concern articles, which were on the market prior to its stepping into force. One might even argue, that RAPEX notifications prove, that the decision is being enforced. E.2.1.1.2. The BD gives more information about this issue.
					E.2.1.1.2. (Proportionality) Given that there is no information on the scale of risk and there is insufficient information to assess the economic burden of the proposed restriction to industry and regulators it is not possible to determine whether the proposal is proportionate to the risk. The dossier states that the proposed restriction seems to give a good balance between costs and benefits – costs and benefits have not been assessed, so it is unclear on what basis the proposed restriction can be said to give a good balance between them? As already mentioned, there may be issues concerning the effectiveness of the existing temporary restriction, and hence it is possible that a permanent restriction may require additional resources to ensure appropriate levels of compliance. It would seem sensible to discuss this	Noted. More information is given in the 1st version of the background document (section E.2.1.1.2.1 Economic feasibility)	Noted. Regarding the risk, the former use of DMFu has caused many severe cases of sensitization and caused a lot of suffering for many individuals in many EU MS. The temporary ban has shown that these cases can be avoided.	

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					further and if necessary cost any resource implications. E.2.1.2.2 (Enforceability) The dossier has considered how the levels of DMFu in individual articles will be measured but not how an enforcing officer would decide which articles to target for measurement. This is an equally important aspect of enforcement and monitoring because it will help to understand the costs of enforcement and monitoring. E.2.1.3.2 (Costs of monitoring) To put the costs of monitoring into context, it would be useful to have information on the scale of testing that will be needed to monitor the restriction, or aggregate costings. F) Socio-economic Assessment of proposed restriction As indicated in our general comments, it is questionable whether the situation with the temporary restriction in place is the most appropriate baseline for this analysis. It is unclear to what extent the existing temporary restriction (and other national measures to address risk) have been properly justified in terms of scientific and socio-economic evidence (and hence can legitimately be considered to represent the baseline situation). It would be useful to include the impact assessment or SEA for the temporary restriction if one was prepared. If this is not available, it may be more appropriate to take the baseline situation as one in which the temporary restriction has expired.	Agreed. The 1st version of the background document will take into account a baseline scenario in which the temporary ban would not be renewed. This baseline scenario will be further discussed.	Such guidance would be helpful, but is not required. RAC has no comments on this section, but we do note that a new baseline has been introduced.	E.2.1.2.2, E.2.1.3.2 (The Forum has suggested, standard analytical method and sampling guidelines should be prapared, however, we can only recommend it. The BD assumesa baseline situation where the temporary restriction has expired, as suggested in this comment. We have no influence the renewal of the temporary restriction (up to 6 times before the new biocidal directive shows its effects) and anyway, it seems unpractical

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					The SEA assessment can then consider the options of putting in place a permanent restriction or renewing the temporary restriction and the effect that the forthcoming Biocidal Products Regulation may have. In its current form, the SEA analysis is not sufficient to aid the decision making process. There is not enough information on scale of impact and there has been no monetisation. There has been no analysis of the costs (or health and environmental impacts) of alternatives. No attempt has been made to evaluate the costs to industry to demonstrate that any alternatives pose lower risks to humans and the environment. Therefore there is no way of gauging the burden of changing to an alternative. If there is not full compliance with the temporary restriction there may need to be an increase in the level of monitoring and enforcement to obtain better compliance with a permanent restriction. The costs have not been highlighted or quantified. Activities to monitor compliance could present significant costs to regulatory authorities in Member States. What is the scale of this burden, are the costs associated with monitoring disproportionate to the benefits and are the resources available? In order to assess the difference in scope between the temporary restriction and the permanent restriction it would be useful to know what other (non-consumer) articles DMFu may be used in.	Noted. More information is given in the 1st version of the background document (section F.2 Economic impacts) Costs of the monitoring are estimated in section E.2.1.3.2		at the point, where this permanent restriction is close to be processed. RAPEX notifications are not a full proof that the decision is not effective, since the reports might well concern articles, which were on the market prior to its stepping into force.

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					This will help to evaluate the impacts of the proposed restriction. In the situation where a permanent restriction is not adopted and the temporary restriction expires (situation A2) there could be an increase in exposure and hence a negative health impact. Is it possible to quantify this impact and, if not, what are the reasons? Is it possible to quantify the benefits that have been obtained from the temporary restriction and, if not, what are the reasons?			
26	Y	2010/08/27 15:17	Germany / Company /	(A) (B) (H)	There might be other potential sources for exposure to DMFu than those originating from TREATED articles.	Noted.	Noted. It would be useful to get more information on these uses.	

Specific question 1

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
62	N	2010/12/20 10:47	/ / Ireland MSCA	(A) (B), (C), (E), (F), (G)	The Health and Safety Authority has no relevant information.			
20	N	2010/07/16 17:23	Germany / Company / BCH Brühl -		Don't know. (we never imported DMFu).	Noted.	Noted.	

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			Chemikalien Handel GmbH					

Specific question 2

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
62	N	2010/12/20 10:47	/ / Ireland MSCA	(A) (B), (C), (E), (F), (G)	The Health and Safety Authority has no relevant information.			
20	N	2010/07/16 17:23	Germany / Company / BCH Brühl - Chemikalien Handel GmbH		Don't know.	Noted.	Noted.	

Specific question 3

Ref	Att	Date	Country/ Organisation/ MSCA	Type *	Comment	DS Response	RAC Rapporteurs comments	SEAC Rapporteurs comments
62	N	2010/12/20 10:47	/ / Ireland MSCA	(A) (B), (C), (E),	The Health and Safety Authority has no relevant information.			

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				(F), (G)				