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Inland Transport Committee

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Working Party on the Transport of Dangerous Goods

Joint Meeting of Experts on the Regulations annexed to the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) (ADN Safety Committee)

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Item 5 (b) of the provisional agenda

Proposals for amendments to the Regulations annexed to ADN

Other proposals

The requirement of 7.2.4.25.5 ADN during loading operations of UN 3082 (Heavy Heating Oil)

Transmitted by the Government of the Netherlands

I. Introduction

1. For the 28th session of the ADN Safety Committee, FuelsEurope submitted document ECE/TRANS/WP.15/AC.2/2016/26 concerning the requirement of 7.2.4.25.5 ADN to return the gas/air mixtures ashore during loading operations of heavy heating oil (UN 3082). FuelsEurope requests the ADN Safety Committee to adopt a new Special Provision 804 which states that the provisions of 7.2.4.25.5 do not apply during loading operations of UN 3082.
2. The proposal is based on the results of the CONCAWE study final report (ECE/TRANS/WP.15/AC.2/26/INF.23) evaluating the risks associated with emissions from UN 3082 barge loadings.

II. Scientific considerations

3. In August 2015, the ADN Safety Committee requested ADN-delegations having doubts about the technical validity of the CONCAWE risk assessment report to consult FuelsEurope to verify the information that they considered problematic (ECE/TRANS/WP.15/AC.2/56 §51). The Dutch government has asked its National Institute for Public Health and the Environment (RIVM) to examine the (updated) CONCAWE study. Experts from the RIVM met with experts from CONCAWE at a meeting on November 27 in Bilthoven, the Netherlands. The final analysis of the CONCAWE study and the final conclusions of the RIVM can be found in Annex I.
4. In conclusion, based on the analysis and conclusions of the RIVM, the Dutch government is not convinced that the conclusions of the CONCAWE study are supported by the data presented in the report.

III. Policy considerations

5. Furthermore, from a systematic legal and policy point of view, the Dutch government is of the opinion that the CONCAWE study cannot justify a decision from the ADN Safety Committee not to apply the requirements of 7.2.4.25.5 to loading operations of UN 3082. The rationale on which the entire legislation (classification, conditions of transport and other safety enhancing measures) regarding the carriage of dangerous goods, is based on the evaluation of the properties of a substance in the physical form in which it is transported. Exempting UN 3082 (Heavy heating oil) from the requirements of 7.2.4.25.5 ADN based on the properties of the emissions, is not in line with this principle as the substance is transported in a liquid state. This concern has already been expressed by other delegations in August 2012 (ECE/TRANS/WP.15/AC.2/44 Paragraphs 15-18): *It was ... inappropriate to reassess the conditions of transport on the basis of whether the products were likely to emit vapours and that would call into question the classification of all products classified as CMR and also their conditions of transport.* The Dutch government still supports this position.

6. As already shortly mentioned above, the Dutch government has significant concerns about the precedent which the ADN Safety Committee would create if it adopts this proposal. If the ADN Safety Committee eases the legislative requirements for UN 3082, other substances might follow. This development is counterproductive to the international work and ambition for regulatory consistency and a level playing field in the framework of the transport of dangerous goods.

IV. Conclusion

7. Based on the scientific conclusions of the RIVM and on the mentioned policy considerations, the Dutch government cannot support the proposal from FuelsEurope which is based on the CONCAWE study.

Annex I

Scientific analyses of the National Institute for Public Health and the Environment (RIVM)

18 January 2016

The Dutch Ministry of Infrastructure and the Environment asked the RIVM (The Dutch Institute for Public Health and the Environment) to review report 1/15R on ‘Risk Assessment for emissions from hot heavy fuel oil during barge loading’ by CONCAWE from a scientific perspective. Technical experts of the RIVM analysed the report and summarized their primary issues of concern in a memo. This memo was discussed at a meeting between the RIVM experts and the experts of CONCAWE on 27th of November 2015. After a fruitful discussion the experts of CONCAWE agreed to revise the CONCAWE report to reflect the discussion.

RIVM received a version of the revised report on 8 January 2016. The newly revised report has been analysed by the experts of the RIVM to the extent possible in the limited time available. Particular attention was given to the points discussed during the meeting on 27th of November 2015.

After this review, the experts of the RIVM concluded that a number of the concerns of the RIVM have been addressed, either during the discussion or in the revised report. However, a number of key issues remain. Due to the limited amount of samples, in combination with the large range of polycyclic aromatic hydrocarbons (PAH) levels reported in HFO samples, there is still doubt that the samples analysed in the study cover the range of HFOs transported. Furthermore, uncertainties concerning the composition of the samples remain. In addition, the modified Ames test presented in the report is verified against a dermal route of exposure while the primary route of concern in this study is the inhalation route. Finally human health hazards other than mutagenicity and carcinogenicity such as reproductive toxicity, or target organ toxicity have not been discussed in the report. Therefore, additional data is needed to support the final conclusion that HFO emissions, exposure and hazards during barge loading are not a source of human health concern.

Below, a point by point summary is given of the analysis performed by the experts of the RIVM. Remarks on report 1/15R that were discussed at the meeting on 27 November 2015 are reproduced below under the different subheadings ‘RIVM remarks on report 1/15R’. A short summary of the discussions and/or remarks on revised report 1/15R are reproduced under sub-headings ‘Discussion and remarks on revised report 1/15R’.

Sampling

RIVM remarks on report 1/15R

In the CONCAWE report 1/15R, five, eight or nine samples of Heavy Fuel Oil (HFO) are investigated. In the exposure study five samples are investigated, in the modified Ames assay nine samples are mentioned and in the 2015/INF.23 paper¹ eight samples are mentioned. However, the CONCAWE report 1/15R also mentions: “The precise composition of HFOs can vary widely with variable quantities high molecular weight olefinic, paraffinic, aromatic, and naphthenic hydrocarbons present together with prescribed

¹ INF.23 (CONCAWE and FuelsEurope) - ConcaWE project results presentation and recommendations for consideration by the ADN Safety Committee

amounts of a lower molecular weight cutter stock that is used to achieve the desired physical properties (Holmes and Bullin, 1983).”

1. Can CONCAWE explain how these samples were chosen?
2. Can CONCAWE explain how the samples used in the different tests relate to each other?
3. Can CONCAWE elaborate whether these samples are representative for the widely varying range of products that can be classified as UN 3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE; LIQUID, N.O.S. (HEAVY HEATING OIL)?

Discussion and remarks on revised report 1/15R

During the discussion, CONCAWE explained that although the precise composition of heavy fuel oils can vary, the variation is always within a certain range. The desired physical properties demand that the variation of heavy fuel oil specifications cannot vary too much. Chapter 5.1 of the revised report has been amended to reflect this discussion. The revised text states that because the investigated samples have PAH levels that fall within the same range as the levels of eight earlier investigated HFOs (Christofer, 2011)² they could be considered representative of HFOs in commerce. However, the Christofer (2011) study “showed that the range and level of PAHs can vary extensively between HFO samples”². The study also reported concentrations of several PAHs (naphthalene, anthracene, fluoranthene, pyrene and benzo[ghi]perylene) up to 10 fold higher than the highest levels reported by the CONCAWE study for these PAHs. In order for robust conclusions to be drawn on the hazard properties of HFO, the samples used should be demonstrated to represent the entire range of HFO that is transported. In CONCAWE revised report 1/15R, it has not been sufficiently demonstrated that the limited amount of samples analysed cover the entire range of HFOs transported.

Composition

RIVM remarks on report 1/15R

In tables 8 and 9 of the CONCAWE report 1/15R, the aromatic hydrocarbon concentrations of the condensate and bulk samples are given. The aromatic hydrocarbon fraction comprises only 4% of the total sample.

4. Can CONCAWE provide information on the composition of the remaining 96% of these samples?
5. Can CONCAWE give an indication of the hazard profile of this remaining 96%?
6. Can CONCAWE explain why only 4% of the composition of the sample is represented in the report?

The CONCAWE report 1/15R states in chapter 3.3.4.2 that: “The aerosol and vapour phase workplace samples were analysed for three PAHs: naphthalene, pyrene, and benzo[a]pyrene. These three PAHs provide an indication of the distribution of 2-ring, 4-ring, and 5-ring PAHs in the workplace air.” And in chapter 4.2.2 that: “These three substances were selected because they are representative of the 2-ring, 4-ring, and 5-ring aromatic hydrocarbons that can be found in HFO samples.”

7. Can CONCAWE explain how these three PAHs are representative of the 2-ring, 4-ring, and 5-ring aromatic hydrocarbons that can be found in HFO samples?

² Christopher, Y. et al. (2011). An Assessment of Dermal Exposure to Heavy Fuel Oil (HFO) in Occupational Settings. *Annals of Occupational Hygiene* 55, 319–328

Discussion and remarks on revised report 1/15R

During the discussion the RIVM suggested that other fractions than the aromatic hydrocarbon fraction might contribute to the carcinogenic potential of HFO. The experts of CONCAWE pointed out that earlier studies have implied that PAHs are the principal, if not sole, mutagens/carcinogens in mineral oils. The 21 individual PAHs presented in the CONCAWE revised report 1/15R comprise only 4% of the total sample whereas a typical HFO consists of 42,4% aromatics content (CONCAWE report 7/12). Naphthalene, pyrene, and benzo[a]pyrene were described as substances representative of the 2-ring, 4-ring, and 5-ring aromatic hydrocarbons that can be found in HFO samples. However, no calculations or estimations of the 2-, 4-, and 5-ring aromatic hydrocarbon distribution based on the naphthalene, pyrene, and benzo[a]pyrene concentrations have been presented in the revised report. Furthermore, the remaining 58% of the HFO samples remains unidentified as well. Information on the carbon number distribution and the quantitative information on the classes of aromatic hydrocarbons would have given a better insight into the composition of the HFOs studied in the CONCAWE revised report 1/15R. Methods to better specify the carbon number distribution and the quantitative information on the classes of aromatic hydrocarbons are available and recommended by CONCAWE (CONCAWE report 7/12).

Hazard profileRIVM remarks on report 1/15R

Earlier studies conclude that Heavy Fuel Oil components have a range of health hazards. Carcinogenicity³ and reproductive toxicity⁴ are mentioned as health hazards for heavy fuel oil components in CONCAWE reports (10/11, 8/12, and 10/14)⁵. These CONCAWE reports (10/11, 8/12, and 10/14) also state that Heavy Fuel Oil components are not considered to have mutagenic properties. Furthermore, Heavy fuel Oil is also classified for Carcinogenicity (Cat 1B) under Regulation EU 1272/2008 (CLP).

The CONCAWE report 1/15R, for the part that concerns hazards, focusses on mutagenicity. For this purpose, 9 samples of heavy fuel oil condensates were tested in a modified Ames assay was used. The assay employed *Salmonella typhimurium* strain TA 98. The modified Ames test is the only test method that is used for the mutagenicity testing. In the OECD guidelines test 471 for testing of chemicals in Bacterial Reverse Mutation tests it is stated that: "At least five strains of bacteria should be used.". The WHO stated in their update of the WHO/IPCS Harmonized Scheme: "It is now clear from the results of international collaborative studies and the large databases that are currently available for the assays evaluated that no single assay can detect all genotoxic substances."⁶

8. Can CONCAWE explain why only mutagenicity is investigated in this study and not carcinogenicity and reproductive toxicity?
9. Can CONCAWE explain why the modified Ames test was selected as the only method to test for mutagenicity?

³ API (1989) Lifetime dermal carcinogenesis/chronic toxicity screening bioassay of refinery streams in C3H/HeJ mice. Study conducted by Primate Research Institute. API Health Environ. Sci. Dep. Rep. 36-31364. Washington DC: American Petroleum Institute

⁴ Hoberman, A.M. et al (1995) Developmental toxicity study of clarified slurry oil (CSO) in the rat. *Fund Applied Toxicol* 28, 38-40

⁵ (Hazard classification and labelling of petroleum substances in the European Economic Area (CONCAWE reports 10/11, 8/12, and 10/14)

⁶ Mutagenicity testing for chemical risk assessment: update of the WHO/IPCS Harmonized Scheme. David A. Eastmond, et al. *Mutagenesis*. 2009 July; 24(4): 341-349.

10. Can CONCAWE explain why a single strain of *Salmonella typhimurium* is used in the modified Ames test instead of the least five strains required by OECD guideline 471?
11. Can CONCAWE react on the quote from the WHO paper which states that no single method could be used to detect all genotoxic substances?

Discussion and remarks on revised report 1/15R

The RIVM brought up the complexity of carcinogenicity. There are several exposure routes, and multiple mechanisms which could result in carcinogenicity. Normal Ames tests only have predictive power for the exposure route against which they are verified and only for genotoxic mechanisms. CONCAWE explained that the modified Ames test has been reported to have a 96% accuracy of predicting carcinogenicity of mineral oils. This modified Ames test has been verified against *mouse skin-painting bioassays* which is a test for dermal route of exposure. The experts of CONCAWE argued that the dermal route has previously been reported to be the main route of concern for HFO². This previous study focused on settings where workers are exposed to direct dermal contact with HFO and inhaled emissions of HFO. In that setting the dermal route is the main route of concern. However, in the CONCAWE revised report 1/15R only the emissions of heavy fuel oil are investigated. Therefore, the main route of concern is the inhalation route. The RIVM acknowledges that it is not practicable for the purpose of this study to test the carcinogenicity potential for all exposure routes. However a qualitative discussion concerning route to route (dermal to inhalation) extrapolation or otherwise discussions about the inhalation route are not sufficiently mentioned in the report.

RIVM remarks on report 1/15R

The CONCAWE report 1/15R concludes that: “Overall, this analysis indicates that HFO emissions, exposures, and hazards during barge loading of commercial HFOs are not excessive or a source of environmental or human health concern.” However, only one hazard property has been investigated in one limited study and only one route of exposure has been taken into account.

12. Can CONCAWE explain how they arrived at the above mentioned conclusion without carcinogenicity data?

Discussion and remarks on revised report 1/15R

The experts of the RIVM remain of the opinion that additional data is needed to support these broad conclusions. Supportive evidence concerning the inhalation route of exposure, a main point of concern of the RIVM, is not provided. Furthermore, other human health hazards of HFO emissions than mutagenicity and carcinogenicity such as reproductive toxicity, or target organ toxicity have not been discussed in this revised report.
