ENVIRONMENTAL ASSESSMENT

1. **Date:** October 4, 2016

2. **Name of Applicant:** Akzo Nobel Industrial Chemicals, b.v.

3. **Address:** Please direct inquiries to:

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4. **Description of the proposed action**

4a. Requested action

The food-contact substance (FCS) dimethyl ether (DME; CASRN 115-10-6) is currently cleared for use as an indirect food additive in food contact notification (FCN) 1440,[1] and in European Commission Directive 2009/32/EC via amendment 2010/59/EU. The European Food Safety Authority (EFSA) has also issued a scientific opinion regarding use of DME as an extraction solvent.[2] The action requested in this notification is to establish the clearance of DME as a solvent/processing aid in the production of poultry collagen used in processed meat products where the mean residual level of the FCS in collagen is 3 ppm.

4b. Need for action

Akzo Nobel Industrial Chemicals, b.v. has developed an extraction process that uses DME as a solvent/processing aid to extract collagen from animal skins (e.g., bovine, pork, and poultry). The traditional extraction process to isolate collagen involves wasking, defatting in hot water (60-80 ^{o}C) for several hours, and drying. This process is relatively slow, requires heat for defatting, and is ineffective at defatting skins with high fat content.

DME, a gas under environmental conditions, can be liquefied under pressure at ambient temperature, and liquefied DME has been found to efficiently remove fat and water from animal skins in a closed-loop process. An overview of the AkzoNobel extraction process is provided in Figure 1.

[1] Akzo Nobel Industrial Chemicals, b.v. FCN 1440, made effective Oct. 25, 2014, cleared DME for use as a solvent/processing aid in the production of pork collagen used in processed meat products with a maximum residual amount of the FCS in collagen of 3 ppm.

[2] EFSA, Scientific Opinion on the safety of use of dimethyl ether as an extraction solvent under the intended conditions of use and the proposed maximum residual limits. EFSA Panel of Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). EFSA Journal 2015:13(7):4174.
https://www.efsa.europa.eu/en/efsajournal/pub/4174

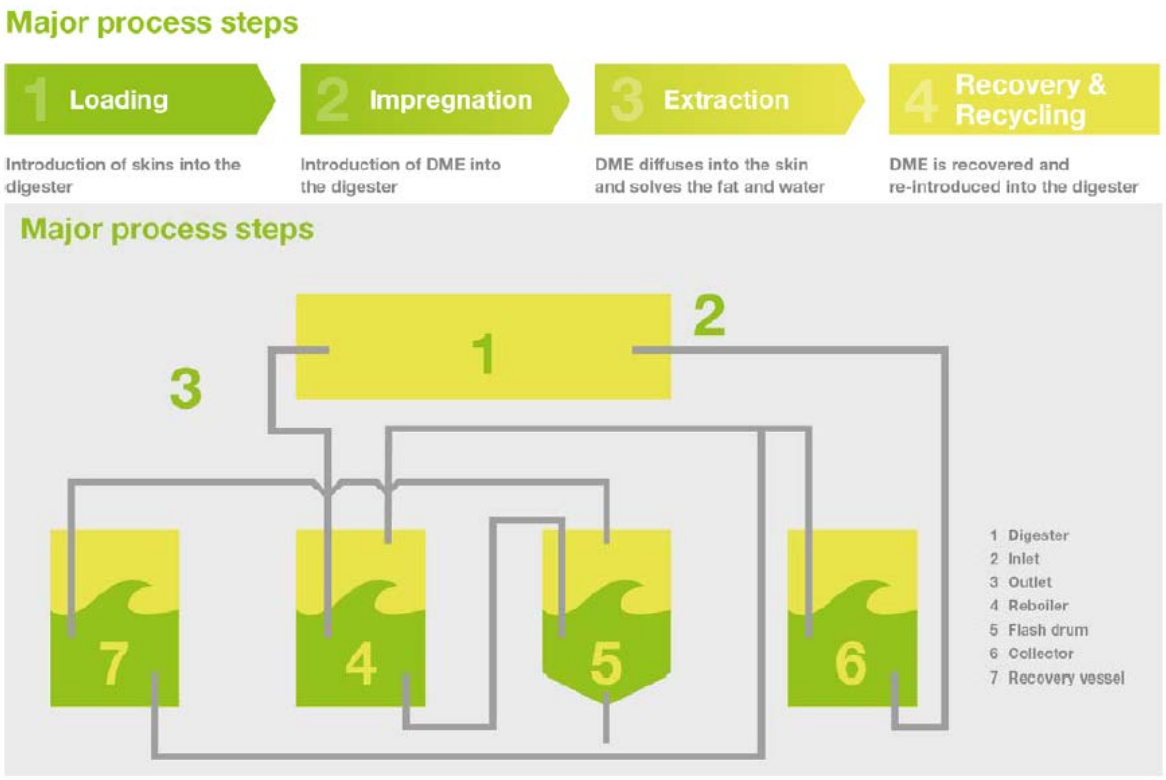


Figure 1. Overview of the AkzoNobel extraction process: 1) animal skins are loaded in the digester; 2) DME enters the digester via the inlet; 3) DME, fat, and water exit the digester via the outlet; 4) DME is recovered and sent to the collector (item 6), fat and water are physically separated and sent to the flush drain (item 5); 5) fat and water are removed from the system via the flush drain; 6) DME is collected and re-introduced into the digester (item 1); 7) DME is recovered and sent to the collector (item 6).

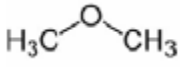
Compared to the traditional process, extraction with liquefied DME enables processing of high-fat content skins, requires less time, uses less heat energy, and generates less waste water. Importantly, DME is recycled at a rate of greater than 99.9% in the closed-loop process.

4c. Locations of use/disposal

DME will be manufactured and used at processing facilities in Europe and sites outside of te United States. DME is recycled at the processing site at a rate of greater than 99.9% and will enter the environment as a trace contaminant in collagen at a level of 3 ppm.

5. Identification of substances that are the subject of the proposed action

Complete nomenclature: Dimethyl ether; methae, 1,1'-oxybis-; methoxymethane
CAS registration number: 115-10-6
Molecular weight: 46.0684 g/mol
Molecular formula: C_2H_6O or CH_3OCH_3

Structural (graphic) formula: 

Physical description: Colorless gas

6. Introduction of the substance into the environment

6a. Introduction of substances into the environment as a result of manufacture

DME is manufactured in Europe and sites outside of the United States. Should there be any environmental impacts from manufacture, these will be under the jurisdiction of a foreign nation and are not occurring in the global commons. Therefore, and evaluation of the impacts from manufacture is outside the scope of this environmental assessment (EA), and information on manufacturing sites and compliance is not provided.

6b. Introduction of substances into the environment as a result of use/disposal

Processing facilities using DME as solvent/processing aid will be located in Europe and sites outside of the United States. Should there be any environmental impacts from processing, these will be under the jurisdiction of a foreign nation and are not occurring in the global commons. Therefore, and evaluation of the impacts form processing is outside the scope of the EA, and information on processing sites and compliance is not provided.

7. Fate of substances released into the environment

7a. Physical/chemical properties

DME has the following physical and chemical properties[3]

- Boiling point: -24 ^{o}C
- Melting point: -138.5 ^{o}C
- Water solubility: 35,300 mg/L at 25 ^{o}C
- Vapor pressure: 4450 mm Hg at 25 ^{o}C
- Henry's Law constant: 9.78 x 10^{-4} atm m^3/mol
- Octanol/water partition coefficient: low Kow = 0.10

7b. Environmental depletion mechanisms

DME released from processed collagen imported into the United States is expected to enter the environment as a gas at an EIC of 3 ppm; potential release to water, soil, and workplace environmental compartments are not addressed here since manufacture and processing operation take place in Europe and sites outside of the United States.

DME is a gas under all environmental conditions. The water solubility of gases is typically measured in closed systems under pressure to achieve saturation, and while DME dissolves in water under these conditions, this is not representative of the behavior of gases in the environment. Similarly, the partition coefficient suggests that DME will partition into soil or water, but the high vapor pressure will cause DME to be redistributed to air. Biodegradation and hydrolysis are not relevant decomposition processes since any DME released to water will rapidly redistribute to air.

Gaseous DME has a short atmospheric lifetime[4] of 5.1 days,[3] and, in the unlikely event of a release, is not expected to persist in the environment. Further, DME is not a greenhouse gas

[3] D.A. Good et.al. "Lifetimes and global warming potentials for dimethyl ether and for fluorinated ethers," Journal of Geophysical Research Bol. 103, No. D21, pp. 28, 181-28, 186; November 20, 1998. http://onlinelibrary.wiley.com/doi/10.1029/98JD01880/pdf

as defined under Section 19(i) of Executive Order 13514, and has a low global warming potential because of its short lifetime, virtual lack of ultraviolet (UV) absorptions, and relativiely low radiative forcing.[3]

Since and DME released to the environment will distribute to air, where it will rapidly decompose, we submit that the use of DME will not present an unreasonable risk to human health or the environment.

8. Environmental Effects of Released Substances

Because of the expected low level of release of DME (EIC of 3 ppm), and the expected short lifetime of DME in the atmosphere, [3] no adverse effects on human health and the environment are expected.

9. Use of Resources and Energy

Compared to the traditional process, extraction with liquefied DME enables processing of high-fat content skins, requires less time, uses less heat energy, and generates less waste water. DME is recycled at a rate of greater than 99.9% in the closed-loop process, and it is expected that use of resources and energy is reduced or comparable with the traditional process.

10. Mitigation Measures

Based on the assessment above, no adverse effects on human health or the environment are expected at the low level DME would be released for the proposed use. Other than the FCN use level restriction of 3 ppm DME in collagen, no other mitigation measures are proposed.

11. Alternatives to the Proposed Action

No potential adverse environmental effects have been identified for the proposed action. Not clearing the proposed action (no-action) would result in the continued use of traditional processes for the production of collagen that: (1) use chemicals more harmful than DME; (2) use large volumes of process water; (3) generate waste water; and (4) have high energy use.

12. List of Preparers:

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[4] 'Lifetime' is defined as the ratio of a molecule's 'atmospheric burden to that of its combined loss mechanisms and is the time it takes for a substance to decrease by (1/*e*) 36.8% of its original concentration [e.g., *WMO*, 1995; *Wuebbles*, 1995]."

13. Certification:

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of their knowledge.

04 October 2016

Ronald Smeink
Technical Manager
Akzo Nobel Industrial Chemicals, b.v.

Date

14. References: Citations for all materials referenced in the EA are provided in footnotes.

15. Attachments: None