

20 November 2020

## **Proposal on the evaluation of the hazard of Carbon Nanotubes**

JBCE believes that the protection of human health and environment is successfully achieved by EU REACH Regulation (EC) No 1907/2006 by assessing exposure and risk derived from the uses profoundly and setting appropriate measures for protection from chemical substances, which have been shown to be hazardous. As a cross-sector association with member companies operating in different industries and stages in the supply chain, JBCE would like to express our position on the evaluation of the hazard of Carbon Nanotubes.

### **(1) Executive Summary**

The purpose of this position paper is to give our perspective on the evaluation of the hazard of Carbon Nanotubes (CNTs), taking into account the huge variety of CNTs currently available on the market. CNTs should not be viewed as one single substance but rather be considered to consist of different substances with varying properties. Only those substances which exhibit toxic behaviour should be viewed as possible Substances of Very High Concern (SVHC).

### **(2) Background**

It has been suggested that all CNTs ought to be identified as SVHCs. The authors of the suggestion are likely unaware of the diverse properties of the various types of CNTs and believe it is appropriate to address them by a grouping approach. That is not appropriate. The suggestion is based on a very narrow subset of scientific data which does not accurately reflect the diversity nor different compositions of CNTs. For example, in 2019, the International Agency for Research on Cancer (IARC) Working Group recommended<sup>i</sup> the re-evaluation of multiwalled carbon nanotubes (MWCNTs) as a high priority due to the availability of new bioassays and mechanistic evidence. On the other hand, based on the body of recent evidence, single walled carbon nanotubes (SWCNTs) have not been recommended for re-evaluation.

### **(3) The Scientific Evidence**

As regards *carcinogenicity*, five years ago the IARC classified a particular type of long and rigid CNT, designated as MWCNT-7, as possibly carcinogenic to humans on the basis of available animal studies, whereas all other CNTs were considered 'not classifiable' with regard to their carcinogenicity<sup>ii</sup>. The findings of the original evaluation on the inadequate or limited evidence of carcinogenicity for most CNTs were confirmed in a thorough follow-up study a few years later<sup>iii</sup> SWCNTs have not been classified carcinogenic based on IARC reports. All SWCNTs and MWCNTs other than MWCNT-7 are listed by the IARC in group 3 as materials not classifiable as to its carcinogenicity to humans.

As regards **reproductive toxicity** a dossier prepared by the OECD<sup>iv</sup> on the reproductive toxicity of SWCNT in mice found<sup>v</sup> no deaths, clinically relevant disorders or evident behavioural changes were observed in all dams. Histological and immune histochemical analysis of maternal tissues revealed no toxicological effects on the liver, lung, kidney and spleen.

As regards **mutagenicity**, the widely used test using bacteria has been classified as "not appropriate" in the Annex of (EU) 2018/1881 amending Regulation (EC) No 1907/2006 at clause 3 (e)<sup>vi</sup>. The CNT industry has started new mutagenicity testing in accordance with the amended regulation. There has been no evidence reporting strong mutagenicity of SWCNTs.

As regards **bioaccumulation**, no bioaccumulation of SWCNTs was observed in the OECD sponsorship programme<sup>v</sup>.

#### **(4) Conclusion**

As summarized in this position paper, there is plenty of evidence showing that CNTs should not be viewed as "one substance", but should address nano-sized substances on a substance by substance basis taking into account varying properties that may elicit distinct biological outcomes *in vitro* and *in vivo*. The JBCE therefore calls for a more balanced debate going forward concerning the use of CNTs. This debate should more accurately reflect the different characteristics of specific CNTs and should be based on the latest scientific evidence on their specific toxicities.

## **ABOUT JBCE**

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organisation representing the interests of over 89 multinational companies of Japanese parentage active in Europe.

Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, textiles and glass products.

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<sup>i</sup> [https://monographs.iarc.fr/wp-content/uploads/2019/10/IARCMonographs-AGReport-Priorities\\_2020-2024.pdf](https://monographs.iarc.fr/wp-content/uploads/2019/10/IARCMonographs-AGReport-Priorities_2020-2024.pdf)

<sup>ii</sup> <https://nanopartikel.info/en/projects/current-projects/metalsafety-en/publications-metalsafety/8-news-en/1838-iarc-evaluate-the-carcinogenicity-of-carbon-nanotubes>

<sup>iii</sup> [https://monographs.iarc.fr/wp-content/uploads/2019/10/IARCMonographs-AGReport-Priorities\\_2020-2024.pdf](https://monographs.iarc.fr/wp-content/uploads/2019/10/IARCMonographs-AGReport-Priorities_2020-2024.pdf)

<sup>iv</sup> [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2016\)22&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)22&doclanguage=en)

<sup>v</sup> "Pregnant CD-1 mice were intravenously injected with SWCNT, oxidized-SWCNT and ultra oxidized-SWCNT at 0 - 30 µg/animal on day 5.5 of gestation (Pietroiusti et al.67, 2011).

<sup>vi</sup> <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32018R1881>