

NBCI Position Statement on REACH Regulation of Carbon Nanotubes
Translation of Official Document: Position Paper on BAuA's REACH
Restriction Proposal for Substances in Fiber Form
Nanotechnology Business Creation Initiative of Japan (NBCI)

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1. Introduction

The Nanotechnology Business Creation Initiative of Japan (NBCI) strongly proposes that continued and detailed scientific discussion be conducted regarding the "uniform grouping based on WHO fiber criteria" proposed in the RMOA (REACH restriction proposal) for Substances in Fiber Form led by the German Federal Institute for Occupational Safety and Health (BAuA).

Imposing uniform use restrictions on carbon nanotubes (CNTs) based solely on shape and size lacks scientific evidence and would significantly impede benefits to European citizens and the global community.

2. Executive Summary

This position paper presents concerns regarding uniform regulation of CNTs from two perspectives:

2.1 Safety Perspective

- CNTs exhibit significant physicochemical diversity; current scientific evidence suggests that regulation based solely on shape and size may not adequately capture this variability"
- CNTs are degradable, presenting low risk of long-term environmental persistence
- With appropriate control measures, exposure risk can be limited as with other chemical substances

2.2 Industrial Importance

- More than 5,000 tons used globally per year, predicted to exceed 10,000 tons within several years
- Restricting CNT use would impede not only European but global competitiveness and carbon neutrality achievement. CNTs are indispensable across broad industries including lithium-ion batteries, semiconductors, automotive, aerospace, and renewable energy
- Upgrade from ISO TR to TS in progress (international recognition of industrial importance)

3. NBCI Position

NBCI requests further scientific discussion regarding the appropriateness of uniform grouping of CNTs as WHO fibers, given the significant physicochemical variation within this material class, the "WHO fiber grouping in BAuA's RMOA (REACH restriction proposal) for Substances in Fiber Form." NBCI proposes continued detailed discussion based on scientific evidence.

The following explains from safety and industrial importance perspectives.

4. Scientific Evidence Regarding Safety

Safety evaluation of CNTs requires a multifaceted approach considering factors beyond shape and size.

4.1 CNTs are physicochemically highly variable materials; uniform regulation by shape or size lacks scientific evidence

The proposed "critical fiber" definition is based primarily on shape (fibrous) and size (diameter/length). However, biological effects of CNTs vary significantly depending not only on shape and size, but also on manufacturing method, surface treatment, aggregation state, and chemical purity.

Regarding scientific basis, most international safety assessments target specific multi-walled CNTs (MWNT-7). In WHO-IARC evaluation, not all CNTs but specific types are classified as Group 2B (possibly carcinogenic to humans) (Reference Material 1).

Evaluation should be based on physicochemical characteristics and toxicity data of individual CNTs, rather than uniform regulation by shape and size.

4.2 CNTs have demonstrated degradability under specific conditions, which may reduce the risk of long-term environmental persistence when appropriate treatment technologies are applied

Multiple studies demonstrate that CNTs can be degraded under controlled laboratory conditions, including (Reference Material 1):

- Chemical degradation: Degradation by sodium hypochlorite solution (concentration and temperature dependent)
- Biological degradation: Degradation via reactive oxygen species (ROS) by macrophages
- Long-term continuous degradation by soil bacteria
- Photochemical degradation: Degradation by photo-Fenton reaction
- In vivo confirmation: Clearance from lungs confirmed in animal experiments

Additionally, ISO/TC 229 (Nanotechnologies Technical Committee) is advancing international standardization (ISO AWI TS 21497) of CNT degradation methods using hypochlorite (Reference Material 1).

This standardization may enable CNT removal from industrial wastewater and laboratory wastewater.

CNTs do not correspond to "materials that persist long-term in the environment and are difficult to dispose of," and environmental risk may be manageable through appropriate treatment technology.

4.3 With appropriate control measures, exposure risk can be limited as with other chemical substances

Similar to other nanomaterials and chemical substances, exposure risk from CNTs may be managed through appropriate control measures tailored to their specific characteristics.

Examples include domestic guidelines such as Ministry of Health, Labour and Welfare guidelines and Ministry of the Environment guidelines in Japan, as well as ISO standards (Reference Material 1).

These guidelines include the following content:

- Knowledge regarding health and safety in work environments
- Management principles and guidance for reducing worker health and safety risks
- Measures to prevent contamination from handling workplaces to external areas

By complying with these, exposure risk can be limited through management of actual use environments, as with other chemical substances.

5. Industrial Importance

CNTs are already widely used globally, and their restriction would have significant impact on European and global economies.

5.1 Global Usage Record

CNTs are indispensable materials as additives that maintain and improve charge-discharge performance of lithium-ion batteries, with more than 5,000 tons already used globally per year (as reported in industry analyses). Market forecasts predict usage will exceed 10,000 tons within several years (Reference Material 2).

5.2 Essential Nature Across Broad Industrial Sectors

CNT use restrictions could have significant implications for the following industrial sectors (Reference Material 2):

Major industrial sectors:

- Automotive industry: High-strength, high-durability composite materials; high-performance batteries
 - Aerospace industry: High-strength, high-durability composite materials; aircraft batteries
 - Semiconductor industry: EUV exposure pellicles and other semiconductor manufacturing processes
 - Renewable energy industry: Solar cells, wind power generation, and energy storage facilities
 - Sports industry: Bicycle and tennis racket frames
 - Medical field: Drug delivery systems (DDS), biosensors, regenerative medicine
- CNTs are particularly widely used in electronic devices such as smartphones and laptop computers, automotive and aircraft batteries, and renewable energy storage facilities.

CNT use contributes to carbon neutrality achievement through:

- Fuel efficiency improvement through weight reduction of automobiles and aircraft
- Promotion of electrification through lithium-ion battery performance improvement
- Energy storage efficiency improvement for renewable energy

Restricting CNT use may affect efforts to reduce fossil fuel consumption and CO₂ emissions in sectors where CNTs contribute to energy efficiency improvements.

Furthermore, CNT use restrictions raise the following concerns:

- Loss of competitive advantage in CNT application products and industries that European companies have developed and adopted
- Decline in European international leadership in green technology and digital technology, and decline in European industrial competitiveness

As described above, there is potential to impede sustainable development of society, including industries worldwide and carbon neutrality.

5.3 International Standardization Trends

In response to CNTs being used in diverse applications worldwide, ISO is moving to upgrade standards for multi-walled CNTs (MWCNTs) from conventional TR (Technical Report) to TS (Technical Specification).

This reflects ISO's recognition of CNTs as materials of significant industrial

relevance that warrant standardized management approaches."

6. Specific Proposals from NBCI

NBCI respectfully requests that BAuA and the European Commission consider risk-based individual evaluation of CNTs based on their specific physicochemical characteristics, rather than uniform grouping based solely on shape and size as WHO fibers.

CNTs are materials with extremely rich variation, and sufficient detailed discussion has not been conducted regarding whether uniform grouping as WHO fibers is appropriate. NBCI proposes to continue conducting detailed discussion based on evidence together.

To this end, NBCI is prepared to consider providing the following cooperation toward construction of a more scientific and rational regulatory framework considering utility:

- Provision of additional safety data and usage status data
- Proposal and consultation on joint research projects
- Active contribution to international standardization activities
- Promotion of dialogue with European industry

7. Conclusion

NBCI reemphasizes that CNTs are innovative materials indispensable to the development of major industries worldwide, including Europe.

At present, it cannot be said that sufficient scientific discussion regarding uniform regulation of CNTs has been exhausted.

Uniform use restrictions based solely on shape and size not only lack scientific basis, but impede technological innovation in European and global industries, making sustainable development of industry and society difficult.

NBCI aims not simply to oppose regulation, but to construct a more rational and scientific regulatory framework together with stakeholders. We believe that through dialogue based on scientific evidence, mutually acceptable solutions may be found that balance ensuring safety with sustainable economic growth and innovation.

As an industry association, NBCI will contribute to realization of a sustainable society through promotion of safe use of CNTs and appropriate management technology.

8. References

[Reference Material 1] Scientific basis regarding CNT degradability, ISO-related

1.WHO-IARC: Carcinogenicity assessment of CNTs (specific types of CNTs classified in Group 2B, not all CNTs)

https://www.jstage.jst.go.jp/article/jjh/71/3/71_252/_pdf

2.IARC Monographs on the Evaluation of Carcinogenic Risks to Humans

<https://publications.iarc.who.int/552>

3.Clarification of temperature and concentration dependence of CNT degradation by sodium hypochlorite

Yang, M., Okazaki, T., Zhang, M. (2021). "Removal of Carbon Nanotubes from Aqueous Solutions by Sodium Hypochlorite: Effects of Treatment Conditions." Toxics, 9: 223.

4.Simple CNT removal method from industrial wastewater and laboratory wastewater

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5.CNT degradation via reactive oxygen species by macrophages

Yang, M., Zhang, M., Nakajima, H., Yudasaka, M., Iijima, S., Okazaki, T. (2019). "Time-dependent degradation of carbon nanotubes correlates with decreased reactive oxygen species generation in macrophages." International Journal of Nanomedicine, 14: 2797-2807.

6.CNT degradation by Fenton reaction with iron derived from soil bacteria and hydrogen peroxide

Takanashi, S., Taguchi, F., Hori, K. (2023). "Contribution of the Fenton reaction to the degradation of carbon nanotubes by enzymes." Frontiers in Environmental Science, 11: 1184257.

7.CNT degradation by long-term continuous Fenton reaction driven by soil bacteria

Takanashi, S., Hori, K. (2023). "Long-term continuous degradation of carbon nanotubes by a bacteria-driven Fenton reaction." *Frontiers in Microbiology*, 14: 1298323.

8. Confirmation of CNT clearance from lungs in in vivo tests

Zhang, M., Xu, Y., Yang, M., Yudasaka, M., Okazaki, T. (2021). "Comparative assessments of the biodistribution and toxicity of oxidized single-walled carbon nanotubes dispersed with two different reagents after intravenous injection." *Nanotoxicology*, 15: 798-811.

9. ISO/TC 229 Nanotechnologies: ISO AWI TS 21497 "Method for the removal of carbon nanomaterials from wastewater using hypochlorite" (International standardization of CNT degradation method using hypochlorite in progress)

10. Ministry of Health, Labour and Welfare Guidelines

Notification No. 0331013 (March 31, 2009) "Preventive Measures for Exposure Prevention to Nanomaterials"

11. Ministry of the Environment

"Environmental Impact Prevention Guidelines for Industrial Nanomaterials" (March 2009)

12. ISO/TR12885 Nanotechnologies - Health and safety practices in occupational settings relevant to nanotechnologies (December 2018)

13. ISO/TS12901-1 Nanotechnologies - Occupational risk management applied to engineered nanomaterials - Part1: Principles and approaches. (November 2012)

14. ISO/TS12901-2 Nanotechnologies - Occupational risk management applied to engineered nanomaterials - Part2: The use of the Control Banding approach in occupational risk management. (January 2014)

[Reference Material 2] CNT industrial application examples

1. Yano Research Institute Ltd., Carbon Nanotube Market: Current Status and Future Outlook (2023 Edition), CNT global market to exceed 50,000 tons in 2028

for automotive LiB applications

https://www.yano.co.jp/press-release/show/press_id/3446

2. Resonac (formerly Showa Denko): Decision to increase production of conductive additives for LIB centered on European automotive manufacturers

<https://www.resonac.com/jp/news/2022/12/21/2266.html>

3. Toyo Color Co., Ltd.: CNT dispersion for LiB adopted by Prime Earth EV Energy, installed in Toyota hybrid vehicles

<https://www.artiencegroup.com/ja/news/2024/24020601.html>

4. Artience: High market share in CNT dispersion liquid for LIB

<https://www.artiencegroup.com/ja/news/2023/pdf/document20230821.pdf>

5. Chinese automotive battery major CATL adopts new material developed by Toyo Color

<https://36kr.jp/223140/>

6. Takenaka Manufacturing: Nanotect® used for pressure vessels and rust-prevention coating

<https://www.takenaka-mfg.co.jp/bolt/nanotect/>

7. Nitta Corporation: CNT composite technology Namd™ acquires aerospace quality management AS9100 certification

<https://prtmes.jp/main/html/rd/p/000000008.000167096.html>

8. Yonex Co., Ltd.: CNT used in carbon frame bikes

<https://www.yonex.co.jp/company/pr/pdf/231214.pdf>

https://www.yonex.co.jp/roadbike/frame_set/carbonex/

9. Mitsui Chemicals: Installation of production equipment for next-generation EUV exposure CNT pellicles at factory

https://jp.mitsuichemicals.com/jp/release/2024/2024_0528_1/index.htm

10. Mitsui Chemicals: Conclusion of license agreement for EUV pellicle business with ASML

<https://jp.mitsuichemicals.com/content/dam/mitsuichemicals/sites/mci/documents/sites/default/files/media/document/2019/190531.pdf>

11.Imec: CNT pellicle explanatory material

<https://euvlitho.com/2023/P15.pdf>

12.Canatu CNT pellicle

<https://canatu.com/products/semiconductor/euv-pellicles/>

13.Review regarding application to DDS for cancer treatment

"Biomedical applications of carbon nanotubes: A systematic review of data and clinical trials"

<https://www.sciencedirect.com/science/article/pii/S1773224724006014>