NBCI　Feedback on Chemicals – new rules on carcinogenic, mutagenic or reproductive toxic substances subject to restrictions

Nanotechnology Business Creation Initiative (NBCI)

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1. Executive Summary

The Nanotechnology Business Creation Initiative (NBCI) has submitted comments since August 2021 regarding the harmonised classification and labelling (CLH) discussions related to multi-walled carbon nanotubes (MWCNT) defined under Index No. 006-104-00-2. With respect to the current proposal described as “new rules on carcinogenic, mutagenic or reproductive toxic substances subject to restrictions,” we would like to suggest a reconsideration and clarification regarding the scope.

As innovative materials, CNTs are expected to contribute to supporting carbon-neutral goals in Europe and globally, including improving lithium-ion battery performance and contributing to vehicle lightweighting. In addition, regulation imposed in a situation where practically applicable measurement and determination methods are not sufficiently established may affect the pace of technological innovation toward realizing a sustainable society and create socio-economic implications that require careful assessment. The effectiveness of the regulation remains contingent upon the precision of the final scope and the practicality of its implementation. Since this proposal presents practical implementation challenges, such as ambiguity in substance identification and measurement difficulties, further deliberation and clarification of its scope are essential. This will help ensure regulatory certainty and the practicability of the proposed rules, based on the scientific evidence and considerations detailed below.

2. Conclusion of Comments

While we have previously raised concerns in relation to the CLH discussions on MWCNT, with respect to the present proposal, to ensure the proposed scope is fully aligned with the latest scientific evidence, we would like to propose a further review—including potential revisions or clarifications—focusing on the following perspectives.

Industrial importance:

MWCNT is widely used and is considered important in key industries supporting social infrastructure, including energy storage (e.g., lithium-ion batteries), mobility, semiconductors, and certain medical applications.

Ambiguity in substance identification:

The definition depends on size and shape; the size is at the nano level. Although there is a guideline, OECD TG125, it requires extremely labor-intensive measurements, and realistic methods have not been established to determine and measure trace inclusion at or above the 0.1 wt% threshold, which is used as the cut-off value for mixture classification under the CLP Regulation. This could raise concerns regarding enforceability and practicability, depending on how workable identification/measurement methods and clear implementation guidance are established.

In addition to the shape-based considerations under the CLP framework, we recommend a more comprehensive approach that incorporates substance-specific toxicity, risk assessment in actual use environments, and the application of scientifically sound, practicable measurement methods.

3. Details

3-1. Industrial indispensability and usefulness of carbon nanotubes (CNT), including MWCNT

CNTs are already used across a wide range of industries, and their socio-economic impact is extremely significant.

Contribution to carbon neutrality:

As a conductive additive for lithium-ion batteries, CNTs play a key role in improving charge/discharge performance and durability. In addition, their use as resin composite materials directly leads to improved fuel efficiency and reduced CO_2 emissions through weight reduction in automobiles and aircraft.

Foundation for next-generation technologies:

Adoption is progressing in cutting-edge fields such as pellicles for EUV lithography in the semiconductor industry, and biosensors and drug delivery systems (DDS) in the medical field.

Expanding market: According to Yano Research Institute (2023), global CNT production was approximately 5,000 tonnes/year in 2021, and is projected to exceed 20,000 tonnes by 2025 and 50,000 tonnes by 2028 (estimates; assumptions may vary). In particular, for conductive materials for LiB cathodes, MWCNT will increase to a 42% share on a weight basis by 2028.

3-2. Ambiguity in substance identification

Index No. 006-104-00-2 in this proposal may be difficult to align with company compliance and inventory management practices that are commonly organised by EC/EC-number identifiers, depending on the final legal text and guidance.

Confusion due to a shape-based definition: Because it is defined not by chemical composition (carbon/graphite) but only by “diameter, length, and aspect ratio,” it is not linked to a specific single EC number, and the criteria for companies to determine whether their own products are covered are ambiguous.

3-3. Difficulty of measurement and practical issues

The application of current measurement technologies may present practical difficulties in meeting all the requirements of the criteria.

Technical and cost barriers: Determining applicability requires statistical measurements using electron microscopy (TEM/SEM). However, since nanomaterials inevitably have distributions, demonstrating compliance could present significant practical challenges if the criteria are interpreted as requiring exhaustive evidence for the vast majority of fibres or tubes that fall outside the specified size range.

Unrealistic measurement methods: If conformity determinations are made within the supply chain based on thresholds such as 0.1 wt%, used as a cut-off value, practically applicable analytical/measurement methods and sampling designs are essential. However, at present, Standard procedures for the identification and quantification of the target substance may require further refinement to be considered sufficiently in place.

For example, depending on the analytical approach and sampling design, demonstrating whether a target MWCNT is present at a 0.1 wt% threshold may require extensive microscopy-based measurements and statistically robust sampling, which could be time- and cost-intensive. Moreover, for mixtures, isolation and purification operations are also added; through these operations, there are changes in the target substance and losses during handling, which further makes measurement difficult and causes the results to deviate from reality. In this way, even if cost and effort are expended, There may be room for further refinement of the criterion, as the current methods might not fully align with actual conditions.

In a framework separate from this CLH, NBCI believes that the establishment of realistic and clear criteria and guidance would be highly beneficial; for discussion purposes, one possible approach could be to consider criteria based on distributions (e.g., a specified proportion of fibres within the size range), subject to scientific validation and regulatory feasibility.

3-4. Necessity of individual evaluation based on scientific evidence

Validity of grouping: Given differences between regulatory hazard classification schemes (e.g., CLP categories) and IARC evaluations, NBCI is concerned that applying a uniform classification to all MWCNT types may not adequately reflect substance-specific evidence. IARC has evaluated certain CNT types (e.g., MWNT-7) differently from others; therefore, We suggest considering a substance-specific, evidence-based approach.

Diversity of physicochemical properties: Toxicity differs greatly depending on manufacturing method and aggregation state. For example, entangled “furball” structures behave entirely differently from rigid fibers like asbestos.

Based on current scientific evidence, NBCI proposes prioritizing MWNT-7 within the scope of this regulation, for which there are scientific data on carcinogenicity, and evaluation should be conducted based on the physicochemical properties and toxicity data of each individual MWCNT.

4. References

[Reference Material 1] CNT safety, measurement, ISO-related

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• Comments on the MWC(N)T CLH report (July 8, 2022)
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[Reference Material 2] Examples of industrial applications of CNT

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