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EXPLORING THE APPLICATION OF OCCUPATIONAL SAFETY AND HEALTH LEGISLATION TO GRAPHENE AS A NANO MATERIAL IN THE MEDICAL SECTOR

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ABSTRACT

Graphene, renowned for its exceptional thinness and strength, has sparked widespread interest due to its potential applications in medical technology, including drug delivery systems, biosensors, and advanced medical devices. This study aims to critically evaluate the rules and regulations surrounding the use of graphene in Malaysia's medical sector, focusing on the Occupational Safety and Health (Use and Standard of Exposure to Hazardous Chemicals (USECHH)) Regulations 2000. Additionally, it examines the Occupational Safety and Health Act (OSHA) 1994 and its 2022 amendments regarding worker exposure to graphene. However, the novel properties raise complex regulatory concerns. The current regulatory environment lacks clarity on how graphene should be handled in the workplace, posing a challenge to ensuring worker safety. To address this, the research explores both formal legal regulations ('hard law') and informal guidelines ('soft law') - including the nanomaterials guideline - that aim to mitigate the risks associated with graphene exposure. Using a doctrinal and qualitative methodology, this study conducts an in-depth legal analysis of existing laws and guidelines. The findings reveal critical gaps in the regulatory framework, particularly in terms of occupational safety standards for graphene. The study underscores the urgent need for updated, more

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stringent policies to safeguard workers, thereby contributing to the broader discourse on occupational health and safety in emerging technologies.

Keywords: Graphene, Malaysia, Nanotechnology, Occupational Safety and Health (OSH) Regulation, Risk Assessment.

MENEROKA APLIKASI PERUNDANGAN KESELAMATAN DAN KESIHATAN PEKERJAAN TERHADAP GRAFENA DALAM SEKTOR PERUBATAN

ABSTRAK

Grafena, yang terkenal dengan ketipisan dan kekuatannya yang luar biasa, telah menarik minat yang meluas kerana potensi aplikasinya dalam teknologi perubatan, termasuk sistem penghantaran ubat, biosensor, dan peranti perubatan canggih. Kajian ini bertujuan untuk menilai secara kritis peraturan dan undang-undang yang mengelilingi penggunaan grafena dalam sektor perubatan di Malaysia, dengan tumpuan khusus kepada Peraturan Keselamatan dan Kesihatan Pekerjaan (Penggunaan dan Standard Pendedahan kepada Bahan Kimia Berbahaya (USECHH) 2000. Di samping itu, kajian ini meneliti Akta Keselamatan dan Kesihatan Pekerjaan (OSHA) 1994 dan pindaan 2022 mengenai pendedahan pekerja kepada grafena. Namun, sifat baharu ini menimbulkan kebimbangan kawal selia yang kompleks. Persekitaran peraturan semasa kurang jelas tentang cara ‘grafena’ harus dikendalikan di tempat kerja, yang menimbulkan cabaran untuk memastikan keselamatan pekerja. Untuk menangani isu ini, kajian ini meneroka kedua-dua peraturan undang-undang formal ('hard law') dan garis panduan tidak formal ('soft law') - termasuk garis panduan bahan nano - yang bertujuan untuk mengurangkan risiko yang berkaitan dengan pendedahan kepada ‘grafena’. Menggunakan metodologi doktrinal dan kualitatif, kajian ini menjalankan analisis undang-undang mendalam terhadap undang-undang dan garis panduan yang sedia ada. Hasil kajian menunjukkan jurang kritikal dalam rangka kerja peraturan, terutamanya dari segi standard keselamatan pekerjaan untuk ‘grafena’. Kajian ini menekankan keperluan mendesak untuk dasar yang dikemas kini dan lebih ketat bagi melindungi pekerja, sekali gus menyumbang kepada wacana yang lebih luas mengenai keselamatan dan kesihatan pekerjaan dalam teknologi yang sedang berkembang.

Kata Kunci: Grafena, Malaysia, Teknolojinano, Peraturan Keselamatan dan Kesihatan Pekerjaan, Pentaksiran Risik.

INTRODUCTION

Graphene is a revolutionary nanomaterial with the potential to transform various industries, especially in the medical sector. Its versatility makes it valuable for applications such as drug delivery systems, biosensors, and advanced medical devices.[1] However, the very properties that make graphene so promising also present unique challenges, particularly concerning the occupational health and safety (OHS) of workers who handle this material.[2]

In Malaysia, incorporating graphene into the medical sector requires a careful review of existing OHS policies. As the country advances in medical innovation, it is crucial to ensure that the regulatory framework keeps pace with the potential risks associated with graphene.[3]

This paper examines the current state of Malaysia's OSH policies and regulations, focusing on the challenges posed by graphene and the measures needed to protect workers while encouraging responsible development. Currently, Malaysia's OSH regulations lack specific guidelines for graphene, especially in the medical sector, creating a regulatory gap that makes safeguarding workers a challenge.

The term 'graphene' was initially referred to as a 'graphite layer' by the International Union of Pure and Applied Chemistry (IUPAC).[4] It was later redefined as 'graphene' by IUPAC. Graphene is considered a chemical substance. Its unique properties arise from its chemical structure, making it relevant to chemistry, materials science, and nanotechnology. Graphene is a material derived from graphite and

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[1] Jiawen Song Qu et al., (2025). Graphene-based wearable biosensors for point-of-care diagnostics: From surface functionalization to biomarker detection, *Materials Today Bio*, 32: 101667. https://doi.org/10.1016/j.mtbio.2025.101667.

[2] Ji Hyun Lee et al. et al. "Exposure Monitoring of Graphene Nanoplatelets Manufacturing Workplaces." *Inhalation Toxicology* 28 (6) (2016): 281–91. doi:10.3109/08958378.2016.1163442.

[3] Maryam Etemadi, and Akbariah Mohd Mahdzir. "Nanotechnology in Malaysia: A qualitative study about the current occupational health and safety issues", *Psychology and Education* 58(1) (2021): 4727-4740.

[4] Madhuri Sharon and Maheshwar Sharon. *Graphene: An Introduction to the Fundamentals and Industrial Applications*. (John Wiley & Sons, 2015).

composed entirely of carbon.[5] Exposure level has consistently been a primary concern in occupational safety and health for workers. Exposure levels to graphene have been measured during the synthesis process using a chemical vapour deposition (CVD) system without engineering controls.[6] Findings suggest that graphene exposure for workers handling graphene-based materials (GBM) is generally very low, however, individuals performing specific tasks face higher susceptibility compared to those involved in routine GBM production activities.[7]

A study by Wu et al suggests that there was no evidence of potential adverse health effects under the existing workplace exposure levels among nanomaterials handling workers, except for the increase of antioxidant enzymes.[8] Limited data exist on the health effects of nanomaterials, including graphene, on workers. Potential risks include inhalation,[9] dermal contact, ingestion, and accidental injection. The absence of confirmed human health impacts may suggest that current exposure levels in controlled workplaces pose minimal immediate

[5]Ying W, Chao An, Yaru Guo, Yanyang Zong et al. "Highly Aligned Graphene Aerogels for Multifunctional Composites". *Nano-Micro Lett.* 16, 118 (2024). https://doi.org/10.1007/s40820-024-01357-w.

[6]Bengt Fadeel et al. "Safety Assessment of Graphene-Based Materials: Focus on Human Health and the Environment", *ACS Nano* 12, 11, (2018): 10582–10620. https://doi.org/10.1021/acsnano.8b04758.

[7]Irene Bellagamba et al., "Workers' Exposure Assessment during the Production of Graphene Nanoplatelets in R&D Laboratory" *Nanomaterials* 10, no. 8, (2020): 1520. https://doi.org/10.3390/nano10081520; see also Seyyed Mojtaba Mousavi, et al.et al. "Development of Graphene Based Nanocomposites towards Medical and Biological Applications." *Artificial Cells, Nanomedicine, and Biotechnology* 48 (1) (2020): 1189–1205. doi:10.1080/21691401.2020.1817052.

[8]Wei-Te Wu, Lih-Ann Li, Tsui-Chun Tsou, Shu-Li Wang, Hui-Ling Lee, Tung-Sheng Shih & Saou-Hsing Liou *et al.* "Longitudinal follow-up of health effects among workers handling engineered nanomaterials: a panel study". *Environ Health* 18, 107 (2019). https://doi.org/10.1186/s12940-019-0542-y

[9] Michael Kendall and Stephen Holgate. "Health impact and toxicological effects of nanomaterials in the lung", *Respirology,* 19(5) (2012): 743-758.

threats. However, this likely reflects insufficient data rather than assured safety.[10]

Graphene, a notable nanomaterial is made from highly stable carbon and is widely utilised globally.[11] With a carbon bond distance of about 0.142 nanometres and a layer height of merely 0.33 nanometres, graphene is the thinnest material discovered so far.[12] Despite its slenderness, it is remarkably strong, nearly transparent, and so densely packed that even helium, the smallest atom, cannot penetrate it. Thus, it poses a high risk to workers exposed to graphene. Graphene is rapidly gaining ground in medicine, with applications in detecting and treating dangerous diseases, including cancer.[13] Handling GBM exposes workers to risks, particularly through inhalation during production and handling. There are also concerns about skin or oral contact with GBM. The oral exposure to GBMs, especially when used for drug delivery, poses safety concerns. Research on genetically modified *Bacteroides ovatus* strains indicated that these bacteria can survive in the mammalian gastrointestinal tract and may exchange genetic material with wild-type bacteria.[14]

This paper aims to evaluate whether graphene usage in the medical sector aligns with Malaysia's OSH (USECHH) Regulations 2000 and the OSH Act 1994, as amended in 2022 (Act A1648). A significant challenge lies in the limited literature on graphene regulation in Malaysia. Addressing this gap may require creative

[10]Shaira Ismail, Salina Budin, and Siti Aminah Mohd Ali. "The nanotechnology application and workforce health and safety - a study of the Malaysia laws, statutory regulations and guidelines on nanotechnology". *Journal of Physics. Conference Series*, 1349(1) (2019):012031.

[11]Kim S. Siow. "Pengelupasan Grafit untuk Mengkomersilkan Teknologi Grafin". Sains Malaysiana, 46(7), (2017): 1047–1059. https://doi.org/10.17576/jsm-2017-4607-06.

[12]Madhuri Sharon and Maheshwar, Sharon. *Graphene: An Introduction to the Fundamentals and Industrial Applications*. (John Wiley & Sons. 2015).

[13]Emily Mullin. "An ultrathin graphene brain implant was just tested in a person", *Science,* (2024). https://www.wired.com/story/an-ultrathin-graphene-brain-implant. Retrieved on May 12, 2025

[14]Udo Wegmann, et al,. "Use of genetically modified bacteria for drug delivery in humans: Revisiting the safety aspect". *Sci Rep*. (2017) May 23;7(1):2294. DOI: 10.1038/s41598-017-02591-6.

applications of OSHA and its regulations or adopting a 'soft law' approach. A focused study on graphene regulation is thus timely and significant.

RESEARCH METHODOLOGY

This study employs a qualitative methodology with a focus on critical analysis. It examines graphene, a nanotechnology material, within the context of Malaysian law. To provide a comprehensive understanding, scientific and medical literature explain graphene's structure and applications in the medical sector, while legal sources, including articles and legislation, explore its regulatory status and implications for worker safety. Key legal documents referenced include the OSH Act 1994 and the USECHH Regulations 2000. Unstructured interviews were also conducted with three respondents (experts) on the issue of the regulatory application of graphene.

THE APPLICATION OF GRAPENE IN THE MEDICAL SECTOR

The use of graphene in the medical field has garnered increasing attention. The incorporation of graphene into nanocomposites highlights its significant contributions to biomedical applications. Graphene's high mechanical strength, exceptional electrical and thermal conductivity, and biocompatibility enhance the performance of these nanocomposites.[15] By integrating graphene, the products become lighter while maintaining or improving their strength, making them ideal for multifunctional biomedical applications.[16]

[15]Zulfiqar Ali, Saba Yaqoob, Jinhong Yu, Alberto D'Amore, M. Fakhar-e-Alam. "Comparative review of processing methods for graphene-based hybrid filler polymer composites and enhanced mechanical, thermal, and electrical properties," *Journal of King Saud University - Science*,36, ssue 10, (2024): 103457. https://doi.org/10.1016/j.jksus. 2024.103457.

[16]Gity Behbudi. "Mini Review of Graphene Oxide for Medical Detection and Applications." *Journal Adv. Appl. NanoBio Tech* 1,3, (2020): 63-66. https://dormaj.org/index.php/AANBT/article/view/52.

Graphene is applied extensively in drug and gene delivery and cancer therapy.[17] Graphene oxide (GO), with its biocompatibility, solubility, and stability, is particularly suited for these uses. Their study extended GO-based drug delivery beyond anticancer treatments to include non-cancer diseases.[18] Researchers developed a double cross-linked GO hydrogel to promote the healing of diabetic ulcers.[19] GO's unique properties make it a valuable tool for enhancing drug and gene therapies, leading to improved patient outcomes. The potential of graphene-based nanocarriers, such as chitosan-grafted GO, for drug delivery and gene therapy, expanded graphene's role in treating genetic disorders.[20] Graphene is pivotal in biosensor technology, especially for cancer therapies.[21] GO's features make it effective in detecting lung cancer with high accuracy.[22]

Graphene is gaining increasing significance in the medical field due to its promising applications in medicine. Functionalised GO nanocomposites have been developed for anticancer drug delivery. For instance, gelatin and reduced GO nanosheets functionalised with folic acid create biocompatible and biodegradable nanocarriers. These carriers demonstrate controlled release and substantial drug-loading

[17]Mojtaba Hoseini-Ghahfarokhiroush Mirkiani, Naeimeh Mozaffari, Mohamad Amin Abdolahi Sadatlu et al, "Applications of Graphene and Graphene Oxide in Smart Drug/Gene Delivery: Is the World Still Flat?" *International Journal of Nanomedicine* 15 (November) (2020): 9469–96. doi:10.2147/IJN.S265876.

[18]Wenxu Liu, et al. "Double cross-linked graphene oxide hydrogel for promoting healing of diabetic ulcers", *Front. Chemistry*, volume 12 (2024). | https://.org/10.3389/fchem.2024.1355646

[19]Wenxu Liu, et al (2024). "Double cross-linked graphene oxide hydrogel for promoting healing of diabetic ulcers".

[20]Safa A Vahab et al." Exploring chitosan nanoparticles for enhanced therapy in neurological disorders: a comprehensive review". *Naunyn Schmiedebergs Arch Pharmaco*, 398(3) (2025): 2151-2167. doi: 10.1007/s00210-024-03507-8.

[21]Anh Tuan Trong Tran et al. "Graphene and metal–organic framework hybrids for high-performance sensors for lung cancer biomarker detection supported by machine learning augmentation", *Nanoscale*, 1: 9084-9095.

[22]AL-Salman, Chou-Yi Hsu, Zainab Nizar Jawad, Zaid H. Mahmoud, Faraj Mohammed, Abdulnaser Saud, Zuhair I. Al-Mashhadani et al. "Graphene oxide-based biosensors for detection of lung cancer: A review", *Results in Chemistry* 7 (2024): 1-22.

capacity, with faster drug release in acidic environments like tumours, enhancing the targeting of cancer cells while reducing side effects.[23]

In dentistry, graphene-silver nano powder hybrids have been used as fillers in dental composites, improving mechanical properties and providing antimicrobial activity.[24] Such advancements demonstrate graphene's potential in both tissue engineering and dentistry. Therefore, its usage in dentistry may pose a risk to workers.

Researchers examined the effects of inhaling graphene oxide and found no immediate detrimental impacts on lung or cardiovascular performance in a controlled human trial.[25] However, they stressed the need for further investigation to understand the effects of higher doses or prolonged exposure. Despite its thickness being thousands of times smaller than a human hair, graphene exhibits properties suitable for electronics, textiles, paints, and water purification. Its potential for targeted cancer therapeutics and implantable devices is also under extensive study.[26]

Before graphene is widely adopted in medical applications, comprehensive testing is crucial to identify any potential adverse effects. While this study found minimal impact on pulmonary function, arterial pressure, coagulation, and inflammation, there was a slight indication that inhaling graphene oxide could affect blood clotting. The findings, as cited in the literature, highlight the need for further exploration into the safety and long-term effects of graphene exposure.

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[23]Geentajali Singh et al., "Fabrication of chlorambucil loaded graphene- oxide nanocarrier and its application for improved antitumor activity". *Biomedicine & Pharmacotherapy*, 129 (2020): 110443.

[24]Fatemeh Emadi et al., "Graphene: Recent Advances in Engineering, Medical and Biological Sciences, and Future Prospective." *Trends in Pharmaceutical Sciences* 4, no. 3 (2018): 131-138.

[25]Jacks P.M. Andrews, et al. "First-in-Human Controlled Inhalation of Thin Graphene Oxide Nanosheets to Study Acute Cardiorespiratory Responses." *Nature Nanotechnology*, 19 (2024): 705-714.

[26]Mehrab Pourmadadi et al., "Properties and Applications of Graphene and Its Derivatives in Biosensors for Cancer Detection: A Comprehensive Review" *Biosensors* 12, no. 5: (2020): 269. https://doi.org/10.3390/bios1205026.

While the previous section highlighted the medical applications of graphene, the next section explores the occupational risks associated with its use.

UNDERSTANDING THE RISKS OF GRAPHENE AS A NANOTECHNOLOGY MATERIAL

Safely managing and disposing of nanomaterials is essential to prevent respiratory risks, particularly with the growing use of graphene and its derivatives. Regular discussions about nanomaterial safety and the development of risk mitigation strategies are critical. Researchers highlight that handling and processing graphene introduces health hazards, making it essential to analyse exposure levels.[27] While measuring airborne graphene exposure in workplaces is necessary, no single method effectively quantifies this exposure. The organic carbon (OC) and elemental carbon (EC) approach is reliable but requires additional characterisation techniques for precise results.

Researchers found that interviewees treated nanomaterials (NMs) like other chemicals, ignoring their unique harmful characteristics.[28] This limited understanding results in inadequate knowledge of both immediate and long-term health risks. Consequently, only general safety measures are implemented.[29] Their survey revealed that current occupational safety and health (OSH) protocols are insufficient for workplaces handling nanotechnology. Workers, regardless of their educational background, perceived powder-form NMs as more dangerous than liquid forms and believed personal protective equipment (PPE) provided sufficient protection.[30]

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[27]Tobias Storsjö et al. "Elemental carbon - An efficient method to measure occupational exposure from materials in the graphene family". *NanoImpact*, 33, (2024):100499.

[28]Arindam Malakar et al., Nanomaterials in the environment, human exposure pathway, and health effects: A review", *Science of tht Total Environment,* 759, (2021), 143470.

[29]Arindam Malakar, et al."Nanomaterials in the environment, human exposure pathway, and health effects: A review, Science of the Total Environment".

[30]Kai Savolainen et al. "Nanosafety in Europe 2015–2025: towards safe and sustainable nanomaterials and nanotechnology innovations". Finnish Institute of Occupational Health, Helsinki, 2013.

Employees' perceptions of different types of nanomaterials influence how they handle safety issues related to graphene.

Nanoparticles enter the body through ingestion, inhalation, skin absorption, or injection. Once inside, they can bypass protective barriers, accumulating in vital organs like the lungs and brain, causing potential harm.[31] Inhaled nanoparticles often deposit deep in the respiratory tract, persisting in the body for extended periods. They may also enter the bloodstream, spreading to other organs, potentially affecting the heart, nervous system, and brain.[32]

Nanomaterials are linked to respiratory and cardiovascular health issues and may have carcinogenic potential.[33] Prolonged exposure could lead to chronic inflammation, causing irreversible lung tissue damage.[34] This could pose a health risk to workers, raising safety concerns for both employees and the public. The following section examines the stance of Malaysian laws on regulating workplaces where chemicals are extensively used.

THE MALAYSIAN OSHA 1994 AND ITS ROLE IN REGULATING WORKPLACE CHEMICALS

The study on the legal application of graphene and nanotechnology in Malaysia is limited.[35] Several writings on this issue, however, have

[31]Christina Buzea, and Ivan Pacheco. "Toxicity of Nanoparticles." In *Nanotechnology in Eco-Efficient Construction*, edited by Pacheco-Torgal, F., Diamanti, M. V., Nazari, A., and Granqvist, C. G., 2nd ed. (Cambridge: Woodhead Publishing, 2018).

[32]Michael Kendall and Stephen Holgate. "Health impact and toxicological effects of nanomaterials in the lung", *Respirology,* 19(5) (2012): 743-758.

[33]Paul A. Schulte et al. "Occupational safety and health criteria for responsible development of nanotechnology". J *Nanopart Res* 16(1) (2014):1–17.

[34]Azrul Azlan Hamzah, Reena Sri Selvarajan, and Burhanoedin Yoep Majlis. "Graphene for Biomedical Applications: A review". *Sains Malaysiana*, 46(7), (2017):1125–1139. https://doi.org/10.17576/jsm-2017-4607-16.

[35]Maryam Etemadu, Akbariah Mohd Mahadzir, and Noorhayati Mohd Noor. Occupational Health and Safety Risk Assessment of Nano Workplaces in Malaysia. (2020). ResearchGate. https://doi.org/10.20944/preprints202301.0478.v1

been informative.[36] The Occupational Safety and Health Act (OSHA) 1994, along with its accompanying regulations, including the USECHH Regulations 2000, is Malaysia's primary tool for managing chemicals in workplaces.[37] OSHA aims to protect workers' health and well-being by mitigating workplace hazards, as outlined in Section 4. This framework emphasises a systematic approach to reducing risks and ensuring safe working environments.

Although graphene is not explicitly listed in the chemical regulations due to its recent emergence, OSHA remains applicable in industries using graphene. The 2022 OSHA amendment mandates risk management procedures,[38] covering activities involving graphene. Respondents interviewed in this study confirmed they use OSHA and related regulations when handling graphene, even in the absence of specific guidelines.[39]

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[36]For example, Shaira Ismail, Salina Budin, and Sti Aminah Mohd Ali. "The nanotechnology application and workforce health and safety - a study of the Malaysia laws, statutory regulations and guidelines on nanotechnology". *Journal of Physics.* Conference Series, 1349(1), (2019).012031.

[37]Krishna Gopal Rampal, and J Mohd Nizam. "Developing regulations for occupational exposures to health hazards in Malaysia". *Regulatory Toxicology and Pharmacology*, 46(2), (2006): 131–135; See also Mohd Anuar Mokhtar. "The Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations 2000". *Planter,* 81, 951, (2005): 355-365;

[38]Aneesya Suffiya Abu Seman and Kamal Halili Hassan. "Analisis Akta Keselamatan dan Kesihatan Pekerjaan (Pindaan) 2022: Perbandingan Sebelum dan Selepas Pindaan serta Implikasinya terhadap Industri", *Jurnal Undang-undang dan Masyarakat* 34 (2024): 122-140.

[39]The researchers conducted interviews with three respondents (experts). One respondent held the position of Deputy Director at the Centre for Research and Instrumentation Management in a research university in Bangi, Malaysia. The interview was held on May 13, 2024. The other respondent is employed as a Senior Associate in a company in Kuala Lumpur, Malaysia, specializing in Nanotechnology. The interview was held on May 29, 2024. The third respondent, a senior officer from the Ministry of Science, Technology and Innovation, Malaysia, was interviewed on May 9, 2025. The first and second respondents views on graphene safety regulations indicated that OSHA 1994 and the USECHH Regulations 2000 were applied when handling graphene in the workplace. Overall, the respondents were of the view that: "The use of graphene in medical

The 2022 OSHA amendment introduced significant changes, including its application to all workplaces, public and private, as stated in Section 1(2).[40] This expansion ensures equal protection for all workers, including those in the public sector and statutory authorities.

Employer Responsibilities

Section 15 of OSHA emphasises employers' proactive duty to anticipate and mitigate workplace risks.[41] In the absence of graphene-specific regulations, employers must adhere to general chemical safety rules. This includes conducting risk assessments and implementing appropriate measures to minimise risks. The general duty clause requires employers to take all practicable steps to safeguard workers, even for new substances like graphene.

devices shows great promise, but regulatory approval is complex and can take years due to stringent safety requirements", and "Laboratories working with graphene have not reported significant health issues related to its exposure, and toxic effects have generally not been observed. While graphene is not considered inherently dangerous, proper handling is still advised to minimize any potential risks", and "There is a general lack of awareness about graphene and its numerous benefits. Many people do not fully understand the product or its potential applications, which creates additional challenges in promoting its use". The third respondent was of the view that: "The Occupational Safety and Health Act (OSHA) 1994 applies to the handling of graphene in the workplace. The Department of Occupational Safety and Health (DOSH) released guidelines in 2018 supporting OSHA 1994 in relation to the use of nanomaterials, including graphene. The application of the Use and Standards of Exposure of Chemicals Hazardous to Health (USECHH) Regulations 2000 to graphene is also considered likely. However, a specific Permissible Exposure Limit (PEL) for graphene has not yet been established, which remains a regulatory gap".

[40]Kamal Halili Hassan, Rozanah Ab. Rahman, and Mariani Ismail. *Legal Aspects of Industrial Safety in Malaysia*. (Kuala Lumpur: Dewan Bahasa dan Pustaka, 2024).

[41]Section 15 provides a general duty on the employer towards his employees. The 2022 amendment includes a duty to provide an emergency response procedure or plan at the workplace via section 15 (2)(f).

A key update in the 2022 amendment is the mandatory preparation of risk assessments under Section 18B.[42] Previously optional, this duty now carries legal force. Employers must include graphene-related risks in these assessments to align with OSHA's self-regulation philosophy, as inspired by the Lord Robens Committee in England.[43] This ensures employers address potential emergencies, industrial accidents, and health threats related to graphene use.

Section 21(1) expands on these obligations, requiring manufacturers, importers, and suppliers to ensure the safety of workplace substances.[44] This includes thorough risk assessments and information dissemination. Precautionary measures, such as protective equipment and limiting direct contact, remain essential due to limited data on graphene's long-term effects.

Employee Responsibilities

Employees also bear responsibilities under OSHA, as outlined in Section 24(1). These include cooperating with employers, using protective equipment, and adhering to safety directives. Given graphene's minute carbon particles and potential health risks, workers must handle it with care, following all safety guidelines. The 2022 amendment increased penalties for non-compliance, with fines raised to not exceeding RM2,000 and 3 months imprisonment. These stricter penalties emphasise the importance of adhering to occupational safety regulations.

General Provisions and Industry Standards

Section 15(2) of OSHA outlines employers' specific duties, such as maintaining safe work systems, handling substances securely, and providing training and supervision. The 2022 amendment further

[42]This new section provides a duty to the employer, self-employed person, and principal to conduct and implement risk assessment.

[43]Kamal Halili Hassan, Rozanah Ab. Rahman, and Mariani Ismail. *Legal Aspects of Industrial Safety in Malaysia*. (Kuala Lumpur: Dewan Bahasa dan Pustaka, 2024).

[44]New subsection 21(1)(d) in OSHA 2022 amendment: Manufacturers or suppliers need to provide revisions of information if there exists a new risk in the substance.

requires employers to implement emergency protocols, particularly relevant for substances like graphene. By adhering to OSHA's general duty clause, employers can create safer workplaces, ensuring compliance and protecting employees.

The concept of "practicable" under OSHA involves assessing the hazard's severity, available knowledge, mitigation options, and associated costs. This structured approach, as highlighted in cases like *Sri Kamusan*[45] and *Westport,*[46] ensures safety measures balance worker protection with practicality and economic feasibility. Employers can make informed decisions that align with industry standards and OSHA requirements while safeguarding their workforce.

ALIGNING THE STANDARDS: MALAYSIA'S USECHH REGULATIONS 2000 FOR GRAPHENE APPLICATIONS

Table 1: Provisions of USECHH Regulations 2000

Part II – Sections 5	Identification of chemical hazardous to health
Part III – Sections 6,7, 8	Permissible exposure limit
Part IV – Sections 9,10,11,12,13	Assessment of risk to Health
Part V – Sections 14,15,16,17,18,19	Action to control exposure
Part VI – Sections 20,21	Labelling and Re-labelling
Part VII – Sections 22.23.24.25	Information, Instruction and Training

[45]See Kamal Halili Hassan. "Ulasan Kes: Jabatan Keselamatan dan Kesihatan Pekerjaan lwn Sri Kamusan Sdn. Bhd. [2014] 9 CLJ 825". *Kanun*: *Jurnal Undang-undang Malaysia*, 8 (2) (2016): 385-388. https://jurnal.dbp.my/index.php/Kanun/article/view/6356

[46] Pendakwa Raya v Westport Malaysia Sdn Bhd [2021] MLJU 261; See also Aneesya Suffiya & Kamal Halili, 2024. "Analisis Akta Keselamatan Dan Kesihatan Pekerjaan (Pindaan) 2022: Perbandingan Sebelum Dan Selepas Pindaan Serta Implikasinya Terhadap Industri", *Jurnal Undang_Undang dan Masyarakat* 34 (2024): 122-140.doi: 10.17576/juum-2024-3402-09

Part VIII - Section 26	Monitoring of exposure at the place of work
Part IX – Section 27	Health surveillance
Part X – Section 28	Medical removal protection
Part XI – Section 29	Warning sign
Part XII – Section 30	Record Keeping
Schedule 1	List of chemicals and its permissible exposure limit

The USECHH Regulations 2000 set strict rules and duties for industries to protect workers from hazardous chemicals (Table 1). Employers are required to identify, assess, and manage the risks posed by chemicals hazardous to health (CHH).[47] This proactive approach emphasises prevention, aiming to reduce occupational illnesses and injuries. By aligning with international standards, the regulations highlight the importance of systematic risk assessments and control measures to safeguard employee health.[48] A study on the compliance status of chemical management among industries in Malaysia revealed that 70% of workplaces inspected between 2016 and 2020 received satisfactory grades.[49] This improvement indicates the effectiveness of systematic risk assessments and control measures in reducing occupational health risks.

[47]Hazlina Yon. "The compliance status of chemical management among industries in Malaysia: The USECHH after 20 years". *Journal of Energy and Safety Technology*, 5(1), (2022): 1-20. https://doi.org/10.11113/jest.v5n1.99.

[48]Mohd Marzuki Mohamed et al., "Semi-quantitative chemical expert tool for occupational safety and health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations 2000". *ACS Chemical Health & Safety*, 30(1), (2023): 9–20. https://doi.org/10.1021/acs.chas.2c00046.

[49]Hazlina Yon. "The compliance status of chemical management among industries in Malaysia: The USECHH after 20 years". *Journal of Energy and Safety Technology*, 5(1), (2022): 1-20. https://doi.org/10.11113/jest.v5n1.99

When it comes to nanomaterials like graphene, the regulatory landscape becomes more complex. Unlike conventional substances, nanomaterials have unique properties, such as higher reactivity and potential toxicity—that challenge traditional regulatory frameworks. While the USECHH Regulations 2000 cover "substances" and "chemicals," graphene is not specifically mentioned. This raises concerns about whether the regulations adequately address the unique risks of nanomaterials.[50]

Graphene, widely used in the medical industry, falls under the general category of chemical substances. However, its specific hazards and applications might push the boundaries of what the regulations cover[51]. To bridge this gap, it is crucial to closely examine the regulatory framework, particularly Regulation 15(1) of the USECHH Regulations. This section offers a starting point for understanding how the regulations apply to emerging materials like graphene and how they might need to evolve to ensure comprehensive protection. The gap in the application of Malaysian laws to graphene arises because graphene is not specifically mentioned in the USECHH Regulations. Although the Schedule in the 2000 Regulations lists various chemicals, it does not include graphene. Therefore, an amendment to the Schedule is necessary to address this gap. Due to the absence of graphene in the Schedule, the authority is unable to provide a permissible exposure limit (PEL) for graphene.

Regulation 15(1) of the USECHH Regulations 2000 highlights the importance of taking precautions when handling chemicals that may harm workers' health. Employers must follow strict safety measures to ensure these chemicals are managed safely. Even though graphene is not specifically mentioned in the regulations, it is considered a chemical substance. Therefore, it still falls under the rules

[50]Shaira Ismail, Salina Budin, and Siti Aminah Md Ali. The nanotechnology application and workforce health and safety: A study of the Malaysia laws, statutory regulations and guidelines on nanotechnology. *Journal of Physics: Conference Series*, (2019): 1349, 012031. https://doi.org/10.1088/1742-6596/1349/1/012031.

[51]Faris Abdullah et al., "Integration of chemical health risk assessment (CHRA) and indoor air quality (IAQ) assessment: from a Malaysian perspective". *International Journal of Environmental Health Research*, 34(5*)* (2023): 2280–2298. https://doi.org/10.1080/09603123.2023.2243843.

and safety measures set out in the regulations. Examining the framework of USECHH 2000 Regulation 15(1) is crucial, even when dealing with modern materials like graphene, as the risk is high. Regulation 3(1)(d) of the regulations notes that they apply to all workplaces, but with a focus on pharmaceutical use. The term "pharmaceutical" is defined in Regulation 3(2) as any drug used by humans for medicinal purposes. The authors argue that if graphene is used in medicines, like for drug delivery, it must follow the same rules. Any process that turns graphene into medicine must follow the safety steps outlined in the regulations.

Although the regulations do not specifically address medical uses of graphene, the general principle still applies since graphene is a chemical substance, and it must be handled according to the guidelines for chemicals.[52] Any process involving graphene must prioritise worker safety and follow the regulations. Findings from interviews with three experts in Malaysia revealed that they unanimously agreed that safety measures for handling graphene should align with the USECHH Regulations 2000 or OSHA 1994. Uncertainty, however, persists about how the USECHH Regulations 2000 and other frameworks, like OSHA 1994, apply to nanomaterials such as graphene. These regulations were not originally designed with nanomaterials in mind, so it is unclear how effective they are for managing the risks of substances like graphene. To help address this, our research investigates whether additional guidelines, or "soft laws," can complement the current regulations. Soft laws, such as best practices, can provide flexibility and allow regulations to keep up with discoveries and risks related to nanomaterials. The use of soft law in foreign jurisdictions regarding graphene safety policies may serve as a valuable example for Malaysia to emulate.[53]

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[52]Mohamad Azli Ahmad. “Medical surveillance on chemicals hazardous to health in Malaysia”. *The International Journal of Medicine and Sciences*, 2(1), (2017): 27-34.

[53]See for examples, World Health Organization. WHO guidelines on protecting workers from potential risks of manufactured nanomaterials. World Health Organization, Geneva, 2017. see also Vladimir Murashov, John Howard. The US must help set international standards for nanotechnology. Nat Nanotechnol, 3(11) (2008): 635–636; Vladimir Murashov et al “Regulatory approaches to worker protection in nanotechnology industry in the USA and European Union.” Industrial

Using Soft Law to Control Graphene

In the realm of Malaysian judicial practice, guidelines function as non-binding instruments that serve to establish moral duties and promote best practices.[54] Although lacking in legal enforceability, these guidelines are instrumental in shaping ethical norms and guiding behaviour within various sectors.[55] Unlike statutory laws or regulations, guidelines are not designed to carry legal weight. Instead, they offer practical recommendations based on industry standards, expert opinions, and relevant legal principles. A notable characteristic of guidelines is their adaptability to changing circumstances. They are frequently revised to accommodate technological advancements, evolving industry standards, and new legal developments. This adaptability ensures that guidelines remain relevant and effective in addressing contemporary challenges. Despite their non-binding nature, guidelines can significantly influence decision-making and conduct within organisations. They serve as a valuable reference for professionals and organisations seeking to align their practices with established norms and expectations.

Health, 49(3) (2011): 280–296; see also Bell, C., & Marrapese, M. Nanotechnology Standards and International Legal Considerations. In V. Murashov & J. Howard (Eds.), *Nanotechnology Standards*(2011): 239–255.https://doi.org/10.1007/978-1-4419-7853-0_10;Michael Riediker, et al. "Development of a control banding tool for nanomaterials." *Journal of Nanoparticle Research* 14(9) (2012): 1228; Vladimir Murashov et al. "Regulatory approaches to worker protection in nanotechnology industry in the USA and European Union." *Industrial Health,* 49(3) (2011): 280–296.

[54] Lome Sossine and Charles W. Smith. "Hard Choices and Soft Law: Ethical Codes, Policy Guidelines and the Role of the Courts in Regulating Government", 40 *Alta. L. Rev*. 867 (2002-2003): 867-892. See also the case of Thong Foo Ching & Ors v Shigenori Ono [1998] 4 CLJ 674. The court acknowledged that guidelines could be used to assist in the interpretation and application of legal provisions.

[55] Ketua Pengarah Jabatan Alam Sekitar & Anor v Kajing Tubek and Other Appeals [1997] 4 CLJ 253 CA. The Federal Court clarified that guidelines are generally not legally binding unless expressly stated in legislation. They serve as a reference or administrative tool to assist decision-makers in maintaining consistency and ensuring proper adherence to the policy goal.

The "Guideline on Control and Safe Handling of Nanomaterials" is an important document issued by DOSH that provides critical information about the risks associated with nanotechnology.[56] It outlines key recommendations for managing exposure to nanomaterials, including graphene, in the workplace. This guideline is comprehensive and covers many aspects of nanomaterial safety; however, it does not fully address some regulatory gaps. These gaps include the establishment of threshold values for safe exposure, exceptions for chemicals used in research and development, and specific requirements for Safety Data Sheets (SDS) and labelling, as highlighted earlier.[57] For instance, while the guideline provides general safety measures for nanomaterials, it lacks specific threshold values for graphene, making it challenging to determine safe exposure levels. Additionally, exceptions for chemicals in research and development can lead to inconsistent safety practices, potentially exposing workers to higher risks. The absence of detailed requirements for SDS and labelling further complicates the safe handling of graphene, as workers may not have access to all necessary information about its hazards and protective measures. Addressing these gaps through enhanced regulations and specific guidelines for graphene can improve safety and ensure comprehensive risk management in workplaces dealing with this emerging nanomaterial.

To evaluate potential dangers, the guideline suggests conducting tests on nanomaterials of utmost importance, such as graphene, by comparing their attributes to establish their "similarity." This process entails analysing the resemblances and disparities among nanomaterials. If substantial disparities are detected, it suggests that the hazard data for one substance may not be applicable to another. Due to graphene's distinctive characteristics and diverse applications, particularly in medical devices and semiconductors, this measure is essential for precise risk evaluation.

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[56]Department of Occupational Safety and Health. Guidelines on control and safe handling of nanomaterials. Ministry of Human Resources Malaysia, 2018.

[57]Halila Faiza Zainal Abidin, Kamal Halili Hassan, and Zinatul Ashiqin Zainol. “Regulating Risk of Nanomaterials for Workers through Soft Law Approach”. *NanoEthics*, 14(2), (2020): 155–167.

Moreover, the guideline recommends the utilisation of a control banding methodology to evaluate the hazards linked to nanomaterials. This approach, endorsed by COSHH Essentials and GoodNanoGuide, entails classifying tasks into bands according to the degree of risk and the necessary control measures to reduce exposure.[58] By implementing this approach, it establishes a well-organised system for handling risks associated with nanomaterials in the workplace, guaranteeing the presence of suitable safety procedures. Tasks related to the manipulation of graphene can be categorised into specific risk levels that determine the required safety measures, including ventilation controls, personal protective equipment, and exposure monitoring. This control banding approach is in line with well-established standards in OSH. It highlights the significance of customised risk management strategies for such materials and exposure scenarios.[59] The purpose is to establish safeguards that effectively shield workers from the potential dangers linked to nanomaterials, such as graphene, by implementing controls that are commensurate with the identified risks.

Given the dynamic nature of nanotechnology, it is recognised that the guidelines provide only limited and incomplete information as a single source of reference. It is advisable to supplement these guidelines with additional pertinent international standards and guidelines to gain a more thorough comprehension, particularly concerning specific matters such as the properties of individual nanomaterials like graphene, classification of hazards, preparation of Safety Data Sheets (SDS) and labels, recommended limits of exposure, and up-to-date tools for managing risks. Integrating knowledge from diverse sources improves the thoroughness and precision of occupational health and safety approaches concerning

[58]Gary Marchant, E. "'Soft law' mechanisms for nanotechnology: liability and insurance drivers". *J Risk Res* 17, 6 (2014):709–719. See also NIOSH (2013) Occupational exposure to carbon nanotubes and nanofibres. Current Bulletin 65. (2014) DHHS (NIOSH) Publication No. 2013-145. https://www.cdc.gov/niosh/docs/2013-145/pdfs/2013-145.pdf. Accessed 17 June 2024.

[59]Stephen Finger, R, Shanti Gamper-Rabindran. "Protecting workers from adverse chemical exposure: do voluntary standards reduce exposure?" (2012). Available at SSRN. http://dx.doi.org/10.2139/ssrn.2070595.

nanotechnology.[60] This comprehensive approach guarantees that both employers and employees reap the advantages of the most recent advancements and optimal methods in the secure management of graphene and other nanomaterials.

CONCLUSION AND RECOMMENDATIONS

The development of robust and precise government regulations to protect workers from potential hazards associated with graphene or nanomaterials is unlikely to occur soon. This delay can be attributed to a variety of factors, including graphene or nanotechnology's complex and rapidly evolving nature, which makes it difficult to establish comprehensive and enforceable regulations. Furthermore, the wide range of nanomaterials and their applications complicate the regulatory landscape. While the use of OSHA and USSECH is implied and assumed to apply to graphene as a chemical substance, it is not explicitly stated in legislation, leading to uncertainty among many stakeholders regarding its actual impact. Some presume that graphene, being a chemical substance, should fall under OSHA and USECCH regulations. While this argument appears reasonable, the lack of clear provisions designating graphene as a chemical or derived from one means that applying these regulations remains speculative. Current practice generally assumes that referring to OSHA and USECHH for graphene is the most practical approach available.

To address this regulatory gap, it is necessary to take a more comprehensive approach to regulation, shifting away from conventional command and control models and towards more flexible methodologies. Implementing mechanisms such as guidelines, industrial codes of conduct, and best practices can be a highly effective strategy. These non-binding legal instruments can greatly enhance stakeholders' comprehension of the potential health hazards linked to nanomaterials. Soft law mechanisms foster trust and consensus in the industry and regulatory communities through promoting dialogue and collaboration.

[60]Halila Faiza Zainal Abidin, Kamal Halili Hassan, and Zinatul Ashiqin Zainol. “Regulating Risk of Nanomaterials for Workers through Soft Law Approach”. *NanoEthics*, 14(2), (2020): 155–167.

Over time, these informal approaches may develop into legally enforceable measures, establishing the foundation for future official regulations. Soft law strategies provide a versatile and clear approach to addressing the challenges linked to nanotechnology, including its applications in the medical and semiconductor sectors. They offer the necessary adaptability to keep up with fast-paced technological progress, all while ensuring that regulatory frameworks do not hinder innovation in these crucial fields.

This approach is particularly important in the field of nanotechnology, as scientific understanding is constantly evolving and there are still unknown risks to consider, especially in sectors like medicine and semiconductors where graphene is increasingly being used. Utilising soft law mechanisms enables regulators to easily adjust to new information and emerging risks, guaranteeing that regulatory frameworks stay up-to-date and efficient in light of technological advancements.

To address this regulatory gap, the following recommendations are proposed:

(1) Develop specific regulatory guidelines for graphene or amend the present Guidelines. Leverage existing guidelines under OSHA 1994 and USECHH 2000, supported by DOSH, to include graphene explicitly as a regulated nanomaterial.

(2) Amend the USECHH 2000's Schedule to include graphene in the chemical list.

(3) Establish Permissible Exposure Limits (PEL). The current regulations lack defined exposure thresholds for graphene. Developing PELs would strengthen compliance and occupational safety.

(4) Strengthen coordination between research institutions, regulatory bodies (e.g., DOSH, Ministry of Science, Technology and Innovation), and industry players to streamline regulatory development and ensure enforcement consistency.

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