

NANOTECHNOLOGY LAW

Best Practices

BY LORNA BRAZELL



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Law & Business

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Lorna Brazell



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Nanotechnology Law

List of Abbreviations

ADME	Absorption, Distribution, Metabolism and Excretion
ANZF Code	Australia New Zealand Food Standards Code
ASTM	ASTM International
BSE	Bovine Spongiform Encephalitis (Mad Cow Disease)
C&L Inventory	Classification and Labelling Inventory (of the European Union)
CASG Nano	REACH Competent Authorities Sub-group on Nanomaterials
CEN	European Standards Centre
CEPA	Canadian Environmental Protection Act
CHMP	European Medicines Agency's Committee on Medicinal Products for Human Use
CLP	Classification, Labelling and Packaging (of Chemicals)
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
CNT	Carbon Nanotube
CSCL	Japanese Chemical Substances Control Law
DAR	Draft Assessment Report
DDP	Dossier Development Plan
DG	Directorate General (of the European Commission)
DNA	Dioxyribonucleic Acid
DSL	Canadian Domestic Substances List
ECHA	European Chemicals Agency
EEA	European Economic Area
EFSA	European Food Safety Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
EMA	European Medicines Agency

List of Abbreviations

EPA	US Environment Protection Agency
EPC	European Patent Convention
EPO	European Patent Office
ETSI	European Telecommunications Standards Institution
EU	European Union
FAO	United Nations Food and Agriculture Organization
FDA	US Food and Drug Administration
FIFRA	US Federal Insecticide, Fungicide and Rodenticide Act
FRAND	Fair, Reasonable and Non-discriminatory
FSANZ	Food Standards Australia New Zealand
FTC	US Federal Trade Commission
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
GLP	Good Laboratory Practice
GMO	Genetically Modified Organism
GRAS	Generally Recognized as Safe
ICCM	International Conference on Chemicals Management
IFCS	Intergovernmental Forum on Chemical Safety
IOMC	Inter-Organization Programme for the Sound Management of Chemicals
IP	Intellectual Property
IPPC	Integrated Pollution Prevention and Control
IPR	Intellectual Property Right
IRGC	International Risk Governance Council
ISO	International Standards Organization
IUPAC	International Union of Pure and Applied Chemistry
IUR	Inventory Update Reporting
JEDEC	Joint Electron Device Engineering Council (now known as the JEDEC Solid State Technology Association)
JRC	Joint Research Centre (of the European Commission)
LED	Light Emitting Diode
MA	Marketing Authorization
METI	Japanese Ministry of Economy, Trade and Industry
MHLW	Japanese Ministry of Health, Labour and Welfare
MHRA	UK Medicines and Healthcare Products Regulatory Agency
MPEG	Moving Picture Experts Group
MSDS	Material Safety Data Sheet
MWCNT	Multi-walled Carbon Nanotube
NICNAS	Australian National Industrial Chemicals Notification and Assessment Scheme
NIOSH	US National Institute for Occupational Safety and Health
NMSP	US Nanoscale Materials Stewardship Program
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
PCB	Polychlorinated Biphenyl

List of Abbreviations

PCT	Patent Cooperation Treaty
PM	Particulate Matter
PMN	US Premanufacture Notice
RAE	UK Royal Academy of Engineering
RAPEX	Rapid [Product Safety] Information System
REACH	European Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals
ROHS	European Regulation on the Restriction on Use of Hazardous Substances
SAICM	Strategic Approach to International Chemicals Management
SARS	Severe Acute Respiratory Syndrome
SCCP	European Scientific Committee for Consumer Products
SCCS	European Scientific Committee on Consumer Safety
SCENIHR	European Scientific Committee on Emerging and Newly Identified Health Risks
SDRAM	Synchronous Dynamic Random Access Memory
SDS	Safety Data Sheets
SIEF	Substance Information Exchange Forum
SNUR	Significant New Use Rule
SPS Agreement	Agreement on Sanitary and Phytosanitary Measures
SVHC	Substance of Very High Concern
SWA	Safe Work Australia
TRIPs Agreement	Agreement on Trade-Related Aspects of Intellectual Property
TSCA	US Toxic Substances Control Act
TTBER	European Technology Transfer Block Exemption Regulation
UN	United Nations
UNEP	United Nations Environment Programme
UNESCO	United Nations Education, Science and Culture Organization
UNIDO	United Nations Industrial Development Organisation
UNITAR	United Nations Institute for Training and Research
USPTO	United States Patent and Trademark Office
UV	Ultraviolet
VCR	Video cassette recorder
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WPMN	Working Party on Manufactured Nanomaterials
WPN	Working Party on Nanotechnology
WTO	World Trade Organization

Preface

It has become increasingly difficult over the last few years for anyone interested in new nanomaterials and products – and how is it possible not to be interested in such intrinsically fascinating technologies? – to ignore the cacophony of debate at national, European and international level over the question of whether, and to what extent, existing laws and regulations apply to nanotechnology. Conferences, working groups, technical committees and learned institutions of all kinds have considered the issues and opined, but the state of scientific knowledge has generally been considered too immature for any real consensus to emerge. Further, although the number of consumer products reaching the market which incorporated any form of nanomaterial was steadily growing, the number any consumer might realistically expect to encounter was still relatively low. Accordingly, research and development have ploughed ahead but the legal and regulatory context for the fruits of that work has been left almost untouched.

In the last two years, the question of what form any such laws and regulations should take has begun to come to the fore with the introduction in Europe and Australia of nano-specific regulation and the USA looking likely to follow suit in the near future. The OECD's Sponsorship Programme, a broad programme of research into the properties of particular nanomaterials being carried out collaboratively between a number of OECD Member States and observers, which is expected to generate some of the fundamental knowledge necessary for rational regulation, is due to report in 2011. It is therefore timely to review the various sectors in which nano-enabled products are expected to be used, the regulation which has applied in the past and the changes which are being proposed to address the potential risks to which nanomaterials are feared to give rise.

Although the book is intended for a non-technical audience, it is impossible to cover a topic in which the technical issues are the crux of the debate without some technical material. I have attempted to explain as clearly as possible the critical

Preface

issues around nanotechnology – including the basic parameters as to what is and is not properly so called. But where health and environmental impacts are concerned, I have not given any detailed explanation, leaving it to the interested reader to follow up the science through the cited publications. In any case, this particular wheel does not need re-inventing: a number of excellent reports including that of the House of Lords Select Committee on Nanotechnology in Food, the Opinions of the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks and that of the Royal Society/Royal Academy of Engineering, do the topic justice.

In writing, the main problem was not lack of material but how to synthesize an excess of source material including guidance, notices, commentary and draft regulation from all corners of the globe. It is almost inevitable that something will have come out between writing and publication which would have been well worthy of comment; but this would have been true whenever the book was written, unless the topic were left for another decade or more until all of the questions have been answered. This text covers the law, including draft new European regulations on Biocides and Novel Foods, as at 18 October 2011, although the treatment of the European Commission's Recommendation on a definition of the term 'nanomaterial' which came out on that date is necessarily rather brief.

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Chapter 1

Nanotechnology in the Twenty-First Century

1.1 INTRODUCTION

In the last few years, the term ‘nanotechnology’ has become fashionable and the subject of passionate debate as to how the subject should be handled through law and regulation. Nanotechnology is discussed as an entirely new development with the potential equally to bring valuable new benefits and also to engender unknown and potentially very serious new hazards, both for human health and for the environment. But in the same period, the average consumer’s chances of actually encountering any product using nanotechnology were extremely low. Until very recent years, nanotechnology has been largely confined to the laboratory with both its potential benefits and its potential risks still substantially speculative rather than actual.

This is about to change. The results of the last decade or so of research are now reaching commercial and industrial reality, and accordingly the need to address any legal and regulatory issues raised by these new products is becoming urgent. A political imperative to be seen to be managing any new risks arising has developed considerable momentum. Yet there is very little agreement as to what, precisely, needs to be done. The state of scientific knowledge is still far from complete, and the evidence for both benefits and risks will only emerge over the next decade or more. Regulators in all of the industrialized countries are grappling with the question of how best to minimize any exposure to a barely identified risk, and at the same time minimize any unnecessary burden on researchers and industry from divergent regulatory approaches around the globe.

The result is a complex and rapidly changing legal landscape. Regulatory instruments addressing nanotechnology in industrial sectors from chemicals to food and waste are now being adopted at an increasingly rapid rate, and in