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Adequate and anticipatory research on the potential hazards of emerging technologies: a case of myopia and inertia?

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ABSTRACT

History confirms that while technological innovations can bring many benefits, they can also cause much human suffering, environmental degradation and economic costs. But are we repeating history with new and emerging chemical and technological products? In preparation for volume 2 of 'Late Lessons from Early Warnings' (European Environment Agency, 2013), two analyses were carried out to help answer this question. A bibliometric analysis of research articles in 78 environmental, health and safety (EHS) journals revealed that most focused on well-known rather than on newly emerging chemicals. We suggest that this 'scientific inertia' is due to the scientific requirement for high levels of proof via well replicated studies; the need to publish quickly; the use of existing intellectual and technological resources; and the conservative approach of many reviewers and research funders. The second analysis found that since 1996 the funding of EHS research represented just 0.6% of the overall funding of research and technological development (RTD). Compared with RTD funding, EHS research funding for information and communication technologies, nanotechnology and biotechnology was 0.09%, 2.3% and 4% of total research, respectively. The low EHS research ratio seems to be an unintended consequence of disparate funding decisions; technological optimism; a priori assertions of safety; collective hubris; and myopia. In light of the history of past technological risks, where EHS research was too little and too late, we suggest that it would be prudent to devote some 5–15% of RTD on EHS research to anticipate and minimise potential hazards while maximising the commercial longevity of emerging technologies.

INTRODUCTION

Investment in technological innovation is a public policy priority in Europe and in many other regions of the world. Large amounts of public money are spent on new and emerging technologies and on their product applications in order to create jobs, prosperity and wealth. For instance, since 1984 more than €18 billion of the EU Framework Research budgets has been spent on developing information and communication technologies (ICTs). And the European Commission announced in 2013 that the two science project winners of the EU's Future and Emerging Technologies competition, on mapping the intricacies of the human brain, and on exploring the carbon-based material graphene, will each receive up to €1 billion over the next decade.¹

There are already thousands of promising and rapidly spreading yet novel commercialised

products that are based on the emerging chemicals and Nano, Bio, and Information and Communication (NBIC) technologies. However, while technological innovations can bring many benefits, they can also cause much human suffering, environmental degradation and economic costs.

In 2001, the European Environment Agency (EEA) published their first of two reports on 'Late Lessons from Early Warnings: the Precautionary Principle 1896–2000' documenting numerous cases such as PCBs, sulfur dioxide, benzene, asbestos, tributyltin (TBT), and the pharmaceutical agent diethylstilbestrol (DES) where failure to apply the precautionary principle resulted in much harm and delayed innovation.² In 2013, the European Environment Agency (EEA) published a second report 'Late Lessons from Early Warnings: Precaution, Science, Precaution, Innovation',³ which analysed a further 20 case studies focusing, as in volume I, on the growth of knowledge about their hazards and related actions or inactions by decision makers. The cases analysed included lead in petrol, Bisphenol A, neonicotinoid insecticides, Minamata disease and perchloroethylene (PCE) contamination, as well as some emerging technologies including genetically modified crops, nanotechnology and mobile phones. The second report also covered cross-cutting issues such as the economic consequences of inaction; why businesses ignored robust early warnings; the precautionary principle; false positives; and science for precautionary decision making. The report showed that precautionary environmental health regulation does not hamper innovation and concluded that there is a need to reduce delays between early warnings and actions, to rethink and enrich environment and health research, to improve the quality of risk assessments, and to foster greater public participation in choosing innovation pathways.

The histories of the now well-known technologies and chemicals in the 'Late Lessons' reports showed that a lack of anticipatory research into the early warning signs of their hazards contributed to the failure to take timely actions to prevent or minimise the serious, widespread and continuing harm to the public and environments caused by these technologies and products. Two of the 'Twelve Late Lessons' from volume 1 of 'Late Lessons' specifically addressed the issue of anticipatory research by calling for 'adequate' research into knowledge gaps and early warnings; for more long-term monitoring; and for the promotion of robust, diverse and adaptable technologies that would help to "minimise the costs of 'surprises' and maximise the benefits of innovation".² Is there evidence that these lessons

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have been reflected in choices about the nature and extent of anticipatory research into the potential environmental, health and safety (EHS) hazards of emerging chemicals and NBIC technologies? In preparation for volume 2 of 'Late Lessons' two kinds of analyses were carried out in order to help answer this question. The first focused on the share of research between the historical and emerging chemicals that are, or have been, the basis for many consumer products. The second looked at the share of European funded research on developing new technologies and on anticipating their potential hazards.

EHS RESEARCH ON CHEMICALS: 'SCIENTIFIC INERTIA'?

In an analysis of 78 environmental and health journals, Grandjean⁴ revealed that since 2000 most research has focused on chemicals whose first early warnings about their hazards were identified some 20–100 years ago, such as those reviewed in the first volume of 'Late Lessons from Early Warnings', namely polychlorinated biphenyl (PCBs), sulfur dioxide, benzene, asbestos, TBT, methyl tert-butyl ether (MTBE) and the pharmaceutical agent DES.² Of the nearly 15 000 articles published on these substances since 1899, Grandjean *et al* found that some 40% had been published since 2000. For other well established toxicants such as lead, mercury and dichlorodiphenyltrichloroethane (DDT) which were reviewed in the second volume of 'Late Lessons from Early Warnings', a similar pattern emerged: there were 15 000 articles published between 2000 and 2009 on lead, mercury and DDT alone. Meanwhile, research on eight of the emerging, large production chemicals identified as priorities by the US Environmental Protection Agency (US EPA),⁵ such as 1,3-dichlorobenzene, featured in only 352 of all the articles published in the 78 environment and health journals over the same period: five other chemicals on the US EPA priority list did not feature in any of the articles. A similar picture emerged when the article analysis was extended to 2011.⁶ Of course new scientific insights can emerge from more research into even well-known chemicals. We are not therefore suggesting the cessation of further research on relatively well-known chemicals but just a rebalancing of total research effort towards emerging priority chemicals.

The focus of research on well-known rather than emerging priority chemicals, which Grandjean calls 'scientific inertia', seems to be due to a number of factors: the traditional scientific requirement for high levels of proof via well-replicated studies; the influence of senior academics who favour the chemicals they know most about; the need to use costly laboratory infrastructure designed mainly for the 'old' chemicals which can be most easily analysed; the need to publish quickly; and the conservative nature of many reviewers and research funders who are more likely to see results on time from studies of well-known chemicals than from the riskier proposals to study the less known.⁴ In addition, a history of corporate pushback against literature exposing risks associated with their products has also been well-documented, which might also add to scientific inertia.^{2,3}

Scientific inertia increases the chance of hazards from new chemical products emerging as 'surprises'. It also tends to stifle scientific innovation in those disciplines needed to identify emerging hazards such as epidemiology, exposure assessment, toxicology, endocrinology and development biology. We know from the well-known hazards, for example, benzene, asbestos, X-rays, lead, mercury, tobacco, vinyl chloride and DES, that many of the early warnings were generated, strengthened, and then confirmed by epidemiological research. More research into the hazards of emerging chemicals and their less intrinsically

hazardous alternatives, as well as more long-term health monitoring of consumers and environments, would encourage the use and development of scientific innovations in fields such as analytical and green chemistry, biomonitoring and epigenetics.

Of course long-term epidemiological monitoring of chemicals cannot be very anticipatory compared with the much less time needed to get results from animal and other laboratory experiments. This is why public health needs to be protected by causal inferences based mainly on good laboratory evidence. This view is supported by the approach used by the International Agency for Research on Cancer (IARC) for attributing carcinogenicity. The value of animal testing in predicting carcinogenicity is discussed by Huff in the 'Late Lessons' chapter on vinyl chloride.³

EHS RESEARCH ON NBIC TECHNOLOGIES: A CASE OF MYOPIA?

Figures on the public funding of research on new technologies and on their potential hazards can be derived from the European Commission reports on its Framework Programmes (FPs) for research and technological development (RTD). There have been seven FPs spanning the last 20 years and in many cases, various Commission reports have accessed the EHS-component of the funded research grants and projects in one manner or another. Often, the EHS-component is unspecified and although we acknowledge that what defines as EHS-research can vary and that not all research grants and project might fall neatly into one category or the other, we rely on the European Commission self-classification of EHS-research in this paper.

For the FP4–6, between 1996 and 2006, the EHS-research corresponded to a mere 0.6% of the total RTD budget (see table 1A). The latest FP7 programme, which ran from 2007 to 2013, continues this focus on research and technological development rather than on anticipating and minimising potential hazards. For example, during the first three FP7 calls for proposals some 79 funded projects had an (unspecified) EHS component according to the European Commission totalling €265 million.⁷ In comparison, the total budget of FP7 is more than €50 billion⁸ which gives a RTD/EHS-research ratio of 200 to 1 as just 0.5% of the total RTD budget went to EHS research.

When it comes to NBIC technologies specifically, the EHS-research proportion is a little higher, although information is not available for all the FPs.

During FP7, €3.5 billion has been provided for Nanosciences, nanotechnologies, materials and new production technologies.⁸ In comparison, 25 projects have been given €82 million by 2011 to study the health and environmental impact of nanomaterials, which corresponds to 2.3%.¹³ These absolute amounts were more than twice the total spent on nanotechnology under FP6,^{10 12 13} but the RTD/EHS ratio was similar corresponding to 2.1%.

On biotechnology, only one EHS-research relevant project has been funded on genetically modified organisms (GMSAFOOD worth €2.6 million) after the first three calls of FP7.⁷ In contrast, €1.935 billion have been set aside under the theme 'Food, Agriculture and Biotechnology' in FP7,⁸ which yields a RTD/EHS-research ratio of about a 1000:1. Under FP6, €2.514 billion was set aside under the thematic priority 'Life Sciences, genomics and biotechnology for health'.¹⁷ In contrast, only some €200 million was spent on EHS-research,¹⁸ which corresponds to 8% for the total RTD budget of this theme. Under FP5 and FP4 the themes on 'Quality of Life and management of living resources' and on the 'Biotechnology programme', received some €3 billion.^{14 15} of which only some €70

Table 1 EU funding of RTD and EHS-research in NBIC technologies and overall under the FP1–7

Research programme	Overall RTD funding (billion €)	Overall EHS funding (million €)	RTD/EHS-research (%)
(A) Research and Technology Development			
FP4	13 215 ⁹	n.a.	n.a.
FP5	14 960 ¹⁰	160 ⁷	1
FP6	17 500 ¹¹	≈200 ⁷	1
FP7	50.5 ⁸	265 ^{7*}	0.5*
Total	96 175	625	0.6
Research programme	Nanotechnology total (billion €)	Nanotechnology EHS research (million €)	RTD/EHS-research (%)
(B) Nanotechnology			
FP1–5	n.a.	n.a.	n.a.
FP6	1.4 ¹²	30 ¹³	2.1
FP7	3.5 ⁸	82 ¹³	2.3
Total	4.9	112	2.3
Research programme	Biotechnology total (billion €)	Biotechnology EHS research (million €)	RTD/EHS-research (%)
(C) Biotechnology			
FP1–5	3 ¹⁵	70 ¹⁶	2.3
FP6	2.514 ¹⁷	200 ¹⁸	8
FP7	1.935 ⁸	2.6 ^{7*}	0.1*
Total	7449	2726	4
Research programme	ICT total (billion €)	EMF EHS research (million €)	RTD/EHS-research (%)
(D) Information and communication technologies (ICTs)			
FP1–5	5.685 ^{9 19}	8.8† ²⁰	0.15
FP6	3.984 ²¹	0 ²¹	0
FP7	9.110 ⁸	8.9 ^{7*}	0.1*
Total	18.779	17.7	0.09

*After three calls.

†Sum of the FP5 projects CEMFEC, GUARD, INTERPHONE, RAMP 2001 and PERFORM A. EHS, environmental, health and safety; EMF, electromagnetic field; FP, Framework Programmes; NBIC, Nano, Bio, and Information and Communication; RTD, research and technological development.

million was spent on EHS research,¹⁶ corresponding to 2.3%. The total funding under FP1–7 came to €7.5 billion of which the EHS component came to €273 million, corresponding to 4% (see table 1C).

The RTD/EHS-research ratio for ICT is much smaller than even the modest ratios for nano and biotechnologies. The FP7 programme provided €8.9 million for EHS projects during the first three calls for proposals⁷ compared with €9.1 billion that has been earmarked for ICT,⁸ yielding a RTD/EHS-research ratio of about 1000 to 1. Under FP6 nothing seems to have been allocated to EHS-research on ICT,²¹ but 8.8 million was spent on EHS under FP1–5.^{19 20} In total the EHS research budget related to ICT was a mere 0.09% of the budget that went into RTD of ICT under FP1–7 (see table 1D). The potential hazards of ICT seem intrinsically less than for nano and biotechnologies and this may justify the much lower RTD/EHS-research ratio. However, the classification of the non-ionising radiations from mobile phones as a 2B ('possible') carcinogen by the IARC in 2011 is a cause for serious concern that should generate follow-up research.²² The IARC classification has been controversial partly because it was based on just two

large epidemiological studies which indicated possible brain cancer risks, according to most experts at the IARC meeting.^{23 24} A lack of relevant animal data and divergent interpretations of the epidemiological data provide much scope for further research.

The overall European public funding of research into the potential hazards of the NBIC technologies during the FP1–7 programmes yields a RTD/EHS ratio of about 100 to 1.3 (some €402 million compared with some €31 billion: see table 1).

The low RTD/EHS-research ratio on the European level may be offset by higher RTD/EHS-research ratios in the EU Member States, but these figures are not readily available. However, it has been noted that between 2004 and 2009 some £220 million was spent on applications of nanotechnologies by the UK Engineering and Physical Sciences Research Council compared with less than £20 million on the potential EHS hazards from nanotechnology by the Medical Research Council and other government funded bodies.²⁵

In contrast, The Netherlands apparently has a public RTD/EHS-research ratio for nanotechnology of 85/15 (Personal communication). Given the human suffering, environmental degradation and economic costs that have been associated with past 'wonder technologies', the question is how the overall RTD/EHS ratios that we have identified have come about and why are they so low? Are they the result of informed deliberation by research funders, or are they emergent properties of a complex and decentralised system of funding which nobody 'chooses' and for which, therefore nobody is responsible? Could there be collective hubris about the low likelihood of potential harm from 'new' emerging technologies? Or myopia about potential hazards, or even 'willful blindness' which seems to be a common feature of life?²⁶

The historical case studies in the 'Late Lessons' reports provide many examples of authoritative but unsubstantiated assertions of safety about the then emerging technologies which helped justify very little research into potential hazards. For example, an expert asbestos witness told the UK Parliamentary inquiry on asbestos in 1906 that "one hears, generally speaking, that considerable trouble is now taken to prevent the inhalation of the dust so that the disease is not so likely to occur as heretofore"²⁷ And the General Motors 'inventor' of leaded petrol told the US Surgeon General in 1925 that "the average street will be so free from lead that it will be impossible to detect it or its absorption" even though "no actual experimental data has been taken".²⁸

Such largely unsubstantiated assertions of safety are to be found in current discussions about the NBIC technologies as well. For example, it is sometimes asserted that there are no long-term health hazards from genetically modified crop in food despite the virtual absence of full-term animal studies to demonstrate this; that there are no brain cancer hazards to children from mobile phones despite there being virtually no long-term studies in children covering the relevant latent period for brain cancers; and that there are no chronic hazards from nanoparticles even though there are virtually no studies to demonstrate long-term safety. These assertions are based on the mistaken assumption that 'no evidence of harm' is the same as 'evidence of no harm'.

Low public RTD/EHS funding ratios could also be due to an aversion against looking for risks that could be 'inconvenient' to find; and a tendency to leave it to promoters and developers of a given technology to complete the EHS research which can 'crowd out' public research. For example, the leaded petrol industry controlled virtually all of the rather meagre EHS

research into leaded petrol hazards from the 1920s to the 1960s²⁸; and the six largest breeding and genetic engineering companies in the food sector control a research budget that is over eight times larger than that of the Consultative Group on International Agricultural Research, the world's largest public sector agricultural food body.²⁹

It is not known how much of this agricultural research by companies is spent on the potential EHS hazards of their biotechnologies. The technology companies' contribution to EHS research on nanotechnology and ICT is also difficult to identify. In 2010, a UK House of Lords report criticised the food industry for "failing to be transparent about its research into the uses of nanotechnology and nanomaterials".²⁵ It would be helpful if this information were to be disclosed for the food industries and for other industries as well. If history repeats itself the technology company expenditure on EHS research is likely to be low in comparison with their total RTD research budget. There is little incentive for companies to do research on the potential hazards of their own products, unless mandated by law, because most health and environmental harm from commercial technology and products is externalised onto societies and their taxpayers.^{30–31} As a consequence there have been some proposals to incentivise technology producers to conduct more anticipatory EHS research, such as product taxes, for example on mobile phones, with the revenue being spent on EHS research²⁴; and anticipatory assurance bonds that would be posted by large-scale novel technology producers which would eventually be returned to them, with interest, if potential hazards do not materialise.³²

EHS research by technology producers also needs to overcome the 'funding bias' and commercial pressures to downplay hazards, which have been extensively reported in the past.^{33–35} It would therefore seem prudent to insulate company EHS-research from commercial pressures by erecting administrative barriers between their funding and its use by independent scientists, while balancing commercial secrecy with access to research materials and regulatory test data, as with genetically modified organisms (GMOs). For example, 24 leading corn insect scientists wrote to the US EPA concerning the way GMO technology agreements 'explicitly prohibit research'³⁶ (in order to access Monsanto test data on the safety of a GM product, submitted to the European Food Safety Agency, independent scientists had to use the German courts to access and verify the data³⁷) and independent epidemiological research into mobile phones was delayed in the USA by legal action.³⁸ Meanwhile, as the public funding of RTD, including EHS research, is a subsidy to the private sector it may need to be repaid to taxpayers by appropriate royalty payments.³⁹

TOWARDS 'ADEQUATE' EHS RESEARCH?

What would be a prudent RTD/EHS-research ratio in light of the histories of asbestos, mercury, leaded petrol and other hazards analysed by the EEA in 'Late Lessons from Early Warnings'?

Ideally we should be able to identify comparable RTD/EHS-research ratios for historical technologies but we are not aware of such figures for the cases covered in the EEA 'Late Lessons' reports. However, it is clear from the historical narratives in the EEA chapters that very little research was devoted to identifying hazards of, for example, asbestos, mercury, leaded petrol, dibromochloropropane (DBCP), and X-rays at the time when such research would have been useful in minimising their future hazards. We have seen from the Grandjean analysis that most of the EHS research into even the most well-established

hazardous chemicals was conducted in the last 10–15 years, which was many decades after their widespread use in consumer products began. Despite some early warnings from epidemiological research about, for example, benzene in 1897,⁴⁰ asbestos in 1906⁴¹ and leaded petrol in 1926,²⁸ there were no follow-up studies until many decades later. It is reasonable to conclude from the historical technologies and products analysed by the EEA that there was very little anticipatory research into their potential hazards and that the EHS-research remained very small until well after the hazards were manifest.

The harmful consequences of EHS research, that was too little and too late has been extensive. The epidemiological and other research into well-known hazards that was eventually carried out has demonstrated that the nature and extent of harm expanded well beyond the hazards that were first identified. For example, asbestos has been found to cause an increasing range of diseases, with the main ones being asbestosis in 1929, lung cancer in 1955 and mesothelioma in 1960. These diseases have been found in an increasing variety of exposed groups, such as asbestos producers and users; bystanders to users; building occupants, families of asbestos workers, and neighbours, teachers, etc, and such diseases have also been shown to be capable of being caused by lower levels of exposure. A similar picture of expanding harm among an increasing variety of exposure groups caused by lower exposure levels than was previously thought possible has been eventually uncovered by research on lead, tobacco, PCBs, DES, etc.^{2–3}

The health impacts on victims are incalculable but the financial costs to societies are also large. Andersen and Club³⁰ have estimated that leaded petrol alone has caused losses of 4–6% of gross domestic product (GDP) in lost productivity from reduced IQ. Other harmful consequences of inaction on early warnings include damage to the commercial longevity of the products; inequitable sharing of the costs of harm between the risk creators, risk victims and risk bearers; skewed and 'information-poor' impact assessments and cost/benefit analyses; delays in the production of scientific knowledge and insights into the biological and ecological effects of the technologies; delays in the creation of technological and 'benign by design' innovations; increased public distrust of industries and regulators who failed to anticipate hazards; and increased regulatory and public pressure to regulate on the basis of hazard, and not risk, particularly when there is an absence of information about relevant exposures.

Identification of the prudent RTD/EHS-research ratio is not possible and any suggested ratio will inevitably seem somewhat arbitrary, but in order to avoid the costly consequences of inadequate anticipatory EHS research, we suggest that a prudent RTD/EHS ratio for NBIC technologies would lie somewhere between 5% and 15%. The exact ratio depends on the intrinsic hazard potential, plausible exposure scenarios, and their novelty, persistence, bioaccumulation potential and spatial range. These are some of the features of emerging technologies that have been identified by the EEA as justifying precautionary actions, including adequate anticipatory research.⁴² Such research would also be part of 'responsible innovation', an idea that is gaining currency.⁴³

There is evidence that there are sufficient knowledge gaps, uncertainties and areas of scientific ignorance in the NBIC technologies that would justify such a substantial increase in EHS funding. For example, a recent report from WHO on nanomaterials notes that there are large knowledge gaps about potentially hazardous properties; biological and ecological exposures; and about biological and ecological fates and impacts of such

exposures. It also notes deficiencies in current analytical techniques and monitoring methods for early warnings.⁴⁴ Similarly, the European Commission's Scientific Committee on Newly Identified Health Risks has regularly identified large knowledge gaps in its reports on radiofrequency (RF) from mobile phones.⁴⁵ For example, "research with some frequencies or modulations is very limited, and this is, particularly true regarding new and emerging technologies; a number of areas were identified where the information regarding health effects is either absent or insufficient, or is too discordant to allow science-based assessment of the possibility of health effects"; a cohort or register-based case control study on magnetic field exposure and Alzheimer's disease incidence or mortality is recommended as a high priority; and further studies of the effects of RF fields associated with mobile phone use and brain tumours in children are recommended as a high priority. There are also large gaps in knowledge and understanding as well as considerable areas of scientific ignorance about GMOs in food. There is also a lack of research into such alternatives to GMOs as agroecological farming methods which address soil and water quality as well as food productivity. This has been noted by the EU Standing Committee on Agricultural Research, which recently concluded that "low input, high output systems...that use nature's capacities, should receive the highest priorities for funding".⁴⁶

There are other complementary issues that increased EHS research could illuminate. These include analyses of the social needs that new technologies are intended to address⁴⁷; alternative ways of meeting these needs; the distribution of risks and benefits from new technologies across social groups and generations; methods for enhanced public participation in helping to shape the strategic innovation pathways to, for example, sustainable food and energy production and the research agendas needed to adequately support such innovations.^{3 48 49}

The sustainability challenges facing Europe and other resource and energy intensive economies are considerable as big business, the Organisation for Economic Co-operation and Development (OECD), and high-level advisory groups have illustrated.^{50–53} Meeting these challenges will need many innovative and sustainable technologies and products but without adequate and anticipatory research into their potential hazards, it is likely that much 'unforeseen' and 'surprising' harm and costs will accompany such innovations.

Contributors DG had the original idea to investigate the EHS/RTD funding ratio. SFH gathered the data and wrote the first draft of the paper, which was subsequently rewritten, revised and edited multiple times by both the authors.

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Corrections

Hansen SF, Gee D. Adequate and Anticipatory research on the potential hazards of emerging technologies: a case of myopia and inertia? *J Epidemiol Community Health* 2014;**68**:890-5. The affiliation of the second author, Dr David Gee, has changed to Science, Policy and Emerging Issues, European Environment Agency, Copenhagen (retired).

CrossMark

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