EDITOR'S CHOICE

Is the increasing policy use of Impact Assessment in Europe likely to undermine efforts to achieve healthy public policy?

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ABSTRACT

European policymakers have recently become increasingly committed to using Impact Assessment (IA) to inform policy decisions. Welcoming this development, the public health community has not yet paid sufficient attention to conceptual concerns about IA or to corporate efforts to shape the way in which IA is used. This essay is a thematic analysis of literature concerning IA and associated tools and a related assessment of the European Union's (EU) new 'integrated' IA tool. Eight key concerns regarding IA are identified from the literature, many of which relate to the potential for undue corporate influence. Assessment of the EU's IA tool suggests that many of these concerns are valid. The findings raise crucial questions about the role of IA in public policy. By focusing mainly on the impact on the economy and business environment, the EU's current approach to IA may undermine healthy public policy. Those interested in public health need to acknowledge and respond to the problems associated with IA and evaluate the effects of 'integrated' IA tools on policy decisions affecting public health.

BACKGROUND

In the past decade, policymakers' commitment to Impact Assessment (IA; see box 1) has grown considerably across Europe, at EU and member state level.[1–3]

Public health advocates have largely welcomed this development[16–18] focusing almost entirely on Health IA (HIA) and Environmental IA (EIA).[11 16–19] Indeed, HIA is promoted by the World Health Organization (WHO) as a means of ensuring decision-makers from a wide variety of sectors are sufficiently aware of the health consequences of their policies.[20] Although concerns have been raised about whether HIA, largely developed to assess local health impacts,[19] can be adapted to national and international levels,[21 22] more fundamental questions about the use of IA within policymaking have received only limited consideration by the public health community.[4 6] In particular, very little consideration has so far been given as to how business-orientated versions of IA, such as Business IA (BIA) or Regulatory IA (RIA), are shaping policy outcomes. Given growing evidence of the links between contemporary public health concerns and the activities of large corporations (particularly those operating in the food, alcohol, tobacco, chemical, energy and transport sectors),[23–26] this seems an important omission, particularly as recent evidence demonstrates that large corporations from many of these sectors played a fundamental role in promoting IA at EU level (see box 2).

The decision to employ or prioritise a particular form of IA (such as BIA) over another (such as HIA) when evaluating policy proposals is likely to have a substantial bearing on subsequent policy choices.[13 37] Such decisions reflect social and political judgements about the importance of human health in relation to other goals, such as economic growth and competitiveness.[38] Consequently, IA needs to be understood as a framing device,[2] which constructs and steers decision-making within regulatory and policy processes, focusing attention on some impacts and not others.

The roots of IA in the EU lie in reforms in the mid-1980s, which separately introduced limited forms of EIA and BIA.[39–42] However, it is only in the past decade that IA has begun to fundamentally change policymaking in the EU.[8] In 1997, a Protocol on the Application of the Principles of Subsidiarity and Proportionality in the Treaty of Amsterdam,[43] mandated that the 'burdens' of legislation should be minimised for 'economic operators'. This Treaty change, which was influenced by the lobbying efforts of large corporations (see box 2)[27 28], has been cited as the constitutional basis for the Commission's renewed commitment to IA.[44] In 2001, the push for BIA was enhanced by the Mandelkern Report[45] and further commitments to undertaking a form of sustainability-orientated IA were made at the Goteborg European Council meeting.[46] These developments informed the Commission's 2001 commitment to introducing 'a coherent method for impact analysis' by the end of 2002.[47] A series of documents subsequently outlined the Commission's new approach to IA, which brought together RIA with other forms of IA, resulting in an 'integrated' approach to IA with economic, social and environmental strands.[33–36] Initially, questions were vague, merely encouraging policymakers to consider potential 'economic, social and environmental consequences',[33] but later versions of the tool detailed three separate sets of questions for economic, environmental and social impacts.[34–36] Since 2005, the Commission has committed itself to applying its IA guidelines to *all* significant legislative developments.[34]

The formal incorporation of EIA, BIA and Social IA (SIA) into a single IA tool (with health impacts largely subsumed in the latter) has enabled the Commission to promote its approach to IA as 'a thorough and balanced appraisal of all impacts'.[48]

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Box 1 What is Impact Assessment (IA)?

Definitions of Impact Assessment (IA), and even Health Impact Assessment (HIA),[4–6] vary greatly[7–9] and specific IA policy tools differ significantly across countries.[9] However, in general terms IA is a means of assessing the social, economic and environmental impact of policy, usually in advance of its implementation.[10–12] When applied to the regulation of substances that pose threats to human health and/or the environment, such as tobacco, alcohol or toxic chemicals, IA effectively provides a framework for making decisions about whether and how to limit the resulting health and/or environmental damage.[13] The first stage of IA usually involves some form of risk assessment in order to assess whether the risks posed by a particular hazard are great enough to warrant regulation.[11 14 15] Once policy intervention is deemed necessary, the likely impacts of each policy option are then assessed in a process similar to cost-benefit analysis (CBA).

Neither the Commission nor the WHO address the obvious conflicts involved in balancing economic, social and environmental considerations.[2 42] They also ignore the fact that northern member states (the UK, the Netherlands, Luxembourg, Ireland, Finland and Austria) have been specifically promoting IA in the EU as a means of enhancing business competitiveness by reducing regulatory and administrative costs,[10 49 50] and that European business interests have been highly active in shaping and using IA in the EU.[27 28]

The public health community has been relatively disengaged from the development of the EU's 'integrated' IA tool. In some member states, this may reflect a broader tendency not to engage in European level discussions about health policy but it is also likely to be a result of the fact that there have been separate efforts to develop HIA at EU level.[21] Unfortunately, however, these efforts appear to have stalled now that increasing emphasis is being placed on 'integrated' IA. Although the Directorate General responsible for health published a guide to assessing the health impacts of policies in 2001,[51] this has not been widely promoted.[38] More recently, the Commission funded a group of public health researchers to develop a generic methodology for HIA of EU policies,[52] which was subsequently piloted on the European Employment Strategy,[38] but despite this (and unlike EIA and BIA), HIA appears to be perceived by the Commission as voluntary, not having been fully incorporated into its mandatory 'integrated' IA tool.[53] This is despite the fact that the EU has been required to take account of the health impact of all EU policies since the 1992 Maastricht Treaty, a requirement now formalised in Article 152 of the Treaty on European Union,[43] which has been interpreted by some legal analysts as requiring HIA,[54] although this requirement remains legally untested.[53]

This is important because analyses of policymakers' use of HIA elsewhere suggest that if it is not formally embedded in policymaking processes, it may fall off the agenda.[38] This raises the possibility that the EU's integrated IA tool may not adequately promote or protect public health within European-level policy decisions, a risk underlined by independent reviews of the IAs that the Commission has produced, which consistently find that coverage across its three 'pillars' is uneven, with economic impacts receiving the most attention[42 55] and environmental[42 55 56] and social (particularly health) impacts the least.[53 57] Indeed, a review of the 137 IAs carried out by the Commission in 2005 and 2006 found that more than half did not even refer to 'health'.[53] For these reasons it is essential for the

Box 2 How British American Tobacco (BAT) and other large corporations shaped the EU's approach to IA

Research based on analysis of internal tobacco industry documents and interviews with relevant actors demonstrates that, from the mid-1990s onwards, one of the world's largest transnational tobacco companies, British American Tobacco (BAT), initiated and led a campaign intended to significantly alter the policymaking process in the EU by promoting a mandatory form of BIA for all policy proposals.[27 28] The corporations involved (which, following BAT's recruitment efforts, included chemical, pharmaceutical and oil companies) believed this would work in their favour by: (1) providing an economic framework for all policy decisions, including those concerning social policies; (2) helping to secure early corporate involvement in policy discussions; and (3) providing regulated industries with a persuasive means of challenging potential and existing legislation affecting their interests.[27] BAT also believed a requirement for BIA could be used to promote a form of risk assessment that, based on its observations of Philip Morris' use of risk assessment to challenge US claims that secondhand smoke was a human carcinogen,[29] BAT hoped could be used to block European legislation relating to secondhand smoke[30 31] and tobacco advertising restrictions.[32] BAT's internal documents do not explain precisely what kind of methodological approach to risk assessment the company hoped to have implemented but they indicate that BAT believed very particular rules on the treatment of epidemiological data were required, rules that were not necessarily being promoted by other industries.[30] The specific objectives of the companies involved in the campaign, notably those from or connected to the tobacco and chemical industries, were obscured by the use of ostensibly independent front groups, including one of the largest think tanks based in Brussels, the European Policy Centre.[27 28 32] The campaign quickly helped secure important changes to the Treaty on European Union, which specified that policymakers must minimise the burdens of legislative developments on 'economic operators' (ie, businesses), a change that BAT and the EPC interpreted as meaning that a form of CBA/BIA (terms which are used interchangeably in BAT's internal documents) had been made mandatory in the EU.[27 28 32] BAT described this Treaty change as 'an important victory in a key trade block'.[32] Once the Treaty change had been achieved, BAT and its allies focused on ensuring that it was interpreted and implemented in a manner that would work to their advantage.[27 28] Subsequently, in 2002, the Commission did commit to undertaking an integrated form of IA for all significant policy proposals.[33] The IA tool developed by the Commission for this purpose incorporates a fairly comprehensive form of BIA, whereas only aspects of HIA are included within a broader form of SIA (a point discussed in more detail later), and, in line with the Treaty, it stresses that any costs to economic operators, citizens or governments should be 'minimised and commensurate with the objective to be achieved'.[34–36] In summary, this research demonstrates that the very actors who profit from manufacturing and marketing regulated products helped shape the EU's approach to IA, significantly influencing this process to ensure that it helped protect and promote business and economic interests, while paying rather less attention to public health concerns.[27 28]

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public health community to begin to explore how public health considerations are understood and prioritised in relation to other (notably economic) interests within integrated forms of IA. In reviewing the vast theoretical literature that critically reflects on IA (and related tools), and assessing the EU's 'integrated' IA tool in relation to these concerns, this essay commences this process.

METHODS

This essay takes a public health perspective in interpreting literature that critically examines IA and related tools (namely cost-benefit analysis (CBA), which shares the same basic elements as IA - see box 1). This body of work is vast, divergent and largely theoretical, and not, therefore, appropriate for a traditional systematic review.[58] Hence, although searches for relevant articles were undertaken in a range of online databases and websites (including EconLit, Google Scholar, the International Bibliography of the Social Sciences and ISI Web of Knowledge), the authors do not claim to have conducted a comprehensive search of a specific topic or question. Instead, an iterative approach was used to search for a wide range of theoretical and qualitative texts (using broad search strings such as ('cost-benefit analysis' OR 'impact assessment') AND policy), and a thematic approach was taken to analysis of the texts that were located. The latter involved reading approximately 10–20 relevant articles at a time, recording key critiques of IA or CBA and then grouping similar critiques together. This process was repeated with further texts returned in the broad searches, as well as some located through more specific searches (which were informed by the texts that had already been analysed), until saturation was reached (ie, no new critiques of IA or CBA appeared to be emerging through additional reading or searching). From this review a typology of eight key concerns was developed, against which the EU's new 'integrated' IA tool was reviewed. This involved examining documents providing technical guidance on the EU's IA system and comparing the stated methodology and proposed processes against these eight concerns, as well as reviewing available empirical accounts of IA in the EU (including independent reviews of some of the IAs the Commission has produced).

RESULTS

Eight fundamental concerns about IA and their relevance to IA in the EU

Over 300 articles were initially identified as relevant (based on abstracts/executive summaries); approximately 180 of these were subsequently disregarded, either because the full text was less relevant than the abstract suggested or because the article turned out to be an alternative account of a text that had already been assessed. In total, 122 articles, books, book chapters and reports were drawn upon to develop a typology of eight key concerns relating to policymakers' use of IA and CBA. For brevity, no attempt is made to reference all of these texts here but instead the focus is on explaining each of the eight concerns in ways that highlight the potential implications for public health. In each case, the Commission's guidelines on IA and/or empirical literature concerning IA in the EU are employed to explain the relevance of the concerns to the Commission's 'integrated' IA tool.

The difficulties in predicting ex ante policy impacts

Supporters of IA often assume that it is possible to know what the impacts of policies are going to be in advance of their implementation, even though many policy decisions have complex, interrelated and unintended impacts.[12 38 59] In reality, although the idea of ensuring policy decisions are evidence-informed can seem innately attractive, it is problematic when evidence is complex and/or contested.[60–62] This is likely to be particularly true for policy-level (rather than smaller, project-level) IAs.[11 22] In practice, such underlying uncertainties are often obscured within IA,[63] which typically condenses evidence into a comparison of predicted costs and benefits, often expressed in concrete (negative or positive) monetary values.[64] As a result, policymakers may have rather more faith in the (seemingly 'hard') outcomes of IAs than is warranted.[4 63–65]

The Commission's IA system has not been in place long enough to test the accuracy of the predicted impacts employed in its IAs (especially as the full implementation of EU legislation can take many years[66 67]) but evidence from IAs undertaken elsewhere suggests that the inherent uncertainties in ex ante IAs mean that a significant proportion of predicted impacts are likely to be inaccurate.[63 68] This does not mean that IAs that attempt to predict the consequences of various policy decisions are not worthwhile or informative but it does seem essential to ensure policymakers are at least aware of the uncertainties involved, particularly where complex estimations are summarised in specific monetary terms, so that they do not become overly reliant on IAs.[65] Yet an early review of the integrated IAs the Commission had produced suggested that the uncertainties involved in predicting impacts were often not being adequately acknowledged.[55]

Information asymmetry

The above difficulties are particularly important given that it is often easier to predict the costs of regulations to business than the potential benefits to populations or the environment (which are often complex and long term and therefore extremely difficult to quantify).[69] This asymmetry is likely to be exacerbated by the fact that much of the information regulators require to undertake IA is held and owned by business,[70–72] presenting this sector with a crucial informational advantage over other types of actor. Given that businesses are commercial organisations, it may appear rational for them to selectively disclose information so that regulatory costs are kept to a minimum.[70–72] In the EU, recent evidence suggests chemical and tobacco companies have both employed IA to deliberately overemphasise the costs of policy proposals relating to the regulation of their products (see box 3).[27 73 74]

Valuing non-market goods in economic terms

IA usually involves attaching quantified (often monetised) values to all predicted 'costs' and 'benefits', a task regarded as necessary by many proponents of IA to allow decision-makers to aggregate dissimilar impacts,[14 91 92] and encouraged by the European Commission's guidelines.[36] Effectively, such an approach to IA involves imposing an economic grid on decisions about social policies, including those involving impacts on the length and quality of citizens' lives.[93 94] Although goods that are traded in market economies may be valued relatively easily, there is often no agreed way of valuing some of the most crucial non-economic outcomes, such as lives saved or changes to the length or quality of lives,[37 65 95] as illustrated by the debates surrounding QALYs (quality-adjusted-life-years) and DALYs (disability-adjusted-life-years).[96–103]

Even if we accept the principle that a monetary value can be attached to a life, which some have questioned,[37 65] questions remain as to how such valuations should be done and whether valuations should vary depending on a person's age, health status

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Box 3 How the chemicals industry employed IA to weaken EU legislation

Recent EU regulation on the Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH),[75] is potentially one of the EU's most important pieces of legislation. Underpinned by the precautionary principle, REACH was intended to ensure that all chemicals (those already in use, as well as new ones) would be tested for safety.[76] It was originally designed to reverse the burden of proof, making companies (rather than regulators) responsible for providing data to support safety claims. However, the chemical industry successfully diluted key aspects of the proposed regulation, including the requirement for mandatory substitution for some of the most hazardous chemicals on the market,[77] and there is evidence that IAs played a crucial role in this process, enabling industry influence in at least three ways. In addition to employing its greater access to resources to dominate the European Commission's internet consultation,[76] and producing its own IAs emphasising the potential costs of REACH,[78–80] the chemicals industry was able to influence the Commission's own IAs of REACH in several ways,[27] most of which related to the significant resources (particularly expertise) required to undertake an IA for such a broad policy proposal. Reluctant or unable to dedicate internal resources to undertaking an IA, DG Research commissioned an external consultancy firm called Arthur D. Little to evaluate the impact of REACH on the competitiveness of the European chemicals industry. However, this company had already produced an IA for the chemicals industry, which estimated that REACH would cause up to 2.35 million job losses in Germany alone.[80] This estimation was later criticised by the German Advisory Council on the Environment, which claimed that, 'the underlying models have fundamental methodological weaknesses in that they systematically overestimate the economic impacts' by, for example, failing to acknowledge that product or process innovation was likely to occur.[74] Arthur D. Little used the same parameters and methods of calculation for the study it undertook for the Commission, resulting in a systematic overestimation of the likely economic impact of REACH.[73 74] Despite the fact this IA was effectively later dismissed by the European parliament,[73] DG Enterprise and DG Environment were also reluctant to undertake an IA internally and in the same year they signed a Memorandum of Understanding with the chemical industry,[81] which led to the industry paying for two further IAs to be conducted by other private sector consultancy firms[82 83] and one by the Commission's Institute for Prospective Technological Studies,[84] all three of which were incorporated by the Commission in their overall analysis of the likely impacts of REACH.[85 86] Several non-governmental organisations were involved in monitoring this process but two later withdrew, claiming that the study methods lacked transparency, were inconsistent and imbalanced, and placed undue focus on business risks.[87] Environmental campaign groups claim that the chemicals industry's overall efforts subsequently resulted in significantly weaker legislation than the Commission had originally proposed.[88–90]

and location or whether he/she is currently alive or not yet born (a future person). Various methods have been proposed to try to overcome these difficulties, the most popular of which (and that employed in the European Commission's guidelines[104]), is the 'willingness to pay' (WTP) concept, which is inspired by economists' belief that the importance of things can be assessed by measuring what people are willing to give up to obtain them. This method involves calculating the value of a life by assessing what people would be willing to pay to avoid a particular risk. However, given that this method usually results in wealthier people valuing their lives more highly than do the less wealthy, concerns have been raised that it ends up attaching higher values to the lives of the relatively rich.[105] This may be partially circumvented by using a (median or mean) average value, but this encourages decision-makers to attach different values to people's lives than they themselves have given. These issues are likely to be particularly pertinent for EU policymakers given that there are now 27 member states and a consequential diversity in cultural values, economic circumstances and health systems. An additional problem with basing a value for a life (or life years) on surveys, as with WTP, is that respondents typically attach greater value to benefits occurring in the immediate future.[13] In response, policy guidance for assessing impacts may propose (as do the Commission's IA guidelines[104]) the use of a 'discounting rate' by which future benefits and costs should be reduced.[92 94] This effectively undervalues impacts on future generations,[106] thus tending to underestimate the impacts of public health measures that provide longer term benefits.

Accounting for the distribution of impacts

In essence, IA/CBA is underpinned by a utilitarian logic,[94 107] dictating that only actions that maximise net benefits should be undertaken.[37] Although this may sometimes be an appropriate basis of calculation, it can be inappropriate in contexts in which there is a commitment to focusing on the distribution of impacts, and not just their totality (eg, commitments to reducing health inequalities). In such circumstances, advocates of HIA have argued that aggregate health impacts should be differentiated for subgroups.[108] However, even this fails to deal with the fact that experiences of a given impact are likely to be highly contextualised.[109] For example, the impacts associated with job losses are likely to be different for affected individuals living in areas in which alternative, similar jobs and/or income support are available, compared to individuals living in areas without either of these options.[108] Taking account of these kinds of variations is likely to be particularly problematic across the EU's 27 member states. The Commission's most recent IA guidelines encourage officials to take account of the uneven distribution of impacts on different social and economic groups and the tool itself includes a few questions specifically relating to the distribution of impacts.[56] Nevertheless, a review of some of the Commission's 'integrated' IAs found that the distribution of impacts tended not to be sufficiently considered.[55] This suggests that policy commitments to tackling inequities, such as the EU's commitment to reducing health inequalities,[110] may need to be more clearly embedded within the tool (eg, by having more questions specifically relating to health inequalities). Given that it is difficult to translate distributional variations into the kinds of quantitative, economic values usually attached to impacts within IAs, it may also be necessary to provide officials with some guidance on what level of priority to afford particular distributional concerns highlighted within IAs.

Reducing the potential for the 'precautionary principle' to serve as the basis for legislation

There are currently two scenarios in which an initial process of risk assessment, which often forms part of the preliminary

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stages of an IA (see box 1), could lead EU policymakers to develop new policy proposals: (1) if it reveals a scientific consensus that suggests a risk is great enough to warrant intervention; or (2) if it reveals no clear scientific consensus but there are reasonable grounds to believe that the given hazard would, if it occurred, result in severe or irreversible damage to public health or the environment.[111] The rule underpinning the scope to act in the second scenario is known as the 'precautionary principle,'[111–113] which is typically understood to prioritise the prevention of harm to human health by removing the requirement for scientific 'proof' of risk in advance of legislative intervention.[107 111 113]

Some commentators (several of whom have links with companies profiting from regulated products[27]) argue that the precautionary principle is inconsistent with scientific approaches to policymaking,[114 115] and claim that IA represents an alternative approach to policymaking.[7] Löfstedt, for example, claims that by requiring firms that profit from regulated products to demonstrate the safety of those products, the precautionary principle represents a 'reverse burden of proof' and argues that it is more desirable, at least from the point of view of European economic competitiveness, for the burden of proof to rest with policymakers via IA (ie, for policymakers to be required to use IA to demonstrate that a regulated product causes enough harm to warrant intervention).[7] Although shifting the burden of proof away from producers and sellers of risky goods towards public officials who are responsible for managing these risks may seem reasonable in many cases,[7 116] it is problematic for issues in which interested economic actors fund research (and/or otherwise influence evidence) with the specific intention of creating scientific uncertainty, as tobacco, chemical, oil and other industries all have.[23–26 117] Not enough time has yet passed to assess whether the Commission's 'integrated' IA system has resulted in a reduction in legislation based on the precautionary principle in the EU. Nevertheless, Löfstedt claims that there has been a decline in the frequency with which the principle is mentioned in official European statements since 2002 (when IA guidelines were first introduced[33]) and argues that this indicates the 'regulatory pendulum' did swing away from the precautionary principle when integrated IA guidelines were officially introduced.[7]

The resources required to undertake IA

IA can be a resource-intensive process,[4] usually requiring access to specialist knowledge and expertise.[2 64] Given that policymakers operate in an environment of scarce scientific and administrative resources (particularly at EU level[118]), a mandatory requirement to undertake IA in advance of formal policy intervention is likely to increase the Commission's dependence on external sources of expertise. It is understandable, therefore, that the Mandelkern Group encouraged the Commission to draw on external expertise for IA,[45] and that a number of new consultancy firms have reportedly been established to cope with the Commission's increasing demand for IAs.[7] This is only likely to be problematic if the consultancy firms undertaking official IAs are simultaneously involved in work for external parties with a vested interest in the results. However, given that large corporations are some of the main clients of consultancy firms,[119] it is perhaps unsurprising that such a conflict has already occurred (see box 3).

Stakeholder involvement

The IA process is frequently understood to require policymakers to consult all potentially affected stakeholders.[39 55] Some assessments of the Commission's IA system suggest it has contributed to considerably greater consultation with affected stakeholders,[39] whereas others suggest the reality is mixed.[55 56] Where consultation works to widen participation in the early stages of policy formation, this can improve the democracy and transparency of formal decision-making.[4] However, requiring public officials to consult businesses with a history of manipulating policy outcomes through covert means, such as the tobacco and chemical industries,[23–26 29 88 89 117 120–125] may work against policies designed to safeguard public health, particularly if other, less well-resourced stakeholders are (due to resource limitations) either unaware of or unable to fully participate in consultation processes.[56] For example, an exploration of the development of the Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH) (see box 3), suggests that the inclusive approaches to consultation privileged business interests because the relevant debates were too technical to be understood by most stakeholders.[126] This is not an issue that has been explicitly considered by proponents of HIA, who often suggest that stakeholder involvement early in the policy process is a crucial aspect of the tool.[12] Although some proponents of HIA have cautioned that broad stakeholder involvement may not always be necessary or useful,[127] there has been very little discussion as to whether specific rules are required in relation to the involvement of particular corporate stakeholders. Meanwhile, large corporations, including Scottish Power, Shell[128 129] and various tobacco companies (see box 4), are actively advocating non-restrictive

Box 4 Tobacco company efforts to secure their inclusion in policy consultations

As part of its campaign to promote a business-orientated form of IA in the EU (see box 2), BAT was involved in producing a report on IA (published by the European Policy Centre, which was working for BAT), which argued that a lack of consultation with affected stakeholders was widely deemed to be problematic in the EU.[27 130] This report fed directly into the Commission's official pilot study of BIA,[131 132] which called for the production minimum standards on consultation with stakeholders and interested parties. Precisely such standards were subsequently produced by the Commission,[133] and they are referred to directly in the various guidelines on IA that the Commission has published.[33–36] The most recent IA guidelines state that 'consulting interested parties is an obligation for every IA', being a Treaty obligation, and say that policymakers must 'maintain contact with stakeholders throughout the process.'[36] Japan Tobacco International has employed the Commission's commitment to consulting interested parties to challenge its interpretation of Article 5.3 of the WHO's Framework Convention on Tobacco Control (FCTC),[134] which seeks to protect public health policy developments from tobacco industry influence, and which the EU has ratified.[135] Imperial Tobacco has launched a similar campaign in the UK,[136] which is also a party to the FCTC and where the approach to IA and stakeholder consultation is very similar. Guidelines for Article 5.3 were only agreed by the parties to the FCTC in November 2008[137] and it is currently unclear how policymakers will deal with any tensions between these guidelines and other policy commitments relating to consultation.[138]

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approaches to consultation within IA processes to secure their inclusion.

A tool to delay and challenge regulation

A mandatory requirement for policy decisions to be informed by IA provides stakeholders with a tool to continually challenge potential and existing legislation. At the very least, this is likely to delay and, in some cases, weaken or block regulation[139] (box 3). It can also be used as a basis for the repeal of legislation. Although this can be an efficient response to the emergence of new scientific or other relevant data,[140] it may also lead to avoidable harm being caused to populations and the environment.[112] This seems particularly concerning given that the EU's approach to IA has roots in a well coordinated, tobacco company-led campaign specifically intended to help avoid tobacco control legislation (see box 2), and that this company, like other tobacco companies, has a history of attempting to undermine policy proposals intended to protect public health.[23 29 120–125] All this suggests official calls to use IA to achieve the recently introduced target of reducing the administrative costs of EU regulations by 25% 141 need to be carefully monitored to ensure this does not result in IA being applied as a means of automatically reducing (rather than improving) EU regulation.[39]

CONCLUSIONS

Advocates of IA, including HIA, have made grand claims about its efficacy in predicting the impacts of policies with sufficient reliability to allow policymakers to maximise the benefits of policy developments,[7 92 114] and of its value in ensuring policy decisions are transparent,[14 141] rational,[7 92 114 141 142] scientific[114] and democratic.[143] Yet, this essay demonstrates how an integrated form of IA, such as that used in the EU, can serve to prioritise economic and business-related impacts over less tangible, long-term impacts relating to health and the environment.

This essay identifies eight key concerns with IA, including the difficulties in reliably predicting, valuing and monetising impacts and accounting for their distribution. Making accurate predictions about impacts is likely to be particularly difficult at supranational levels of policymaking such as the EU, where multiple stakeholders are involved, policies are broad and impacts are likely to differ by area (qualitatively and quantitatively).[11] For policy areas in which large corporations fund research or otherwise influence the evidence-base, as the tobacco and chemical industries have,[29 74 88 120 144] making accurate, evidence-informed predictions may be particularly challenging.

These findings suggest that the public health community should reflect carefully on its current support for IA as an approach to policymaking. If we accept that HIA increases 'the probability that the impact of policies is more likely to benefit than to harm health,'[38] the public health community needs to do more to ensure that HIAs are undertaken or sufficiently incorporated into 'integrated' IAs. Given that Article 152 of the EU Treaty can be interpreted as requiring HIAs of all EU policies,[54] there are serious grounds for appealing for the status of HIA to be increased.[53] Yet in seeking to ensure that HIA is better integrated in the EU, it is worth reflecting that many of the 'promises of HIA'[4] overlap significantly with the advantages that large corporations seek to gain from IA, including: greater engagement with stakeholders at an early stage in the policymaking process; more recognition of sectoral impacts; and increased transparency of the policymaking process.[27 28] Simply asking for greater consideration to be given to health impacts within integrated IA systems may not be sufficient, given the far greater resources usually available to large businesses in comparison to other social actors,[56] and, in the EU at least, a policy system into which business interests are often highly integrated.[145 146] As Krieger and colleagues suggest,[4] the public health community also needs to consider who undertakes IAs, on whose behalf, who provides the required resources including the data, who decides who is involved/excluded, who influences methodology and who validates the results.

In some respects, the limited progress of HIA in the EU is not unexpected, given wide recognition that health is a relatively low priority in the EU and subject to a narrow and medicalised policy focus.[38] It is, however, surprising that neither the WHO, which has established an office to promote HIA in Europe,[17] nor many of the other public health advocates active in the EU, have yet questioned the Commission's approach to IA[53] (indeed, the WHO appears actively supportive, with a recent WHO report citing the EU's approach as an example of good practice[20]). This may be because public health advocates tend to be more concerned with establishing mechanisms for HIA at member state-level.[11] If so, this is potentially short-sighted, given that national regulation increasingly originates from EU institutions.[147 148] Alternatively, it may be that the public health

What this study adds

- Eight fundamental concerns have been raised about IA (and its close relation CBA), most of which suggest the process can be advantageous to the interests of large corporations and does not necessarily help promote or protect public health or environmental interests. By focusing almost exclusively on HIA and EIA, the public health community has failed to adequately engage with these concerns.
- Existing research on IA in the EU demonstrates: (1) that large tobacco and chemicals companies were able to influence this approach (see box 2); (2) that companies from these sectors have subsequently employed IAs in attempts to delay, weaken or prevent legislation intended to promote public health and/or protect the environment (see box 3) as well as to ensure their inclusion in policy discussions (see box 4); and (3) that the IAs produced by the Commission under this system tend to undervalue health impacts. Taken together, and combined with an analysis of the European Commission's guidelines for its 'integrated' IA tool, all eight concerns appear to be relevant to IA processes in the EU.

Policy implications

- More attention needs to be given to criticisms of IA and CBA, in order to better understand how IA can work against, as well as support, policies intended to improve public health and protect the environment.
- The EU's current 'integrated' version of IA appears to prioritise business impacts over health impacts. A legal requirement for the EU to protect human health suggests that urgent consideration should be given to assessing how health impacts can be better incorporated into this system.

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community's sectoral focus on HIA (albeit occasionally considered in relation to EIA[18 19]) has restricted awareness of the implicit tensions within 'integrated' IA tools and the potential challenges that these raise for public health.

It is important to acknowledge that HIA has the potential to help ensure either that policy proposals actively help improve public health or that any potential damage is limited. If applied in a genuinely open and informed way, it can perform a useful role in defending health proposals against challenges by other interests.[149] Hence, the case being made in this essay is not that the public health community should entirely abandon IA but that it is important to acknowledge IA does not necessarily facilitate linear, evidence-based policymaking and is, rather, a tool that can be creatively employed by a variety of interests. It is suggested that the present findings imply: (1) that public health advocates should give more attention to forms of IA that challenge, as well as support, the prioritisation of health impacts; (2) that further research is required to explore how 'integrated' forms of IA, such as the EU's new system, impact on policies affecting public health and environmental outcomes; and (3) that public health groups need to become more actively involved in these issues at EU level.

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