European Heart Network's response to the European Commission's consultation on draft Impact Assessment Guidelines

25 July 2008

Introduction

The European Heart Network (EHN) is a Brussels-based alliance of heart foundations and other concerned non-governmental organisations throughout Europe. EHN has 31 members in 26 countries.

The European Heart Network plays a leading role in the prevention and reduction of cardiovascular disease – in particular coronary heart disease (CHD) and stroke - through advocacy, networking and education so that it is no longer a major cause of premature death and disability throughout Europe.[1]

Cardiovascular disease (CVD) is the number one cause of death in Europe. It accounts for nearly half of all deaths in Europe causing over 4.3 million deaths each year in the member states of the World Health Organization (WHO) European Region. CVD causes more than 2 million deaths each year in the European Union.

Cardiovascular disease is estimated to cost the EU economy over €192 billion/year – more than the EU's annual budget (€129 billion in 2008). Production losses due to cardiovascular disease mortality and morbidity cost the EU almost €41 billion/year, representing 21% of total cost of those diseases, with around two-thirds of this cost due to premature death (€26.9 billion) and one-third due to illness (€13.9 billion) in those of working age. An additional and another important cost is that of informal care which is just under € 42 billion/year.[2]

General Comments

EHN welcomes the European Commission's (EC) consultation on its draft Impact Assessment Guidelines. We welcome the principle of better regulation that includes an evidence-based approach to policy-making and take into account the benefits and costs of regulatory proposals to both the economy and the society at large. In this context, we would like to stress that achieving a 'high level of health protection' for all European citizens has been a

[1] http://www.ehnheart.org

[2] for more information on mortality, morbidity etc statistics and the cost of disease study http://www.ehnheart.org/content/sectionintro.asp?level0=1457

clear objective of European Treaties since Maastricht (1992) and health has a key role to play in achieving Europe's full potential for prosperity, solidarity and security. Furthermore, the health of the people living in Europe has profound practical implications for economic success in a highly competitive, globalised world.[3,4]

Comments to specific questions

Question 1: Do the Guidelines explain sufficiently the logic of the steps to be followed in the impact assessment process (problem definition, objectives, policy options, assessment of impacts, comparison of options, monitoring and evaluation)?

EHN believes that the logic of the steps to follow in the impact assessment process is well described.

What is the problem?

EHN would like to draw the attention to one of the questions to help identifying the problem (top of page 22):

> *A good problem definition has to provide the following:*
> ….
> *It should **identify clearly the drivers or underlying causes** of the problem. Why does the problem exist? To what extent is this the result of a market failure or regulatory failure?*
> ……

In one particular case of exceptionally high relevance to public health – tobacco use – the drivers of the problem is exclusively the tobacco industry which may at the same time be considered a stakeholder. EHN will comment more specifically on the problem this creates in terms of conflict of interests in its comments to question 2.

What are the policy objectives?

EHN agrees with the Commission that objectives should be directly related to the problem and its root causes and that they should be 'SMART (i.e. Specific, Measurable, Achievable, Realistic and Time-bound). We also agree that policy options must be closely linked both to the causes of the problem and to the objectives. However, we would like to stress that considerations regarding compliance costs or considerations of proportionality should not block long term benefits and the appropriate level of ambition for the best possible options, particularly when the objectives are related to achieving a 'high level of health protection' for all European citizens.

[3] Suhrcke, M, McKee,M, Arce, RS, Tsolova, S, Mortensen, J. "The contribution of health to the economy in the European Union". European Commission 2005 (http://ec.europa.eu/health/ph_overview/Documents/health_economy_en.pdf)

[4] Suhrcke, M., Rocco, L., McKee, M. "Health: a vital investment for economic development in eastern Europe and central Asia". WHO 2007 (http://www.euro.who.int/Document/E90569.pdf)

What are the policy options?

EHN agrees that options should preferably have public and/or political support but that this should not be the sole determining factor in defining and analysing them. When identifying the options, the EC should also carefully consider existing EU policies and, if possible, relevant proposals which are still discussed in the European Parliament and Council.

EHN would like to comment specifically on the question '**To regulate or not to regulate?'** The draft Guidelines (page 34) state that:

> *Tackling the problem does not mean that you need to choose a directive or a regulation. Consider the full range of alternative actions available to the Commission. Is self-regulation a feasible option? Could the same objectives be met by securing a voluntary agreement? Is an information and education campaign sufficient?*

From a public health point of view, EHN would suggest that voluntary agreements in areas such as tobacco control and in policies that aim at addressing nutrition-related diseases, notably cardiovascular diseases and obesity, voluntary agreements are not effective policy options.

The tobacco industry cannot be relied upon to regulate itself. Indeed, as early as the 1960s tobacco industry sponsored research showed that nicotine was addictive: this information was never willingly disclosed by the industry. The tobacco industry also engages in activities in the developing world that are either considered inappropriate or even against the laws in other parts of the world[5], for example promotions to children[6] and young people. The tobacco industry also exploits farmers to such an extent that they struggle to break-even.[7]

In the context of combating child obesity and its severe health consequences in adulthood, strict restrictions on marketing to children of food products that are high in fats, sugar and salt are strongly recommended. Although several food companies have committed to introduce, on a voluntary basis, some restrictions they are limited in scope, i.e. to television advertising as opposed to all marketing approaches[8], often general rather than specific, setting the age limit too low (under 8 or 12 years vs under 16 years). There is a lack of monitoring of the adherence to the codes or delivery of commitments. There are rarely any sanctions for companies that do not adhere to their own rules.

Assessing administrative burdens and simplification potential should not only be considered for businesses, citizens or public administrations but should also include the administrative burden on the third sector and non-governmental organisations.

With regard to simplification of existing legislation, it would be useful if the Guidelines gave some clear examples of when this is necessary and why. Examples should not only specify

---

5 Davies, P.(2003), Malawi: addicted to the leaf. Tobacco Control. 12; 91-93

6 Hammond, R., Rowell, A. (2001) Trust us we're the tobacco industry. Campaign for Tobacco-Free Kids & Action on Smoking and Health. Washington DC and London.

7 Framework Convention Alliance. The Tobacco Trap: The hidden cost of doing business with the tobacco industry. Producer: P. Stein. (2006).

8 http://www.which.co.uk/documents/pdf/food-fables-2-152486.pdf

10 http://fctc.org/iwg_cops/bp1.php

the extent to which each of the policy options achieves simplification, and the difference that this will make in practice, but also clearly spell out why the simplification is beneficial and for whom. In cases where simplification benefits are likely to be significant for business but have a negative impact on public goods, such a health and the environment, the potential cost savings for business should be assessed, including quantitatively, against cost to the society at large.

What are the likely economic, social and environmental impacts?

EHN believes that that the section on 'public health and safety' listed under social impacts could be expanded and would like to suggest including 'well-being'.

The first bullet point under 'public health, well-being and safety' should read:

- Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on the socio-economic environment (working environment, income, education, occupation, transport, housing, education, agriculture and social cohesion)?

The sixth bullet point under 'public health, well-being and safety' should read:

- Does the option affect lifestyle-related determinants of health such as use of tobacco, diet, drug or alcohol use, physical activity, sexual behaviour or accidents and stress?

Add a bullet point to the section on 'access to and effects on social protection, health and educational systems':

- Is there likely to be a significant demand on any of the following health and social care services: primary care, community services, hospital care, need for medicines, accident or emergency attendances, social services, health protection and preparedness response?

Altogether, EHN would favour a separate mentioning of Health Impacts (see also below) to underline the importance hereof.

How do the options compare?

EHN welcomes the table summarising the comparison of the policy options in terms of their effectiveness, efficiency, and coherence (page 52) and particularly the attention to potential negative unintended impacts. EHN stresses the importance of also considering negative unintended impact on public health.

Arrangements for future monitoring and evaluation

EHN fully agrees that policymakers need to be able to verify if implementation is 'on track' and the extent to which the policy is achieving its objectives.

Involving civil society in monitoring and evaluation ought to be considered. For example, in tobacco control, Non-Governmental Organisations (NGOs) have played a leading role in combating tobacco use in many countries and, on a global level, were instrumental in

ensuring the success of the FCTC negotiations. Recently negotiated treaties have recognised the crucial role played by civil society organisations in such treaty development and implementation.[10] It is important for the EU to follow this trend and welcome the involvement of NGOs.

Question 2: Do the Guidelines preserve the proper balance between economic, social and environmental impacts that is required in the integrated and balanced approach to impact assessment?

First, with regard to the **balance between economic, social and environmental impacts,** i.e. identification of economic, social and environmental impacts of a policy, why they occur and who is affected, the primary objective for the Impact Assessment Guidelines should be to ensure that a potential policy option/proposal respects the European Treaty objectives. Thus, the Impact Assessment must ensure that proposals promote throughout the Community a harmonious, balanced and sustainable development of economic activities, a high level of employment and of social protection, equality between men and women, sustainable and non-inflationary growth, a high degree of competitiveness and convergence of economic performance, a high level of protection and improvement of the quality of the environment, the raising of the standard of living and quality of life, and economic and social cohesion and solidarity among Member States.

This is recognised in the draft Guidelines which specify that *"Impacts should be considered in the context of Treaty objectives and the EU's overarching policy goals, such as promoting sustainable development, achieving the goals of the Lisbon Strategy, the EU energy strategy, and respect for Fundamental Rights"*. EHN would like to point out that the Lisbon Strategy includes objectives on healthy life years. Whereas the Lisbon Strategy may have contributed to growth in certain sectors, it has been insufficient to address real needs and ambitions for health, well being and quality of life as successive *Eurobarometer* surveys[11] and other indicators of public opinion and demand have shown. Unless the European Union embraces a truly sustainable development approach to growth, with a primary purpose of improving its societies, it will fail in its founding objectives. We recognise that there is a balance to be struck between economic and social and environmental impacts; but are worried by the sentence *"a proposal may be very beneficial for consumers, while the costs fall mainly on enterprises"* as if this was necessarily a negative aspect of an option. An Impact Assessment should beware of inappropriate incentives for growth and competitiveness which may jeopardize general health and well-being. Health and well-being, as we stated in our general comments, are integral part of the EU's policy goals and also have profound practical implications for economic success in a highly competitive, globalised world.

Secondly, EHN would like to suggest that health should be singled out in step 1 which should say: identify economic, social, health and environmental impacts. We believe the inclusion of 'health' is warranted by Article 152 of the Treaty.

With regard to stakeholder consultation processes and an integrated and balanced approach to impact assessment, we understand that Consultation with stakeholders is an important part of the impact assessment process that must be carried out according to a set of minimum standards.[12] We would like to stress that in the case of tobacco control policies,

[11] http://ec.europa.eu/health/ph_publication/eurobarometers_en.htm
[12] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF

special consideration should be given to the direct conflict that exists between the objectives of the tobacco industry (to increase sales) and the negative impact this inevitably has on public health. Article 5.3 of the FCTC states that when Parties are setting and implementing public health policies related to tobacco control, they shall '*act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law*.' It is recognised that tobacco industry is not just another industry; this is due to the nature of the product it manufactures and places on the market as well as to actions by the tobacco industry itself. There is solid and overwhelming evidence (for the most part provided by internal documents from the tobacco industry itself) that the tobacco industry has actively and systematically sought to hinder, delay, and prevent the adoption of effective tobacco control policies.[13,14] Therefore, normal rules of engagement cannot apply.

We support Protocol No 7 on the application of the principles of subsidiarity and proportionality, annexed to the Amsterdam Treaty, which states that '*The commission should consult {.....} widely before proposing legislation and, wherever appropriate, publish consultation documents*'.[15] However, whilst we support the principle of engaging with a wide range of stakeholders in consultation processes, we are concerned about the degree of participation that may be extended to the tobacco industry and question the legitimacy of the tobacco industry's contribution to any public health policy. As the Impact Assessment Guidelines also mention that consultations *"may be restricted to a specific category of stakeholders… or limited to a set of designated individuals"*, we suggest that the Commission should interpret the guidelines in such a way as to avoid 'face to face' meetings with the tobacco industry because of the unique role of its products in causing harm and because of its track record of deceptive behaviour.[16] We understand that the impact of Article 5.3 on the Commission and its consultation procedures has yet to be clarified. However the European Community is a signatory to the Treaty and is therefore legally bound by its provisions (the EU ratified the FCTC on 30 June 2005).

It should also be noted that the *Communication on general principles and minimum standards for the consultation of interested parties by the Commission*[17]*, COM (2002) 704* was adopted in 2002, three years before the FCTC entered into force. Accordingly the impact of Article 5.3 on the Commission and its consultation procedures has yet to be clarified. However the European Community is a signatory to the Treaty and is therefore legally bound by its provisions (the EU ratified the FCTC on 30 June 2005). It is our hope that the Commission will consider revising its consultation procedures in light of its new obligations resulting from FCTC ratification.

Question 3: Do the Guidelines cover sufficiently the specific aspects of these impacts

Referring to our comments above on assessing administrative burdens, EHN believes that the Guidelines need to asses further impacts specifically affecting NGOs and the voluntary sector**.**

[13] Ong EK, Glantz SA (2000).The Lancet **355** (9211): 1253-1259
[14] Hong, M. K., Bero, L. (2002) How the tobacco industry responded to an influential study of the health effects of second hand smoke. BMJ. 325: 1413-1416
[15] http://www.eu2006.gv.at/en/The_Council_Presidency/subsidiarity/dokumente/protokollsubsidiarity.html
[16] See for example: BAT's Big Wheeze - http://www.christianaid.org.uk/indepth/404bat/index.htm
Hooked on Tobacco: http://www.christianaid.org.uk/indepth/0201bat/index.htm or BAT in its own words – The alternative BAT social report http://www.ash.org.uk/html/conduct/pdfs/bat2005bw.pdf
[17] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0704:FIN:EN:PDF

EHN agrees that SMEs can be affected by the costs of regulations more so than their bigger competitors. However, many policies affect NGOs just as they affect SMEs (e.g. public procurement as 50-70% of third sector's activity is funded from public finance). Still, as NGOs do not identify themselves as economic operators, they are often dismissed as being an integral part of the economic sphere. The Union of International Association (UIA), established in 1910, collects information on international non-profit organisations throughout the world in a '*Yearbook of International Organisations*'. In 1959 there were 985 entries in the yearbook, by 2003 this had risen to almost 21,000 organisations. The World Bank estimates that the number of international non-state actors (NSAs) has increased from 6,000 in 1990 to 26,000 by 1999. Some commentators have called this a 'global associational revolution'[18]. The lack of an agreed definition of this sector has hampered the collection of data on the size and importance of NSAs. However, the John Hopkins Comparative non-profit project[19] has gathered information from 35 developing and developed countries for the period 1995-1998. The statistics point to the overall importance of the non-state actor sector:

- 1.3 trillion dollars in expenditure, equivalent to 5.1% of combined expenditure.
- The world's seventh largest economy.
- 39.5 million full-time equivalent employees or 4.4% of the economically active population. In fact this represents 10 times the number of employees in the utilities and textiles industries and 5 times the food manufacturing industry in these countries.
- 190 million people volunteer for the sector. This represents more than 20% of the population or the equivalent of 221 volunteers per 1,000 of the adult population.

These figures underline the centrality of the third or non-state sector to the economy and society. It shows their ability to mobilise volunteers and contribute towards social capital. The Impact Assessment needs to acknowledge the importance of this sector which is quite neglected in the draft Guidelines. Furthermore, when the analysis shows that NGOs are disproportionately affected or disadvantaged compared to large companies, mitigating measures should be considered.

Question 4: Do the Guidelines cover a sufficiently broad range of analytical methods, and are these methods treated in sufficient detail?

EHN emphasises the importance of providing full information on the origin of data. EHN refers to the report and conclusions following the DG SANCO 2006 Peer Review Group on Stakeholder Involvement. The Peer Review Group noted that quality and reliability of data are of considerable concern and that data can be controversial and contested by stakeholders. EHN suggests that for all data used in Impact Assessments there should be clear quality indicators on how the data was obtained, assessed and how it will be used.

Question 5: Do the Guidelines Indicate sufficiently clearly how input from experts and stakeholders should be collected during the preparatory stage based on the Commission's Minimum Standards for Consultation ?

[18] Matthews 1997; Rosenau 1997; Boli and Thomas 1999

[19] Data on 35 countries from the Johns Hopkins Comparative Nonprofit Sector Project managed by the Centre for Civil Society Studies at the John Hopkins University.http://www.jhu.edu/%7Ecnp/research.html

With reference, again, to the DG SANCO Peer Review Group, EHN would like to call attention to the challenge of 'engaging the un-engaged'. A particular challenge is engaging groups that may not identify themselves as stakeholders or may not have a full understanding of the relevance of EU policy.

Engaging the right stakeholders in terms of quality and representativeness is a vital factor in achieving a successful involvement process. Although, the responsibility for engaging people in consultations does not rest merely with the Commission service responsible for the Impact Assessment and the stakeholder consultation, EHN suggests including in the Guidelines a recommendation to seek out pro-actively relevant stakeholders. This can be done by contacting European federations and networks.

EHN welcomes the following recommendations in the draft Guidelines:

> *You should also be careful in drawing conclusions if there are only a small number of responses and they come from a narrow range of interests.*
>
> *While you should be careful, however, not to be unduly influenced by the views of one particular group, no matter how professionally these have been presented, you should also give a response its due weight if it represents a large number of citizens or stakeholders.*

Conclusions

Today's Europe and today's world call for a coherent approach to tackle major global challenges. This needs to be adequately reflected in the Impact Assessment Guidelines. Health has a crucial role to play in achieving Europe's full potential for prosperity, solidarity and security. We therefore hope that a good balance will be reached between improving health in its own right and valuing health as a key part addressing the challenges facing Europe.

Summary of EHN' comments and recommendations:

EHN:

- welcomes the principles of better regulation that include an evidence-based approach to policy-making and take into account the benefits and costs of a regulatory proposal to both the economy and the society at large

- emphasises that achieving a 'high level of health protection' for all European citizens has been a clear objective of European Treaties since Maastricht (1992) and health has a key role to play in achieving Europe's full potential for prosperity, solidarity and security

- expresses concerns about conflict of interests where the drivers or underlying causes of a problem are also considered stakeholders

- submits that voluntary agreements are not adequate when it comes to establishing policies that also aim at improving and protecting public health

- believes that the assessment of (positive or negative) effects on administrative burden resulting from EU legislation should not only be considered for businesses, citizens or public administrations but should also include the administrative burden on the third sector and non-governmental organizations

- suggests to involve civil society in monitoring and evaluation

- highlights that the primary objective for the Impact Assessment is ensure that a potential policy option/proposal respects the European Treaty objectives

- recommends that health impact assessment be a separate part of the Impact Assessment further to the provision in Article 152 of the Treaty

- recommends special rules for tobacco industry respecting Article 5.3 of the Framework Convention on Tobacco Control (FCTC); such rules must also be set out in the Commission's general principles and minimum standards for the consultation of interested parties by the Commission

- suggests including in the Guidelines a recommendation to seek out pro-actively relevant stakeholders