

EU Stakeholder Dialogues
2006

Final Report- Harm Reduction

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Harm Reduction

Summary

Harm reduction is seen as a clear priority for BAT by several stakeholders, and is discussed at length in the policy session. Despite the recognised difficulties in engaging the Commission on this issue, stakeholders want BAT to engage and use their tobacco research expertise to address the harm reduction challenges. Some stakeholders are sceptical of BAT's sincerity, and cannot reconcile the company's profit motive with its professed concern with harm reduction. They question BAT's terminology, and the importance of plain speaking is emphasised.

Some science and research stakeholders think BAT should prioritise smokeless tobacco products, and argue strongly for the reduced health risks posed by snus compared to cigarettes. Of course, the EU ban on snus is recognised as a major barrier, and very few stakeholders are optimistic regarding the chances of a repeal. Nevertheless, several stakeholders would support this, and the key issues are seen to be the impact of snus on smoker behaviour patterns and the experience of countries such as Sweden where snus is available.

Some stakeholders suggest BAT should concentrate on developing non-EU markets for snus, while others think snus could be seen as an alternative to nicotine replacement therapies. There are some concerns with snus in relation to TSNA's (two stakeholders suggest methods of reducing these) and the effects of nicotine (one stakeholder suggests the health risks have been underestimated).

Regarding harm reduction in conventional and modified products, one stakeholder feels that the objective should be to reduce harmful substances across all tobacco products, rather than brand differentiation. The importance of taking account of adaptive consumer behaviour is emphasised; filter analysis and smoker panels are suggested as techniques. Epidemiology and whole smoke approaches are also recommended. There is some disagreement over the harm reduction potential of lower delivery products, and some suggest that the role of nicotine in creating appeal has been over-estimated.

There are seen to be major challenges in engaging with the Commission on harm reduction, not least the negative perceptions of the tobacco industry and its associates, and the highly politicised nature of the debate. There is also a fast turnaround of non-expert EC staff. The influence of the WHO, the pharmaceutical industry and the tobacco control lobby is also seen as problematic. One stakeholder suggests the success factors for dialogue are a commitment to be part of the solution, to give serious effort to the process, and to be guided by the outcomes. Others suggest collective industry action.

The importance of engaging with scientists and researchers is emphasised in order to avoid duplication of effort and to ensure robust public policy research. Two stakeholders would like better consumer information on reduced risk products; others prefer differential pricing to drive behaviour change.

Priority Issues

Harm reduction is seen as a clear priority for BAT by several stakeholders, and (along with snus) it is discussed at length in the policy session, suggesting that stakeholders feel harm reduction is a particularly important responsibility issue facing BAT. Clearly this is an area where there is a limit to the progress that can be achieved by tobacco companies alone, and stakeholders feel that the influence of several other parties including regulators is needed to make significant progress. Nevertheless, tobacco companies are seen to have an important role to play, and despite the difficulties of engaging with the Commission discussed later, stakeholders want BAT to engage on harm reduction issues and to bring their research expertise to bear on the challenges in this field:

I defend the tobacco industry because they are the only ones who can improve the products.

Some stakeholders feel that BAT has a clear responsibility to limit the negative health impacts of smoking on the smoker and on others who may be exposed to the smoke. One stakeholder sees harm reduction as a priority not only for public health, but also as a priority in the interests of individuals and companies (in terms of workforce health).

Another stakeholder points out that changes in public health are often gradual, and so BAT will need long-term engagement in harm reduction issues. He thinks that it is not appropriate for BAT to diversify out of the cigarette market, preferring a harm reduction strategy to the calls for tobacco companies to be dismantled:

Another company will come along. The public will get bad tobacco and ones with filler products. I am not a fan of destroying the tobacco industry. People who suggest this have never thought of the consequences of their actions ... Shouldn't we be giving people the choices to live better, [i.e.] harm reduction for those who are unable or unwilling to quit?

The issues discussed comprise:

- Non-combustible products and snus;
- Reduced risk conventional and modified products;
- Engaging the Commission on harm reduction (the challenges and suggested solutions);
- Engaging the science and research community on harm reduction; and
- Disclosure of ingredients and consumer information.

Some science and research stakeholders prioritise non-combustible tobacco products and snus as the area where BAT should focus. Many would also like to see industry association involvement and more collaborative effort.

A few stakeholders are not convinced of BAT's sincerity on this issue, due to what they see as an inherent conflict between the company's harm reduction activities and its core business:

So your primary aim is to fight smoking not to promote it?

A couple of stakeholders question the terminology used by the company in its stated positions, one referring to the 'carefully managed presentation', and there is a sense that plain speaking is needed from the company (both on the website and in presentations) if stakeholders are to give credence to BAT's stance on harm reduction:

Do you accept when you say 'substantial harm' that you mean death, cancer, heart disease? Do you accept that it's hundreds of thousands of deaths every year? Do you accept the findings of the WHO and credible scientific journals? It's not a 'significant risk', it's a very serious risk of death.

There are two other general points mentioned relating to harm reduction. Two stakeholders think the harm reduction issue is so fundamental and controversial, that litigation might be a threat: "It's a legal and moral dilemma". They think that there will come a time when the industry could be litigated against for developing a snus product that is perceived as something people don't want (i.e spending shareholders' money unwisely), but equally, there is also the risk of litigation for not developing a lower risk product for consumers.

Finally one stakeholder in the policy session challenges the company to support smoking cessation projects to prove it is serious about harm reduction:

Are you prepared to open smoking dependency centres to help people stop smoking?

Non-Combustible Products and Snus

Non-combustible tobacco products such as snus are seen as a priority by some stakeholders due to the potential public health benefits of consumers using this type of product rather than conventional cigarettes. One science and research stakeholder is particularly impressed by BAT's work in this area:

I think it is positive that BAT and others are working on snus. [It] brings visibility. I'm delighted to see your involvement – other companies will follow.

Some science and research stakeholders argue strongly for the reduced health risks posed by snus, compared to conventional tobacco products. For example,

one stakeholder sees a need to move away from the cigarette as the dominant medium of tobacco consumption in order to achieve significant harm reduction. This is not to say that he does not see scope for reducing the harm produced by cigarettes, but rather that for a significant reduction to take place, he thinks that it is necessary to move to other ways of consuming tobacco:

Progress has been made in reducing the harm of cigarettes, but I don't think that cigarettes are the way forward. I think tobacco has its use, but cigarettes are the worst way to use it. If the tobacco industry could extract what the user wants from tobacco and market it in other ways, I would have no problem with the industry.

However, a few stakeholders acknowledge that even if snus were made available to European market, the rate of uptake would be slow, since "It's not a quick fix". Nevertheless, several science and research stakeholders feel that there is, in many ways, a moral obligation to offer products such as snus to European consumers, on the grounds of both consumer rights and public health:

The consumer has a right to the product and a right to information [about the health risks].

By not making it available, we disregard people's choices; we say 'we should give them this or that' ... You are deprived from providing [consumers] with what they want. [It's like saying] you can't drink Coca-Cola Light, you have to drink Coca-Cola until you have diabetes.

It is pointed out in the policy session that smokeless tobacco products also overcome the challenges of environmental tobacco smoke:

Smokeless tobacco is the way to go ... there's no passive chewing! From the point of view of public health it could cause a decrease in the harm.

Two science and research stakeholders also identify significant potential for BAT to use snus as a tool for improving its current relationship with its customer base. Another would like to see BAT expand its range of snus products and develop other forms of smokeless tobacco:

The days of getting nicotine into consumers by burning is over, that's the end goal ... You are seeing an increased strain with your consumer, and you can see snus as rebuilding that relationship.

Oliver Twist [a Danish snus with a peppermint flavour] – ... They like the flavour and it's heavily cured. It is discreet. It is a "modern" product even though it is 100 years old. We need these types of products ... I am [also] talking about different product development – Listerine strips, products that appeal to women (like a tic tac) – something more appealing to consumers other than a pouch of tobacco.

Of course, the EU ban on snus is recognised as a major barrier to progress in this area, and several science and research stakeholders do not believe this is justified scientifically:

You have the Royal College of Physician's report. They say [snus is] 10 to 100 times less dangerous [than conventional tobacco products].

Its lowering of risk is about 98%, so it's properly criminal to ban snus.

One stakeholder is particularly angry at the lack of consistency in the EC's policies relating to tobacco. Taking his country as an example, he sees the EC on the one hand forcing it to open up its markets to cut-price competition (thus encouraging smoking by making it cheaper), and on the other, closing the market to snus on public health grounds:

For minimum price, they say free market, we say public health. Snus? We say free market, they say public health!

Despite these opposing views, a repeal of the Snus ban is seen as unlikely (one stakeholder goes as far as saying "don't count on it in the next ten years", since there is "no prospect" in the current Commission). Stakeholders point out that the Commission is not very open to amending or simplifying previous regulations, and suggest that it would cause problems politically for the Commission to be seen to be changing its stance on snus:

It's very difficult for policy men to change their minds. If something is forbidden, why clear it now? ... How can you tell the consumer why it was banned last year and not this year, with no new scientific evidence?

I remember debating Sweden joining the EU. There was a passion in Parliament at that time against snus, because of one issue – cancer of the mouth. If you try again now, with the stronger feeling [against smoking] in the EC, you would be roundly defeated. Don't even try it.

Politically, I can't see any prospect of it being overturned, although looking at it dispassionately there is a strong case ... The fanaticism of the anti-smoking lobby would make it very difficult politically to overturn. Politics doesn't necessarily follow logic!

One stakeholder also links this reluctance to repeal the snus ban to the US experience of heavy campaigning against snus after a child's death from oral cancer was linked (possibly erroneously) to the product:

In the US, smokeless tobacco escaped advertising bans and became very popular. An eleven-year-old boy died of mouth cancer though [the death may or may not have been linked to snus], so there was a heavy campaign with a huge impact on EU regulation.

Another stakeholder questions the science behind the perceived link to oral cancer:

If you look at US studies, they go back to 1957. Almost none show signs of risk for oral cancer. So why did people get the idea that there is significant risk of oral cancer? We think it is [one] article [which showed a] small impact on a long term user ... What most people don't understand is that the article was based on one type of tobacco, a powder form of tobacco dating back to the 1800s.

A few stakeholders think that there may be scope for the Commission to re-visit the question of the snus ban, and one stakeholder in the policy session who in other respects is fairly critical of BAT and tobacco products, is actually supportive of a review of snus:

If there is any product like snus – and it sounds interesting – if it's demonstrated to be less harmful, I would gladly assist to have that product [made available] rather than a more harmful one.

There are questions on the comparative nicotine delivery in snus compared to conventional products, but when it is explained that the amount of nicotine the consumer receives is similar in both cases, the key point for stakeholders in the policy session seems to be the impact of making snus available on patterns of smoking behaviour:

It's difficult to sell in Parliament because it is expanding the market for smoking products. If the evidence shows a significant shift from tobacco burning to snus, and this has resulted in a [positive] health impact, that would be significant in our view of the issue.

The key question is – if the ban was overturned, is it possible to predict whether it would result in new users [of tobacco products], or would existing smokers switch to snus? That’s the question that would win or lose the debate.

One stakeholder feels that the only way to constructively engage the Commission in this debate is by giving a voice to countries that have experienced the impacts of smokeless products, such as Sweden presenting evidence on the positive health impacts of products like snus:

The way to raise [the profile of the debate on snus] is to elicit the opinion of people who have a practical view; and that would be the Swedish. Maybe they could push it – they know there hasn’t been any increase in the rates of mouth cancers, general cancers [and] no increase in heart infarction.

One stakeholder in the policy session calls for further research studies into the impact of snus: “*I would like to see more studies than Sweden*”.

Two science and research stakeholders can even foresee a situation where the Commission might face legal action for its present stance on snus:

A lung cancer patient [could] sue the European Commission [arguing] that to get nicotine, they were forced to smoke a dangerous product.

Another stakeholder suggests that it might be more valuable for BAT to work on influencing future regulations instead of campaigning to repeal the ban on snus. Nevertheless, stakeholders feel that BAT is justified in advocating the use of snus and, given the stalemate over EU regulation of smokeless tobacco products, some suggest that BAT should concentrate on non-EU markets:

Putting myself in your shoes, you need to concentrate on [snus] markets that aren’t regulated.

They suggest promoting the product by communicating the reduced risks that it presents, when compared to smoking:

In your communication with smokers, tell them there is a low-risk, smoke-free alternative. Ten times less risk, 90% reduction.

In terms of possible action within Europe, two science and research stakeholders talk about the possibility of treating snus as an alternative to existing nicotine

replacement therapies (NRT) for people who can't give up smoking, and believe that this might work in their country:

There's potential for developing an alternative which is closer in taste [to cigarettes] ... You could market these alternatives as a kind of 'fun' alternative to NRT products.

The position in [my country] is that we want the EC to have a closer look [at snus] for people who can't give up smoking. Our director general of public health would say 'OK, let's register it as a pharmaceutical'.

Another stakeholder feels that there is a need to position reduced risk products not as pharmaceutical treatments, but as products that the consumer will enjoy:

When you appeal to consumers, it needs to be something other than a medical message. Consumers resist being treated as a patient – having to take medication. They don't like feeling like someone that has to be pitied – like 'I am an addict.'

However, one stakeholder believes that snus might not work everywhere, and believes that harm reduction solutions depend on different cultures and consumer preferences:

Snus is a model for a safer product – snus is not the model product. It is an acquired taste. It has deep social roots in Sweden. People act like the Swedish experiment is recent. It is over the last 100 years. There are historical reasons why it became popular. Snus may not appeal to other cultures.

One remaining harm reduction challenge is raised by two stakeholders in relation to snus - the need to reduce the risks presented by TSNA (tobacco specific nitrosamines):

I think TSNAs are more important with snus than with combustible tobacco products because in the clouds of smoke you have so many compounds.

They mention a few techniques which might be used to keep the levels of TSNAs low, such as early picking of the tobacco leaves, refrigeration and producing the end product without curing the leaves. They also cite one manufacturer who claims not to have TSNAs in its snus because of the harvesting methods used:

- *Pick the product and keep it refrigerated. Swedish Match is doing analysis on batches and passing it further on if TSNAs content is too high. They are then refrigerated to avoid [TSNAs] increasing.*
- *Is there a possibility, with smoke free tobacco, of picking the leaves early? Does it need to be cured if it's smokeless?*
- *Thomas Ericsson claims to have no nitrosamines in his snus. He takes green tobacco.*

One stakeholder in the policy session also feels that the potential health risks of nicotine in smokeless tobacco products are being underestimated:

The impression has been given that nicotine is harmless if it enters the body not through combustion. As a pathologist ... [I can tell you that] nicotine itself as a chemical substance has an effect on the cells lining the blood vessels. [Smokeless tobacco products] will have an effect.

However, a science and research stakeholder disagrees, saying that the health risks of nicotine in snus have been exaggerated:

Nicotine has been demonized. That has to be changed to make progress ... To be comfortable with snus, people have to be comfortable with nicotine maintenance. We need to treat nicotine more like we deal with caffeine.

Given the difficulty of proving any health benefits of reduced risk products, and the resistance of many in the public health community to these messages, he also suggests that it is important to demonstrate the case regarding snus if progress is to be made on persuading people about harm reduction more generally:

Is there anyone that believes or knows that snus products have less risk than smoking? The risk potential is very wide. How in the world will you make progress in conventional products, if you can't make progress on the snus product?

Reduced Risk Conventional & Modified Products

One stakeholder feels strongly that BAT's objective should be to reduce hazardous substances in cigarettes across the board. This stakeholder does not see a role for regulators and standards institutes in advising consumers on which brands are less harmful than others. Instead, he would prefer the companies to

take the lead in reducing any hazardous substance across the board, where it is possible to do so:

We can say [to tobacco companies] that you have to reduce some substances. But we cannot recommend to consumers that if they smoke this brand A it's better for their health than brand B – it's impossible. Some in the industry would like this advertising – that's not possible from my point of view ... If they can reduce any kind of hazardous substance, they have to do it. It's the duty of the company.

He has a sense that tobacco companies are currently trying to dodge this responsibility, while another science and research stakeholder thinks that both tobacco companies and regulatory bodies are keen to avoid taking responsibility:

The industry is trying to move the responsibility for the product too fast to the regulatory body.

Tobacco control experts would prefer that BAT would make the call. BAT would prefer that public health would make the call. They're chasing their tails.

Several science and research stakeholders emphasises the importance of relating measurement of the risks of tobacco products to the behaviour of consumers:

It makes no sense to measure things that have no context or relevance to consumer behaviour.

One stakeholder states that reduced risk products will only be successful if they appeal to the consumer, and believes that BAT should use its expertise to develop products which offer satisfying features to the user and appeal to both men and women:

People forget that tobacco is a popular product and has been for a long, long time ... Humans love tobacco – just like they love caffeine. It makes the case for making products that they can enjoy ... [Harm reduction] will only take place in society when the [reduced risk] products are satisfying and appealing ... No one can get into the mind of cigarette smokers like you [BAT] can. You can determine what satisfies smokers.

One science and research stakeholder states that epidemiological studies on the health impacts of smoking are needed to satisfy the public and regulatory commissions, despite the long-term nature of such research:

The bottom line for public health is the epidemiology ... You just have to wait – 10 to 20 years ... The changes are so gradual and incremental, that I am impatient. I don't think there is enough change. [But] that doesn't absolve BAT from doing research.

Another agrees that filter analysis is an important technology in this respect and another suggests using a panel of smokers to more accurately measure the health impacts of smoking on real people:

You can never be sure what a group of smokers will be taking out of a cigarette, so the tobacco industry should have a panel representative of the overall population, going round with holders for a week and then set the laboratory measurements accordingly.

There is some disagreement on lower delivery products. While one science and research stakeholder feels that “*Light and mild cigarettes are not the way [forward]*”, another does see some merit in exploring the harm reduction potential of lower delivery products:

I believe if you smoke a cigarette with low tar, it's better for you than one with 10 mgs. You can measure all kinds of Hoffman analytes, it's less with low tar [products].

This stakeholder has some reservations about using nicotine levels alone to classify cigarettes:

There is a discussion by regulatory bodies about cancelling the tar level and making some distinctions on nicotine ... From the regulatory body's point of view, it's easier to base it on nicotine, [but] ... I know [you can't decouple nicotine and tar completely]. This is the main problem for the system.

Another stakeholder sees the debate about lower delivery products as an example of the increasing inflexibility of the public health community on harm reduction issues:

A lot of people in tobacco control, they are resolute in not making any admission that there is progress. Modified cigarettes were a combined effort between the tobacco companies and the public health parties. Now [in the eyes of the public health community] it has become a ploy by the tobacco companies with no [health] benefit.

Three stakeholders discuss the role of nicotine in creating the appeal of tobacco products. Two are not convinced that nicotine is solely responsible for the appeal of cigarettes and for people's addiction to smoking. Another stakeholder questions the effect of nicotine in smokeless tobacco:

Whenever chemists have found the active substance in drugs, it has been abused – opium, cocaine, etc ... Nicotine has been known for hundreds of years, and it has never been abused ... I suppose that if there existed some pure addictive substance, other than nicotine, it would be known. However, there may be a complex effect, in conjunction with nicotine. Smokers prefer cigarettes without nicotine to nicotine gum, yet if we market cigarettes without nicotine, it's a complete flop.

Nicotine plays a role, but it's not what people think it does. The first few hits are nicotine fixes – after that it is a sensory and social environment thing. I followed a bunch of switchers for several years. We had some people who were fine for years, then they had a life crisis – a death or something – and they go back to smoking. People say the desire never leaves them.

Sweden has a non-nicotine snus product which has 3% of the total smoke-free market. What's the explanation? Is it [being used for] cessation? Or to replace cultural use – a placebo to snus?

The first stakeholder carries this theory through to his views on smoking cessation to explain what he views as the failure of nicotine replacement therapies (such as nicotine gum) to facilitate cessation:

Like the presenter becoming more important than his guests, nicotine alone is not important in smoking cessation. It doesn't fulfil all the effects [of the cigarette, but] it has an effect on the neuron; the smoker feels a relaxing effect on his muscles, not on his brain.

One science and research stakeholder feels strongly that a harm reduction approach should look at 'whole smoke' rather than trying to identify and reduce individual smoke constituents, which he sees as costly and nonsensical:

It's not the best way, to isolate specific substances and reduce them. To me, it makes no sense. You have to look at all the smoke constituents, you have to look at the impact on the whole mainstream smoke ... Whole smoke

is best – to isolate one [constituent, such as Hoffman analytes] makes no sense and costs a lot of money.

Another science and research stakeholder has reservations about the use of biomarkers:

There are not really good biomarkers – the ones measured are the sexy ones. There are many markers – we measure the ones that are easy to measure. We don't know if they are the real ones that cause disease. Biomarkers are a diversion. They have to be done, but they are not the Holy Grail.

In the policy session there is some discussion of the possibilities of exploring other ways of smoking tobacco to try and reduce the health impacts, for example smoking through water, as with a water pipe, or designing a type of combustible tobacco product with an independent heat source:

It would be more complicated, but there should be some independent heat source to allow for the vaporisation of the nicotine without the formation of tar and particles.

Challenges in Engaging the Commission

The challenges for BAT in trying to engage with the Commission on harm reduction are seen to be substantial by the science and research stakeholders. Firstly, there are seen to be very negative perceptions of the tobacco industry, and anyone associated with it, within the Commission and in other regulatory bodies. Several of the science and research stakeholders seem to feel that any voice even briefly affiliated with tobacco companies is immediately tarnished in the eyes of the Commission. One says he feels “*completely censored*” given the reaction after he invited a tobacco company representative to speak at a seminar. Another feels his views are discounted for similar reasons “*If I say that in [my country] though, they say ‘oh, it’s only [me saying it].’*” Another stakeholder feels that research from tobacco companies is dismissed as inherently biased, while NGOs are seen as somehow impartial:

The extremists, who don’t know anything about lower risk products, suggest that the only information is biased because it comes from tobacco companies. They want to talk to so-called ‘unbiased’ sources like the Cancer Society.

Nevertheless, despite the recognised poor relations between the Commission and the tobacco industry, two stakeholders do see a division in the attitudes of people at the Commission:

The Commission will be divided into two parts: people thinking that nicotine is very interesting but questioning how to deliver it, and others wanting a nicotine-free world and saying that tobacco is bad.

Because of the more positive perspective on the debate in some quarters, one sees some hope for what the Commission might say in its green paper:

I don't think [they can all] sign up to something that is mostly negative.

Two stakeholders also discuss pressure to expand the scope of the forthcoming Commission enquiry, particularly regarding snus:

- *They're asking, is [snus] safe? Is it addictive? Of course, they don't compare it to cigarettes.*
- *The group would like to come up with recommendations that they are not free to make.*

Nevertheless, the tobacco debate at European level is widely recognised as highly politicised, making it difficult for the Commission and regulatory bodies to collaborate with the tobacco industry, and slowing debate and decisions on key issues:

It's always difficult for the Commission or the regulatory bodies to collaborate with the tobacco industry.

We're between science and politics – you always have to find a compromise.

One stakeholder thinks that the situation in the US is similar in terms of making policies based on political agendas. The current US Congress has two years before a “big” election and he thinks they will feel a need to demonstrate progress in the area of tobacco control:

They have to show [they have done something to increase control] over the ‘evil’ tobacco companies ... I don't have a lot of hope for [reasonable] US legislation – I am not optimistic ... I think companies are going to be caught by this new legislation.

Other perceived barriers mentioned by science and research stakeholders include dealing with junior EU personnel who do not always have the flexibility of top

level officials, the fast turnaround of staff and changing contacts, and explaining the scientific and technical issues to non-experts:

People are changing every year – we’re always talking to new people. You have to sit opposite a guy who’s not an expert, and spend one year teaching him – for nothing because he only stays in the job for one to two years. A new guy comes in and you have to start from the beginning.

Usually people sit there who don’t know what they’re talking about. They are always the same people commenting and the rest stay asleep.

When Europe organises something, it’s the lay people they invite. It’s like the science is so complicated, they don’t trust it.

One science and research stakeholder differentiates between “good science” and “politicised science”, feeling that anti-tobacco “extremists” twist scientific findings to support their lobbying positions. This is also seen as a particular issue in the ETS debate (see next section).

Several of the science and research stakeholders discuss the influence of the WHO on Brussels decision-making about harm reduction issues, although there is some disagreement on its importance. One stakeholder feels that the strong influence of the WHO in the Commission is a powerful barrier, while another sees the WHO influence in the EU waning and believes that it is instead important in markets outside the EU and the US, such as China and Thailand:

The influence of the WHO is too strong in the Commission. They cannot [be seen to] be working against the WHO.

My impression is that now, the game is in Brussels. The WHO is really losing impetus [in Europe].

The first opinion sees inaction in EC officials because they are waiting for WHO decisions, or unreasonable decisions made because it is known the WHO wants quick action in some areas:

The danger for the European Commission is that it is easy to sit there and say they are waiting for the opinion of the WHO. It’s an easy solution for a politician, and it’s not meaningful ... The problem is that the WHO want something [on communicating the risk levels of different cigarettes that is simple, easy, implementable]. The

European Commission has to do something, whether it makes sense or not.

Two science and research stakeholders think there is a particular problem in relation to the WHO, in that there are only a few people driving tobacco policy forward. One suspects that the top level of the WHO is not always aware of what more junior personnel say and do in its name. The other feels they are not willing to communicate with those working outside the NGO sector:

It's a three- or four-man club. I think sometimes the headquarters of the WHO do not know what their guys are saying about tobacco ... At a higher level, they have no idea of the behaviour of [their representative] in the name of the WHO.

I'm actively kept away from these [WHO] meetings now ... Reasoned scientists are feeling that they're having to stand down.

One stakeholder thinks that the focus of opposition should be directed to the WHO's Tobacco Free Initiative, rather than the WHO itself.

One stakeholder believes that the dialogue needs to be broader, not just targeting the extremes of opinion:

You need to re-evaluate who you are talking to. I see companies trying to engage the most extreme people in the tobacco control/public health areas. They are the minority and they are never going to move ... People in tobacco control and research do not all have the same views – the minority are people who are the loudest ... It is a matter of trying to reach out to those who could change.

Two stakeholders point to a perceived problem in the reluctance of some NGOs and public health groups to engage on harm reduction at this level. One says that NGO representatives refuse to be present at meetings to which tobacco companies are invited, which he thinks limits the potential for dialogue and is a real sticking point. The NGO refusal to engage with tobacco companies is seen as rather unfair by the stakeholder given that similar sessions have been organised for obesity and including industry representatives such as McDonald's. Another stakeholder thinks that public health groups are less open to dialogue than the tobacco companies, although there has been an improvement in recent years particularly in Europe:

I have had more and better dialogues with companies than with public health [organisations] ... They are not in a position to carry forward a scientific rationale ... I have

seen changes over the past few years, more people who are willing to talk – more so in the EU than in the US.

The influence of the pharmaceutical industry is also seen as active in the harm reduction debate:

Don't underestimate the power and capabilities of the pharmaceutical companies today.

Pharma company control of smoking control is huge. A lot of it is flat out [about] money.

Several science and research stakeholders see this as problematic, since the pharmaceutical industry is perceived to be working with anti-tobacco activists and pressure groups to restrict the debate on harm reduction. They feel that nicotine replacement therapies (which are not considered to be the most effective harm reduction solutions) are being promoted at the expense of other approaches:

If an activist speaks about harm reduction, it's about nicotine substitutes.

I was banned from talking about harm reduction, and that shows the collusion between the activists and the pharmaceutical industry. Snus would be a direct competition to the gum, and the gum doesn't work.

I see pharmaceutical companies lobbying against snus all the time.

Another example of this influence is given by one stakeholder, citing people connected to the development of nicotine replacement therapies who also influence the WHO.

Suggestions for Engaging the Commission

Despite the challenges, dialogue with the Commission and other regulators is seen as vital by several stakeholders. One high-level EC stakeholder gave several pieces of advice for BAT when attempting to engage the Commission on harm reduction issues:

- In the dialogue process, it is about getting access, listening and responding.
- Those companies that pursue voluntary activities to respond to public health concerns are more likely to get a seat at the table, because they have something to talk about, and they continue to have new things to say.
- On getting access, it's importance to have a "critical mass" of participants, so that it is recognised as a fair process, even if some of the major players are missing.
- When coming to engage BAT must:
 - 1) present a commitment to be part of the solution (it is not actually necessary to admit that it is part of the problem);
 - 2) commit to putting serious and increasing effort into generating solutions, in terms of money and people. The key word is increasing – it is not enough to simply repeat what it did in the previous year;
 - 3) commit not only to dialogue, but commit to being guided by the outcome of the dialogue regarding what BAT should and should not contribute. That is, take the shape of the dialogue into the management of the continuing process. This last step is where engagement usually fails.

Several science and research stakeholders think BAT should engage with the Commission through collective efforts rather than on its own. One stakeholder feels strongly that BAT should engage through its industry associations rather than as an individual company, and would like to see a consensus from the industry on issues of harm reduction:

We are a country of associations ... For a regulatory body it makes it very complicated when one day Philip Morris goes to them, the next day BAT, etc. They're not experts, they get confused when they hear three different opinions ... I have the impression that BAT [could] also go its own way [like Philip Morris] – I think that's not the way for the future ... I would say that's not the right way to do it – come into the same room ... That kind of discussion with single companies is very dangerous, even for the company.

Another stakeholder would also like to see the tobacco industry working together on this issue. He wants to see, for example, BAT working with Philip Morris to come up with consistent initiatives.

Two science and research stakeholders think there are possibilities for engagement with the Commission and the WHO via smokers' groups, expressing a need for "*a pressure group of smokers*". They feel that consumers are currently being left out of the decision-making process, and that smokers' interest groups could be a solution, although they stress that the tobacco industry cannot be seen to be orchestrating consumer groups:

I always hammer on that tobacco consumers should be part of the game.

They also suggest that tobacco shop owners, for example, might offer an alternative voice in the harm reduction debate – especially with regards to regulation on snus:

I've just spoken to tobacco shop owners – they want to sell snus.

Three science and research stakeholders feel that it is the job of the Commission or DG SANCO to set up a forum for discussion on these issues of harm reduction, rather than BAT, and advise against BAT being too proactive. Some science and research stakeholders are themselves reluctant to engage in the group dialogue process, which might influence their views of the chances of success with dialogues at the Commission level. Nevertheless, several stakeholders from the Commission itself say they are open to engagement on harm reduction initiated by BAT:

This bit of the Commission at this time is open and participative – we are always open to it if you have something to say.

One stakeholder thinks that part of the solution to engaging the Commission is establishing the JRC and the European Network as the source of scientific advice for the Commission on tobacco issues. It would cover questions "*on all kinds of analysis, product science and toxicological science, how to test ingredients, methods of burn testing – all kinds of scientific questions.*" They are currently exploring funding options, perhaps similar to the German system of having a pot of money from the industry for consumer information since "*we have enough scientific knowledge but not enough [resources].*"

Engaging with Scientists & Researchers

The science and research stakeholders are open to engagement with BAT to an extent, although many would prefer to meet on a one-to-one basis in private rather than participate in a group dialogue session. Nevertheless, at least one stakeholder emphasises the importance of engagement between the two parties:

We should have these kinds of conversations – it's very important ... I'm very open for discussing with the tobacco industry.

He feels strongly that co-operation with scientists in the industry is important to prevent duplicating effort and to ensure that robust methods are used to input into public policy:

We have to involve the interested industries to come to any solutions ... Otherwise the [tobacco] industry can come and say 'you are working with the wrong data, the wrong science'. It's a danger for the Commission ... Why should we do the work twice? Industry has done it all already. We can hear the results from BAT and if we think it's a good idea we can repeat it as an independent laboratory.

Other science and research stakeholders emphasise that their willingness to work with tobacco companies depends on shared harm reduction motives:

I can work with the tobacco companies if it is to reduce the harm of cigarettes, but not if it is to sell more of them.

I'm not against tobacco, I'm against cancer, infarction, lung disease and poverty.

Several science and research stakeholders are worried about the impact on their own reputation of appearing to be working with tobacco companies because of the negative perceptions of the industry:

I am able to do a lot of good things for tobacco companies, but I can't appear to be close to them.

Another stakeholder raises the issue of NGO scrutiny of scientists' relationships with tobacco companies – apparently they quickly discover who is talking to whom and the subjects discussed, and presumably, this could potentially deter other scientists from engaging with the industry:

We're talking to BAT or PMI and they know what we're talking about, I don't know from what source.

Given that all affiliations with the tobacco industry are seen so negatively, there is also a problem surrounding the lack of public sector research on tobacco. One stakeholder clearly identifies a need for research: "We cannot progress until we know the active ingredients", but points to a reluctance for public funds to be dedicated to it: "They don't want research". He expresses a sense of hopelessness in a situation in

which researchers are forced to accept industry money to conduct much-needed research, but then see their findings discounted because of the taint of their association with tobacco companies:

There's the argument that ingredients is the same as [they are in] food, but [there's] always the problem about what happens with combustion ... I tried for 25 years to promote research on tobacco but there's only one place [in my country] researching it. It doesn't exist; it's a complete flop ... There is no other research [but] if you take tobacco money, you are the agent of the devil.

It is seen as unlikely that more resources can be provided to the Commission and member states to get more scientific experts on tobacco issues – one stakeholder expects that tobacco industry funds will be rejected, and the chances of other sources of funding being made available (such as a levy on products) are seen as remote. Another stakeholder speculates about the creation of a 'Super Agency' for funding research, and thinks that both Europe and the US are looking into such an agency to collect money and distribute it for certain types of tobacco research. However, he is not optimistic about the outcome:

The devil is in the details. It is not clear about the makeup of the review committee. The type of research I do will be excluded.

Two other stakeholders wonder whether, given the difficulty of any industry-provided scientific information being accepted at face value, other bodies could be involved in providing it:

If it is a matter of resources, could Bill Gates and Microsoft contribute? George Soros has an open society foundation really concentrating on harm reduction.

Another stakeholder suggests engaging people other than tobacco specialists, in other areas of harm reduction such as illicit drugs, or other disciplines such as economics:

You need to engage people outside of tobacco. There are other areas of harm reduction, illicit drugs which have baggage, or economists – people that have different views. You need to have dialogues with others.

One stakeholder feels that engagement between scientists and industry associations such as CORESTA is particularly important, both for networking and sharing information (for example on methods for measuring cacao used as flavouring in cigarettes), and also for helping to organise potential collaborative studies (for example, on research into analytes):

CORESTA is very important, I don't want to keep them out of the door ... It's a lot of work to start a collaborative study. I will be very happy if CORESTA can support in the organisation and evaluation of results [for example on research into analytes] ... For example, we need a method to measure cacao [flavouring in cigarettes]. I want to ask the industry, do they have a method to measure this? If so, please forward it to the JRC and they can have a vote [on the best two methods] ... [Then they can undertake] a collaborative study with the industry on these methods to find one method [to use in the future]. The European Network or JRC as an independent organisation can put forward this method to ISO.

This stakeholder also suggests that when engaging with bodies such as the JRC and the European Network, it is better for BAT to wait to be invited to become involved, rather than trying to be proactive:

If you come with a proposal to the European Network to develop something, it is not a good idea. The starting of the discussion should come from the European Network.

Disclosure of Ingredients & Consumer Information

There is some concern that the proposed database to supply information on ingredients will be unwieldy for health authorities to use. Two stakeholders do not seem convinced since they think it would be difficult for health authorities to manipulate such information and argue that the ingredients themselves have little bearing on what smokers actually absorb:

- *What should the [national] Ministry of Health do with it?*
- *The contents in the tobacco and the chemistry are almost irrelevant. They need to measure what's down the line.*

One stakeholder in the AIT session is critical of the industry's disclosure of ingredients, taking BAT's policy of not disclosing all the ingredients in product flavourings as a sign of unwillingness to be fully transparent:

You don't even want to disclose in the industry all the ingredients [in a product]

However, one science and research stakeholder is impressed by BAT's current level of disclosure and agrees that it is acceptable for tobacco companies to continue to protect their trade secrets by not disclosing flavourings:

Your internet page with public information [on ingredients] is very open ... I think [disclosing] 98% [of the ingredients] is enough.

He does not view wider disclosure to researchers as secure:

I don't want to see your brand by brand data ... The system is too open in Europe ... You cannot be sure your trade secrets will be well-kept.

He suggests a possible solution which might be acceptable to regulatory bodies – a group of two or three independent toxicologists or chemists would look at the trade secrets of each tobacco company and identify if any of the secret ingredients might be cause for concern, without public disclosure of the specific ingredients.

Two stakeholders also feel strongly that it is important to inform consumers of the research findings on the health risks of tobacco products in a meaningful way, so that they can take action to reduce the risks. One objects to what he perceives as WHO's approach in not giving information to the consumer:

How can you give this information to the consumer? ... Why do you want to do [this research] if not for the consumer?

We need to present information that gives people choices. Give them the information, the rationale.

One stakeholder feels that research on consumer attitudes and usage patterns regarding reduced risk products is now needed, as opposed to scientific research on their health effects:

I thought we would be beyond the science at this point. [We need to know] where we think the interest is – [through] market-based research. What are the social hurdles? What are the market hurdles? What are the barriers?

This stakeholder feels strongly that tobacco companies themselves should be more forthcoming in disclosing information on harm reduction to consumers, and he believes that BAT is a leader in this area:

American tobacco companies should be at a place where BAT is – fully disclosing that cigarettes and smokeless products have an order of magnitude in terms of risk.

BAT has gone farther than any other company in this area.

He also points to the need to educate consumers on new types of smokeless tobacco product:

You need to teach people how to use these products – you wet it first before putting it under your lip.

However, another stakeholder feels that the key issue to drive changes in consumer behaviour is not information, but differential pricing and taxation for reduced risk products. Another stakeholder would like to see a minimum price maintained for tobacco products in general:

[Differential taxation] should be the way to inform consumers. That's what they understand.

There will be price wars over again unless we do something. I do not want minimum prices to go down, full stop.