Harm reduction

What the future might look like

We have a responsibility to seek to reduce the health risks of our products. In the future, we expect to be able to offer adult tobacco consumers reduced toxicant cigarettes and new categories such as low-toxicant smokeless tobacco and regulatory approved nicotine products.

Demonstrating that new products are less risky poses many scientific and regulatory challenges. To tackle these, we expect to see many more research collaborations being established involving the tobacco industry, academia and tobacco research centres. This will hopefully lead to the development of a regulatory assessment framework for potentially reduced-risk products that is underpinned by sound science.

How we’re preparing for the future

- Identifying which smoke toxicants pose the greatest health risks and developing new technologies to reduce these.
- Developing a framework of scientific tests to evaluate the likely health impacts of potentially reduced-risk products.
- Our stand-alone company, Nicoventures, is exploring the development and commercialisation of regulatory approved nicotine products.
- Engaging with regulators, scientists and the public health community to develop the scientific and regulatory frameworks needed to deliver reduced-risk products.

Our material issues

Reported
- Reduced-risk products
- Engagement

At bat.com:
- Information on the health risks of smoking
- Second-hand smoke

Our materiality test determines which topics are of the greatest significance to our business and stakeholders.

YOU ASK US

Can scientific research paid for by tobacco companies really be impartial?
- Read our response in the sustainability and our business section

Do you have any questions or feedback on our approach to harm reduction or other sustainability issues?

We will donate £10 to the Global Trees Campaign for each of the first 200 responses we receive to the feedback survey.

www.bat.com/sustainability/feedback
Viewpoint from the Group Scientific Director

Of course, the only way to avoid the health risks associated with tobacco products is not to use them. However, with the global population increasing, the World Health Organisation has estimated that the number of smokers worldwide is going to increase.

More and more, it seems clear to me that, to reduce the health impacts from smoking, prevention and quitting initiatives alone will not be enough. We need a broader approach – one that accepts that many adults are going to continue to use tobacco and nicotine products. That means developing reduced-risk products.

In order to achieve this, first we need to collaborate with others to determine the appropriate scientific and regulatory frameworks for the development and scientific assessment of these products and monitoring of their use. In my newly created Management Board position as Group Scientific Director, I am committed to seeing that our product strategy continues to be based on robust scientific evidence.

What’s the issue?
The greatest negative impact of our business is the real and serious health risks of tobacco products. So developing reduced-risk products for those adults who use tobacco products is a priority. There are many challenges in this: the science is complex; collaboration is needed between scientists, tobacco companies and regulators; products need to meet consumer expectations; and we need a regulatory framework that supports tobacco harm reduction. We are committed to meeting these challenges.
Our approach

What is tobacco harm reduction?
The US Institute of Medicine defines tobacco harm reduction as “minimising harms and decreasing total morbidity and mortality, without completely eliminating tobacco and nicotine use”. This recognises a well-established public health policy concept that seeks pragmatic ways to minimise the impact of an activity or behaviour that carries inherent risks. Well known examples of this are the use of seat belts in cars and crash helmets for motorcyclists.

In terms of tobacco this could mean that, in addition to a continued emphasis on prevention and cessation efforts, adult tobacco consumers should have the option of choosing less risky products instead of existing more risky products, such as conventional cigarettes. However, few governments currently support this view.

Our role in tobacco harm reduction
As a manufacturer of tobacco products, we have a responsibility to pursue ways in which we might reduce the health risks of our products. Although nicotine is not completely harmless, contrary to what many people believe it is not associated with most tobacco-related diseases. There is widespread agreement in the scientific community that it is the toxicants in the tobacco and tobacco smoke that are responsible for the majority of these. Indeed in a Public Assessment Report, the UK Government’s Medicines and Healthcare products Regulatory Agency (MHRA) states that: “Nicotine is strongly addictive and stopping smoking results in cravings and withdrawal effects, but it is the tobacco smoke that produces the diseases and premature deaths associated with smoking.”

So, on a ‘product risk continuum’, where products can be lined up in a decreasing order of risk, conventional cigarettes can be considered the riskiest; some forms of low-toxicant smokeless tobacco products, while not risk free, much less risky; and regulatory approved nicotine products almost risk free.

Our previous efforts at test marketing lower-risk products have given us important insights into tobacco consumers’ varied product preferences and different needs for potentially reduced-risk products. We believe that a ‘one product fits all’ approach cannot achieve tobacco harm reduction, so our approach is to make available a range of reduced-risk tobacco and nicotine products for adult consumers.

Alongside this, we are engaging with the scientific and public health community to try to build more widespread support for this broader approach to tobacco harm reduction.

EXTERIOR VIEWPOINT

If lots of people stop smoking but switch to medicinal nicotine products, it would be no more harmful than the existing use of caffeine... We need to liberalise the medicinal market and introduce a decent cigarette substitute. We may end up with millions of people addicted to nicotine inhalers, but so what? Millions are addicted to caffeine.

Professor John Britton, Chair of the Tobacco Advisory Group of the Royal College of Physicians (RCP). Speaking at the launch of the Tobacco Advisory Group of the RCP’s report 'Harm reduction in nicotine addiction: helping people who can’t quit', October 2007

Our risk continuum – our view
Tobacco and nicotine products can be considered to sit on a continuum of risk.

Conventional cigarettes
Reduced toxicant cigarettes
Heat not burn cigarette-like devices
Low-toxicant smokeless tobacco
Regulatory approved nicotine

Higher
Potential ranking of overall risk
Lower

Developing reduced-risk products

We are working on three broad product categories based on the way they are designed, manufactured and consumed: reduced toxicant cigarettes; low-toxicant smokeless tobacco products; and regulatory approved nicotine products.

Reduced toxicant cigarettes

It is well established that people who smoke more cigarettes a day and over a longer period of time have an increased risk of developing a smoking-related disease. So we are researching whether cigarettes with lower levels of toxicants in the tobacco smoke might lower health risks for those adults who don't want to quit.

Our approach is to:

- Determine which toxicants in smoke are significant for disease and develop tools to measure smokers’ exposure to them;
- Develop products that may substantially reduce exposure to these significant toxicants and, through clinical testing, demonstrate that they do; and
- Assess whether this reduction in exposure can reasonably be expected to reduce the risk of one or more specific diseases.

Our work on developing laboratory models of disease has progressed in two areas: establishing the most effective way for us to expose cells to tobacco smoke so that we can evaluate the impacts; and creating more sophisticated models to mimic the processes involved in the development of cancer and other diseases.

We have set up a new research group, Predictive and Experimental Toxicology, which is focused on developing the science to evaluate which smoke toxicants are the most significant in the development of various smoking-related diseases.

We have made good progress in increasing our understanding of how and where smoke particles are deposited in the respiratory system. This will help us to develop new technologies that could reduce these impacts.

We have also reinvigorated our biotechnology research, using our understanding of the tobacco plant genome to work out how to develop new plant lines with lower levels of certain toxicants or the precursors to these toxicants.

In our last Sustainability Report, we discussed our clinical study, which showed that smokers who switched to modified prototype cigarettes had reduced exposure to certain smoke toxicants compared to people smoking conventional cigarettes. This short-term clinical study is a good first step, but we need stronger scientific evidence to establish reduced risk. Our next step is a longer clinical study starting in 2012. This will measure biomarkers of biological effect in body fluids that could indicate biological changes related to disease processes. Although these changes will not tell us whether the modified prototype cigarettes actually present lower overall health risks, they provide evidence we need to see whether we are on the right track.

The cigarette technologies being tested in this study use novel processes that would need to be scaled up to be viable for large-scale commercial production. This is an important area of our current research and development effort.

Recent publications from the US Food and Drug Administration’s Tobacco Products Scientific Advisory Committee and the World Health Organisation’s scientific advisory group suggest that future regulation of combustible tobacco products could be based on the toxicant levels emitted from them. The harm reduction potential of such regulation is not clearly understood. We believe that our research into reduced toxicant cigarettes will prepare us for such a regulatory future and allow us to contribute to the evidence base for the development of regulation for this category.
Regulatory approved nicotine products

The UK Government’s recently updated public health strategy for England considers adults to be responsible for their choices and so there may be many smokers who may not want to quit smoking. In 2010, the Medicines and Healthcare products Regulatory Agency approved a ‘harm reduction’ element for some regulatory approved nicotine products for their use as either a complete or partial substitute for cigarette smoking. We believe that the products currently on the market are not meeting the needs of these smokers.

Nicoventures was recently established to focus exclusively on the development and commercialisation of regulatory approved nicotine products. It is a stand-alone company within the British American Tobacco Group and is managed separately from our tobacco business.

Nicoventures is exploring the development of nicotine products that, subject to regulatory approval, will provide smokers with a safer alternative to cigarettes that they actually want to use. If it is successful this will also meet the objectives of some leading public health professionals and make commercial sense to us and to our shareholders. It forms part of our long-term business sustainability agenda.

For more information, please see www.nicoventures.co.uk.

Smokeless tobacco products

Independent evidence shows that certain low-toxicant smokeless tobacco products, such as Swedish-style snus, present substantially lower overall health risks than cigarette smoking. We tried to bring snus to new markets, but had a number of setbacks: it is banned from sale in some parts of the world; in countries where we test marketed it, the regulatory environment did not allow the communication of the relative risks of snus compared to cigarettes to adult smokers; and smokers often did not like using it in preference to cigarettes.

We believe that smokeless tobacco products could still play an important role in a harm reduction approach. So we are looking at developing other innovative low-toxicant smokeless tobacco products that we hope will appeal to tobacco consumers and be approved by regulators.
Engagement

Our work to develop reduced-risk products will be pointless if we cannot successfully bring them to market. So we are engaging with the scientific community and regulators to build support for tobacco harm reduction as a pragmatic public health policy.

We are trying to build support for a broader approach to tobacco harm reduction by making presentations at scientific conferences, publishing our research in peer-reviewed journals and engaging with the scientific and public health communities. At the heart of our approach is the belief that we must always be transparent about our science, making it publicly available for review by other experts and scientists. We publish details of our scientific research on www.bat-science.com and contribute to debates around tobacco harm reduction through conferences and journals.

In 2011, we carried out research into views on tobacco harm reduction among healthcare professionals in the UK, Sweden and Norway. We asked a representative sample what they thought about tobacco use, approaches to quitting and smoking reduction, their understanding of the risks of nicotine and the key factors associated with the health risks of smoking. Most advocated a ‘complete cessation’ approach to tobacco use, rather than broader harm reduction strategies. Some held inaccurate views on what it is about cigarette smoking that poses serious risks to health. For example, many wrongly believed nicotine to be as harmful as tobacco smoke, when in fact it is toxicants in the tobacco and tobacco smoke that are responsible for most smoking-related diseases. Given the expertise of those surveyed, this general lack of understanding was surprising.

Another surprising result was that a number of those interviewed in Sweden were unaware of the impact of snus use on public health. A substantial number of Swedish men switching from cigarette smoking to snus use coincided with a lower rate of male lung cancer in the country than any comparable developed nation. Oral cancer rates also decreased and cardiovascular health significantly improved.

This research has highlighted the need to raise awareness about the different risk profiles of cigarettes, smokeless tobacco products and nicotine products.

Regulation

We believe tobacco product regulation should be underpinned by sound scientific evidence and developed through transparent and accountable consultation with all relevant stakeholders. Our extensive experience in tobacco science means that we could make a valuable contribution to the development of tobacco harm reduction policy. We have encountered resistance to this in the past, but are beginning to see more opportunities opening up for us to contribute, as well as some governments starting to take broader approaches to tobacco harm reduction.

In 2011, our Chief Scientific Officer sat on the expert panel of a workshop held by the US Food and Drug Administration (FDA) on developing scientific standards for the evaluation of modified risk tobacco products. The FDA’s approach is inclusive and evidence-based, something we strongly support.

The UK National Institute for Health and Clinical Excellence is developing guidance on harm reduction approaches to smoking. It sought contributions through a consultation process involving a range of stakeholders from across society, including the tobacco industry. We welcomed the opportunity to contribute and responded with our views.

Published details
of our scientific research continually on www.bat-science.com

ASSURANCE
COMMENT FROM ERNST & YOUNG LLP

Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy... It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century.


EXTERNAL VIEWPOINT

There are many challenges associated with bringing potentially reduced-risk products to market, many of which are discussed in this Report. We have seen evidence of engagement with the regulatory and scientific communities and some public health bodies on the topic of harm reduction. Despite this engagement, public health policies remain targeted at prevention and cessation efforts, illustrating the continued importance of stakeholder engagement if further support for harm reduction is to be progressed.
Growing up, I had little experience of the tobacco industry, but like most people I was familiar with anti-tobacco rhetoric. So I never in a million years thought I would be part of the industry. But it is the best job I’ve ever had.

I trained as a geneticist in Canada and worked in plant biotechnology before moving to London in 1997 to work in science publishing. In late 2010, I gave a presentation to staff in British American Tobacco’s Group Research & Development (GR&D) department on how to get their manuscripts published. It was a real eye-opener: the quality of the work these scientists were doing was really good and they were passionate about it. And I could see why – it was genuinely interesting.

So when a permanent role came up a few months later, I decided to take the leap into working for a tobacco company. I would be using my experience of publishing to help the Group bring their scientific research to a wider public, by improving the impact of published work and helping the scientists to better navigate the publishing landscape. After all, what’s the point of being a science communicator if you can’t jump in at the deep end and work on a big challenge?

What I really enjoy about my role is being part of this exciting, emerging discipline. It’s one that spans lots of different scientific areas, from traditional analytical chemistry to nanotechnology and aerosol science, taking in computational toxicology and biological models of disease along the way. And I can see the difference I make in this role to our scientists.

Our GR&D labs in Southampton have also become a place to bring visitors – both external stakeholders as well as British American Tobacco employees from around the globe who want to learn more about the science we are doing to support our approach to tobacco harm reduction. We’ve identified some of the top communicators among our scientists and I’m proud that the training I’ve delivered has helped to build their skills and confidence. They’re now more comfortable going out into the world and communicating our science.

Sarah Cooney, Head of Scientific Collaboration and Communication British American Tobacco Group Research & Development
Harm reduction goals and commitments

Our harm reduction commitment

We will strive to bring commercially viable, consumer acceptable reduced-risk products to market.

2012 goals

■ Take our laboratory models of diseases through an external validation phase involving collaborative research with scientific partners by end 2013;

■ Register and undertake a longer clinical study of biomarkers of exposure to tobacco smoke toxicants and biomarkers of biological effect under ethical approval and to high clinical standards by end 2012;

■ Submit for publication more of our research on the tobacco genome and undertake further field trials on tobacco plants with lower toxicant levels by end 2012; and

■ Present our scientific findings at international conferences and continue to improve the standard of our publications in peer-reviewed journals.
About this Report

This is the British American Tobacco p.l.c. Sustainability Report 2011. It reports on the activities of British American Tobacco companies in the UK and internationally and covers the calendar year 2011. Associate companies are excluded. References to ‘British American Tobacco’, ‘we’, ‘us’ and ‘our’ when denoting opinion refer to British American Tobacco p.l.c. (the Company) and when denoting tobacco business activity refer to Group operating companies, collectively or individually as the case may be.

Statements and assurance

This Report contains forward-looking statements that are subject to risk factors associated with, among other things, the economic and business circumstances occurring from time to time in the countries in which the Group operates.

It is believed that the expectations reflected in these statements are reasonable, but they may be affected by a wide range of variables which could cause actual results to differ materially from those currently anticipated. Ernst & Young LLP has been engaged by British American Tobacco to provide external assurance of this Report. Ernst & Young LLP reviewed all commitments and statements of progress, data, GRI information, text and, specifically, performance-related information for the period 1 January 2010 to 31 December 2011.

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The full version of the Report can be found online at www.bat.com/sustainability