

Tobacco Strategy Review

Funding of Group Fundamental Research Programme

A. L. Heard

Background

Since decentralisation of R&D in 1985, the great majority of projects in the six CAC R&D Centres are directed to short-to-medium business objectives. Applied research/development projects and technical support now far outweigh fundamental R&D activities. For the most part the R&D Centres are guided by local demands and their activities are approved/monitored and funded by their Boards but much of their work has wider relevance to other Group companies. Through the Group information system (by which all projects in all centres are similarly described, classified and monitored) and the various technical specialist meetings we seek to maximise technology flow within the Group. This is generally agreed to be working well.

Group Fundamental Research

Our Fundamental/exploratory research, addressing the longer term strategic issues, is agreed, steered and funded by the CAC countries. Currently the principal location of such projects is Southampton (and Brazil since they cannot contribute financially to Central R&D) though increasingly other centres are becoming involved.

This category of research can be summarised under four headings:

- (i) Fundamental Research (BATUKE R&D).
  - This programme divides into projects responding to Regulatory Issues (such as Environmental Tobacco Smoke) and those aimed at improvement of Product Quality. Projects are agreed and reviewed annually by CAC companies.
- (ii) Project Airbus (B&W R&D)
  - this is our direct response to RJR's smokeless cigarette, Premier.
- (iii) Project Greendot (BATUKE R&D)
  - this project aims for a product of very low tar content but normal nicotine delivery.

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(iv) Smoking & Health Research (External)

- this comprises a group of projects by medical and other scientific departments of universities, hospitals or other reputable institutions that are identified and agreed with CAC companies.

Progress

(i) Fundamental Research Programme - Southampton

Important Group projects in the Regulatory area include reduction of specific smoke compounds ('other noxa') to levels below their respective threshold limit value. Tobacco leaf treatments (extraction, enzymic etc.) look promising. For nitrosamines, however, our best approach is through tobacco biotechnology.

A careful monitor is maintained on developments in biological testing of products in general. A limited repertoire of in vitro methods is being built up (either in-house or under contract), chosen on the basis that they could be used (and indeed are by R J Reynolds with Premier) to compare cigarette brands.

A key approach to our work on Environmental Tobacco Smoke is to set this phenomenon in perspective in relation to other atmospheric pollutants. This has involved a good deal of real-world monitoring; this has shown not only that levels of ETS constituents are generally low but that many other sources contribute to indoor air contamination. The other approach is to monitor the fate of specific smoke components in terms of build-up and decay in highly controlled environmental rooms. Results of these studies are being published and presented at many external international conferences and more such activities are planned.

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A limited basic research investigation into a Fire Safe cigarette has started since this is fast developing as an important issue in the USA. Test methodology is being established.

Fundamental studies now underway on the release of nicotine from tobacco at different temperatures and in the presence of different carriers will lay a basis for improving our current products and for creating radically new products.

(ii) Project Airbus

This project represents our direct response to Premier by R J Reynolds. The key issues surrounding Premier can be summarised as:

P R E M I E R

POSITIVE

Very low sidestream

Zero biological activity

Very low 'tar'

Rapidly dissipating exhalate

No ash

Low ignition propensity

NEGATIVE

FDA ISSUES:

- is it a cigarette
- source of nicotine
- does it make (infer) health claims
- is it a drug dispenser

FTC ISSUES:

- product description (tar?)

EPA ISSUES:

- disposal of butts

CONSUMER ISSUES:

- is it a technological device
- poor smoke taste
- objectionable aroma

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Partly to avoid patent restrictions and partly to pursue directions suggested by limited consumer research on Premier, the concept being pursued for Airbus has a few important additional targets. Our product should burn down yet produce low levels of visible sidestream and leave a traditional butt. Inevitably the product will produce ash which although undesirable for non-smokers, is an accepted feature of normal cigarettes. Overall, however, Airbus should aim for similarly low levels (less than 1mg) of conventional 'tar' as Premier and have broadly similar biological properties. This implies practically no tobacco combustion.

Research on Airbus began in February this year following Group discussions on possible concepts and the establishment of a team by B&W (8 full time plus 12 part time technical marketing, legal). We envisaged a 4 year project to reach the stage of machine-manufactured product for test market.

The Ellis concept (an outer furnace surrounding a fine tube containing components that on heating generate the mainstream 'smoke') was chosen as the basic principle with the aim of establishing a design prototype by October 1988.

Based on the Ellis concept as a working model B&W have addressed the individual technical challenges in making a smokeable product meeting the agreed criteria. These include release and transfer of nicotine (without combustion), aerosol formation from such materials as glycerol and propylene glycol, flavour release/transfer and smoke analysis. The problem of setting up a heat source that produces the right amount of heat at the right time from the outer furnace (and with normal sidestream release) has been a particularly stiff challenge and a major external research contract to support this was established.

Although B&W have produced simple mock-ups to demonstrate the principles of two possible designs, the goal of achieving a prototype on which a full project can be mounted by October has not yet been achieved.

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The major problems are in heat management and in materials technology to convert ideas to practical feasibility. We expect the project to be six months delayed and March 1989 would seem an appropriate target for the prototype. However, to meet this target, we recommend two approaches:

- (1) involvement of identified innovative technologists from our other Group R&D centres in advancing the current concept.
- (2) involvement of the most creative scientists from the Group in developing back-up ideas in the event that the current principle cannot be made to work.

This requires full support of CAC company management since these personnel are few and generally committed to high priority shorter term work.

(iii) Project Greendot

There are many who believe that Premier (and possibly Airbus) are products that will only be serious market contenders in 10 years time. Greendot, by contrast, is the BAT view (scientists and management) of the kind of product that may create sizeable opportunities in the interim.

The objectives of Greendot, established in January 1988 are:

"To determine the practical route to create, within a five year development project, products which retain the attributes of a conventional cigarette in terms of appearance, smoking mechanics and taste while delivering a highly modified tar (in terms of composition, quality and dose) with a significant reduction in sidestream. From the outset, the project will incorporate the influence of consumer acceptability into the design of products and will identify the markets and the degree of consumer flexibility in accepting such products."

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A team of six scientists (plus a further 6 man-years of part time) was set up in March in a separate small building on the Southampton site. Whilst the technical team set about exploring the possible routes to these objectives a parallel activity in consumer research was initiated, the aim of which being to clarify attitudes to smoking and to gain views on possible product concepts. This work will reach its first phase in December. From this point it will be possible to firm up our product target(s).

(a) Technical Status

During this period a number of routes explored had to be abandoned. For instance, tobacco extraction and pyrolysis gave low tar yields but adverse Ames test results. However, GreenDot has produced a range of four initial research prototypes that give a wide spectrum of smoke deliveries; none yet have acceptable smoking characteristics and some would not meet regulatory standards without considerable debate (referred to as "contentious"). They comprise:

1. An "all tobacco" option using a blend, of high nicotine tobaccos and glycerol which demonstrate the 'tar'/nic ratio minimum when using non-contentious product development routes. The 'tar'/nic ratio is 5:1 at a 'tar' delivery of 5mg.
2. An "all synthetic" option employing non-tobacco materials such as inorganic filler, carbon, glycerol and a nicotine alginate complex. This demonstrates the degree to which smoke components and deliveries can be controlled when using synthetic materials. Biological activity is similar to Premier and 'tar'/nic ratio is 1:1. This option is recognised as contentious from regulatory aspects since it contains no tobacco yet delivers nicotine.
3. A "tobacco-plus-synthetic" option employing a small proportion of high nicotine tobacco (15%) and a large amount of non-tar producing filler (85%). This demonstrates the ability to produce low 'tar' products (2mg) with low (80% reduction) biological activity and 'tar'/nic ratios of the order of 5:1. It is not likely to prove contentious.

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4. A "tobacco-plus-synthetic" option which contains tobacco but relies on nicotine fortification to produce highly modified 'tar'/nic ratios in the range of 2:1 to 1:1. Nicotine fortification may be contentious but the option does contain a significant amount of tobacco (20%) and it is envisaged that the nicotine and flavour components will be directly derived from a tobacco source (as in Premier) which may overcome the regulatory constraints.

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(b) Future Direction

In the light of 6 months experience of this project, it is now feasible to identify three possible Greendot product delivery profiles that might be achieved over a 2-5 year period.

These are:-

	GREENDOT		
	1	2	3
Wet TPM mg (a)	9	6	4
Nic mg (b)	0.8	0.6	0.5
Water mg (c)	1.5	1-	1
PMNPF mg [a-(b+c)] =d	6.7	4	2.5
Glycerol mg (e)	3	2	1
PMNNGF mg (d-e)	3.7	2	1
"Tar"/nic [(d-e)/b]	4.6	3.3	2
Bioactivity	← normal	← normal	low
Nic fortification	no	possible	probable
Composition	Tobacco	Tob/synth	Tob/synth
Sidestream	← normal	← normal	low
Timescale (years)	2	2/3	4/5

We propose to pursue these three variants although, in resource terms, the Greendot 1 project will call for more conventional product development than for radical fundamental research.

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