

RESTRICTED

18 June 90

Rationale for current Fundamental Research Projects

Regulatory Authorities have identified a number of aspects of cigarettes that should be addressed by research. It is anticipated that in time these issues will become the basis of regulation on cigarettes.

The key issues are:

- (i) Tar and (less importantly) nicotine levels.
- (ii) "Tar quality" and its assessment.
- (iii) Levels of "Other Noxae".
- (iv) Sidestream smoke composition and levels.
- (v) Environmental tobacco smoke composition and levels.
- (vi) Additives composition and levels.
- (vii) Ignition potential (of fabrics).

The challenge of achieving measurable changes in (i)-(vii) whilst still achieving acceptable smoking quality gives rise to one further issue for FRC:

- (viii) Chemosensory research to fund means of overcoming sensory barriers as products are modified.

Finally, in order to achieve significant results with many of the foregoing projects, it will almost certainly be necessary to create a new set of material "building blocks" for construction of cigarettes:

- (ix) The use of alternative materials/structures as "building blocks" for cigarette design.

These targets can be brought together under one strategic objective for the Fundamental Research of the Group as follows:

To carry out research for the CAC companies in order to provide the scientific information and technical avenues required for evolutionary products aimed at delivering adequate levels of nicotine with minimum accompanying levels of other components, so as to meet future consumer and regulatory authority needs.

"Fundamental research" embraces research which is aimed at improving the basic knowledge of the science and technology of the tobacco business. Its timescales are long (of the order of years) and its output is scientific information.

"Regulatory authority" refers to any organisation, official or unofficial, that results in legislation, advises governments, or influences public opinion.

This research provides concepts for the longer term product development. The CAC R&D establishments, including the BATCo. Technology Centre (BTC), will take the concepts and develop them into prototype products as necessary.

400756376

Ultra-low tar with medium nicotine levels

(a) Greendot

When Premier was launched by RJR BAT firstly set in train a research programme (AIRBUS/NOVA) to pursue a similar option but also initiated our own programme towards a future product that whilst traditional in format, would be extensively modified relative to current products. This was known as Project Greendot, the aim of which was to investigate the use of tobacco (or tobacco-derived materials) to generate modified tar delivery in terms of composition, quality and dose. This work continues.

A product development project (NATO) within the BATCo. Technology Centre, is pursuing the first option to emerge from this research. This has 4 mg tar and 0.6 mg nicotine.

The continuing fundamental research is aimed at achieving still lower tar/nic. ratio products and is exploring cast sheet or extruded materials of 75-80% tobacco origin. Biological properties will be checked by Ames and other in vitro test methods.

(b) Project NOVA

The principle behind RJR's Premier was that it looked and smoked like a cigarette but it produced its "smoke" by heating capsules containing nicotine and flavour ingredients. The "smoke" contained much fewer chemicals than cigarette smoke and it had zero biological activity in all known biological tests. *used* X
Although Premier was a marketing failure, this type of product has future potential as a nicotine delivery system with minimal delivery of other substances.

Project NOVA is aimed at providing the scientific and technological foundation for the development of alternative cigarette-like products in which the combustion of tobacco is not the primary source of smoker satisfaction. All of the R.J. Reynolds technology is patented so we must seek alternative methodology. The work is concentrating on how nicotine and other chemicals are stripped from various materials into "smoke", what heat is required and how it may be generated, and what are the properties of suitable materials.

It is not the intention of this work to make prototype devices but to provide the necessary scientific base for their development. Although the ultimate goal of the project has a long timescale, it is envisaged that there will be shorter term spin-offs from the work, for example on filter and smoking material concepts.

Search for Additional Bioassays

A variety of different biological tests (or bioassays) exist which can measure the "biological activity" of chemicals, including cigarette smoke. These tests range from exposing rats to smoke and measuring changes in their lungs (which can

400756377

take up to three years) to tests on small groups of cells in test tubes (in vitro tests which can take a few days). Which of these tests, if any, is the most relevant/human smoking is open to speculation. However, the short term tests are relatively easy to perform and Regulatory Authorities have the potential to use them to rank cigarettes. For example, the UK Independent Scientific Committee on Smoking and Health has recommended that the use of such tests should be investigated. Furthermore, since R.J. Reynolds have used all existing bioassays to test their Premier product it is probable that any similar product development in the future could do no less.

The aim of this work in the FRC is to assess which bioassays have a high probability of being used by Regulatory Authorities, and to acquire the technology to permit BAT products to be positioned optimally in such bioassays.

One short term in vitro test, known as the Ames test, has been in use for fourteen years. Expert biological opinion is that at least two different in vitro tests should be used for screening new product developments and that negative results in both tests should be further substantiated by full animal tests.

The biological work in the FRC is investigating the use of tests in addition to the Ames test. The work is also monitoring the biological activity of product developments. Bioassays using animals are done under contract.

Reduction of "Other Noxae"

"Other noxae" is a term coined by the UK Independent Scientific Committee on Smoking and Health, which advises the UK government on the stance to take in various smoking-related issues. It refers to substances in smoke in addition to tar, nicotine, and carbon monoxide "which may contribute to the health hazards of smoking". The Committee recommended research aimed at their elimination.

Regulatory Authorities in other countries such as Germany and Canada also have lists of substances in smoke which they consider to be particularly undesirable. These lists all differ from country to country. The BAT Scientific Research Group has constructed a master list of "other noxae" based on the various national lists and the reasons for their inclusion.

The FRC work on "other noxae" is aimed at finding means of reducing these substances in smoke over and above current techniques such as filtration. The work involves modifying tobacco in various ways such as treatment by chemical, enzymic, or physical means and determining the effect on the relevant smoke deliveries. So far much of the work has been in a learning phase - developing methods for measuring the "noxae" and determining which parts of the tobacco they are derived from. This work represents one route to a highly modified product concept in which the base cigarette material is still essentially tobacco. Attitudinal tests have suggested that consumers have a preference for tobacco to be retained as the base cigarette material.

400756378

Total Sidestream Reduction

To minimise social concerns associated with sidestream smoke, research has been undertaken during the last six years on finding means to reduce sidestream. Much of the work has concentrated on modifications to cigarette paper in combination with the amount of tobacco in the cigarette. Several patents have been obtained and prototype product developments are being taken to consumer testing by the BTC.

The efforts to date reduce the visible sidestream smoke by about 50% but the sidestream gas phase is only reduced by about 20%. This small reduction in the gas phase means that sidestream odour and irritation are only marginally reduced. In order to reduce sidestream smoke and gas phase by similar amounts further research is concentrating on modifications to the tobacco rod structure. This will involve using extrusion and other techniques to produce novel rod structures with the objective of interfering with the amounts of the rod burnt to mainstream and sidestream.

Environmental Tobacco Smoke (ETS)

ETS and passive smoking have received considerable attention in recent years because some reports have claimed that ETS can be harmful to the health of non-smokers (e.g. US Surgeon General 1986, UK Independent Scientific Committee on Smoking and Health, 1988). The claims are based on differences in epidemiological data which are very small and ambiguous - this work is continuously assessed for BAT by Corporate R&D, Millbank.

In Southampton, research over the last two years has been aimed at putting ETS into context with other substances present in the air. A variety of discrete measurements have been made in real world environments - pubs, restaurants, homes, public transport, offices etc. In general the work has shown that ETS levels are very low compared to other chemicals in the air. Much of this work has been published, presented at scientific conferences and fed into public affairs departments.

Following recommendations from the BAT Industries Tobacco Strategy Review Team, future work on ETS will involve less effort than previously. The work will be involved much less on external studies, and will concentrate on internal laboratory work to provide an information base useful to public affairs initiatives. The work area will be able to respond rapidly to future public affairs requirements. Typical activities currently in the programme include details of the formation and decay of specific groups of chemicals including nitrosamines and the search for reliable methods of exposure of humans to ETS.

Additives and Materials Advice (Tobacco and smoke chemistry for Regulatory Authority needs)

Throughout BAT many additives and materials are used both on cigarettes (tobacco, paper, filters, packaging) and in their manufacturing operations. An Additives and Materials Guidance Panel exists to evaluate new additives and materials proposed

400756379

for use by Operating Companies. This is done using both legislative information (what is allowed in various countries) and toxicological and chemical hazard information.

Chemistry
(R. G. Cole)

It has been found from practical experience that in order for new products and processes to be accepted by Regulatory Authorities, detailed knowledge of smoke and tobacco chemistry needs to be supplied. For example, in order to use DEER (a material made by extruding, *inter alia*, tobacco dust) in cigarettes the UK Independent Committee on Smoking and Health required chemical information on all the ingredients and how they would react when the material was burnt in a cigarette.

This work area is aimed at obtaining this type of information for new processes and products under development (e.g. ammonia technology) or new flavour additives. It includes the following areas:

- (a) For new flavour additives or their precursors, determining whether they are naturally present in tobacco, even in very small amounts. When this is the case it greatly enhances the chances of their acceptance by Regulatory Authorities.
- (b) For new flavour or other additives, determine whether they transfer intact to smoke. If they decompose or react in the burning cigarette, determine their products.
- (c) Assess smoke chemicals which are produced from residues or impurities in the tobacco, e.g. insecticide residues.

Reduced Ignition Potential Cigarettes

In the USA there is much pressure at both the federal and state government level to introduce legislation which will stipulate that all cigarettes must pass a furniture ignition test. A technical study group set up by Congress concluded in late 1987 that "it is technically feasible, and may be commercially feasible, to produce cigarettes with substantially reduced ignition propensity". Further work was recommended to develop suitable test methodology. Congressman Mookley has submitted a private bill for federal legislation to be introduced and individual states such as Michigan are threatening to introduce legislation if Congress does not do so.

Developing realistic test methodology is not easy considering the large number of furniture materials and configurations. One serious problem is that an inadequate method could lead to false results under certain conditions.

Work at the FRC is aimed at developing suitable test methodology. Much of this work is done in collaboration with CORESTA - a world-wide association which promotes co-operation in scientific research relative to tobacco. This collaboration means that the emerging methodology can be tried in different laboratories around the world which will give a good understanding of its reproducibility.

400756380

The FRC work is also determining how the different cigarette parameters affect ignition potential. We already know that low cigarette diameter and high use of expanded tobacco give improved performance.

Chemosensory Research

Our traditional approach to reducing deliveries is to reduce both tar and nicotine. Regulators in, for instance, the UK and Germany support the concept of reducing tar whilst retaining nicotine at more traditional levels. Nicotine alone in smoke is not practical, nor are extreme tar/nicotine ratios, since nicotine is too irritating - other substances are required for sensoric reasons.

The objective of chemosensory research is to understand the chemical and physical properties of smoke important to sensory perception. This type of work has been done intermittently within BAT for many years although not in the context of low tar/medium nicotine smoke. The present projects, whilst having broad potential application, will focus on this type of product. The work area will provide the scientific foundation for the development of low tar/nicotine cigarettes with acceptable sensory attributes and will, of necessity, interact with many of the other projects on the research work programme.

The programme includes work in impact, irritation and taste.

Material Science

(a) Ultra-Light-Weight Structures

On the basis of cigarette smoke levels required by today's smokers there is clearly far too much tobacco in the conventionally sized cigarette. Attempts to reduce dimensions lead to an association with poor value or inferior products (with the notable exception of Capri). To reduce yields of major components (tar, nicotine, CO) and the minor components and, at the same time, to reduce sidestream yields, we need to create light-weight tobacco structures. These should burn less tobacco, yet deliver appropriate smoke levels and puff numbers.

Several approaches are being considered. One system that offers considerable appeal is the creation of foamed structures. Although work to date has focussed on extrusion of tobacco dust (and additives) to form a foamed rod, there are other foaming approaches to pursue.

Another means of producing light-weight structures depends on folding semi-rigid tobacco sheet to produce a firm matrix within the paper envelope.

400/56581

(b) Alternative Materials

Although we recognise the existing reluctance in relation to use of non-tobacco combustible materials (failure to be classified as a cigarette, use of "chemical" additives etc.) there are some opportunities for modifying current cigarettes that will necessitate such a move. Gaining agreement for their use may necessitate considerable discussion with Regulatory Authorities.

18th June, 1990

400756382

BATCo document for Province of British Columbia 27 October 1999