

Regulatory Issues relevant to Greendot

The conclusions of the RPG meeting in Vancouver on regulatory issues relevant to GREENDOT were as follows:

1. Relationships with Regulatory Authorities

We should talk to regulators on the premise that they should accept the wishes of smokers to continue to smoke, but with products which they have an opportunity to influence.

BATCo were already involved in such discussions in the UK and were exploring starting a similar exercise in Germany. It was further agreed to expand the scope of such discussions wherever possible.

2. Company Guidelines

Formulation of company guidelines for novel products, with the agreement that the products should not increase toxic potential.

3. Work necessary by BAT Group on GREENDOT as basis for approach to Regulators

3.1 Additional external research on effects of nicotine (since nicotine is the key to GREENDOT).

3.2 Response to regulatory concern within GREENDOT objectives e.g. gradual reduction of tar/nicotine ratio, biological activity, other noxa, Carbon Monoxide and sidestream.

3.3 Clarification of glycerol inhalation toxicology.

3.4 Validation of the properties of smoke aerosols containing increased levels of humectants.

3.5 Sufficient knowledge of additives/processes used in any GREENDOT variant to meet criteria laid down by the SRG/AGP. This could include agrochemicals.

4. External Panel

The RPG, noting that approval by regulatory authorities was mandatory in several European countries, favour direct talks with regulators (1 above) rather than attempting to obtain leverage through the formation of an ad hoc external review panel.

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5. Action Points

Numbers refer to items above.

- 1. Initiate discussions on appropriate time scale with regulatory authorities in the following countries.

	BAT Group (as appropriate)
U.K.	"
Germany	
France )	With
Italy )	ultimate
Spain )	view of
Denmark )	influencing EEC
Portugal	"
Norway (to prevent proposed legislation banning novel products)	"
Brazil	"
USA/Canada/Australia	Lost causes? "

- 2. Formulate Company Guidelines (TGH/RET)
- 3. 3.1 Review nicotine projects (SRG)
- 3.2 Project Guidelines (ALH et al)
- 3.3 Glycerol inhalation toxicology (JW)
- 3.4 Validation of aerosols (RET)
- 3.5 Additives/processes (SRG/AGP)

6. Items not covered by RPG Meeting

While noting 1 and 4 above, it is nevertheless considered that approaches to influential scientists could be advantageous.

Those identified so far include:

Professor Dr Ulrich Mohr (Hannover)  
Dr Helmut Bartsch (Lyon)

*Ray*

RET/LEW  
29th September 1989

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Research Policy Group Meeting

18-22 September 1989

Pan Pacific Hotel, Vancouver, Canada

Present: Mr. A. L. Heard BATCo.  
Dr. R. E. Thornton BATCo.  
Dr. R. Binns BATUKE  
  
Dr. P. J. Dunn Imperial Tobacco  
Dr. S. R. Massey Imperial Tobacco  
  
Dr. E. Rittershaus BAT-CF  
Dr. E. Kausch BAT-CF  
  
Dr. J. S. Wigand B&W  
  
Mr. G. McGregor WD & HO Wills  
Dr. C.J.P. de Siqueira Souza Cruz

Guests: Mr. J. L. Mercier, Imperial Tobacco, Tuesday,  
September 19, p.m.

Guest Speaker: Professor Jeffrey Idle, U.K., Wednesday,  
September 20, a.m.

The Research Policy Group met 18-22 September, 1989. In connection with discussions on several topics, the Group decided the items described in this report.

The role of the SRG needs to be more directly focused on scientific issues facing the companies and smoking-associated diseases including, among others, research to better understand nicotine. RET should review existing projects and make recommendations.

The SRG should undertake the coordination of approaches to additives among the companies in the group and RET should develop recommendations to clarify this. Additive guidance groups at individual companies should continue to be responsible for the clearance of individual additives.

The review of scientific literature should be carried out within Millbank, possibly augmented by specialists in Southampton. Millbank staff should keep an updated data bank of external research funded directly or through manufacturers' associations of the companies in the group.

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JW should arrange a technical specialist meeting regarding bioassays (particularly as they relate to ingredients and other nontobacco materials) including experts from the group companies to identify possible new biological testing methods and applications. BAT companies should avoid the conflict of interests with competitors by selecting an independent contract facility.

More precise information on tobacco and smoke chemistry is required and Mr. T. G. Mitchell should prepare recommendations.

Either the AGP, SRG, or both should develop a policy on agro-chemicals. CORESTA is not an appropriate forum for the discussion of pesticide toxicology.

Development of products with reductions in specific constituents should be carried on, if at all, by the individual operating companies and not Southampton; Southampton should concentrate on basic research in this area.

A coordinating meeting for biotechnology should be held in late 1990.

A presentation was made pertaining to objectives for product innovation, but agreement was not reached.

RET should seek external opinions on any work necessary to explore the properties of smoke containing increased levels of humectants.

The all synthetic product development work should be transferred to project Nova, where it will be an extension of the materials technology project. Elements of the Day project could be built into the Greendot project. The objectives and work plan for project Nova should be rewritten to be sure that they embrace technology but not product prototype goals.

Dr. Proctor should convene a group meeting in Canada in November, 1989, to propose a program for external ETS research showing projects staged by topic and location.

The total cost of Group Fundamental research at Southampton (plus Greendot and Nova) will exceed 1989 only by inflation. Contributions by the four CAC contributors are recommended as follows (with BATCo. accepting the former 7% paid by Wills):

BATCo.	32%
B&W	30%
ITL	19%
BATCF	19%

With regard to the SRG funding, the minimum commitment for 1990 was £294,000, but as the SRG had been asked to recommend additional projects, the maximum budget will be £344,000, to be divided equally amongst the four contributors (£86,000).

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Future Technical and Specialists meetings will be organized according to the following schedule:

- |   |                      |                  |
|---|----------------------|------------------|
| 1. Product Testing  | Southampton          | Dec 89           |
| 2. ETS External Programme   | Canada               | Nov 89           |
| 3. Flavour  | Germany              | 4 Q 90           |
| 4. Product Development incl. ammonia technology, filters sidestream, etc. | U.S.A.               | Mid 90           |
| 5. Tobacco Biotech  | Europe               | 4 Q 90           |
| 6. SRG  | Copenhagen<br>Canada | Oct 89<br>Apr 90 |
| 7. Fundamental Research Review (incl. CORESTA position)                   | Southampton          | Mar 90           |
| 8. RPG  | Germany              | Jun 90           |

Coordination of BAT delegates to organizations such as CORESTA will be best done by RPG members giving clear instructions to the participating members from their company. Guidelines would be agreed at the Southampton review in March 1990.

The next meeting of the RPG was arranged for June 1990 with the venue Hamburg, Germany.

The meeting concluded with a critique of its activities and a vote of thanks to the Canadian hosts.

12th December 1989

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