

TECHNICAL EXCHANGE MEETING

BIOLOGICAL

How best can we ensure that future Group products have the lowest possible activity?

Biological testing should include the following aspects:

Objectives

- (1) To establish BAT products in a favourable position compared to competitors.
- (2) To produce cigarettes of low biological activity, including a medium-delivery low-biological activity product. Although the reductions in total biological activity so far rely mainly on reductions in delivery, such a product has some attractions, especially in the areas of consumer satisfaction, product differentiation and in combatting quitting.

Long-term Tests

Skin-painting

Although there were no immediate plans for re-starting this programme, this should be reviewed if skin-painting is required to further validate other tests, particularly the Ames Test.

Inhalation Toxicity

The possibility of carrying out a further long-term study, using another rodent (probably hamster) was discussed. As it was still not certain that a satisfactory biological end-point could be achieved in such studies, a positive recommendation that such work be undertaken could not yet be made.

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Short-term Tests

Test Batteries

It was agreed that diseases other than lung cancer should be considered as the basis for tests. It was also agreed that a battery of tests (for example as used by BAT Germany) would be required in meeting or anticipating legislation and encouragement was given for the further extension and definition of the required battery. It was likely that the Ames test and a chromosome-damage test would be the essential minimum features of any battery.

However, as this is a notoriously difficult area rapid progress was not expected. The literature and external research in the health area largely determine the success and rate of introduction of 'new' tests, particularly those thought to be related to specific human diseases.

Ames Test

This should be standardized as far as possible among the three laboratories now using the test. It has the potential of becoming an index for comparing products and is likely to have wide acceptance in spite of its shortcomings.

Additives

For volatile additives existing information is usually sufficient to obtain clearance from regulatory authorities. However, in some European countries food regulations now apply to the tobacco industry, and may be symptomatic of a trend to increased legislation. Additives which are pyrolysed might require adequate toxicological testing before being accepted by regulatory authorities and we must be in a position to meet such requirements.

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Interpretation and Understanding of Results

Understanding of the importance of the tests and how the results are interpreted was essential if the results were to be used correctly, for example in product design. Biological tests rarely give unequivocal yes-no answers.

Effects on the Foetus

This is an emotional area and it was agreed that it was one that we could not ignore.

It was agreed that teratology studies were required for the toxicological evaluation of new additives.

In the human area a collaborative study into the effects of low tar versus medium tar cigarettes on birthweights was being discussed in the UK. However, it was not at all clear if the effects of smoking could be dissociated from other factors affecting birth weight. In addition, animal studies were underway in Canada involving the induction of the enzyme AHH in the foetus.

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