

THE ADDITIVES AND MATERIALS GUIDANCE PANEL IN BATCO LTD

The purpose of the Additives and Material Guidance Panel is to provide authoritative advice on the acceptability of additives and materials proposed for use within the Company. This service is provided to the Board of BATCO Ltd, its functional departments and operating companies.

The specific objective of the Panel is the protection of consumers of BATCO products and of operatives involved in their production against potential adverse effects from proposed additives and materials.

Terms of Reference

Companies in the BATCO Group must submit to the AMGP for consideration to the AMGP all new items which they propose to use or existing additives which they would propose to use at level greater than those previously agreed, within the following categories. Such submissions must be made for all materials falling in the following areas:-

- (a) Direct, or intended, additives to the product including flavours and casings, ingredients of papers, filters and adhesives.
- (b) Materials used in processing which may lead to residues or unintentional contamination of the product. These may include biocides used in the field and store, components of processing equipment and packaging materials.

The main concern is the possibility of adverse toxicological consequences, whether from the specific substance being proposed or from its degradation or reaction products formed in processing, or from products of pyrolysis. In its assessment, the panel takes account of any other source of possible adverse consumer response, eg., environmental concerns, but such matters are not its principal concern.

The Panel responds only to submissions and needs of operating companies and departments within the Group and does not undertake to provide clearance or advice to external suppliers.

When such assessments relate to matters of company-wide interest they will be communicated to all operating companies in BATCO.

In addition; all companies must keep R&D Department Southampton informed on the components currently used for each brand which they manufacture (and advise on the origins of any licensed brands which they sell). This review audit will be carried out by companies on a six-monthly basis, each January and July. Changes in additive and material usage, within the AMGP guidelines, should be advised when they occur.

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Membership

Chairman and two Scientific Members - to provide expertise on toxicity of materials and consequences of use, nominated by Research Department.

Departmental representation - Production, Leaf, Purchasing, Legal, to provide information relevant to the operational consequences of submissions and decisions; members nominated by appropriate Heads Of Department.

Secretary - to record decisions, control information and act as contact between Panel and companies submitting materials. Nominated by Research Department.

Meetings and Decisions

Formal meetings of the Panel can be held at any time, but are normally arranged to occur between 2 and 4 times a year.

Urgent submissions should be made to the Secretary, who together with the Chairman will decide whether an interim decision is possible. This will be contingent on supporting information being available: the interim decision is subject to formal confirmation at the next meeting of the Panel.

Formal meetings of the Panel can also be requested to obtain a view on specific topics of concern at any time.

A quorum of the Panel must be present at meetings: this being defined as 3 out of 4 Scientific members including either Chairman and Secretary and 2 out of the 4 departmental members.

The decisions of the Panel are recorded in the form of Minutes. In general, assessments of additives apply to all Companies within BATCo Ltd. By contrast, the assessment of materials relate specifically to individual cases, as the area and conditions of use of a material within a process will influence the assessment.

Restrictions or caveats may be attached to Minutes accepting the use of a proposed material. It is the responsibility of the user to ensure that such conditions are both understood and followed.

The rejection of a proposed additive or material will be recommended by the Panel where there is evidence that its use could lead to adverse effects. In addition, rejection will be proposed where there is inadequate information available to base a sound decision.

It is not the responsibility of the Panel to recommend alternatives to rejected materials, nor to initiate testing to fill gaps in the data. However, if requested, the Panel will make recommendations concerning the additional information required and the procedures for obtaining it which might allow a positive view to be taken subsequently.

Following meetings the Secretary will circulate the Minutes, which are distributed to Panel members and a list of individuals agreed by the Board of BATCo Ltd. The Secretary will also report on the outcome of submissions to individual operating companies, and to all companies if the matter under consideration is of wide interest.

It is emphasized that such communications may contain commercially-sensitive information, the circulation of which must be carefully controlled within all departments and companies.

Status

The BATCo Board has determined that all BATCo operating Companies should follow the recommendations of the AMGP unless and to the extent that any non-compliance has been sanctioned in advance by the BATCo Board.

R E Thornton

RET/ag
4 February 1992

Additives and Materials Guidance Panel (AMGP BATCo)

Current Chairman ~~T.G. Mitchell~~

Secretary G. Smith

Leaf

Product development/R&D

Technical Services

Materials Development

Production Department

Legal Department

Additives and Materials Advisory Committee (AMAC; B&W)

Chairman S. Appleton

Compliance Group being formed (BATCF)

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Regulatory and compliance issues

A. Additives and product components:

- flavourings, casings, humectants, manufacturing aids.
- filters and paper additives.
- inks and adhesives.
- agricultural chemicals, pesticides.
- accidental inclusion of manufacturing materials.

B. Product development:

- reduced ignition propensity products.
- reduced sidestream products.
- significant design changes.

C. Product innovation:

- Premier type products.
- radicle design changes.

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AMGP ACTIONS

Number of Operating Companies:	44
Number of Coded Products used as Tobacco Additives:	542
Number of Individual Tobacco Additives in Use:	784
Number of Individual Tobacco Additives Recorded:	1329
Number of Supplier Companies Involved:	153
Number of New Tobacco Additives Submitted in 1993 (to September 30th)	153

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Group Biological Programme and Regulatory Issues

1. In-vitro genotoxicity bioassays.
2. In-vitro assessment of aerosols and vapour mixtures.
3. Cytotoxicity assays.
4. Benchmarking procedures for application of genotoxicity assays.
5. Adducts of proteins and DNA.
6. AMGP.
7. Database maintenance/development on regulatory status of additives, materials and legislative issues.
8. Formulation and Material analytical testing.
9. Agricultural residue issues; testing.
10. Regulatory developments on additives and materials.

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Process of risk assessment (additives and residues):

1. Chemical and physical characterisation of the compound (incl. purity and vehicle for application).
2. What is the known toxicology; is it used in another industry (history of use).
3. Is it on at least one current Government positive list.
4. What are its likely transfer and combustion properties.
5. What is its application and use level (TLV's, ADI's, MTD's)

Requirement for supplementary data

- metabolic studies.
- in-vitro genotoxic assays (cascade).
- human 'bio-data'.
- short, medium and long-term feeding and or inhalation studies.

Problems:

- mixtures, natural extracts, analytical sensitivity.
- in-situ flavours (reaction flavours).

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Group Biological and Regulatory Issues (compliance)
Programme

- Reporting line through the Group Technical Steering Committee to the TSG.

- Co-ordination through the Group Technical Programme mechanism.

- Technical issues relating to additives/pesticides reviewed by relevant attendees of the SRG prior to the SRG meeting.

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APPENDIX 1

TERMS OF REFERENCE AND GUIDING PRINCIPLES OF THE
ADDITIVES GUIDANCE PANEL AS RECORDED AT ITS MEETING
5TH FEBRUARY, 1964

- a. To discuss the toxicity aspects of additives in the light of published information from the technical press or other sources such as Government Ordinances.
- b. To obtain the best scientific opinion available on each additive under question by corresponding within the orbit of the Group Research.
- c. To make recommendations as to the use of such additives in such proportions as it considers will be non-injurious, or to their non-use.
- d. To make recommendations, when required, as to the kind and extent of any further testing of such additives as it considers necessary and desirable.
- e. To give advice, as required, on any aspect of additives and health.

1. Guiding Principles

What will be our basic guide for deciding whether we use, restrict or ban an additive?

Question (a) Do we satisfy ourselves that it is safe to use it?

Answer The Panel will, if all its evidence suggests that the additive is safe, so indicate to those concerned.

Question (b) Do we satisfy ourselves it is safe but restrict or ban it because of possible public opinion, or because of the possibility of furnishing competitors with ammunition?

Answer The implications involved in each case will be considered and referred to Mr. Davies and possibly others.

Question (c) To what extent are we going to take into consideration the general use of a commodity by competitors in a particular area?

Answer The Panel's principal job is to give advice. Decisions on the basis of this advice and having regard to considerations such as those outlined will have to be taken by the B.A.T or local Board.

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