BRITISH AMERICAN TOBACCO

fax

Globe House
4 Temple Place
London
WC2R 2PG
United Kingdom

To	Distribution List	**From**	Rolf Bielefeldt
Company		**Tel**	0207 845 1666
cc		**Fax**	0207 845 2176
Fax		**Subject**	Experts Meeting on February 18th, 2000
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Message

Please find attached my notes from the above meeting.

Please feel free to comment on changes as appropriate and let me have your reaction by this Friday, 25th February. I will then distribute the notes to all members of the Additives group.

Best regards,

Distribution List – Experts Meeting on February 18th, 2000

Dr. Ian Bailey	Imperial Tobacco	01179 668013
Dr. Lutz Mueller	R.J. Reynolds	0049 22 1164 6658
Ruth Dempsey	Philip Morris International	0041 32 888 5776
Yves Saintjalm	Altadis	0033 238 437 283
Wilfried Dembach	CECCM, Brussels	0032 2 541 0045
Guy Dutrex	Seita, Paris	0033 1 45 56 6577

UNOFFICIAL MEETING NOTES – ADDITIVES
18th February 2000, Luxembourg

Participants: John Ryan, European Commission
Professor Peter Boyle, Epidemiologist, European Institute of Oncology
4 other cancer scientists, mostly Epidemiologists
Wilfried Dembach, CECCM
Guy Dutriex, Gites
Yves Saintjalm, Altadis
Lutz Mueller, R.J. Reynolds
Ian Bailey, Imperial Tobacco
Ruth Dempsey, Philip Morris
Rolf Bielefeldt, British American Tobacco

1. General Description of the Proposal in Article 7

John Ryan intervened very early to state from his point of view that Article 7 did not contain a public health proposal, but the procedure as described therein was the minimum harmonisation proposal. It was stated by Mr. Ryan that in the last session of the Health Working Group on 7-8 February, a number of member states had stated their disappointment at the proposal generally not going far enough, but the Commission does not want to upset the existing system.

2. Existing National Regulations on Additives and Mutual Recognition

The current provision in Article 11 on existing national regulations should, according to Mr Ryan, be made more specific. National regulations should remain in force until additional community regulation is available.

3. General Assessment of the Proposal in Article 7

Clearly the Commission's view is now forming in the direction of a stepwise approach to additives. On several occasions Mr. Ryan reiterated his position that first there should be complete information on additives actually used in tobacco products and only then in a second stage would harmonisation follow.

Current control mechanisms for additives were described as less than adequate. There was also opposition to saying that the current principle of mutual recognition works well, as only 4 member states in the Community had a sufficiently well developed system of regulating additives.

4. Confidentiality of Commercial Information on Additives

The current provisions on confidentiality have been strongly criticised by the industry. Mr Ryan and the Commission are very aware of this. They also see confidentiality as linked to the precautionary principle as they have now established it.

There is not going to be a scientific review by the Commission on top of any scientific review of additive data by the member states. Later on there will be a proposal by the Commission on possible scientific data.

It was also stated that in the meetings of the Health Working Group, the UK administration had cast grave doubts on whether the voluntary agreement in the UK really served its purpose.

Mr. Ryan then reiterated that current permitted lists in individual EU member countries who are well founded in legislation would continue. A single EU positive list will only be established afterwards. Generally, the Commission is proceeding on the assumption that less legislation is better and would therefore review the need for a single EU positive list before publishing one.

5. Smaller Companies

In an ESTA presentation, apparently some statements have been made to the effect that smaller companies have no knowledge of substances going into their product, which they buy in bulk from outside suppliers. This statement of course was used as an example of the industry not exercising sufficient control.

6. Calculation of Quantities

There was agreement that the calculation of quantities needs to be standardised. From the way the discussion went, it was clear that the problem of establishing a unique scheme of calculating which quantities of additives go into the product had not been established and so far neither the Commission nor any of the scientific advisors had given any thought to this.

7. Confidentiality on the part of The Commission

In reply to a question, Mr. Ryan stated that confidentiality on the part of the Commission generally was no problem whatsoever as confidentiality for the Commission was already regulated in the Treaty and the Commission had to respect strict confidentiality of information submitted for all its members and employees. The example used of confidentiality being absolutely respected was where the proceedings brought by the Commission against Mr. Bangemann for breach of confidentiality. With reference to Article 7 and the statement of the Commission on the precautionary principle, there will possibly be an inclusion of public interest in Article 7. It would, according to Mr. Ryan, be that the Commissions view would always have to be worded in the way that if there was an additive

suddenly found to have dangerous effects on human health, the Commission should act on the information immediately

8. Pharmacological Effects of Additives – Ammonia

Mr. Boyle made a statement to the effect that he was not satisfied with the presentations on additives and the pharmacological nature of additives had not been properly addressed in our presentation. He specifically referred to the addition of ammonia compounds. It was agreed after the meeting that Wilfried Dembach and Guy Dutreix would write jointly to Messrs Boyle and Ryan, attaching the available scientific response from the German Verband and therefore try to solve this question immediately.

9. Duty of Care

During the discussion there was a quarrel between Mrs. Dempsey and Mr. Boyle on the use of the words 'Duty of Care'. Professor Boyle objected to the use of these words for an industry which was responsible for killing 500,000 community citizens each year and did not wish to this form of words to be referenced to in any way when dealing with the tobacco industry. The industry was according to his opinion not entitled to talk about 'Duty of Care'.

10. ASH Paper

From the discussion with Professor Boyle, it was apparent that the only arguments on additives he was referring to be basically taken out of the ASH paper on additives. There was no other substantive evidence to be seen.

11. The Way Forward

From the meeting last week between the German Verband and all interested German ministries in the German Ministry of Health, Mr. Ryan had had the report that it was to be expected that the German industry would oppose the legislation on the grounds of the lack of a legal base. This assessment was discussed and Lutz Mueller from Reynolds reaffirmed the view that the industry was taking part in a constructive dialogue and no decision regarding opposal of the legislation had yet been taken.

The potential dangers of uncoordinated testing were discussed. It was agreed that there needed to be a common assessment of risks, a common reference point, that the question of how to develop testing methodology had to be answered. There would need to be a common testing protocol and Mr. Ryan agreed that this dialogue should be continued. There was an assumption that progress would be made in the Council and in the Health Working Group. According to Mr. Ryan's words a lot would depend on the evolving text. He is generally receptive to having a follow up meeting and discussing especially some of the points raised in Friday's meeting again, most probably on the toxicology and the need for toxicological agreements.

12. European Draft Directive and WHO Tobacco-Free Initiative and Framework Convention on Tobacco Controls

Mr. Ryan mentioned the apparent contradiction between the work currently going on re the convention for tobacco control and the European Draft Directive because the WHO is very much intent on developing common laws for the use of additives and it has been made absolutely clear both orally and in writing that in this development of common laws the tobacco industry is not to be involved at all, whereas in Europe as this meeting with the Commission experts shows, there is an active dialogue between the regulating authority and the industry.

Mr. Ryan said that the Commission generally followed the principle that stakeholders are important and their views and issues should be heard, therefore this dialogue with the representatives of the tobacco industry was also important to him.

13. Small and Medium-Sized Companies

There was a specific reference as well that small and medium sized companies, would be able to obtain derogations or specific regulations for transitional periods so that competition would be maintained at a suitable level in some sectors of the tobacco industry and the small/medium sized companies would not have to leave the market. This is a point that could possibly be taken up by ESTA.

14. Overall Assessment of the Meeting

In the overall assessment of the meeting, three points are interesting:

14.1 The Commission, and especially Mr. Ryan now proceeds on the assumption that the whole regulation of additives will be a stepwise process. This process starts with disclosure in all member states and then goes on to defining common approaches to a safety assessment for the substances used in tobacco products.

14.2 There is a genuine opportunity for engaging in a scientific-based discussion, what tests and test protocols are needed for a safety assessment of a particular substance. It is not advisable to talk from our side on 'duty of care' and that we have fully exercised our 'duty of care'. This whole question is emotionally charged.

14.3 The question of the pharmacological effects of additives needs to be treated with great care. The industry will immediately reply to the charges made on ammonia. Any other charges out of the ASH paper should be examined in an industry context and a suitable mode of reply determined.

London, 21st February, 2000 RB/KLH