

SAFETY EVALUATION OF CIGARETTES

The evaluation of safety of smoking or of cigarettes is imposed on two main bodies, the cigarette manufacturers and the public authorities. It might be said that such an evaluation is entirely the responsibility of every adult smoker and for the manufacturer this is a tempting proposal. But if this view were to be sustained then cigarettes would have to be regarded entirely differently from most other items - agro chemicals, cosmetics, food additives, motor cars, etc. In any case this argument merely transfers the onus of decision - guidance on the evaluation would still be required from manufacturers and public authority. It is unlikely then that the cigarette manufacturer can avoid involvement with safety evaluation and it might be helpful to look at the factors involved.

Safety is not a measured or indeed a measurable factor. Safety is best defined as the degree to which attendant risks are judged to be acceptable. And risk is the probability and probable severity of harm - which is measurable. Because it is measurable the evaluation of risk is susceptible to a scientific approach. Judging or evaluating safety (the acceptability of risk) however is a normative, political activity and is not therefore susceptible to a scientific approach. It is to be expected then that there will be wide variance in safety judgment between, say government and interested industry or between one well informed smoker and another. There should not be - and in truth there is not - as much variance of the views on risk between scientists whether in industry or public service.

As far as smoking is concerned there is much confusion caused by scientists and particularly by doctors becoming emotionally involved and making judgments in the political area where they may not be competent. On the other hand politicians and industrialists venture into the scientific area of risk where they may be clearly incompetent. The position is not helped by some doctors belief that they are trained to be competent in both areas. Whereas, in my judgment, their general training quite properly leads them to preoccupation with individual (i.e. unique) decisions and away from both social or scientific generalisation.

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But even in the risk area the position is not clear cut for smoking. In spite of the general similarity in the results of various epidemiological studies there are no precise measurements of the various risks involved in smoking. There is also considerable scope for different interpretations of data and some fairly formidable problems with self selected samples in epidemiological studies. Thus although the evidence on which risks of smoking may be estimated is well known, perhaps the only conclusion supported by all scientists is that the risk is above zero.

When it comes to safety evaluation, although it is true that the same sort of factors are involved whether judgments are made for social or business purposes, when presented with a variance in risk probabilities industrialists are justifiably inclined (at least publicly) to choose the lower and those held responsible for public safety similarly to choose the higher risk. There is thus an understandable and justifiable divergence in the evaluation of the safety of cigarettes. In a highly civilised society it is in the interests of all to aim to get these evaluations to converge. This can be done by 'more research' to get closer agreement on risk. However, value judgments must still be made and it may be worthwhile indicating some of the factors which are involved in making such judgments. One factor is concerned with benefits - and it must be made clear that benefits are value judgments. Scientific research can indicate efficacies in achieving measurable results but it cannot indicate or measure benefits.

The sort of questions which must be asked are as follows:-

- Is the risk voluntary or involuntary?
- Is the effect immediate or delayed?
- Are there alternatives?
- Is the risk known with certainty?
- Is the exposure essential?
- Is the risk encountered occupationally?
- Is the hazard common or "dread"?
- Does it affect average people or sensitive people?
- Will the product be used as intended or is it likely to be misused?
- Are the consequences reversible or irreversible?

We are thus concerned with considering, as well as risk, social cost, custom, reasonableness, best available practice, benefits etc., and in making a decision these several or many components must be appraised, compared and

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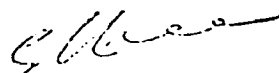
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weighed against each other.

The difficulties in food safety evaluation are similar to those for cigarettes. There are considerable differences in judgment on food and it is to be expected that there will be wide differences in the judgments of smokers, politicians, and industrialists.

The cigarette manufacturers, in my opinion, are entitled to say: "As long as there is insufficient consensus on risk (but not until there is clinical proof of the mechanism) we are not able to make useful safety judgments" - this is in effect the tight rope. Coupled with my previous argument on general (probabilistic) and special (mechanistic) causality which enables the manufacturer to say, even if there ever is consensus on risk, this can only be construed as a general causal relationship applying to the incidence of disease in populations and is not applicable to any unique individual these are very effective defensive P.R. and legal positions. Coupled further with support for research, a recognition that this only can establish (or reduce) risk etc., and that in the end safety, benefits, fairness and balance are all value judgments our public position is logically quite respectable. If at the same time we recognise that those with wider responsibilities to the public are entitled to make different value judgments with respect to the acceptability of risk and the loss of benefit and to act on them, I believe we have the best public position obtainable in the circumstances. In summary this is -

- (a) Risk is the business of science and there is not consensus.
- (b) Safety is dependent on value judgments and wide differences are to be expected.
- (c) More research at all levels should help evaluations to converge.
- (d) While there is evidence that smoking is associated with higher incidences of some diseases and general causality may be claimed, special causality can never be proved.
- (e) The slogan is informed responsibility - of adults governments and industry.



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