

Initial comments in response to WHO draft precautionary framework October 2004

These initial comments are made after reading the generic framework and the appendices on risk assessment and on power frequency EMF. I have yet to look at the last appendix. I may wish to add to these initial comments before the response date. Meanwhile I would welcome any response from colleagues from the EC/WHO workshop or other groups.

The main generic Framework

Pages 1 to 16 set out the background clearly and in general accord with the Luxembourg meeting, and are warmly welcomed. There are some particular drafting points, and a couple of serious points of principle, on which I comment below. I suggest alternative wording where I can.

There is a key fundamental disagreement, which comes out more clearly in the case studies. That is the apparent “defensive” use, in the draft, of the lack of an IARC classification, in order to exclude consideration of other identified potential risks, and even in the case of 2B classification to constrain policy options regardless of other factors such as contingent (transferred) benefits or societal factors.

Such a defensive approach seems to contravene the essential basis on which the WHO PF is constructed, namely of inclusiveness, openness and transparency, rather than censorship or disqualification of science-based considerations, however uncertain.

Page 10

On page 10 line 8 the words

“(i.e. assuming that a risk does not exist when it actually does)” are used to define a false negative. The wording perpetuates the false distinction between risk and non-risk, whereas there is always a level of uncertainty in science. It is similar to the distinction between “established” from “uncertain” effects cited a couple of lines earlier. The new approach seeks to avoid such an artificial distinction. A possible alternative wording might be

“(i.e. assuming falsely that a risk does not exist)”.

The underlying problem here is the existential concept of risk, and its semantic denial through the Royal Society type of definition of risk as the numerical probability of an established cause of harm. In ordinary language an uncertain risk is still a risk. The idea of risks existing or not existing is very unhelpful. It is essentially a matter of degree of plausibility, neither zero nor 100%. Sorry to be so pedantic!

The same sort of edit could be made to the definition of a false positive a couple of lines later.

False negative and false positive are snappy terms which are easily communicated. But what is really going on is under-statement and over-statement of an uncertain situation. Indeed, the next two paragraphs on page 10 describe it very well.

Pages 11 - 12

On page 11, section 3.2, the words “other than in exceptional circumstances, based on

publications in peer-reviewed journals” apply to normal science-based risk assessment. It would be helpful to add a paragraph at the top of page 12 along the lines of:

“In the precautionary approach, scientific evidence will, where possible, be based on publications in peer-reviewed journals, though this should not prohibit consideration of other plausible evidence nor of timely action pending completion and publication of rigorous studies”.

After the paragraph on page 12 about risk perception, it would be helpful to add: “Consideration of risk perception should not be used to suggest that the concerns are purely down to false perception by an ignorant public. Consideration of perception needs to be taken together with the scientific basis for concern.”

Page 13

On page 13, I would favour replacing “very” by “extremely” in two places in the first bullet point.

In the sixth bullet point on page 13, I would favour replacing the words “in the extreme” by “even”. It need not be extreme. I have in mind the 1989 SBO (Specified Bovine Offal) ban (from the human food chain) in the UK, while the evidence at the time was extremely weak, and the risk of transfer of BSE to humans at that time was hypothetical with the weight of evidence against. That was six years before new variant CJD was identified and prion connected with it. The cost would also be significant. Yet it proved to be a valuable precautionary measure. The problem was that it wasn’t implemented properly!

Page 14

On page 14, line 2, the words “the option assessment will inevitably be less objective, less satisfactory and less supportable” may not be justified in all cases. It would be better to replace “will inevitably be” by “may be”.

Sometimes there may be dominant factors other than the health risk, so an option may be supported by other larger benefits. The new factor with “uncertain risks” is the confidence in causation (to use the term from the draft 2001 report of the California Department of Health on EMF). While the assessment of such a factor is necessarily approximate, it may sometimes be possible within reasonable bounds. For example the IPCC assessment of past and future climate change effects uses a graded system in percentage confidence. This idea may in any case be more appropriate to the Appendix on risk assessment.

The use of “may” in the following sentence is appropriate. It allows the possibility of non-low cost options. The 1989 SBO ban is a good example. The Framework shouldn’t prohibit it.

In the second paragraph on page 14, it would be helpful to replace “intrusion” and “intrusive” by “intervention” and “interventionist”, because, especially with powerlines and telecoms masts, the developments and their fields are regarded as intrusive, so removal of the health concern would remove the physical and visual

intrusion.

Page 15

On page 15 we have:

“Such approaches remain central to the WHO Precautionary Framework; guidelines should not be undermined by additional, arbitrary exposure reductions in the name of "precaution", since this would devalue their scientific credibility.”

While this sentiment is understandable, it is one-sided and defensive as stated. Guidelines, drawn up on one basis, should not be enshrined as irrevocable impositions upon precautionary considerations. It is entirely plausible that a guideline reference level, based on an established cause at IARC 1 or even 2A, could be lowered on a precautionary basis based on possibly many more potential causes at IARC 2B or lower. This is because the precautionary framework introduces factors, such as social considerations, which may not have been considered in determining the reference levels.

Having said that, it may be that, quite often, precautionary measures below exposure reference levels will be measures short of an exposure restriction. But a dogmatic prohibition of extended exposure restrictions should have no place in a reasonable precautionary framework, especially with the principles and flexibility which the WHO framework supports.

Undermining existing guidelines should not be a consideration. That is a matter of “face” for the guideline setters, not a matter of objective assessment. It would be much wiser to end the sentence after “Framework”, rather than display such a defensive emotional reaction, which may itself undermine the credibility of the Precautionary Framework.

There is however a case for not allowing the precautionary considerations to override (note, not undermine) exposure restrictions based on established risks, meaning that the exposure restrictions should not be removed or alleviated on precautionary grounds. That, however, does not need saying.

Section 4.2 on page 15 might benefit from mentioning inclusiveness as a key principle for stakeholder consultation. There is a prize for inclusiveness - the potential to agree on precautionary measures, even if there is disagreement (as their usually will be, especially among scientists) on the interpretation of the science. The stakeholder group SAGE, working through the UK department of Health, has noted “if all the stake-holders accepted a process or conclusion then this would be an effective test of its independence from bias through interest”.

Page 16

Section 4.5 on page 16 includes:

“It should be expressly acknowledged that in implementing precautionary measures, persons,

national authorities or companies are not to be taken to be admitting liability for any consequences of not having taken precautionary measures earlier; or to be even acknowledging that the precautionary measures imposed are either necessary or appropriate.”

I do agree with that. However, I would add:

“This should not imply legal immunity of any of those bodies in respect of negligence or of failure to take reasonable precaution. Compliance with exposure restrictions based on established causes should not give legal immunity with respect to uncertain hazards, though in some countries it may in effect do so.”

Case study and IARC rating (page 20)

The case study on EMF raises questions, or interpretations, on matters of general principle not exactly covered in the generic framework.

In particular on page 20 for hazards less than IARC 2B there is a presumption:

“Under the WHO Precautionary Framework, a presumption that the evidence would not be strong enough to justify precautionary interventions with significant costs.”

I disagree with this as worded. Yes, there should be consideration of the weaker IARC rating, although there may be cases which have simply not been considered by IARC. Further the IARC rating does not take account of incidence. For example, long-term mobile phone exposures are not IARC rated yet the very high exposure rates and the inevitable lack of long-term evidence, may outweigh the strength of an IARC 2B classification. Therefore presumption is too strong a word.

Further, in the case of EMF, exposure has been rated a 2B carcinogen, albeit on the basis principally of evidence of childhood leukaemia. But this has consequences for the likelihood of causality of adult cancer, not least by the meaning of “carcinogen”. This is not the place to update evidence on biological effects and mechanisms, the melatonin hypothesis, the radical pair mechanism, biological light receptors not using rods-and-cones, and so on. There is a very wide ranging basis of evidence, and of uncertainty, relevant to multi-factorial and multi-outcome processes relevant to both childhood and adult leukaemia and other potential outcomes. It is therefore not reasonable to draw such a dividing line between IARC 2B and other uncertain risks.

An alternative wording might be:

“Under the WHO Precautionary Framework, a consideration that the evidence may not be strong enough to justify precautionary interventions with significant costs, although the strength of evidence has also to be taken with the incidence of exposure.”

In making that consideration, the inter-play between evidence for child and adult leukaemia, as well as the high incidence of mobile phone use, can then be

considered.

I appreciate that where a hazard has been classed IARC 3 or 4, this gives prima facie grounds for considering it less certain than IARC 2B, and possibly less important. But this consideration alone should not give a presumption, or a veto, of potentially countervailing considerations.

The Precautionary Framework needs to be comprehensive, not allowing one factor taken in isolation to block all other factors. This is tantamount to scientific censorship! The remainder of the box on page 20 also needs re-wording.

Page 21

In “Uncertainty also arises from the absence of reliable supporting evidence from in vivo or in vitro experiments and consideration of mechanisms.” I suggest replacing “absence” by “incompleteness”, or else re-wording this highly misleading and dismissive sentence.

Also on page 21 it should be acknowledged that some uncertainties are likely to mean that the risk is understated. For example, an inappropriate exposure metric (e.g. not including a nocturnal exposure measure relevant to the melatonin hypothesis), or a general population study ignoring known genetically susceptible subgroups, are likely to dilute or hide or understate effects.

Consider susceptible subgroups. Mel Greaves and others have identified genetic damage in utero which is strongly associated with childhood leukaemia. The result is that children with such damage, which can be readily detected from a blood sample, could then face a relative risk for childhood leukaemia potentially in the region of 1 in 200 per annum (1 in 13 lifetime).

The last two bullet points on the page are fair, but should be balanced by a point about understatement of potential risks.

Page 22

The planning measures on page 22 should also include guidance on proposals for building new homes, schools etc. in the vicinity of existing EMF sources such as powerlines.

I disagree with the section:

“WHO believes exposure limits should be based on effects conventionally regarded as established and are not an appropriate mechanism for implementing precautionary approaches. Therefore WHO does not recommend including exposure limits based on the childhood leukaemia data as an option.”

The first sentence is not justified, especially in its general form, on the grounds outlined in my earlier comments. It would be wrong to prohibit adjustment of exposure restrictions for IARC 2B (or even non-2B), especially in the spirit of the WHO PF, for the specific reasons I gave earlier. I would however support a position of not imposing adjustment of exposure limits.

The uncertainty of causation would be better represented by a confidence factor, such as in the approach of the California DH, which may be around 0.5 in this case, rather than to constrain the policy options.

An alternative wording might be:

“While recognising that different states may take different positions, depending on local and societal factors, WHO does not recommend including exposure limits based on the childhood leukaemia data as an option.”

Page 23

The set of 6 bullet points on page 23 could usefully be extended. Hopefully consultation will bring further suggestions. I would add:

- the likely understatement of relative risk and attributable incidence of childhood leukaemia;
- the implications for adult leukaemia and other cancers from the IARC 2B carcinogen finding;
- other less certain and possibly more common biological effects, from depression to headaches and sleep disorder;
- other non-biological health effects, such as interference with pace-makers (and, in the event of exposures to a hospital or medical centre, other medical equipment);
- contingent (or transferred) benefits, including reduced visual impact, property value, improved utility assets, safety and security, improved radio and TV reception, computer screen stability.

Again, it would be wrong to prohibit or disqualify considerations of additional, less well established, potential non-cancer effects, such as depression and headaches, or effects on pacemakers, simply because they have not been IARC classified. The WHO PF should be inclusive, transparent and open, not censoring scientific considerations however uncertain, nor restricting consideration of contingent benefits.

Page 24

The engineering options should include undergrounding powerlines. In most cases this may not be justified because of the high cost and limited exposure. However there may be cases where the totality of benefits, including contingent benefits, makes it worth while.

An interesting test case has just arisen in London where a development of 570 apartments for social (welfare) housing is proposed alongside an existing powerline and close to several telecoms masts, including an 8-storey block within 20 metres of the powerline. There are many factors and possible contingent benefits, in this high density housing proposal.

In other cases where a new powerline is proposed through an urban area with high density housing, the decision to underground may already be in the balance without health considerations. Indeed, many urban lines are underground on the balance of technical and economic considerations. In a marginal case, health considerations could tip the balance.

Elsewhere in the table on page 24 property value is listed as a cost consideration, with regard to sterilisation of otherwise valuable land if a development is restricted. In other instances property devaluation will be a benefit consideration, favouring re-sited or underground alternatives.

A further option for the table might be changed housing and land use policy. Considerations for benefits would include the ability to protect vulnerable or susceptible people from exposures. Costs would include restrictions on available housing and land use.

Following the table is the sentence: "In accordance with the WHO PF, costs should be considered at the level of the society as a whole and all costs should be included, whether born by industry, taxpayers or others." I would recommend inserting "and benefits" after "costs", otherwise it may give the impression that the writers were biased and wished to emphasise only costs while playing down benefits.

The last 3 bullet points on page 24 are repetitive reinforcement of the defensive (costs) points, and serve only to reinforce a possible appearance of bias. I recommend that they simple be deleted.

Page 25

In view of the above comments, this page needs some amendment:

in line 2, insert "in many cases" after "it seems likely that";

in the first bullet, insert "general" before "exposure limits" and delete the second sentence;

in the second bullet change the first word "any" to "general" and insert "major" before "changes";

also in the second bullet the word "are" seems to be omitted in error;

in bullet 5, replace "are unlikely to be" by "may be";

add a bullet "care should be exercised in placement of children or vulnerable or susceptible people in exposed housing".

In the second set of 5 bullets, put IF and DEPENDING in lower case, as the capitalisation gives the impression of a defensive emphasis on aspects negative towards precaution. Also in the introductory lines, replace "would seem to be" by "could include", so as not to be interpreted as prohibitive or censorious.

Page 26

At the top of page 26 add an third bullet

- this policy shall not be taken to imply that companies, governments and other bodies should be immune from legal liability, for example in recklessness or negligence.

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