## IARC on Glyphosate – what to do when a mistake is made?

The Governing Council of the International Agency for Research on Cancer (IARC<sup>1</sup>) is meeting<sup>2</sup> today and tomorrow.

Not listed on the published agenda is glyphosate, but much of the conversation will be about the hotly disputed decision<sup>3</sup> that glyphosate is 'probably carcinogenic to humans' (Group 2A). Was it the right finding, why was so much of the animal experimentation evidence deemed unsuitable for consideration, is it ethical to make pronouncements of any sort if there is no published evidence of how often IARC decisions are wrong? How should scientific expert opinion be held to account? Who underwrites the effect of mistakes? Is it ethical not to take responsibility for mistakes?

## Holding IARC to account

It seems obvious in hindsight that institutions of all kinds whether commercial or public should publish an account of how accurate their published findings are<sup>4</sup>. In time, false positives, false negatives, true positives and true negatives can be counted and simple statistics can be generated<sup>5</sup>. Has anyone done this for IARC's Monograph series?

One of the problems in producing such a validation test is what to do about chemicals where no pronouncement is made. If chemical x has not been pronounced upon is this a false negative or a true negative? Fortunately, the Positive Predictive Value<sup>6</sup> (<u>PPV</u>) is not influenced by this problem and is the statistic which is most needed.

## Why is PPV important to the risk management industry?

When IARC say "is carcinogenic" or "is probably carcinogenic" some regional authorities<sup>7</sup> respond with requirements to publish warnings and this inevitably has an effect on liability risk. Sometimes the IARC view leads to an automatic response<sup>8</sup>, sometimes the IARC view is further judged before action is triggered. I argue here that PPV values for "is carcinogenic" and "is probably carcinogenic" should in principle influence the form of the response. Some proposals are made below.

For the purposes of liability risk management, if the positive predictive value is below 50% then on average all pronouncements are more likely wrong than right. I propose that in effect the public authority position should be that implied common law responses be ruled out automatically. If a warning issued by IARC or anyone else is 'probably wrong' then a warning label would probably misinform the public or other intended audience. This cannot be in the public interest. If ruled out, generators of risk and their insurers would continue to be free to apply their own assessment and be prepared to justify it. How well is IARC doing? What are their PPVs? Surely this is a matter that should be on today's agenda.

For individual substances, if <u>one</u> authoritative body disagrees with IARC then common law responses should in the same way be ruled out automatically. *One vs one* cannot pass the balance of probabilities test; a warning would be as likely wrong as it is right and the public is not informed.

<sup>&</sup>lt;sup>1</sup> The International Agency for Research on Cancer was established in May, 1965, through a resolution of the XVIII<sup>th</sup> World Health Assembly, as an extension of the World Health Organization (WHO).

<sup>&</sup>lt;sup>2</sup> <u>http://governance.iarc.fr/GC/GC61/index.php</u>

<sup>&</sup>lt;sup>3</sup> <u>https://www.iarc.fr/featured-news/media-centre-iarc-news-glyphosate/</u> (2015)

<sup>&</sup>lt;sup>4</sup> Recent audit scandals for example have drawn attention to the need for the "big four" to be held to account for their false findings. How often do they mislead shareholders? How are they held to account for their errors?

<sup>&</sup>lt;sup>5</sup> <u>https://www.medcalc.org/calc/diagnostic\_test.php</u>

<sup>&</sup>lt;sup>6</sup> PPV is the ratio of true positives to the sum of true positives and false positives.

<sup>&</sup>lt;sup>7</sup> Perhaps the best known is Proposition 65 in California. <u>https://oehha.ca.gov/proposition-65</u>

<sup>&</sup>lt;sup>8</sup> https://oehha.ca.gov/proposition-65/crnr/regarding-certain-iarc-international-agency-research-cancer-2b-chemicals

WHO should say that 'reasonable people armed with the same evidence can come to opposite conclusions'. When this happens, the IARC finding should be labelled as "pending review".

In case of glyphosate, IARC is disagreed with by just about every independent authority! The very least that IARC should do, in the public interest, is to <u>suspend</u> the finding until a definitive view is forthcoming. What will the Governing Council do today? And, do regional authorities have the regulatory capacity to suspend regulatory action if IARC don't first suspend a finding? Would it be unethical for IARC to respond to independent expert review?

Of course, liability risk management consultants should face the same sort of scrutiny when they publically identify liability issues. But this rarely happens<sup>9</sup>.

If the PPV is less than 50% one logical view is that it is automatically unreasonable to make an accounting provision such as a reserve. The PRA<sup>10</sup> would indicate their displeasure. Even if a deeper evaluation reveals a given item to be a true positive, the question for liability risk managers is, how many "predictions" can you afford to analyse in order to find one good one?

Dr Andrew Auty



<sup>&</sup>lt;sup>9</sup> Readers may like to know that Re: Liability (Oxford) Ltd has developed a methodology to make such an evaluation and has applied it to a well-publicised market report which contained more than fifteen liability "predictions". A full report on this is available for a fee. Contact: <u>andrew@reliabilityoxford.co.uk</u>.

<sup>&</sup>lt;sup>10</sup> In the UK, financial services firms are regulated by the Prudential Regulation Authority (PRA) <u>https://www.bankofengland.co.uk/prudential-regulation</u>