

感作性分類基準（暫定）の提案理由

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許容濃度等に関する委員会

従来の分類では、人間における疫学研究および症例報告の情報を基に化学物質を 2 群に分類してきた。これは、人間への感作性を問題にした場合に極めて直接的な分類根拠であり、動物実験の結果の取り扱いにおいて常に問題となる、人間への外挿の不確実性を考慮する必要がなく、簡便で合理的な分類基準である。しかしながら、一方で近年の動物を用いる試験手法は大きな進歩をとげた。それにより明らかになってきた人間での試験結果との相関に関する報告をみた場合、限られた物質のデータではあるが、動物実験の結果と人間の結果に、従来の定性的相関に加え、定量的相関もあることが示唆されている。更に、原理の異なる複数の試験手法が確立されたことにより、ひとつの化学物質に対して、多面的な考察を行うことも可能となった。一方、呼吸器感作性に関しては、これまでのところ公的に認められた、確立した試験手法はない。しかしながら、動物においても呼吸器アレルギー反応は検出されている。皮膚感作性試験と比較して、評価された物質の種類が少なく、比較しうるヒトでの情報も少ないことから、現時点で評価に値する試験手法を特定はできないが、逆にすべてを棄却することも適当ではないと判断した。即ち、皮膚感作性および呼吸器感作性のいずれにおいても、化学物質の人間に対する感作性を、動物実験の結果をもとに予測することは、科学的にみて十分根拠があり、労働災害の予防の立場からも望ましいと判断した。

以上の基本的立場から、人間における皮膚感作性及び呼吸器感作性の予測における動物実験の情報の利用について、以下に提案する。今回は、あくまで人間に対する感作性の分類という観点から、従来の第 1 群の判断基準は変更しないが、皮膚感作性に関しては確立した動物実験法があるため第 3 群の判断基準に動物実験を取り入れた。呼吸器感作性に関しては、評価に値する結果を得るための、動物実験法の基準を示す形で、第 3 群の判断基準に取り入れた。第 1 群は人間に対して明らかに、第 2 群は人間に対しておそらく感作性がある物質で、第 3 群は動物試験などにより人間に対して感作性が懸念される物質である。

感作性物質リストは感作性の強さによってではなく、その確からしさによって分類したものであり、専門家が文献的考察を行って決めるものである。また本分類で感作性ありと分類されないことは、感作性がないというこ

と同意ではない。許容濃度の表に掲載されている全ての物質を調べたわけではない。掲載されている許容濃度値は感作を必ずしも考慮したものではない。

本分類の参考文献の中には、現代の倫理観では不適切な実験を含む論文もあるが、感作性の判断を行なう上で、ほかに参考文献として適当な論文がなかったためにやむを得ず引用したことを、補足させていただく。

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