

Fatty Acids is an essential reference source for professionals and researchers in food science and nutrition, dietitians, students, and the food industry.

Fatty Acids, Supplement to McCance & Widdowson's *The Composition of Foods*. ISBN: 0854048197; softcover; Approx. 200 pages; Price: GBP 32.50.

The book may be ordered from: Turpin Distribution Services Ltd, Blackhorse Road, Letchworth SG6 1 HN, UK

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Metabolic Pathways of Agrochemicals

This major new reference source was launched at the 9th IUPAC Congress on Pesticide Chemistry held in London, 2–7 August 1998. The two-volume publication provides comprehensive coverage of the chemical degradation and metabolism of agrochemicals in soils, plants, and animals. Organized by compound class for ease of use, and covering 40 years of literature, it comprises:

- Separate entries for each pesticide
- Overviews of the metabolism of specific classes of agrochemicals
- Key similarities and significant differences between individual chemicals in the class
- Extensive bibliography
- Comprehensive, high-quality indexes

Editor-in-Chief Terry Roberts, of JSC International Ltd, and his team of international experts have extensive experience in the field. Part 1, available now, covers Herbicides and Plant Growth Regulators, while Part 2 will feature Insecticides and Fungicides. For further details, contact: The Sales & Promotion Department, The Royal Society of Chemistry, Thomas Graham House, Science Park, Milton Road, Cambridge CB4 4WF; Tel.: +44 1223 420066; Fax: +44 1223 423429; E-Mail: Sales@rsc.org; Web Site: <http://www.rsc.org>.

New Publications from the World Health Organization

Benefit–Risk Balance for Marketed Drugs: Evaluating Safety Signals, Report of CIOMS Working Group IV

CIOMS 1998, 160 pages (English), ISBN 92 9036 068 2, CHF 15.-/USD 13.50; In developing countries: CHF.

10.50, Order no. 1840020. WHO distribution and sales, CH-1211 Geneva 27, Switzerland.

This report presents and explains a standardized methodology for reassessing the established benefit–risk relationship of a marketed drug when a new safety problem arises. Addressed to drug manufacturers and regulatory authorities, the book responds to the absence of any standard, systematic procedure for assessing newly detected hazards, balancing risks against benefits, and reporting the results. The recommended approach, which reflects the consensus reached by 24 representatives of industry and government regulatory authorities, includes detailed advice on concepts and procedures for determining the magnitude of the safety problem and deciding on the appropriate action, whether involving a routine change in product information or immediate withdrawal of the drug from the market. The use of a standard reporting form, presented here for the first time, forms a central part of the recommended procedure.

The report adopts a public health approach aimed at encouraging consistent practices, on the part of both regulators and companies, when a major safety problem is signaled. Throughout, examples from case studies are used to illustrate pragmatic responses to the many difficult problems involved. Information ranges from a checklist of questions to consider when evaluating benefits, through an agreed-upon method for scoring the relative seriousness of different adverse reactions, to recommendations for the standard visual presentation of data. Particular attention is given to procedures that can help minimize bias when risk profiles are prepared for competing products from the same therapeutic class.

The report has five chapters. The first provides an overview of recommended principles, the factors influencing benefit–risk assessments, and the types of data and analytical approaches that should be used. Chapter 2, which forms the core of the report, presents a standard five-part reporting form and provides detailed guidelines for its completion. Examples from case histories are used to illustrate basic principles and methodologies for collecting and analyzing the data needed for benefit estimation, risk estimation, benefit–risk evaluation, and the analysis of options for action. The chapter also suggests standardized ways of displaying data when profiling and quantifying risks or comparing the risk profiles of competing drugs.

Chapter 3 covers the decision-making process, including advice on how to select the best options for action and how to determine the responsibilities of regulators and companies. The remaining chapters discuss issues unaddressed or unresolved by the working group, and summarize key recommendations and proposals.

The report concludes with a series of appendices, which include in-depth case histories for seven drugs, a model for the quantification of risks (accompanied