As a third step, the FDA contracted with FASEB through its Life Sciences Research Office (LSRO) to evaluate the material presented in each monograph and the relevant use data from the NAS survey, and report to the FDA an opinion on the health aspects of using each substance in food.

In approaching the evaluation of the GRAS substances, LSRO organized a group of qualified scientists—now called the Select Committee on GRAS Substances—to review the available information and make evaluations. These scientists were chosen for their experience and judgment with due consideration for balance and breadth in the appropriate professional disciplines. From time to time as needed, the Select Committee retains ad hoc consultants with special expertise to obtain advice in particular areas. These consultants do not participate in the formulation of the Select Committee's opinions and conclusions.

In its evaluations, the Select Committee and staff regularly find it desirable to search beyond the material supplied in the monographs to assure currency and completeness. This includes citations and abstracts from such sources as the MEDLARS system for which FASEB has a terminal communication with MEDLINE, TOXLINE, and other computer data banks. Routinely searched are such sources as the bibliographies of the Environmental Mutagen Information Center; the Toxic Substances list; material prepared by the Toxicology Information Resource Center; the Biology Data Books; the volumes on drug interactions of the Toxicology Information Program; the Food Chemicals Codex; the statements of food additives standards from various countries such as West Germany, France, and Japan; reports of the Codex Alimentarius Commission; the series of volumes of the Public Health Service on compounds that have been tested for carcinogenicity; the World Health Organization food additives and technical report series; and the files of the FDA. It is the Committee's practice to consider and cite in its reports only the original research publications rather than secondary sources of the information.

In addition, the Select Committee holds public hearings after it has reached its tentative conclusions. The tentative report on each evaluation is made available for public examination and an invitation is made in the Federal Register for those interested to request opportunity to make an oral presentation before the Committee of data, information, and views not included in the materials already available to the Committee. The information presented at these hearings will be considered by the Select Committee before reaching its final conclusions and a transcript of each hearing will be available for public use.

As a final step in the process, each report is reviewed and approved by LSRO's Advisory Committee, comprised of a member representing each of the constituent Societies of FASEB. The reports as filed with the FDA are, accordingly, reports of FASEB.

LSRO has received 112 monographs covering 330 GRAS substances and some work has been done on all but 19. Reports have been filed with the FDA on 30 monographs covering 78 substances. In addition, tentative conclusions have been reached on some 150 substances.

Based on the Select Committee's conclusion and other considerations, the FDA can take action to reaffirm the substance as GRAS or otherwise regulate it. For the more than 200 substances on which the Select Committee has reached at least a tentative conclusion, about two-thirds could be reaffirmed as GRAS and about one-third could require other disposition, provided the FDA elects to act in accord with the Committee's conclusion.

In the two and a half years of the Committee operations, a few problems have arisen beyond the normal difficulties that one would expect in a task of this nature and magnitude. It is difficult, for example, to develop realistic estimates of human consumption of many of the GRAS substances, even with the help of the excellent report of the NAS, production and import statistics, and the willing assistance of the food industry.

The making of judgments, when the publications of reputable scientists differ on the interpretation of their findings, is not easy. The sorting of the credible from the noncredible in published research, much of it done decades ago with methods and equipment less sophisticated than those available today, extends the ingenuity of the Committee in making rational decisions.

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