YET MORE DATA ON PVC PACKAGING REQUIRED

Further data on PVC usage in food, drug and cosmetics containers and in medical devices was requested by the FDA on 22 April, with a deadline set for 21 June. The information required involved the extent of usage of PVC for different types of containers and container liners and the types of product; the vinyl chloride content of PVC used for such purposes, including descriptions of the methods and extraction systems used for its determination; the rate and level of vinyl chloride extracted from such containers by various foods, drugs and cosmetics, including data derived after periods of storage; the rate and level of percutaneous absorption of vinyl chloride from cosmetics and devices in contact with skin or mucous membranes; the vinyl chloride content of various drug fluids after contact with PVC devices; and the effect on blood and tissues of vinyl chloride extracted from such devices inserted or implanted in the body.

The FDA has already taken action against cosmetic products with vinyl chloride in the propellant, and the Environmental Protection Agency has taken similar action against pesticide aerosol products. An inter-agency task force has been formed to gather data on the overall effect of vinyl chloride on the total environment, and to initiate co-ordinated action to minimize this impact.

The FDA has now apparently abandoned the idea of imposing limits on residual vinyl chloride monomer in PVC (BIBRA Bull. 1974, 13, 237) but the end-test limit of 50 ppb in the contained food is still expected to be introduced.

INDUSTRIAL EXPOSURE TO VINYL CHLORIDE TO BE REDUCED

The limitation of industrial exposure to vinyl chloride to a level undetectable by an accurate method sensitive to $1 \pm 0{\cdot}5$ ppm, was proposed on 10 May by the Occupational Health and Safety Administration (OHSA). This followed the issue on 5 April of an emergency temporary standard, which reduced the ceiling value set by OHSA for vinyl chloride exposure from 500 to 50 ppm (Federal Register 1974, 39, 12342).

At the February hearing (BIBRA Bull. 1974, 13, 179), evidence was

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presented by Professor C. Maltoni of the Istituto di Oncologia, Bologna, Italy, that haemangiosarcomas of the liver had developed in animals exposed to vinyl chloride concentrations in the air as low as 250 ppm. No tumours had been seen at 50 ppm in this or in an earlier study (Torkelson et al. Am. ind. Hyg. Ass. J. 1961, 22, 354); however, Professor Maltoni is now conducting a more comprehensive study which involves the exposure of 300 animals at the 50 ppm level (see also p.248 of this issue). OHSA concluded that although 50 ppm could not be regarded proven as safe for lifetime exposure, it was the lowest level that could be complied with immediately and was well below levels to which some workers were currently being exposed.

The emergency standard (Part 1910, Title 29, Sec.1910.93q) applies to all areas and operations in which vinyl chloride is manufactured, reacted, handled, processed, released, repacked or stored, and requires weekly monitoring for at least 3 weeks to establish that concentrations do not exceed 50 ppm; thereafter, monthly monitoring is required. In all operations involving concentrations above 50 ppm, respirators or other breathing apparatus are required, and engineering or operational controls to reduce such concentrations to the permissible level must be introduced as quickly as possible.

The standard will remain in effect for a maximum period of 6 months.

COSMETICS REGULATIONS RECODED

All regulations on cosmetics made under Title 21, Chapter I of the Code of Federal Regulations have been recoded under a new Subchapter G, in an attempt to provide greater clarity and convenience for the user (Federal Register 1974, 39, 10054). This brings together the regulations on packaging and labelling formerly under Part 1 of Subchapter A, the statements of policy and interpretation formerly under Part 3 of that subchapter, and the former Subchapter D, which included the recent regulations on voluntary filing of reported adverse reactions (BIBRA Bull. 1974, 13, 52). Because forms for the filing of adverse reactions would not become available until May 1974, the initial reporting period was deferred to January-June 1974. Reports for this period should be submitted to the FDA by 1 September 1974 (ibid 1974, 39, 9185).

NEWS OF BIBRA

DR. D.W. KENT-JONES, O.B.E.

On behalf of the BIBRA staff, we congratulate our Vice-President, Dr. D.W. Kent-Jones, on the award of an O.B.E., for services to the food industry, in the recent Birthday Honours List.