

The Committee has extended the reach of the regulatory authority of the bill to all chemical substances and mixtures whether in interstate commerce or not since the size and scope of the chemical industry makes it impossible to distinguish between those in interstate commerce and those which are not. Further, commerce in those which are arguably only in intrastate commerce may affect commerce in those which are in interstate commerce, and consequently there cannot be effective regulation of the latter without regulation of the former. Also regulation of only those in interstate commerce without regulation of the others could depress commerce and discriminate against those in interstate commerce and adversely burden, obstruct, and affect such commerce.

Subsection (b) provides that it is the policy of the United States that (1) hazardous and potentially hazardous chemical substances and mixtures should be adequately tested with respect to their effect on health and the environment; (2) such testing should be the responsibility of those who manufacture or process the chemical substances or mixtures; (3) adequate authority should exist to regulate chemical substances and mixtures which may cause or significantly contribute to an unreasonable risk to health or the environment, and to take action with respect to chemical substances and mixtures which are imminently hazardous; and (4) these authorities should be exercised so as not to unduly impede or create unnecessary economic barriers to technological innovation while assuring that such chemical substances and mixtures do not cause or significantly contribute to an unreasonable risk to health or the environment.

Subsection (c) of section 2 provides that it is the intent of Congress that the Administrator of the Environmental Protection Agency shall carry out the bill in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action proposed to be taken under the bill.

The Committee intends subsection (c) for the guidance of the Administrator in fulfilling the purposes of the bill. However, this statement of intent by the Committee as to the manner in which the Administrator is to exercise the authorities and fulfill the Administrator's responsibilities under the bill is not to be construed as a direction to the Administrator to make any statement of findings in addition to those required by specific provisions of the bill or to involve the Administrator in any cost-benefit justifications.

### SECTION 3, DEFINITIONS

Section 3 defines the terms used in the bill. While most of the definitions are self-explanatory, a few are of particular importance and merit discussion.

The term "Administrator" means the Administrator of the Environmental Protection Agency.

The bill grants the Administrator certain regulatory authority over "chemical substances" and "mixtures" of chemical substances. The term "chemical substance" is defined in this section to mean any organic or inorganic substance of a particular molecular identity, including a combination of such substances occurring in whole or in part as a result of a chemical reaction or in nature. The term also includes any element or uncombined radical.

The Committee recognizes that basically everything in our environment is composed of chemical substances and therefore the definition of "chemical substances" is necessarily somewhat broad. However, because of the breadth of the definition, the Committee has carefully defined the authorities of the Administrator respecting such substances.

Certain categories are specifically exempted from the term "chemical substance" and thus are exempted from coverage under the bill. Pesticides (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; tobacco or tobacco products; source material, special nuclear material, and byproduct material (as defined in the Atomic Energy Act of 1954 and regulations issued under that Act); and articles which if sold would be subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (i.e., pistols, firearms, revolvers, shells and cartridges).

Although the language of the bill is clear on its face as to the exemption for pistols, revolvers, firearms, shells, and cartridges, the Committee wishes to emphasize that it does not intend that the legislation be used as a vehicle for gun control. Consequently the Administrator has no authority to regulate ammunition as an unreasonable risk because it injures people when fired from a gun. However, the Committee does not exclude from regulation under the bill chemical components of ammunition which could be hazardous because of their chemical properties.

Also excluded from the definition of the term chemical substance and consequently from coverage under the bill are any food, food additive, drug, cosmetic, or device when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. As used in this exclusion, the terms "food", "food additive", "drug", "cosmetic", and "device" have the same meaning as is given them by section 201 of the Federal Food, Drug, and Cosmetic Act. The intent of the Committee in excluding these items is to exclude from coverage under the bill items which may be regulated under the Federal Food, Drug, and Cosmetic Act. By adopting the definitions given the items by that Act the Committee has made the exclusion of these items from the bill coextensive with the authority to regulate them under the Federal Food, Drug, and Cosmetic Act. Thus, if an item cannot be regulated as a food, food additive, drug, cosmetic, or device under that Act because it does not come within the definitions in that Act, it is not the intent of the Committee to exclude it from coverage under the bill.

An amendment was offered during Committee consideration of the bill to add a provision which would add to the exclusion described above an exclusion of "any substance produced for research and devel-

opment purposes and intended only for use in or on any such food, drug, cosmetic, or device". It was stated that the intent of the amendment was to make it clear that catalysts, intermediates, and precursors which are intended for use in the production of drugs in their final dosage forms or substances which are used in research and development of drugs and which do not necessarily become ingredients of the drugs in their final dosage forms would not be subject to regulation under the bill. The amendment was withdrawn with the understanding that the definition of the term "drug" in the Federal Food, Drug, and Cosmetic Act included the items described in the amendment, but that to the extent that any such item is not included in that definition and thus not subject to regulation under that Act, such item should be subject to regulation under the bill.

The definition of "drug" in the Federal Food, Drug, and Cosmetic Act includes "articles intended for use as a component" of substances included in the definition of "drug". As used in that Act, the term "component" does not mean only an item which may be identified as an ingredient of a drug in its final dosage form. Component includes any item used in the production of the drug. Thus, precursors, intermediates, and catalysts intended for use in the production of drugs in their final dosage form are "drugs" within the meaning of the Federal Food, Drug, and Cosmetic Act.

Further, the Federal Food, Drug, and Cosmetic Act clearly covers drugs during the "investigation" or research stage. Consequently, the definition of "drug" in that Act includes chemical substances used for drug research and development. The same is true of the definitions of food, food additives, and cosmetics.

Likewise, the definition of pesticide in the Federal Insecticide, Fungicide, and Rodenticide Act defines "pesticide" to include "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." Thus the definition in that Act would include chemical substances on which research is being performed with the intent that the substance be used for any of the purposes described in the definition of the term "pesticide". Such substances would be subject to regulation under that Act and, by virtue of the exemption for pesticides, are exempted from regulation under this bill.

The exclusion from the definition for any pesticide, food, food additive, drug, cosmetic, or device is conditioned upon its being manufactured or distributed in commerce for use as a pesticide, food, food additive, drug, cosmetic, or device. Such a condition is necessary because some chemical substances and mixtures which can be used as pesticides, foods, food additives, drugs, or cosmetics can also be used for other purposes. For example, aluminum subacetate is used as a burn treatment, but it is also used as a mordant in dyeing and for flame-proofing. Cuprous oxide is used as a pesticide, but it also is used as a flame-retardant.

Aluminum subacetate when used in dyeing or for flame-proofing could not be regulated under the Federal Food, Drug, and Cosmetic Act, nor could cuprous oxide when used as a flame-retardant be regulated under the Federal Insecticide, Fungicide, and Rodenticide Act.

The Committee bill assures that the exemption will extend only insofar as the exempted substance or mixture is actually manufactured, processed, or distributed in commerce for use as a pesticide, food, food additive, drug, cosmetic, or device and thus is subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Federal Insecticide, Fungicide, and Rodenticide Act.

Although the term chemical substance excludes mixtures of chemical substances, mixtures are not excluded from regulation under the bill. However, mixtures are regulated in a different manner than chemical substances—they are not subject to the manufacturing and processing notices for new chemical substances under section 5 and special findings are required before testing of them may be required or before they can be subject to rules under section 8(a) requiring recordkeeping and reporting for them. Consequently, it was necessary to establish chemical substances and mixtures as two separate identifiable terms.

The term "mixture" is defined to mean any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction. Certain combinations of chemical substances which do occur, in whole or in part, as a result of a chemical reaction are included within the term mixture and thereby excluded from the definition of chemical substance. If each of the chemical substances comprising the combination is not a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the substances comprising the combination were combined, then the combination will be a mixture rather than a chemical substance.

The inclusion of such reaction-produced combinations within the definition of mixture is necessary to prevent disparate treatment of identical combinations simply because of the number of steps used in the production of the combination. For example, a soap product may be manufactured by combining coconut oil soap, sodium tri-poly phosphate, sodium sulphate, and sodium bicarbonate. When combined, these four ingredients do not react chemically. Thus if a manufacturer combined the four ingredients, the resulting combination would clearly be considered a mixture. However, if another manufacturer simultaneously mixed two substances which react to form coconut oil soap, the first ingredient, together with the latter three ingredients, the resulting combination would have been produced in part by a chemical reaction. The two end products would be identical, and they should be subject to identical treatment under the bill. The Committee definition assures that they will be.

The term "environment" is broadly defined to include water, air, and land and the interrelationship which exists among and between water, air, land and all living things. Thus by providing for the protection of the environment, the bill includes protection for all living things within the environment.

The term "manufacture" means to import, produce, or manufacture. As a result, imported chemical substances and mixtures will be subject to regulation in the same manner as domestically produced chemical substances and mixtures are. In addition, importers of chemical

substances and mixtures will have the same responsibilities and obligations as domestic manufacturers.

The bill does not attempt in the definition of the term "manufacture" to define exactly what activities are to be included in that term because the activities embraced by the term are generally well understood. However, it has come to the attention of the Committee that there are activities incidental to the end use or storage of certain substances or mixtures which under a literal reading of the definition would make a person engaging in them a manufacturer and thus subject to the provisions of the bill applying to manufacturers.

For example, there are certain substances or mixtures, such as adhesives, paints, inks, and drying oils, which during storage or upon end use, when exposed to environmental factors such as air, moisture, or sunlight, undergo a chemical reaction which produces a different substance or mixture. Similarly, plastic resins subjected to heat for purposes of molding undergo a thermal setting which produces a different substance. In such cases, the chemical reaction is merely incidental to the end use or storage of the original substance or mixture. The substance or mixture produced is not used as a chemical substance or mixture, per se. It is not the Committee's intent that a person, such as a painter, who is engaged in the end use or storage activity in which such a chemical reaction occurs is to be considered a manufacturer because of the reaction. Thus, such a person would not be subject to the notification requirements of section 5 even though a chemical substance resulting from the reaction is not included on the inventory compiled under section 8(b). Substances which occur incidentally to the storage or end use of such combinations should be considered as byproducts, and the responsibility for meeting the testing, notification, and other requirements with which manufacturers must comply would fall upon the manufacturer of the substance or mixture from which the byproduct is produced.

For example, there are certain combinations of substances, such as adhesives, paints, inks, and drying oils, which during storage or upon end use, when exposed to environmental factors such as air, moisture, or sunlight, undergo a chemical reaction which technically produces a different chemical substance. However, the chemical reaction is merely incidental to the storage or end use of the substances. The substance produced is not to be used as a chemical substance, per se.

It is the Committee's intent that a person who is engaged in a use or storage activity in which such a chemical reaction occurs is not to be subject to the notification requirements of section 5 even though the chemical substance resulting from such activity is not included on the inventory compiled under section 8(b). Substances which occur incidentally to the storage or use of such combinations should be considered as byproducts and the responsibility for meeting the requirements of the bill respecting such byproducts is to be met by the manufacturer of the substance from which the byproduct is produced.

During the hearings, a number of witnesses recommended that the bill include a definition of unreasonable risk. Because the determination of unreasonable risk involves a consideration of probability, severity, and similar factors which cannot be defined in precise terms

and is not a factual determination but rather requires the exercise of judgment on the part of the person making it, the Committee did not attempt a definition of such risk. In general, a determination that a risk associated with a chemical substance or mixture is unreasonable involves balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action on the availability to society of the benefits of the substance or mixture, taking into account the availability of substitutes for the substance or mixture which do not require regulation, and other adverse effects which such proposed action may have on society.

The balancing process described above does not require a formal benefit-cost analysis under which a monetary value is assigned to the risks associated with a substance and to the cost to society of proposed regulatory action on the availability of such benefits. Because a monetary value often cannot be assigned to a benefit or cost, such an analysis would not be very useful.<sup>1</sup>

As noted above, the Committee recognizes that risk is measured not solely by the probability of harm, but instead includes elements both of probability of harm and severity of harm and those elements may vary in relation to each other. Thus, the Administrator may properly find that health or the environment are exposed to an unreasonable risk by a lesser probability of a greater harm as well as by a greater probability of a lesser harm.

Although the standard for defining the regulatory authority of the Administrator throughout the bill is "unreasonable risk", the implementation of the standard will of necessity vary depending on the specific regulatory authority which the Administrator seeks to exercise. For example, a testing rule under section 4 will ordinarily not result in depriving the public of the benefits of a substance or mixture subject to the rule. This is because such a rule does not prohibit the manufacture, processing, etc., of existing substances or of mixtures. At the most a testing rule may, through section 5(d), delay the commercial availability of new substances and new uses of existing substances subject to the testing rule. Similarly, a requirement imposed under section 5(g) (regulation of new substances and significant new uses of substances pending the development of information) will only delay or restrict the availability of a substance subject to it until adequate health and safety data can be developed and evaluated.

However, this is to be contrasted with the effect of the imposition of a requirement under section 6 on a substance. Such a requirement may remove a substance from the market or impose lesser restrictions on its availability and such a requirement is not of limited duration. Thus, the effect on society may be far reaching. As a result regulatory effect will be of greater significance in a determination of unreasonable risk for purposes of section 6 than for a determination for purposes of section 4 or 5(g). Conversely, with respect to section 4 or 5(g), be-

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<sup>1</sup>A recent study by the National Academy of Sciences on regulating chemicals agrees. It states: "Highly formalized methods of benefit-cost analysis seldom can be used for making decisions about regulating chemicals in the environment. Thus the development of such methods should not have high priority." *Decision Making for Regulating Chemicals in the Environment*, Committee on Principles of Decision Making for Regulating Chemicals in the Environment, Environmental Studies Board, Commission on Natural Resources, National Research Council, National Academy of Sciences, xxv (July, 1975).

cause the regulatory effect of action taken under either of those sections is less than that of action taken under section 6, the requirements for a determination of unreasonable risk for purposes of section 4 or 5(g) are less demanding.

The Committee has limited the Administrator to taking action only against unreasonable risks because to do otherwise assumes that a risk-free society is attainable, an assumption that the Committee does not make.