(collectively referred to as "glycidyls") for priority consideration for health effects testing with regard to the following endpoints: carcinogenicity, mutagenicity, teratogenicity, and other adverse health effects, with particular emphasis on the reproductive system. Epidemiological studies were also recommended. The rationale for the original designation is discussed in the same **Federal Register** notice. This chemical category was defined by the ITC as all substances with the general formula:

$$\begin{matrix} & & & & \\ & & & \\ R-O-CH_2 & CH-CH_2 \end{matrix}$$

where R is a hydrogen atom or any alkyl, aryl, or acyl group. R is unrestricted as to the number and type of substituents it may carry.

On December 30, 1983, EPA published an advance notice of proposed rulemaking (ANPR) in the **Federal Register** (48 FR 57562) to require testing glycidyls under section 4(a) of TSCA.

In the November 7, 1991 Federal Register (56 FR 57144), EPA published the Notice of Proposed Rulemaking for Glycidol and its Derivatives. EPA evaluated the testing needs for glycidyls as described in Unit I.D. of the Notice of Proposed Rulemaking for Glycidol and its Derivatives. In this notice, EPA proposed that GMA manufacturers test GMA for subchronic toxicity. developmental toxicity, and subchronic neurotoxicity (functional observation battery, motor activity, and neuropathology). Mutagenicity testing (a sex-linked recessive lethal assay and a rodent dominant lethal assay) was proposed for glycidyl acrylate as a representative test substance for Subgroup VII-B of the glycidyls, of which GMA was the other member.

## II. Enforceable Consent Agreement Negotiations

On July 17, 1992, EPA published a Federal Register notice (57 FR 31714) announcing an "open season." The "open season" was a time during which manufacturers could submit to EPA proposals for testing chemical substances which had been proposed for testing by EPA but had not been subject to a final test rule. In that notice, EPA indicated that it would review the submissions and select candidates for negotiation of ECAs pursuant to 40 CFR part 790. EPA also indicated that it would later publish a Federal Register notice soliciting persons interested in participating in or monitoring negotiations for the development of ECAs on the chemical substances selected.

On September 15, 1992, the Companies submitted a proposal for testing GMA under an ECA (Ref. 1). The Companies proposed subchronic toxicity testing (including an evaluation of male reproductive function), subchronic neurotoxicity testing (functional observational battery, motor activity, neuropathology, and electrophysiology), and reproductive toxicity testing.

On March 30, 1993, EPA published a **Federal Register** notice (58 FR 16669) establishing EPA's priority for initiating ECA negotiations on certain chemical substances. The notice identified GMA as a Tier II chemical substance for which some factors were considered favorable to proceed towards negotiating an ECA. This notice and another **Federal Register** notice (58 FR 19253, April 13, 1993) gave manufacturers the opportunity to supplement their test proposals for Tier II chemical substances, including GMA.

In response to the April 13, 1993 **Federal Register** notice, on April 26, 1993, the Companies submitted a supplement to their September 15, 1992 proposal (Ref. 2).

On August 18, 1993, EPA published a **Federal Register** notice (58 FR 43893) that solicited interested parties to

participate in or monitor ECA negotiations on GMA.

On November 18, 1993, the Companies submitted a draft proposed ECA package for GMA (Ref. 3) that offered subchronic toxicity testing (including an evaluation of male reproductive function), subchronic neurotoxicity testing (functional observational battery, motor activity, neuropathology, and electrophysiology), and developmental toxicity testing.

EPA held a public meeting attended by representatives of the Companies and other interested parties on July 27, 1994. During the public meeting and following the meeting (Refs. 4, 5, and 6), consensus was reached on the tests to be included in the ECA (See Table 1, "Required Testing, Test Standards and Reporting Requirements for GMA", below.).

On October 18, 1994, EPA received the ECA signed by the Companies. On January 13, 1995, EPA's Assistant Administrator for Prevention, Pesticides and Toxic Substances signed the ECA and accompanying Order.

## III. Proposed Test Rule

EPA has decided not to finalize the proposed test rule for GMA contained in the proposed test rule for the category glycidol and its derivatives (56 FR 57144, November 7, 1991). EPA has instead reached agreement with the companies that the GMA testing requirements in the proposed rule will be met by implementing the ECA and Order, and that the issuance of the ECA and Order constitutes final EPA action for purposes of 5 U.S.C. 704. Should EPA in the future decide that it requires additional data on GMA, the Agency will initiate a separate action.

## IV. Testing Program

Table 1 describes the required testing, test standards, and reporting requirements for GMA under the ECA. This testing program will allow EPA to further characterize the potential health hazards resulting from exposure to GMA.

TABLE 1.—REQUIRED TESTING, TEST STANDARDS AND REPORTING REQUIREMENTS FOR GMA

Description of Tests	Test Standard (40 CFR citation)	Deadline for Final Report <sup>1</sup> Months	Interim Reports <sup>2</sup> Required Num- ber
90 Day Subchronic Toxicity Study (Inhalation in rats)	(Appendix II.) (Appendix II.) (Appendix II) 798.6050	24 24 24 24 12 <sup>4</sup> 12 <sup>4</sup>	3 3 3 3 1
Motor Activity Test: Acute (Inhalation in rats) <sup>3</sup>	. 798.6400	12 <sup>4</sup> 12 <sup>4</sup> 15	1 2