

**INFORMATION COLLECTION REQUEST (ICR)
Requirements for Electrically Operated Toys
SUPPORTING STATEMENT**

A. Justification

1. *Information to be collected and circumstances that make the collection of information necessary*

The requirements for electrically operated toys and other electrically operated articles intended for use by children were issued by the Food and Drug Administration under the authority of the Federal Hazardous Substance Act (FHSA) (15 U.S.C. 1261, 1262). Responsibility for enforcement of the FHSA was transferred to the Commission when the agency was established in May 1973. The safety requirements were designed to reduce or eliminate unreasonable risk to children of electrocution, electric shock, electrical burns and thermal burns from hot surfaces.

The regulation describes certain criteria to use in determining whether or not electrically operated toys and other electrically operated children's products are banned. Certain warning and identification labeling is required on both the product and the packaging. The regulation also requires that the manufacturer establish and maintain a quality assurance program and that records be made, kept and maintained for 3 years, of the sales and distribution, the material and production specifications, a description of the quality assurance program, and the results of all inspections and tests conducted.

2. *Use and sharing of collected information*

If a product subject to the regulation were found to be banned and the hazard were severe enough to warrant recall, the required records would be useful to both the manufacturer and the Commission. Records of testing might help limit the products subject to recall by pinpointing a specific production run which would enable the manufacturer to send notices of the recall to those customers who received the items being recalled and would enable the Commission to conduct recall effectiveness checks of the manufacturers' customers.

3. *Use of information technology (IT) in information collection*

The recordkeeping requirements of this regulation can be fulfilled by records kept for other purposes. Most manufacturers and importers keep records for sales and distribution for control of inventory and planning future production. Records of material and production specifications, the quality assurance program and testing may be kept for insurance and product liability

purposes. Manufacturers and importers subject to the regulation may use any improvements in information technology they deem suitable for compiling and maintaining the records required by the regulation.

4. *Efforts to identify duplication*

These records are generated by a firm in the normal conduct of its business. There are no other sources of this information. There is no duplication.

5. *Impact on small businesses*

All manufacturers and importers of electrically operated toys and other electrically operated children's products are subject to the requirements of this regulation. Few are considered to be small businesses. Recordkeeping and other testing requirements are commensurately less for small businesses.

6. *Consequences to Federal program or policy activities if collection is not conducted or is conducted less frequently*

If the records were not kept, the purpose explained in item 2 above would not be achieved.

7. *Special circumstances requiring respondents to report information more often than quarterly or to prepare responses in fewer than 30 days*

Not applicable.

8. *Agency's Federal Register Notice and related information*

An FR notice was published July 8, 2009. Comments were not received.

9. *Decision to provide payment or gift*

Not applicable.

10. *Assurance of confidentiality*

Any information required to be maintained by the Commission's rule which the manufacturer or importer claims to be confidential is subject to procedures for withholding confidential information from public disclosure set forth at 16 C.F.R. Part 1015, Subpart B.

11. *Questions of a sensitive nature*

There are no questions of a sensitive nature.

12. Estimate of hour burden to respondents

In discussion with the trade association for the toy industry, the Commission determined that the recordkeeping requirements do not impose any significant additional burden on manufacturers and importers since records are kept for other normal business purposes and testing is conducted for other reasons than complying with the regulation. Firms following good business practices believe that a quality control system ensures that customers who expect good quality products are satisfied. A quality control program also helps a company avoid product liability suits by ensuring that products are safe. The Commission estimates that there are about 40 manufacturers and importers. Each one may have an average of 10 products each year for which testing and recordkeeping would be required, resulting in 400 records.

The Commission estimates that the tests required by the regulations can be performed on one product in 16 hours and that recordkeeping and maintenance can be performed for one product in four hours. Therefore, the total testing burden hours are 6,400 (16 x 400) and the total recordkeeping burden hours are 400 records x 4 hours or 1,600 hours.

We estimate each firm may spend 30 minutes or less per model on the third party notification (label) requirements. Assuming each firm produces 10 new models each year, this amounts to a total of 200 hours per year.

13. Estimate of total annual cost burden to respondents

Using the rate of \$54.88/hour as average total compensation for testing (Bureau of Labor Statistics, September 2008, All workers, goods – producing industries, management, professional, and related), and a rate of \$27.14/hour as average total compensation for record-keeping and third-party notification (labeling) requirements (Bureau of Labor Statistics, September 2008, All workers, goods-producing industries, Sales and office), we estimate the annualized cost to be \$400,084 (6,400 x \$54.88 + 1,800 x \$27.14).

14. Estimate of annualized costs to the federal government

The cost to the government involving recordkeeping is estimated at \$79.84 per hour. This is based on an average wage rate of \$55.97 (the equivalent of a GS-14 Step 5 employee) with an additional 29.9 percent added for benefits (BLS, September 2008, percentage total benefits for all civilian management, professional, and related employees). The total estimated cost to the government is expected to be less than 1 staff month, or less than \$13,839 per year. Record review will be performed during compliance inspections conducted to follow up on consumer complaints and reports of injury which indicate possible violations of the regulations.

15. *Program changes or adjustments*

Burden estimates for third party notification (label) requirements have been included.

16. *Plans for tabulation and publication*

Not applicable.

17. *Rationale for not displaying the expiration date for OMB approval*

Not applicable.

18. *Exception to the certification statement*

Not applicable.

B. *Collection of Information Employing Statistical Methods*

Not applicable.