

European Electrical and Electronics Industry's Positions and Proposals on the Draft for Approval of Callback (Recalls) Administrative Regulations for Defective Product

In order to further enhance transparency of legislation and improve the quality of legislation, the Legislative Affairs Office of the State Council published full text of the Draft for Approval of the *Callback (Recalls) Administrative Regulations for Defective Product (hereinafter refers as 'Callback Regulations')* which was submitted by the General Administration of Quality Supervision, Inspection and Quarantine (hereinafter refers as 'AQSIQ') to the State Council for deliberation and descriptions thereof on its official website on April 8, 2009, to solicit opinions from all circles of society so that it can further study the Regulations, make due alterations, and then submit it to the Executive Meeting of the State Council. As the European Electrical and Electronics Industry, we support standardization of defective products recalls for maintaining social security, public interests and economic order and protecting health and security of consumers. On the Draft for Approval, we hereby propose the following opinions and suggestions:

I. Overall evaluation

Compared with the Draft for Comments of the year 2008, the Draft for Approval is more practical in many ways. For instance, it specifies the division of responsibilities among Quality Supervision, Inspection and Quarantine (*hereinafter refers as 'QSIQ'*) departments at all levels, and make it explicit that defect investigations shall be carried out by QSIQ departments at or above the provincial level. However, as the Callback Regulations is a framework document, many specific concepts, definitions and scopes need to be further clarified. It'll be better if definitions of products and defects can be defined in more details. For example, whether immovable objects, software and services are within the scope of products? And how should products like telephone booths and railways which are not sold to consumers but consumers use be treated? We suggest that detailed rules and regulations be drawn up in time. In addition, as specified in Article 62 Detailed Rules, "specific work concerning product information system, and investigation, identification and risk assessment of defects can be undertaken by a defective products recall management institution designated by the QSIQ department of the State Council, and relevant work rules shall be separately formulated by the QSIQ department of the State Council." We hope that relevant departments can solicit opinions from all various sources in formulation of the above work rules to ensure operability of the rules.

II. Detailed opinions and suggestions

1. Article 2 [Scope of application] The Regulations apply to the recall of products manufactured and sold within the territory of the People's Republic of China and the supervision and administration of such recalls.

The Regulations do not apply to the recall of medicine and military products.

In 2008, the AQSIQ formulated the Measures for Administration of Medical Devices (Draft for Comments) for recalls of medical devices. Draft rules of the department provide that pharmaceutical supervisory and administrative departments are responsible for supervising and administrating recalls of medical devices, while the Regulations specifies that QSIQ departments are responsible for the supervision and administration of recalls.

Given the specialty of the medical device industry, is it possible to make departments responsible for supervision and administration of medical devices in charge of the supervision and administration of medical device recalls so that legislative purposes can be realized more effectively.

Besides, the Global Harmonization Task Force (GHTF) has a series of documents on medical device recalls which we hope China can use for reference in establishment of a specific system for medical device recalls.

We suggest that this Article be amended to read: The Regulations apply to the recall of products manufactured and sold within the territory of the People's Republic of China and the supervision and administration of such recalls.

The Regulations do not apply to the recall of medicine, **medical devices** and military products.

2. Article 8 [Defect investigation by manufacturer] Under any of the following conditions, the manufacturer shall launch a product defect investigation:

- (1) It receives consumer complaints that a product causes personal injuries;**
- (2) It is informed of personal injury accidents of a product;**
- (3) It receives a defect investigation notice from local QSIQ department at or above the provincial level;**
- (4) It believes that a product may carry defects related to human health and life safety;**
- (5) It learns from other sources that a product may have defects.**

The manufacturer shall report findings of the defect investigation to local QSIQ department at or above the provincial level in time; where a defect related to human health and life safety is identified, the manufacturer shall report situation, cause and sphere of influence of the defect according to the Regulations and voluntarily take prompt measures to control and eliminate the defect.

In this Article, definition of the severity of a personal injury will have certain effects on implementation of the Callback Regulations in the future. For instance, whether a defect investigation shall be conducted concerning minor injuries like scratch of a finger by radiation fins of an outdoor unit? Who shall be responsible for the decision when it is impossible to confirm content of the defect investigation report of a manufacturer?

We suggest that detailed standards for findings of a defect investigation a manufacturer needs to report to local QSIQ department at or above the provincial level, such as severity of a personal injury, occurrence possibility of a defect, and quantity of a product in the market shall be specified. If the

Regulations on Defective Products Recall cannot provide regulations on detailed standards concerning personal injuries and the defect investigation report, specific rules shall be drawn up, and relevant clauses shall be made more specifically and in more detail.

3. Article 9 [Defect investigation by province-level administrative department] Under any of the following circumstances, provincial QSIQ departments shall, in compliance with their functions and duties and division of responsibilities, conduct a defect investigation of products manufactured and sold within areas under their respective jurisdiction and report findings of the investigation to the QSIQ department of the State Council: (1) The manufacturer fails to implement a defect investigation according to Article 8 of the Regulations;
(2) The manufacturer thinks there are no defects related to human health and life safety in its products after a defect investigation conducted upon notice of the provincial QSIQ department;
(3) A notice is released from the QSIQ department of the State Council;
(4) Other circumstances that require provincial QSIQ departments to launch a defect investigation.

In implementation of this Article, how should the case be handled if the QSIQ department holds no doubt about findings of a manufacturer's defect investigation?

We suggest that principles for handling such cases shall be added to this Article. That is, contents under the condition that "where QSIQ departments at or above the provincial level hold doubts about findings of the manufacturer's defect investigation" shall be added under sub-article 2. Then, the Article will be amended to read: under any of the following circumstances, provincial QSIQ departments shall, in compliance with their functions and duties and division of responsibilities, conduct a defect investigation of products manufactured and sold within areas under their respective jurisdiction and report findings of the investigation to the QSIQ department of the State Council:

(1) The manufacturer fails to implement a defect investigation according to Article 8 of the Regulations;
(2) The manufacturer thinks there are no defects related to human health and life safety in its products after a defect investigation conducted upon notice of the provincial QSIQ department, **but the QSIQ department at or above the provincial level holds doubts about findings of the defect investigation;**
(3) A notice is released from the QSIQ department of the State Council;
(4) Other circumstances that require provincial QSIQ departments to launch a defect investigation.

4. Article 10 [Defect investigation by the QSIQ department of the State Council] Under any of the following circumstances, the QSIQ department of the State Council shall either launch a defect investigation or ask provincial QSIQ departments or manufactures to do the investigation:

(1) A product triggers major injury accidents which have great influences;

- (2) A product is found not up to standards for safeguarding health and safety in a state quality supervision and inspection;**
- (3) The defective product supervision information system reports that a product may have defects related to human health and life safety;**
- (4) Other circumstances that require the QSIQ department of the State Council to launch a defect investigation.**

We believe that standards in sub-article 2 can be specified as compulsory standards for safeguarding health and safety. We suggest that sub-article 2 be amended to read: a product is found not up to **compulsory** standards for safeguarding health and safety in a state quality supervision and inspection;

5. Article 14 [Dispute over defect investigation] Where there is a discrepancy between findings from the defect investigation by the manufacturer and findings from the defect investigation by the QSIQ department at or above the provincial level, the manufacturer shall give an account of the matter and raise objections to the QSIQ department at or above the provincial level.

The QSIQ department shall carry out an investigation based on information from the defective product supervision and administration information system; or, when necessary, listen to opinions of concerned parties by means of hearing according to law, and come to a decision.

It is our concern whether the QSIQ department at a higher level can make the final judgment when there is a dispute between both sides on a discrepancy between findings from the defect investigation by the manufacturer and findings from the defect investigation by the QSIQ department at or above the provincial level. We think that principles for handling such cases shall be specified and relevant regulations shall be added to this Article. We suggest that this Article be amended to read: where there is a discrepancy between findings from the defect investigation by the manufacturer and findings from the defect investigation by the QSIQ department at or above the provincial level, the manufacturer shall give an account of the matter and raise objections to the QSIQ department at or above the provincial level, **and the latter shall submit the case to the QSIQ department of the State Council for judgment.**

The QSIQ department of the **State Council** shall carry out an investigation based on information from the defective product supervision and administration information system; or, when necessary, listen to opinions of concerned parties by means of hearing according to law, and come to a decision.

6. Article 15 [Initiation of recall] Where it is confirmed that a product carries defects related to human health and life safety, the manufacturer shall immediately stop making and selling the defective products, voluntarily recall the defective products, and report the situation to local QSIQ department at or above the provincial level.

We think that, according to Article 3 of the Articles, “Recall in the Regulations refers to any activity of the manufacturer to effectively prevent, control and eliminate potential damages of a defective product through warning, complementing or modifying the instructions for consumers, withdrawal, sales returns, replacement, repair and destruction, etc, according to established procedures and requirements.” Besides simply stopping production and sales of defective products, there are many other recall measures. It is more reasonable to adopt measures corresponding to the risks.

We suggest that the Article be amended to read: where it is confirmed that a product carries defects related to human health and life safety, the manufacturer shall **immediately take recall measures corresponding to the risks**, voluntarily recall the defective products, and report the situation to local QSIQ department at or above the provincial level.

7. Article 17 [Recall plan] After a product is identified as defective, the manufacturer shall promptly draw up a recall plan for effective control and elimination of the defects, and submit the plan to local QSIQ department at or above the provincial level for filing within five workdays from implementation of the plan.

The recall plan shall comprise the following basic contents:

- (1) Type of defects related to human health and life safety in the product, causes, people who may be affected, and severity and urgency of the defects;**
- (2) Implementation method, scope and time limit of recall measures pursuant to Article 16;**
- (3) Organization to carry out the plan and its contact information;**
- (4) Scheme to inform consumers and related operators of the defects;**
- (5) Measures after defective products are recalled;**
- (6) Desired effects of the recall.**

Grades of severity and urgency of defects as mentioned in sub-article 1 shall be defined so that manufacturers can use them for reference in implementation. We hope that specific rules for carrying out *the Callback Regulations* can be formulated and provide more specific and detailed implementation on relevant articles.

8. Article 20 [Summing-up and effect assessment] The manufacturer shall submit a summary report to local QSIQ department at or above the provincial level within 30 days from completion of the recall.

Local QSIQ department at or above the provincial level shall examine the summary report and assess effects of the recall; where it concludes that the manufacturer’s voluntary recall fails to achieve the desired effects, it can require the manufacturer to make another recall or adopt more effective measures according to law to eliminate the defects.

There is not a clear definition of “completion of recall” here. To what extent can a recall be deemed “completed”? We do hope that this Article can clarify its meaning. If the definition cannot be specified in the *Callback Regulations*, we suggest that detailed rules be formulated to provide more concrete and detailed regulations on this Article and make it more operable.

9. Article 21 [Harmless treatment of defective products] The manufacturer shall innocuously treat the defective products recalled and destroy those severely jeopardizing the health and safety of consumers.

We think that the definition of “harmless treatment” is not very clear. The word “harmless treatment” is normally used in the field of ecological environment. It is realized by physical, chemical or biological means to ensure that no harm or potential hazards will be caused to human health, safety of plants, animals and microbes. It will be more suitable to change the expression to “eliminate defects”.

Moreover, destroying does not apply to all defective products which severely jeopardize the health and safety of consumers, because it is not conducive to reasonable utilization of resources. Destroying is reasonable and appropriate only for defective products that cannot be effectively disposed.

We suggest that this Article be amended to read: the manufacturer shall take technical measures to eliminate defects in relevant products, and destroy those which severely jeopardize the health and safety of consumers but the defects cannot be effectively removed.

10. Article 23 [Supply discontinuation of the manufacturer] Upon receipt of the notification of mandatory recall from the QSIQ department of the State Council, the manufacturer shall immediately stop making and selling the products concerned.

We suggest that this Article be amended to read: where the recall plan has been examined and approved by the QSIQ department of the State Council, the manufacturer shall immediately implement the recall according to the date set in the recall plan. Refer to opinions on Article 15 for the reasons.

11. Article 26 [Time limit for initiation of recall] Where the recall plan is approved by the QSIQ department of the State Council, the manufacturer shall implement the recall within two workdays from receipt of the approval notice.

We think that a product recall involves many aspects and the preparatory work is very complicated, so two days is pressing for manufacturers. We suggest that the period be reasonably prolonged.

12. Article 32 [Duty of the manufacturer to keep records] The manufacturer shall record and keep information about design, production and sales of its product. The retention period of the records shall correspond to the safe-use period of the product.

Article 33 [Record of defect elimination] The manufacturer shall record control and elimination of product defects and held the records for not less than three years.

There is not a unified safe-use period for electronic products in China. Even in Europe and America, there are not relevant regulations. Under such circumstances, how should the manufacture keep the records according to this regulation? Does it mean that during the safe-use period, all records need

to be kept? If record keeping cannot be geared to the safe-use period, how should the *Callback Regulations* be implemented? According to Article 32, all records within the safe-use period shall be kept. This contradicts Article 33 which provides that the records shall be held “for not less than three years”. These need to be clarified.

In Europe, it is prescribe by law that a product shall still be guaranteed safe and reliable when its useful life expires. This ensures that manufacturers will be dedicated to the production of safe and reliable products. Whether the same legislation mode can be considered and introduced to China? Otherwise, a more explicit definition of safe-use period shall be proposed. For instance, it can be clearly defined that the safe-use period for household appliances is five years, and that for information products is ten years.

We suggest that detailed rules for implementing the *Callback Regulations* be drawn up and issued, and specific regulations be made for relevant articles.

13. Article 34 [Defect information report] The manufacturer shall not conceal or lie about facts about harms of the defects in a product it has produced. It shall report all of the following information to local QSIQ department in time:

- (1) Information about defects related to human health and life safety that may exist in a product;**
- (2) Information about product injury accidents;**
- (3) Information about personal-safety related defects found abroad.**

The professional competence of local QSIQ departments is varied, and they are not at the same level in law enforcement and handling of quality issues. Considering current realities, we think that it shall be specified that local QSIQ departments shall be at provincial level or above.

Therefore, we suggest that this Article be amended to read: The manufacturer shall not conceal or lie about facts about harms of the defects in a product it has produced. It shall report all of the following information to local QSIQ department at or above the provincial level in time:

- (1) Information about defects related to human health and life safety that may exist in a product;
- (2) Information about product injury accidents;
- (3) Information about personal-safety related defects found abroad.

14. Article 36 [Period of responsibility for defect elimination] The period of responsibility for defect control and elimination by the manufacturer shall correspond to the safe-use period or the expiry date of the product.

Please refer to opinions on Article 32. We suggest that detailed rules for implementing the *Callback Regulations* be drawn up and issued, and specific regulations be made for relevant articles.

15. Article 37 [Expenses for defect elimination] Where a product is defective, the manufacturer shall undertake expenses for defect investigation, inspection and identification and expenses for defect control and elimination.

In light of Article 7 (3), it shall be clarified whether the manufacturer shall bear relevant responsibilities and expenses for products which have been used for 15 years.

16. Article 61 [Disposal of property damage-related defects] Where products of a certain batch, model or category, when used correctly, have defects that may cause property damages due to defective design, production or instructions, the manufacturer shall initiate a recall with reference to the Regulations.

In view of the definition of defective product in Article 3, we think that this Article shall be amended to read where products of a certain batch, model or category, when used correctly, have defects that may cause damages to **human health and life safety** due to defective design, production or instructions, the manufacturer shall initiate a recall with reference to the *Callback Regulations*.

III. Final

We do hope that relevant legislators can fully heed opinions and suggestions from industry and enterprises, and scientifically and reasonably formulate the *Callback Regulations* to ensure it can play an important role in standardizing defective product recalls, maintaining social security, public interests and economic order. If necessary, we can further our communication and exchange in this field.