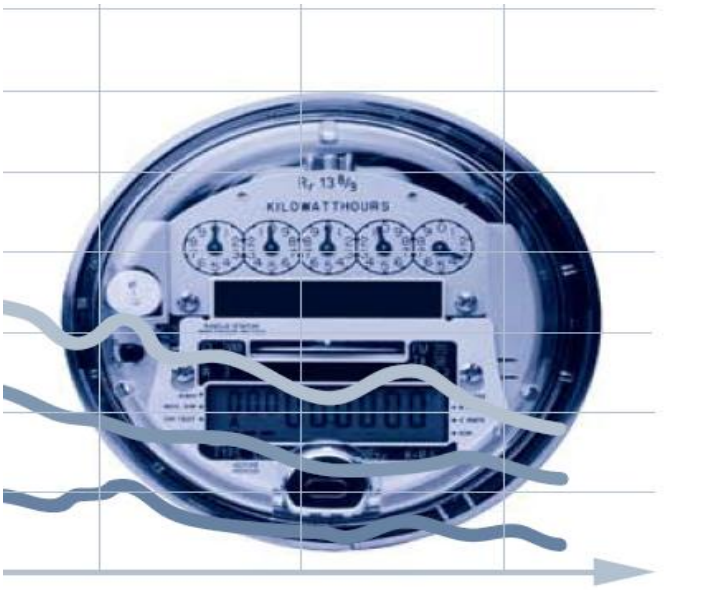
National Measurement Office

Enforcement Authority

A Protocol for the Withdrawal of Products from the Market under the Ecodesign of Energy Using Products Regulations 2007



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A Protocol for the Withdrawal of Products from the Market under the Eco-design of Energy Using Products Regulations 2007

Scope of the Protocol

This protocol is designed to support regulated entities in establishing effective corrective actions procedures. It might be used to review the effectiveness of existing procedures within a quality management system or to develop new systems that will enable the effects of non-compliance to be mitigated. When non-compliance is discovered the regulated entity will have to make objective decisions about the corrective actions necessary to take in order to protect consumers, energy security and the commercial viability of the business. This protocol is only designed to address those circumstances prescribed by law when positive action in the form of a market withdrawal is necessary.

Within the Ecodesign for Energy Using Products Regulations 2007 there are two situations that require this type of action. Regulation 8 provides for situations where the non-conformity comes to the attention of the business and it is not possible to take steps to bring the product into conformity, often this will be because it is physically unavailable or the cost of alterations is too great. Regulation 21 covers situations where the enforcement authority has discovered non-compliance and by "enforcement notice" requires the business to undertake a market withdrawal.

What is a market withdrawal?

A market withdrawal is the removal from the market of any products which contravene the regulatory requirement, or are subject to an enforcement notice.

This means any products which have been first placed on the European market since the coming into force of the regulations. Those products may be: in storage, at a distribution centre, in retail outlets, in transport, awaiting further incorporation into other products or indeed already in use by businesses or consumers.

This definition covers all the possible locations of product once it has been first placed upon the market. This might be from the point at which it is imported, but may also be the point immediately after it is manufactured and placed in storage or distribution.

The Legal Requirements

Regulation 8 of the Ecodesign of Energy Using Products Regulations 2007 places a responsibility on manufacturers, authorised representatives and importers of listed products to act when they become aware that they have placed a product on the market which does not comply. They must as soon as possible take steps to bring the product into compliance. This is possible where the product is still within the control of the business concerned. However, if it is not possible to take such steps or they prove not to be effective then the business MUST withdraw the product from the market and notify the Secretary

of State and the Enforcement Authority (for the purpose of the UK a notification to NMO meets both these requirements).

The regulations make no reference to the scope of such a withdrawal just that the product must be withdrawn from the market. The market is considered to be the European market and extends from the point of manufacture or import through the distribution chain up to and including the use of the product by the consumer.

The UK courts are tasked with determining if a company that has become aware of non-compliant product has conducted a sufficient market withdrawal, should it be considered necessary by the Enforcement Authority to take a legal action of this type. In making such a determination the Enforcement Authority will seek evidence that the withdrawal is planned and effective but also that it is proportionate to the non-compliance and its impact on the energy conservation issues that it raises.

It is an offence contrary to Regulation 23 of the Ecodesign of Energy Using Products regulations 2007 for a manufacturer, authorised representative or importer of a listed product to contravene Regulation 8. Any single offence under Regulation 24 is liable to a fine up the statutory maximum.

The Process of Market Withdrawal

When first confronted with information which indicates that products do not comply with the legal requirements there are a number of stages that should be followed;

1. Critically evaluate the information that has been presented relating to non-compliance
2. Assess the risk associated with the non-compliance
3. Make objective and proportionate decisions about the variety of actions that can be taken
4. Undertake the market withdrawal activities
5. Keep comprehensive records of all activities
6. Ensure that the Enforcement Authority is kept fully informed
7. Dispose of non-compliant product in an appropriate manner

Evaluate the information relating to non-compliance

Regulated entities may receive information about their product from a number of internal and external sources. It should not all be treated with the same degree of authority. Often such information requires additional interpretation to put it in the context of the legal framework. Some sources of information are less well informed about the product, appropriate test methods and the scope of the regulations and may adopt more “common sense” approaches to compliance.

In the first instance the business should consider placing a stop order on any product that remains within its control pending further information.

Consider, from whom, the information is received, is it the businesses technical department, is it a trusted supplier, a customer, the enforcement authority, a “green” lobbying group or a test house. Do you need to undertake further analysis to ascertain the validity of the information?

Information presented in the form of test certificates from recognised test houses or the enforcement authorities requires little further validation and can be acted upon immediately. Information supplied by bodies that do not have a clearly independent remit should be validated before taking action.

It is an important part of any businesses approach to market withdrawal to have a clear communicated policy on how it will manage compliance information. How will it seek to validate or contradict the information and perhaps most importantly what time scales the business will apply to these processes.

Assess the risk

When a regulated entity is confronted by non-conformity it is important that they assess the risks in an objective way and take appropriate and proportionate action. The Enforcement Authority will use the same techniques when they are considering the appropriateness of any market withdrawals that they may subject to “enforcement notices”.

Once the basic non-conformity has been brought to the attention of the regulated entity and validated a wide range of contextual information is necessary to assess the risk effectively. This may include but is not limited to;

1. What is the nature and magnitude of the non-compliance
2. Over what period is the product affected
3. What is the effective life of the product
4. How many products are affected
5. Are those products in use already
6. What is the total energy use discrepancy and its cost

Once the information has been collected the acceptability of the risk can be evaluated. As this legislation relates to energy conservation rather than safety the acceptability criteria is energy specific. Some factors that might inform such criteria are;

- Have consumers or businesses been misled to the extent that they may have made different purchasing decisions?
- Are there prevailing industry standards over and above those required by the legislation?
- Are more appropriate design solutions available?
- Are there high numbers of product alternatives on the market?
- Is the energy burden significant in terms of its individual or national use?

Once the risk has been assessed it needs to be communicated in a graduated scale reflecting the severity of the risk. In the table below a graduated scheme using three parameters is used. In more complex distribution systems more parameters may be necessary. This sort of matrix provides an indication of the sort of activities that will be expected when considering the scope of the market withdrawal.

No.	Parameter	Descriptor
1	High risk	Requiring action throughout the distribution chain
2	Medium risk	Requiring some action
3	Low risk	Not generally requiring action for products that have already been dispatched

Make decisions about the scope of the market withdrawal

The range of actions that a regulated entity can take is very wide and depends on the type of product and its distribution chain. However, there is a correlation between the direct and indirect costs of any actions and the number of steps that the product has taken through the distribution chain. In deciding what action to take, it will almost always be a combination of different activities at different stages of distribution reducing in effectiveness and increasing in cost as the product disperses.

To decide the scope of the withdrawal the costs and benefits of each different activity should be analysed. Some possible criteria to be considered for each stage of a withdrawal are as follows:

1. How many items are in this stage of distribution
2. What is the likely success of a withdrawal at this stage
3. What is the likely value of the energy saving
4. What is the direct cost of such action
5. What is the indirect cost of such action
6. What additional benefits can be gained from a withdrawal at this stage
7. What other impacts might a withdrawal have on compliant products

It may also be appropriate to consider other corrective actions that can be part of the same process. Can the product be brought into compliance, is an alternative product available, is a compliant product available for exchange. It is at this very early stage that the regulated entity should be able to reference its own procedures to ensure that its contractual liabilities are effectively managed.

If the different distribution stages are mapped against the withdrawal criteria a basic action plan can be developed that demonstrates an appropriate and proportionate withdrawal program. The figure below shows how the risk assessment is balanced with the withdrawal activities. In most cases low risk (green)

actions will be limited to upstream locations, as the risk increases (red) and the product is more dispersed, actions will have to include more downstream locations. Each assessment criteria needs to be evaluated and "scored", it would be very unusual not to see the energy costs as one of the main criteria in such a model. Using this figure the 6th column is the decision to act or not in each type of location.

Risk	Stage of distribution	Criteria 1	Criteria 2	Criteria 3	withdrawal	Other actions
	Own warehouse				YES / NO	
	Mainstream distributors				YES / NO	
	Component distributor				YES / NO	
	2nd stage distribution				YES / NO	
	Chain retailers				YES / NO	
	Independent retailers				YES / NO	
	Consumers already using				YES / NO	

This is a very simple model that has limited variables, many distribution chains will require consideration not only of the types of business that may have product but individual businesses may require their own assessment.

Undertaking the market withdrawal activities

In this stage of the process the estimates of where various products are currently located need to be checked. Product needsto be traced, possibly throughout Europe.

The decision as to how product is withdrawn is a purely business one based on the relationships between the different parties concerned. The Enforcement Authority in the UK will be concerned about the effectiveness of the withdrawal. It is essential at this stage to keep good records of the numbers and locations of products.

By working through the stages of the withdrawal identified in the planning phase systematically the records can be used to review success and difficulties and divert actions and resources accordingly.

What records are required?

The business will need to maintain a set of records that can be used to demonstrate to the Enforcement Authority that the withdrawal process was based on sound information that it was well planned and that it was effective.

The documentation might include;

- Invoices detailing the total population of product
- Sales data indicating first stage distribution
- Communications with customers

- Returns documentation or evidence of quarantine
- Disposal or re-export documentation

As the process of withdrawal progresses a simple numbers summary would be appropriate, building on the scope of the withdrawal form, using predicted success of each stage of withdrawal as an effectiveness measure.

Keep the Enforcement Authority Informed

The legislation places the responsibility on the manufacturer, authorised representative or importer to inform both the Secretary of State and the Enforcement Authority whenever they undertake a market withdrawal under Regulation 8. The notification must be "as soon as possible" this means that the notification must be received as soon as the first products are withdrawn even if the scope of the withdrawal is for products under still under the control of the business itself.

The benefits of informing the Enforcement Authority at this early stage include assistance in the process, advice on the proportionality of any proposed action, identifying any unintended consequences and support in minimising any unfair market advantage that might be taken by competitors.

The legal obligation to inform the Secretary of State and the Enforcement Authority can be fulfilled by completing the form in annex 1 which is reproduced in electronic form on the NMO Enforcement Authority website. www.rohs.gov.uk/EuP

Product Disposal

This is an area of market withdrawal that is often not considered until the end of the process and by doing so costs businesses more than is necessary. Disposal is a key part of withdrawal from the market but does not necessarily mean destruction. Product may also be reworked, returned to the original exporting country, exported to a third country and in some cases used for an unregulated purpose within the European market. This stage of the process brings together much of the planning and record keeping to ensure that there is traceability for products removed from the market and that the those disposed of in phases as a withdrawal progresses are clearly accounted for.

CASE STUDY 1

This example is drawn from environmental legislation that prevents the use of heavy metals in electronic products. Company A as part of their regular product inspection regime received a test report that indicted that the last three batches of product imported from the Far East had higher than acceptable levels of one of the restricted substance. They confirmed the test results with the laboratory and undertook some screening tests of products currently in their warehouse that duplicated the results. The levels of hazardous substance were 20 times the acceptable level. The company immediately placed a “stop” process on existing and new orders and quarantined all warehouse stock.

An analysis of the risk indicated that the there was “medium” risk mainly due to the fact that the product could also be used as a component in computers and computer systems and would affect key customers products. The company recognised that they had to take some action beyond the product that was currently in their control.

The company analysed each of the distribution networks that the product used and identified the location of 80% of the non-compliant product. 30% was in their warehouse and had already been withdrawn. 20% had been supplied to a major distributor only the previous week and they still had most of that stock, 20% had gone to four major computer assemblers and the remaining 10% had been sold to small independent retailers or direct to consumers over the web. The decision was taken to attempt to withdraw the product still with the major distributors and to work with the assemblers to source alternative suppliers.

The major suppliers applied their own “stop” processes and quarantine product. The individual assemblers undertook their own business risk modelling based on a full information disclosure from company A.

Meanwhile company A negotiated a destruction protocol with the Far East exporter that ensured that new compliant product was shipped immediately to replace existing stocks.

A clear document chain was produced and monitored by the enforcement authority and the final outcome saw 69% of the products withdrawn from the market with 60% being replaced with complaint alternatives.

The outcome was successful in both environmental terms and without significant damage to company A’s trading relationships with their customers. The majority of the costs were finally recouped from the Far East supplier.

Notification Officer
National Measurement Office Enforcement Authority
Stanton Avenue
Teddington
TW11 0JZ

Annex 1

Date …/.../…

Dear Sir

Ecodesign of Energy Using Products Regulations 2007
Notification Under Regulation 8 of a market Withdrawal

It has come to the attention of;

[Full company name and indicative brand title]

That certain products for which the company is responsible do not comply with the requirements of the above regulations. Those products are;

[List affected products by name and model number]

In accordance with the requirements of regulation 8 the business is in the process of undertaking a market withdrawal. More detailed information about the withdrawal can be obtained by contacting;

[Provide contact details of the person managing the withdrawal]

Yours sincerely

Guidance for completion of Ecodesign of Energy Using Products Regulations 2007 (Market Withdrawal Protocol)

1	Give a brief summary of the nature of the non-compliance for example; excessive energy use in standby mode, failed to meet energy use requirements in simulated ISO standard testing
2	If the cause of the non-compliance is apparent at this stage provide a very brief synopsis for example; non-complaint components in power supply, South American product on EU market, Incorrect labeling of product
3	How easy would it be to rectify the problem if the business had access to the product? Can the non-compliant component be replaced, can consumers fit replacements or is the problem fundamental to the design of the product
4	Provide clear model and type parameters that enable all those that might come into contact with the product to be able to identify it.
5	This period may be known if all supply has been non-compliant and assumptions should be made that product has been produced in a consistent manner. There are circumstances where a change in design may affect the products compliance from a known point in time.
6	Most products are produced under a quality management system and non-compliance will be systematic but in some cases assembly can be product specific introducing the possibility of random errors
7	For random errors estimate the percentage of the product on the market which is affected
8	If the non-conforming product can be identified from that that is compliant by serial number, colour, model number or other manner detail that information here. If it is only detectable through analytical testing indicate what tests and any screening that can be done.
9	Use this part of the form to indicate the degree of non-compliance this might state the results of testing or as a %. For example; three times the permitted tolerance, significant energy loss such that consumer information incorrect, would not have received energy rating etc.
10	If any misrepresentations have been made they should be detailed in this part of the form.
11	Excessive energy consumption may lead to electrical failure or excessive thermal energy build up. Any such considerations should be noted and communicated to the appropriate authorities.
12	What is the design life of the product in terms of years
13	For how many hours is it expected to operate within that life span
14	If the non-compliance relates to a specific mode (stand-by) how long is it likely to be in that mode during its life span.
15	What is the legal requirement, expressed as simply as possible so a comparison can be made. This may well involve a simplification of the standard to enable less complex calculations
16	Indicate in this section the magnitude of the non-compliance e.g. 2Kw or as a percentage +100% acceptable levels
17	How much excess energy is being used by each product (16-15)
18	For how many hours is it likely to be used in this mode
19	What is the excess energy use for the life of the product (17*18)
20	The total number of products affected
21	What is the total energy burden of the non-compliance (19*20
22	Cost price of the product
23	Retail price of the product
24	If the product requires any special disposal processes or costs they should be detailed in this

	section of the form.