Department for Business, Energy & Industrial Strategy

Office for Product Safety & Standards

NEW PRACTICES IN PRODUCT SAFETY ENFORCEMENT

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New Practices in Product Safety Enforcement

LEARNING OUTCOMES

- ‘By the end of this session delegates will have been provided with an overview of the current challenges and issues in product safety market surveillance and using this will be in a position to develop the strategies and skills necessary to tackle them effectively to reduce the risk of unsafe goods reaching the marketplace.’

HOW WE DID IT IN THE ‘OLD DAYS’

‘ENFORCEMENT’ LED

- The sole objective of enforcement was to take punitive action against those traders who did not comply with the law in relation to goods. This obviously remains an option in some cases now.
- When a non-compliant product was discovered the ‘offence’ is investigated and a report was often submitted for consideration, and legal process considered.
- Products are often tested against recognised standards and investigations started when a failure to comply with the standard was discovered.
- The primary focus of the investigation was often the potential defences that the trader responsible for supplying the product was able to use to avoid criminal liability for the offence.
- Work was primarily initiated through consumer complaints and sampling surveys – the use .
- Sampling surveys were usually based on what was topical but there was rarely quantification of the risks and benefits of carrying out work in the specific sector.

LIMITATIONS OF THIS APPROACH

- No recognition of consumer risk, or the threats and benefits of carrying out or not carrying out specific types of work.
- No basis for corrective actions to mitigate the risk posed by a product which is not ‘safe’.
- Difficulties in determining what can be considered ‘safe’ and ‘unsafe’ in law and therefore criminal liability.
- Challenges in terms of proving that a product is ‘unsafe’ beyond all reasonable doubt when a test report contradicting the one TSS had commissioned was produced in support of the product.

NEW LEGISLATIVE FRAMEWORK

- The new paradigm started with the General Product Safety Directive.
- Started to consider ‘risk’, ‘harm’ and ‘corrective action’.
- Ensuring product safety is now ‘market surveillance’ and enforcement is a facet of this, but is not the primary objective.
- The framework is designed to manage consumer and business risk with the objective of reducing the probability of harm to product users to a tolerable level.
- Tolerability is determined by consideration of the principle of ensuring a high level of protection of health, safety and the environment.

THE LEGISLATION

- The NLF provides better overall coherence and consistency across the range of legislative instruments;
- Improves market surveillance rules;
- Improves the accreditation of conformity assessment bodies and conformity assessment procedures (modules);
- Clarification of the meaning of the CE mark;
- Lays down clear definitions and obligations of economic operators;
- Provides for uniform rules for the designation and supervision of notified bodies.
- Regulation 765/2008/EC, Decision 768/2008/EC
- Provides a basis for market surveillance as part of the customs process for imported goods.

ECONOMIC OPERATORS

- Economic operators are defined by their position in the supply chain and their respective obligations are defined by this, the scope of their activities and influence on the safety of the end product.
- Manufacturers, importers, distributors and authorised representatives all have clearly defined obligations with respect to the safety and conformity of products.
- The underlying principle is that economic operators have the obligation to demonstrate that products are in conformity, rather than market surveillance be required to demonstrate that they are not.
- Goods cannot be CE marked unless the relevant economic operator can demonstrate that the product design is in conformity with the relevant safety objectives, and that all production is in accordance with this design and therefore presents the same level of risk.
- Goods cannot be placed on the market or supplied under GPSR unless they can be considered ‘safe’.
- Monitoring of user risk is an obligation of the producer/manufacturer/importer.
- This demonstration of conformity is carried out through the production and retention of conformity assessment documentation.
- Market surveillance can be carried out by examining this documentation rather than by getting products tested.
- Economic operators are obliged to supply technical documentation and other details further to a ‘reasoned request’ from a market surveillance authority. Where does the Consumer Rights Act 2015 fit into this?

RISK

CORRECTIVE ACTION

- All products will present a risk of harm, and this can be determined as being ‘tolerable’ or ‘intolerable’.
- Obviously this can be a subjective judgement so a model is needed in which the data can be entered and unknowns and uncertainties can be considered. This model reduces uncertainty and inconsistency.
- Corrective action is what is necessary to reduce the risk of harm to a ‘tolerable level’.
- Corrective action must be proportionate to the risk of harm or the degree of harm, and can include bringing the product to conformity, warning, marking, withdrawal or recall.
- PAS 7100: 2018

FORSEEABLE USE

- What is foreseeable use?
- Manufacturers have to match a level of protection corresponding to the use they prescribe for the product under the conditions of use which can be reasonably foreseen.
- Hazard elimination, guarding, warning – the steps of risk management in design.
- The difference between instructions and warnings.
- Usual human behaviour, including cognitive or physical impairment and vulnerability must be considered. Different assumptions must be employed during the design risk assessment for each.
- The manufacturer has to consider the conditions of use that can reasonably be expected at the design stage, and should be included in any design risk assessment.
- Essential requirements, standards and foreseeable use.

DOCUMENTS AND TRACEABILITY

- Documents are key to determining a product's conformity and the degree of risk that it presents.
- Where a product is found to be unsafe or not in conformity technical documentation will be part of the risk assessment data.
- If there is missing conformity assessment documentation then that will add to the 'unknowns' in any risk assessment, and consideration of the 'precautionary principle' will be necessary.
- If conformity assessment documentation is incomplete then the product was not legally placed on the market, and corrective action will be necessary – compliance notices.
- Beware fake or irrelevant documentation and remember traceability – more on this later.

INTELLIGENCE LED WORKING

- Even in an ideal world, market surveillance activities cannot verify the compliance or safety of all products on the market.
- Therefore a risk analysis is necessary – which products are most likely not in conformity and what harm could they cause? How likely is it that they will cause this harm?
- Therefore data needs to be collected from the market as a whole, analysed and developed as intelligence and then prioritised on the basis of risk – such risk will relate directly to the degree and probability of harm that may be present.
- Market surveillance activities also inform future risk profiles.
- The most effective place for market surveillance carry out interventions to reduce risk is at ports, as if non-conformities are discovered corrective action is relatively simple.

NEW TRADING MODELS

FULFILMENT HOUSES

- A new model developed by online sellers to ensure rapid delivery of goods to customers.
- The fulfilment house offers storage, packaging and delivery services to the online economic operator.
- The online economic operator may not be based within the EU.
- Some fulfilment houses offer all of the services listed above, while others only cover them partially. Their size and scale also differ, from global operators to micro businesses.
- The activities of fulfilment service providers as described go beyond those of parcel service providers that provide clearance services, sorting, transport and delivery of parcels.
- Fulfilment houses can be considered distributors for the purpose of product safety legislation as their activities are different from those of parcel couriers.

MODEL OPERATION

STEP 1: The fulfilment house stores product on behalf of client(s) which are already in transit packaging but not assigned to consumers.

STEP 2: The client(s) send picking lists based on their online sales enabling the fulfilment house to pick products using the SKU code (Stock Keeping Unit) printed on the packaging.

STEP 3: The fulfilment hose attaches the consumer's name and address label to the product.

STEP 4: The fulfilment house distributes the product via a courier or the postal service.

There are many other variations to this model including the taking from bulk not in packaging and pre-packaged with address labels.

THE BLUE GUIDE

- Considers products held in fulfilment houses to be supplied for distribution, consumption or use in the EU market and therefore placed on the EU market.
- When an online operator uses a fulfilment house, by shipping the products to the fulfilment house in the EU the products are in the distribution phase of the supply chain.
- ‘Placing on the market’ is crucial as it is the definitive point at which products must meet the requirements of union harmonisation legislation.
- Therefore a fulfilment house can be considered to be placing products on the market.
- Case law?

COUNSEL'S OPINION

- Counsel was asked for an opinion with respect to product liability and the enforcement of product safety legislation for fulfilment houses when distributing goods that were imported from outside the EU.
- In his opinion, GPSR could be used to prosecute a fulfilment house as a distributor of a product, where the fulfilment house knows or is made aware that the product is unsafe.
- However, he also believes that using the enforcement provisions of Part II of the Consumer Protection Act is problematic as it restricts the definition of 'supply'.
- A number of Trading Standards Services have followed this legal opinion and successfully prosecuted fulfilment houses under the GPSR.
- What about obligations, powers, notices and corrective actions?

PRACTICAL MARKET SURVEILLANCE

Traceability is often difficult when looking at goods in fulfilment houses:

- Use of seller ID.
- Test purchasing.
- HMRC fulfilment house register.
- Inventory checks and risk assessment
- Carrying out checks on random packages and risk assessment.
- Seize and test or require production of conformity assessment documentation.
- Suspension and safety notices..?

ONLINE SALES

- Who is the website registrant?
- Where is the vendor based?
- Does the vendor use a fulfilment service or do they supply the product themselves? Who will take responsibility for conformity assessment and providing technical documentation etc?
- Obtain as many product details as possible, including bar code, manufacturer details, supply chain, any other traceability information.
- Check ICSMS, RAPEX, ESF/recall portals, IDB and Memex for past work.
- Review online ‘chatter’ with respect to product.
- Risk assessment and corrective actions challenges…

ONLINE MARKETPLACES

- Online marketplaces are where known retailers act as a store front for other retailers, and often orders are serviced by fulfilment houses.
- Many websites that offer online marketplaces now have cooperation facilities with market surveillance authorities – e.g. Amazon, Alibaba and eBay.
- Products can be removed from sale if there is evidence to suggest they are either non-compliant or dangerous.
- The nature of online market places do make recall of unsafe products significantly easier as all customers will be contactable instantly, but this is often offset by the challenges presented by unidentifiable sellers who change identity as soon as they come to the attention of market surveillance authorities and the host.
- Some online marketplaces (e.g ‘Wish’ based in the US) have no such arrangements.

TRACEABILITY

- Traceability is the key to carrying out effective market surveillance activities.
- It permits the confident verification of a products conformity assessment both at the design and production phase, and therefore its safety both before and after it has been placed on the market.
- It does assume that there is a recognisable economic entity who takes responsibility for the product in the EU and will be willing or able to provide conformity assessment documentation.
- Traceability is the use of documentary evidence to demonstrate and provide evidence of compliance from the factory to the end user;
- It can demonstrate that a product was manufactured at a particular factory, on a particular date using a particular set of components, which have their own specific audit trails demonstrating both conformity and traceability;
- Traceability is not just about regulatory compliance – it is essential for economic operators to ensure that the goods that they have in their supply chain are exactly what they believe them to be;
- Without traceability, document examination and verification is a meaningless exercise.
- Fulfilment houses and online market places pose a challenge to this paradigm.

HOW IS TRACEABILITY EVIDENCED?

DG Sanco report on traceability:

- Traceability is the key to consumer safety and confidence;
- It is an integral part of an economic operator's quality and risk management systems;
- Complex markets and supply chains, with production far removed from the entity taking responsibility for the product on the market makes traceability more important than ever;
- Product identification in terms of origin is the main hurdle at the moment – traceability can be taken much further than this but one step at a time;
- Many producers of the same/similar products make this difficult at the moment.

PRODUCT IDENTIFICATION

To collect information about product identification:

- Information on product identification (product name, brand, model, barcodes, batch number…);
- https://www.barcodelookup.com/api
- Visual inspection of the product itself;
- Supply chain details;
- Without confirming this information it is impossible to confirm that the documentation verifies the product concerned.

TRACEABILITY EVIDENCE

- Supporting documents such and invoices and packaging lists if available – used to confirm supplier address and the entity responsible for placing the product on the market;
- Technical information related to the product for manufacturers;
- Internet to check for brand, product codes and names;
- Depending on the product category, economic operators have specific reference numbers, e.g. white goods;
- Bill of Lading (if stopped at port of entry);
- Other Customs related documents;
- Certificate of conformity and quality testing protocols or compliance documents;
- Contracts: with information on how to deal with non-conformity (corrective actions, responsibility…);
- The OECD Global Recall platform (http://globalrecalls.oecd.org/);
- Website to check product codes and brand owner (www.gepir.org).

CHALLENGES

- Missing or no conformity assessment documentation;
- Product identification, copying and counterfeiting;
- Parallel importation;
- Supply chain anomalies;
- Fraudulent or unrelated documents;
- Copy conformity assessment documentation;
- Questionable laboratories;
- Multiple product units making the same or cosmetically similar product;
- No unique producer identification;

IN THE REAL WORLD…

It will be impossible to verify traceability beyond all reasonable doubt, but the following is usually provides some confidence:

- Manufacturer, model number and some kind of production coding;
- Details of the supply chain that led to the product being placed on the market;
- Documents, with specifications and descriptions showing the design conformity assessment of the product;
- Production control records from the manufacturer in question, related to the factory that produced the product, showing quality assurance and/or quality control.
- Declaration of conformity;
- Test reports;
- Traceability details with respect to components and raw materials;

Currently it is relatively rare to get all of this when requesting technical documentation in support of a product, but this adds to the uncertainty in relation to conformity and risk.

ANY QUESTIONS..?