



PROTECT – GUIDANCE (REDACTED)

	RSD Internal Guidance	RIG-2011-01		
ICSMS - the European market surveillance system				
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RIG postholder/owner		Sally Williams, Regulatory Management Team		
RIG cleared by		John Gillespie, Safety Policy and Central Regulation Division		
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		Information_____	<input type="checkbox"/>	
		Procedure_____	<input checked="" type="checkbox"/>	
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	RPP_____	<input checked="" type="checkbox"/>	Inspectors_____	<input checked="" type="checkbox"/>
			Admin_____	<input type="checkbox"/>
Keywords	ICSMS; machinery; product safety; PSR; prohibit; withdraw; restrict; recall;			
Summary	This document explains the process to be followed by all RSD and RPP Inspectors to ensure that details about products that they consider either unsafe or non-compliant with EU harmonisation legislation are notified to other EU enforcement authorities.			
Original consultation	Investigation and Legal Support: Rupert Lown and William Keag RSD Network Rail National Team: Richard Thomas Legislative development: Stefano Valentino Safety Enforcement Team: Chris Simms			
Subsequent consultation (reviews only)	Regulatory Management Team: Rupert Lown RSD Network Rail National Team: Richard Thomas Legislative development: Stefano Valentino Safety Enforcement Team: Chris Simms Regulatory Management Team: Helen Ayers			

Detail

Background

1. In 2008, the European Commission reviewed the various market surveillance provisions under different areas of European law. They proposed improvements to align national systems and provide a consistent framework. These were brought into effect by a new direct acting [Regulation \(EC\) No. 765/2008](#) , which came into force in 2010 and concerns accreditation and market surveillance.
2. All member states are required to:
 - organise and carry out market surveillance to ensure that products liable to compromise health and / or safety - or which otherwise do not conform to legal requirements - are withdrawn from the market or have their availability prohibited or restricted; and
 - communicate these arrangements to the Commission and the public
3. Communication is via the ICSMS (Information and Communication System on Market Surveillance - www.icsms.org). This is an IT system owned by the European Commission which provides a comprehensive communication platform for the market surveillance authorities of the Member States.
4. The system allows information on non-compliant products (test results, product identification data, photographs, economic operator information, risk assessments, accident information, information on measures taken by surveillance authorities etc.) to be shared quickly and efficiently among authorities.
5. ICSMS has an internal and a public area so some information is also available to the public.
6. ORR is a market surveillance authority as defined under the Regulation. This role requires ORR Inspectors to identify and investigate unsafe and non-compliant products used at work on the railway. ORR is required to report its findings about such matters, and details of any action taken (either by us or the manufacturer), to other EU enforcement authorities via ICSMS so that action can be taken where appropriate to remove or restrict the use of a product across the market.
7. Once a product has been logged on ICSMS, if the initiator (ORR) considers that the issue would be more appropriately dealt with by another enforcing authority, the system allows responsibility to be passed automatically to that other body for investigation. For

example, if we found an unsafe item that was primarily used in the construction industry rather than on the railway we would log the item on ICSMS and might then 'pass' it to HSE for their action. ORR would normally be expected to deal with products manufactured specifically for use on the UK railway.

8. The regulation, gives Inspectors the power to:
 - prohibit or restrict the use of, or withdraw from the market products which are unsafe or which otherwise do not conform to Community Harmonisation Legislation (such as the Railways (Interoperability) Regulations 2011); and
 - recall, withdraw, or prohibit products presenting a serious risk.
9. Similar provisions are included in the revised Railways (Interoperability) Regulations 2011.
10. Where an Inspector identifies an unsafe or non-compliant item they should follow the process outlined below. More information about ICSMS can be found on the HSE intranet at <http://www.hse.gov.uk/work-equipment-machinery/market-surveillance.htm>

Process



11. Once an item has been identified the Inspector should firstly search the ICSMS database to identify whether the issue has already been logged. If it has, the associated record will provide information about (amongst other things):
 - The manufacturer / importer
 - Type / model of item
 - Photographs
 - Relevant standards for compliance
 - Test and examination reports
 - Types of injury caused
 - Descriptions of defects
 - Accident details
 - Measures taken



Inspector notification of unsafe or non-compliant product

12. If an Inspector considers that an unlisted product is unsafe or non-compliant and should therefore be entered onto the database they should complete a Product Safety (ICSMS) Request Form.
13. Further guidance on this process can be found on the HSE intranet. It should be noted that HSE has a Product Safety Team to take action forward whereas within ORR individual inspectors are

charged with this work.

14. Once completed this form, along with any relevant photographs or other documents, should be sent to one of ORR's authorised ICSMS users for entering onto the database:  
15. The ICSMS database has limits on the size of attachments and data. The maximum length of free text fields is indicated in the ORR-PSR form. If required additional information can be added via a separate attachment (preferably in pdf format). Any documents should be scanned to pdf format (noting that there is a 3Mb limit for such documents in the system). Photographs should be in jpg format (with a 100Kb limit for each).
16. A Product Safety Investigation Case should also be added to Mosaic. This should include the ICSMS Product Information (PI) Number provided by the authorised ICSMS user, and a copy of the ORR-PSR form which will be returned to the inspector once the information has been added to the database.
17. As any investigation progresses Inspectors should notify the authorised ICSMS user of any further information that needs to be added to the database. They should do this by completing a further version of the ORR-PSR form, including the ICSMS PI No in the 'Mosaic case no' field on page one, and only completing those fields that are relevant.
18. Inspectors should notify the authorised user immediately if they believe that the product does not relate solely to the railway and should be more properly dealt with by another enforcing authority.
19. Any measures taken to restrict the use or supply of a product must be notified to the EU at the earliest opportunity as a 'safeguard action'. Should any such cases arise the Inspector should pass the details to an authorised ICSMS user who will then discuss how to proceed with the HSE Product Support team. This approach should also be followed if a manufacturer voluntarily withdraws a product that ORR was going to prohibit. For further information see the HSE guidance on their intranet.
20. Any general questions on the process should also, in the first instance, be addressed to one of the authorised ICSMS users.

Action

ORR Inspectors should ensure they are aware of the requirement to report unsafe or non-compliant products via ICSMS, and take the necessary action in accordance with this guidance document when required to do so.