ACEA European Automobile Manufacturers Association

STATUS OF AIR-IONISERS UNDER THE BIOCIDAL PRODUCTS REGULATION

SCOPE

This guidance note addresses automotive air-ionisers that function specifically by ionisation of water molecules in the ambient air to form free radicals, forming clusters with impurities in the air and having an antibacterial function to eliminate unwanted odours.

The European Biocidal Products Regulation ("BPR", Regulation (EU) No 528/2012)[1], which entered into force on 1 September 2013, included requirements for the first time for active substances that are generated in situ from ambient precursors that are not themselves supplied (e.g. air). In March 2016, the EU Commission issued further guidance[2] to the relevant Competent Authorities (CAs) specifically covering the example of air-ionisers used to generate free radicals in situ. Subsequently the Automotive Task Force – Biocides gained further understanding from correspondence[3] with the UK Competent Authority, which has been used as the basis for this ACEA guidance note.

If an air ioniser device does not intentionally create free radicals for a biocidal effect, but instead has a controlling effect on harmful organisms only by physical or mechanical action, then the device would not fall under the scope of the BPR or this guidance note. Note however, that in case of investigation by a competent authority, the burden of proof would be on the manufacturer or importer to prove that no biocidal action was intended.

[1] http://echa.europa.eu/regulations/biocidal-products-regulation/legislation

[2] CA-March16-Doc.5.1, "Guidance to specify information requirements for in situ generated free radicals for substance approval in the context of the BPR"

[3] Emails between Claire Holstein, UK HSE Biocides Helpdesk (biocidesenquiries@hse.gov.uk) and Jonathan Swindell, Jaguar Land Rover, 8th - 26th June 2017

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EXPLANATION OF TF-BIOCIDES UNDERSTANDING

- The BPR applies only to biocidal products or treated articles (BPR Art. 2.1).
- An air ioniser device, or a vehicle containing an air ioniser, is not a biocidal product, because by definition (BPR Art. 3.1.a) a biocidal product can only be a substance or a mixture.
- The "free radicals generated in situ from ambient air and water" by the air ioniser when switched on constitute both the active substance and the biocidal product; this means that the authorisation obligation first applies to use of the air ioniser when it is switched on.
- Since it is obviously impractical for each vehicle owner to obtain biocidal product authorisation before they can use the air ioniser, the more practical solution proposed by the UK Competent Authority is for the air ioniser device manufacturer or device supplier in the EU to obtain biocidal product authorisation to cover all uses of their device.
- In case the air ioniser device manufacturer or device supplier fails to take responsibility for authorisation, the obligation would fall on the vehicle manufacturer, whether the vehicles were manufactured in the EU or imported into the EU.
- Authorisation can only be granted under the BPR where the active substance has been approved.
- "Free radicals generated in situ from ambient air and water" were not under the scope of the Biocidal Products Directive 98/8/EC (BPD), and are therefore eligible for transitional provisions (BPR Art. 93); active substance approval applications had to be submitted by 1 September 2016 in order to benefit from the transitional provisions so that the air ionisers may still be used while the approval applications are under review; otherwise the device cannot be operated after 1 year following this deadline, meaning after 1 September 2017.
- From the above, it follows that an air ioniser device has not been treated with, and does not intentionally incorporate, a biocidal product when the device is placed on the market, and therefore the device does not meet the definition of a treated article (BPR Art. 3.1.l); by the same logic, a vehicle containing an air ioniser also does not meet the definition of a treated article.
- Similarly, since the biocidal product is "free radicals generated in situ from ambient air and water", there is no biocidal product present when the air ioniser is supplied (either on its own or in a vehicle), and therefore the biocidal product labelling requirements (BPR Art. 69) do not apply to the air ioniser device or vehicle and cannot apply in practice to the generated free radicals.
- Notwithstanding the above, it is possible that labelling requirements for the air ioniser device (or vehicle containing the device) will be stipulated in the active substance approval or biocidal product authorisation conditions, so it is important that they are referred to and complied with when published.

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SUMMARY: RECOMMENDED ACTIONS FOR AIR-IONISERS UNDER THE BPR

Basis for regulation of air ionisers:

BPR requirements are triggered if the ioniser is used to generate an active substance (i.e. free radicals generated in situ from ambient air and water) "…with the intention of … exerting a controlling effect on any harmful organism by any means other than mere physical or mechanical action".

Requirement	Reference	Responsible*	Action	Deadline
Active substance approval	BPR Art. 19	AIDM	Submit application for approval of the active substance and the relevant product-type.	Before 1 Sept 2016**
Biocidal product authorisation	BPR Art. 17(1)	AIDM	Submit application for Union authorisation of the biocidal product.	Before active substance approval decision
** If the active substance approval application was not submitted by 1 Sept 2016, then the transitional measures of BPR Art. 93 do not apply, and both the active substance approval and the biocidal product authorisation must be granted before the air ioniser can be operated.				
Product notification	BPR Art. 17(6)	AIDM	If authorisation application (see above) was made for of a biocidal product family, notify European Chemicals Agency and Commission of each product within the biocidal product family.	> 30 days before EU sale of each product within the family
Record-keeping	BPR Art. 68	AIDM	Keep records of biocidal products placed on the market.	Ongoing
Product labelling	BPR Art. 69	AIDM	The air ioniser device is not itself a biocidal product, and therefore biocidal product labelling does not apply automatically; check and follow any conditions of the authorisation, when granted, since this may refer back to the generating device.	Not applicable
Treated article labelling	BPR Art. 58	AIDM	Neither the air ioniser device itself, nor the vehicle fitted with the device, are treated articles, and therefore treated article labelling does not apply automatically; check and follow any conditions of the active substance approval, when granted, since this may refer back to the generating device.	Not applicable

** Responsible: AIDM = Air Ioniser Device Manufacturer (or their agent in the EU)*