

WHAT ARE THE ISSUES THAT MUST BE CONSIDERED FOLLOWING THE CHANGE OF BIOCIDES REGULATIONS IN THE EU?

“WHAT SHOULD I DO AFTER 1ST FEBRUARY?”

Industry across the EU has, belatedly, woken up to the fact that the use of copper as a biocide is not permitted after 1st February 2013 until a technical review of copper has been completed, probably sometime in 2016. To address this Industry has now started to jostle to form consortia to support the formal EU review of the use of copper as a biocide in ionisation devices to control legionella.

It is important to remind ourselves that this is not a UK problem - this regulatory issue affects all 27 Member States of the EU - all ionisation suppliers and all Member State Competent Authorities (MSCAs) across the EU are affected by this issue.

It is also important to remember that, as copper is already included in the UK's Approved Code of Practice L8, which copyright is owned by the HSE, there appears to be no question or doubt in the mind of the HSE over its safety or efficacy if used for the purpose described and in the manner set out in this document. The ban is entirely down to EU bureaucracy and administrative process.

Given the current status of EU biocides legislation, there is only one way for copper to stay on the market legally - and that is for each MSCA to decide, in its own right, that the use of copper is so badly needed in the territory over which it has regulatory responsibility that it will apply to opt out ('derogate') from the law banning the supply of copper on grounds of "essential use".

The decision to apply for a derogation is a decision for government, not industry. It is the State itself that submits the application to derogate from EU legislation to Brussels. Individual companies cannot do this.

But preparing and pursuing a derogation takes time.

Once the HSE has submitted its derogation application to Brussels (its target date is presently 31st January) the application is likely to take about six months to progress to conclusion. Subject only to the

derogation being granted, this means that copper will once again be lawfully supplied for use in copper silver ionisation systems in the UK, probably in Q3 or Q4 2013.

But to simply say "Stop using copper now" is not such an easy task. Consider a selection of the dilemmas that face all affected parties:

1. If an anxious nursing home owner decides to decommission a copper silver ionisation system and replaces it with an alternative in February, and spends perhaps £30,000 to accomplish such a task, how will they feel if they discover, later this year, that copper is legal again?
2. If a hospital with perhaps twelve installations switches them off on 1st February to comply with the strict interpretation of the law, and orders alternative systems that will take months to select, install, commission and operate, and a patient contracts legionella and dies while the hospital is waiting for the de-commissioning/re-commissioning process to conclude, who is culpable?
3. How does a duty-holder comply both with his or her primary responsibility to uphold a policy for legionella control and treatment while at the same time complying with EU biocide regulations during this interregnum?
4. What are the legal ramifications for a company and its directors if it buys or installs replacement electrodes containing copper after 1st February to maintain the efficacy of installed systems ?
5. If a facilities manager refuses to switch off a copper silver ionisation system on or soon after 1st February and calls the HSE, asking them to come and turn the system off and indemnify him or her and the operating organisation from the consequences, will the HSE comply?

Finally, it may also be prudent to consider that copper silver ionisation is the only method of legionella control that delivers residual disinfection. To reference just two studies published regarding US hospitals:

Liu *et al*, 1994 observed an excellent residual effect of copper and silver as water fixtures continued to be free of *Legionella* for two months after the copper/silver ionisation unit was turned off and only one sampling site, out of 26, was positive for *Legionella pneumophila* after four months.

and

Liu *et al*, 1998 studied the efficacy of copper-silver ionisation in controlling Legionella in a 541-bed hospital in the US A residual effect was also observed during this study as *Legionella* re-colonisation did not occur in both test buildings for twelve weeks after inactivation of the system.

If the gap between the implementation of the biocides regulation and the granting of the derogation is six months, these studies may influence the sense of urgency in making any decision to switch off or de-commission during this period.

The following paragraph of text, pasted from the HSE legionella web page, summarises the HSE's approach to continued use:

The primary concern of HSE and Local Authorities is that legionella control is not compromised. HSE and LAs will take a proportionate approach if they come across these systems. This will take into account the system being used, the steps taken to consider an alternative system of control and the latest status in relation to an application to Europe to exempt the use of copper in legionella control systems from the ban. The focus of any HSE enforcement activity will be on the failure to control the risk of exposure to legionella bacteria and the likelihood of legionnaire's disease developing in a given situation.

“So, what do I do?”

Whatever decision is to be taken, it is necessary for any affected organisation to maintain a policy for the control and treatment of legionella.

The processes that comply with current best practice are contained in L8.

Copper Silver ionisation is one of the three dispersive systems that are accepted under this Approved Code or Practice because it works.

Many of our customers will confirm that they have turned to copper silver ionisation because other forms of control have failed and copper silver ionisation is the only modality that works in their particular circumstance.

Tarn-Pure has repeatedly asked the question “If a duty holder has no option but to make a choice either of ensuring that he is not compromising legionella control or complying with EU Biocides Regulations, which has priority?” We believe that the HSE statement above provides the answer.

Tarn-Pure hopes that this article provides some context to help inform such decisions and some clarity in respect of the options and implications.

Please do not hesitate to contact us should you wish to discuss this matter further.