



Llywodraeth Cymru
Welsh Government

ATISN 15035

27 April 2021

Dear

ATISN 15035 – Ethylene Oxide Residues

Thank you for your request to the Welsh Government for information under the Freedom of Information Act (2000) received on 26 March 2021. I have interpreted your request as follows:

In relation to the Innova lateral flow test being used across schools in Wales. The swab used is sterilised by ethylene oxide; given the known toxicity and potential carcinogenicity of ethylene oxide you request:

- a. information as to what, if any, independent tests have been carried out to check for any residues of ethylene oxide on a random sample of swabs*
- b. information as to what, if any, assessments have been conducted to ensure that the invasive use of these swabs for children is safe?*

Our response

- a. The UK Government Department of Health and Social Service (DHSC) is leading on the validation and assessment of lateral flow tests procured under the UK Testing Programme. DHSC has confirmed:
 - Lateral flow tests have been rigorously tested and are safe to use on a regular basis.
 - Ethylene oxide is only used in the sterilisation of swabs and it is one of the most commonly used sterilisation tools in the healthcare industry, principally applied by manufacturers to keep medical devices safe.
- b. DHSC has also provided the information outlined below:
 - Any traces of ethylene oxide remaining in the lateral flow device or packaging after sterilisation are below limits that would be considered hazardous for health and comply with international standards.

- The types of devices that are sterilized with ethylene oxide range from devices used in general health care practices (for example, wound dressings) to more specialized devices that are used inside the body.
- The manufacturers have confirmed that 1-2ug/g of ethylene oxide is used in the swabs, which is well within national/international safety standards.

Next Steps

If you are dissatisfied with the Welsh Government's handling of your request, you can ask for an internal review within 40 working days of the date of this response. Requests for an internal review should be addressed to the Welsh Government's Freedom of Information Officer at:

Information Rights Unit,
Welsh Government,
Cathays Park,
Cardiff,
CF10 3NQ
or Email: Freedom.ofinformation@gov.wales

Please remember to quote the ATISN reference number above.

You also have the right to complain to the Information Commissioner. The Information Commissioner can be contacted at:

*Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF*

However, please note that the Commissioner will not normally investigate a complaint until it has been through our own internal review process.

Yours sincerely,