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**Question & Answer N. 24/2006**

**Diagnostic kits**

<b>Status</b>	<b>Public</b>
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## **QUESTION**

Can you help me clear through the regulatory path for veterinary diagnostic kits? Is there any group within the EU responsible for regulating veterinary diagnostic kits and if so can you tell which one? I understand that only a few kits are currently regulated at EU level, but it is not clear from my reading if it is the EMEA, EU Food Safety Authority (EFSA), DG Sanco, HEVRA, etc.

Are there any regulatory guidelines available in the EU that applies in any way to Veterinary diagnostic kits. I was told that the Veterinary Medicines Directive might apply but as far as I can see this only refers to veterinary medicines, not diagnostics.

Your help and guidance on this would be most appreciated.

## **ANSWER**

Regulatory guidelines regarding diagnostic kits are available in the EU for human in-vitro-diagnostics.

All companies producing and distributing human in-vitro-diagnostics in the European Union (EU) have to comply with the regulations according to the Directive 98/79/EC issued by the EU on in-vitro-diagnostics (IVD guideline). The purpose of this IVD directive is to establish and to guarantee a uniform quality standard of medical diagnostics within the EU. One basic requirement of the guideline is a Technical Documentation, which has to be presented for each diagnostic product. The IVD guideline distinguishes pathogens of the category A, category B and non listed products. According to these risk categories the Technical Documentations need to be approved by the Notified Body.

Similar regulatory guidelines for veterinary diagnostic kits are not available at this time within the EU.

In the Member States different legal requirements are in place. Therefore it is recommended to contact the national authorities for national regulatory requirements and guidelines.