

NEW OECD GUIDELINE 407: IMPLICATIONS FOR NOTIFIERS OF NEW SUBSTANCES

The OECD Guideline number 407 for the Repeated Dose 28-day Oral Toxicity Study in Rodents has been revised and was adopted on 27 July 1995.

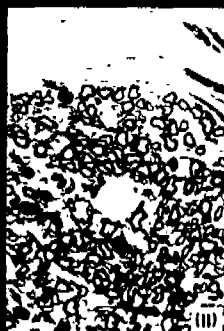
The main changes in the revised guideline are:

- addition of neurobehavioural screening
- an increased list of tissues for histopathological examination in the study protocol

The European Commission has recently incorporated the revised OECD Guideline number 407 into its legislation as test B7 in Directive 96/54/EC which adapts to technical progress for the 22nd time Directive 67/548/EEC. For all Notification of New Substances (NONS) submissions made after 31 May 1998, the use of the new study design will be mandatory.

At Huntingdon Life Sciences, we strongly recommend that the new protocol is followed for all NONS programmes started after 1 June 1997 to ensure compliance with the legislation. We believe we can provide you with invaluable assistance in this for the following reasons:

- we are considered to be one of the world's leading laboratories in conducting neurotoxicity studies
- we have been conducting 28-day studies to the revised protocol since its adoption in 1995



Transverse section of peripheral nerve

(I) Control

(II) Acrylamide, 50mg/kg/day

- we have considerable experience in neurobehavioural screening and neuropathology and have validated and published methods for the Functional Observational Battery and motor activity tests
- we have been conducting neurotoxicity studies of this type, to EPA guidelines, since 1992
- we have a background database on over 35 chemicals comprising both validation data and commercially performed studies

For studies performed at Huntingdon Life Sciences, there will be no impact on time taken to perform and report the new study design and the price of the additional investigations is competitive.

For further information, please fill in the details below and fax us in UK +44 (0)1480 892205 or USA (908) 873 3992 or Japan (03) 3238 6388

Please send me a copy of the new Neurotoxicology brochure ☐

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Alternatively, please call us:

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Our standard service, meeting defined regulatory requirements, is offered at a fixed price depending on the nature of the material and the tests required.

All studies are carried out to GLP under the direction of an experienced project manager who will provide regular progress reports.

New Japanese Support

With thirty years experience in the chemical industry behind him, Mr Nobuo Shimizu has joined our Tokyo office to control all translation and registration work and liaise with MITI and MOHW on behalf of our Sponsors.

New Korean Support

Mr Jong-Soo Kang, president of Shin Won Scientific Company, operates as our in-house expert for Korean notifications under the Toxic Chemicals Control Act. He leads a team which translates reports, prepares dossiers and conducts any negotiations with the Ministry of the Environment.

FAX BACK

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