WRITTEN QUESTION E-1017/09
by Jens Holm (GUE/NGL)
to the Commission

Subject: Botox

Botulinum toxin A (known by the brand name Botox) is a nerve poison which is used for medical purposes, but increasingly also for cosmetic applications. Injections to smooth out facial wrinkles are often carried out off-label, because only few products are licensed for cosmetic applications.

Each batch and each bulk is tested before marketing for both medical and cosmetic applications. The standard procedure required by the European Pharmacopoeia is a classic LD 50 test (lethal dose which kills 50% of a group of animals). A sample is injected into the abdomen of mice. The mice suffer paralysis and respiratory distress before they die after three or four days in agony. The European Pharmacopoeia allows three alternative testing methods (one animal-free test and two tests which reduce the suffering). But currently the manufacturers continue using the LD 50 test on mice.

I would like to ask the Commission the following questions:

1. Which EU Member States carry out LD 50 tests on mice for botulinum toxin A products?
2. How many mice are being used for this purpose in each of these EU Member States per year?
3. To what extent (percentage) are botulinum toxin A products used for cosmetic purposes to smooth wrinkles?
4. To what extent is the Cosmetic Directive (76/768/EEC) affected by the use of botulinum toxin A products for cosmetic purposes? Why are injectable cosmetics not included in the Cosmetic Directive?
5. What does the EU do to encourage and support the development and validation of non-animal methods to replace the LD 50 test on mice for the batch testing of botulinum toxin A products?
6. What is known about the long-term adverse effects of the use of botulinum toxin for cosmetic purposes to smooth wrinkles.