

**SEC-03-DRS-2016: Validation of biological toxins measurements after an incident:  
Development of tools and procedures for quality control**



# EQuATox - Establishment of Quality Assurances for the Detection of Biological Toxins of Potential Bioterrorism Risk

Projektet syftade till att förbättra EU's beredskap och kunskap samt förbättra samarbetet mellan de Europeiska länderna med avseende på analys av biologiska toxiner.

- 35 laboratorier i 23 länder är representerade i projektet.
- Proficiency tests på 4 biologiska toxiner.
  - Ricin.
  - Botulinum toxin (BoNT).
  - Staphylococcal Enterotoxin B (SEB).
  - Saxitoxin (STX).
- FOI var en av 9 medlemmar i konsortiet.
- FOI var ansvarig WP2 (Screening for information within Europe).
- FOI karakteriserade referensmaterial för Ricin och BoNT.
- FOI arrangerade utvärderingsmöte av SEB & BoNT PT.
- FOI deltog i proficiency test för Ricin, STX och BoNT.
- Livsmedelsverket deltog i proficiency test för STX och SEB.
- Statens Veterinärmedicinska Anstalt deltog i proficiency test för BoNT.



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**Specific Challenge:** Recent incidents in Europe and worldwide recalled that biological toxins can be produced by laypersons or acquired illegally and intentionally released in a criminal act to harm people. While different technologies are available for toxin detection and analysis, recent findings have shown that the comparability of analytical results from different laboratories is poor, which cast severe doubts about the validation of current methods and about the overall validity of analytical data. This means that in case of a bioterrorist act using compounds such as e.g. ricin (or others such as abrin), saxitoxin, botulinum, neurotoxins, enterotoxins, etc. there is no guarantee that decisions to react are made based on data meeting basic quality requirements. The lack of quality assurance/quality control tools (e.g. certified reference materials of ricin, botulinum, etc.) and standard operating procedures hampers the validation and the EU-wide comparability of biological toxin measurement data. There is therefore a need to develop an EU-wide approach for enhancing validating analytical capacities for biological toxin measurements in case of bioterrorism threats, similarly to what exists regarding chemical threats.

**Scope:** The large variability among families of biological toxins complicates their measurement and unambiguous identification in human specimens, and environmental or food samples. Toxins are rapidly metabolized and degraded after incorporation, limiting the time window for successful identification and forensic analysis. Proposals should **develop quality control tools**, as well as the **Standard Operating Procedures** necessary for establishing a mechanism to systematically **validate laboratory-based measurement techniques**, including sample preparation strategies and analyses made in-situ issued by mobile and quickly deployable laboratories, which should be proposed for adoption at EU level.

# EQuATox-2 konsortiet

<b>Nr.</b>	<b>Institut</b>
<b>1</b>	Robert Koch-Institut (Tyskland)
<b>2</b>	European Commission - Joint Research Center (Belgien)
<b>3</b>	Institut Scientifique de Santé Publique (Belgien)
<b>4</b>	Finnish Institute for Verification of the Chemical Weapons Convention, VERIFIN (Finland)
<b>5</b>	French agency for food, environmental and occupational health safety (Frankrike)
<b>6</b>	Toxogen GmbH (Tyskland)
<b>7</b>	Swedish Defence Research Agency, CBRN Defence and Security (Sverige)
<b>8</b>	SPIEZ LABORATORY (Schweiz)
<b>9</b>	Institut X (nytt)
<b>10</b>	Institut Y (nytt)
<b>11</b>	Institut Z (nytt)

# EQuATox-2

## Förhandlingar och planering pågår inom konsortiet.

- FOI är bundet av ett sekretessavtal gentemot konsortiet. Ingen information rörande förhandlingarna kan delges tredje part.

## Svenskt deltagande i projektet.

- FOI är en av 11 medlemmar i konsortiet.
- Livsmedelsverket har anmält intresse för att delta i profiency test för STX och SEB.
- Statens Veterinärmedicinska Anstalt har anmält intresse för att delta i profiency test för BoNT.
- Security board medlem önskas från Polisen.

Kontakt FOI: [daniel.jansson@foi.se](mailto:daniel.jansson@foi.se)