

Prevention of Misuse of Biological Materials and Toxins for Biowarfare

Roche Position

Commitment

Roche uses biological materials and corresponding equipment for research, development and production of pharmaceutical and diagnostic products for the benefit of patients. However we do not produce and sell biological materials or production equipment which can be used for biological weapons. If we resell used biotech equipment, we strictly follow the relevant regulations.

Current situation at Roche

Roche is aware that there are biological materials, including toxins, which can be misused for purposes of warfare or terrorism. However, at Roche we possess the knowledge and experience to handle such materials safely. Hence neither the international pharmaceutical industry in general nor Roche in particular is a source of misuse of biological materials and toxins and corresponding equipment and know-how (the biological and biotechnological know-how is anyway in the public domain and therefore readily available).

Most biological materials handled by Roche belong to risk groups 1 (no or low individual and community risk) or 2 (moderate individual and low community risk) – especially those used in large quantities in production. Materials of risk group 3 (high individual and low community risk) are handled or stored only at very few company sites, in minimal quantities and under rigorous control. Materials of risk group 4 (high individual and community risk) are neither handled nor stored.

Roche is in close contact with the International Committee of the Red Cross (ICRC), which has been mandated by the UN to further develop control measures and commitment by all countries.

Regulatory compliance

Roche fully complies with all obligations derived from the **UN Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction** (including in those countries which have not signed the Convention), as well as all corresponding laws and regulations. In order to be effective, regulations on biowarfare must be multilateral and cover not only activities of the industry, but all types of activities, including those of authorities and non-governmental and scientific organizations.

The UN Convention, which came into force in 1975, has been enacted by the United Nations Bureau of Arms Control to prohibit misuse of biological materials. Its signatories undertake not to develop, produce, stockpile or

acquire biological agents or toxins of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes. In September 1986 the parties agreed to implement data exchange measures to enhance confidence and promote cooperation in areas of permitted biological activities, which also include potential verification measures with respect to the prohibitions of the Convention.

The Convention stipulates that its implementation should not hamper the economic or technological development of States parties to it. Nor shall the international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes be hindered.

The main areas to be regulated are

- the biological materials and toxins;
- the equipment used to produce or handle them; and
- the corresponding know-how.

Implementation

In applying the Convention we have set up strict internal regulations and processes for dealing with such materials, equipment and know-how – similar to the regulations for materials, equipment and know-how which could be misused for chemical weapons.

The main elements of how to prevent misuse of biological materials and of corresponding equipment and know-how are laid down in a Roche Group directive, enforced across all Roche sites by the Corporate Executive Committee.

These main elements are:

- Authorities must be informed of work with biological materials / toxins, and permits must be obtained where necessary, based on locally applicable laws and regulations.
- The local Safety, Health and Environmental Protection (SHE) Officer must be notified immediately if work is planned involving biological materials / toxins mentioned on international lists aimed at preventing bioterrorism and biowarfare (list of dual-use items and technology, Annex 1 of EU Council Regulation 394/2006/EC and “Select Agents and Toxins” listed by the US Department of Health and Human Services).
- Appropriate training and security measures must be established to avoid the misuse of such materials, of facilities and equipment and of know-how at all Roche sites concerned.
- Work with and storage of such agents or toxins must be reported to the Corporate SHE department annually as part of the SHE key figure reporting scheme.

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