

## **PROTOCOL WITH REGARD TO NOTIFYING AUTHORITIES OF “ALARMING” RESULTS valid per 5 July 2011**

### ***Introduction***

RIKILT carries out research for third parties under specified conditions. It cannot be ruled out that research results reveal the existence of certain risks to public health or the violation of certain legal provisions. In such cases, further arrangements need to be made with the third party. This protocol defines the steps to be taken by RIKILT in such situations. This protocol is also valid when RIKILT carries out research for foreign governments.

### ***General code of conduct***

The general code of conduct used by RIKILT when reporting results is described in the General Conditions of Wageningen UR (University & Research Centre). The EU guidelines 178/2002 and 882/2004 also apply to RIKILT's work for third parties.

As dictated by the Dutch government (EL&I), RIKILT has the following policy: in case of danger to public health or to the general interest of the public, the research results have to be reported to the responsible regulatory authority.

Situations that RIKILT considers as requiring immediate notification include the following violations of legal standards:

- I the presence of illegal substances or illegal constituents;
- II results exceeding the maximum permitted level of residue;
- III results exceeding the legally specified tolerance for additives;
- IV results indicating fraudulent product preparation;
- V results indicating situations that are in conflict with legal provisions;

and in addition:

- VI any other case that RIKILT deems to be dangerous to the public health.

The Dutch government (EL&I) considers any results that fall under criteria I through VI obtained in the course of the research project as requiring notification. This includes results derived on the basis of the actual research target and results discovered indirectly ("by coincidence") when performing the research.

### ***RIKILT's reporting of "alarming" results to client***

RIKILT will notify both the client (by fax or e-mail and registered letter) and the Dutch regulatory authority (VWA notification office, by fax or e-mail) simultaneously of any results RIKILT regards necessary to report. The notification will clearly indicate why the results require reporting to the relevant authorities (situations I, II, III, IV, V or VI). The written notification will be signed by the managing director of RIKILT.

The notification will not be sent to the Dutch regulatory authority when the research was performed for a National Regulatory Authority or an officially appointed laboratory of a member country of the European Union.