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QUESTIONNAIRE ON IMPLEMENTATION OF THE 1989 COUNCIL ACT ON COMPLIANCE WITH GLP - C(89)87(FINAL)

(as revised in 2006)

Questionnaires should cover all GLP Compliance Monitoring Programmes which have a Member or an Observer on the Working Group on GL, and which have their legal basis in a single act or ordnance. Countries which have more than one Monitoring Programme can submit questionnaires for all of their Monitoring Programmes in a single consolidated questionnaire or separate questionnaires can be submitted for each Monitoring Programme. In every case, sections 1 and 2.1 should be filled out in each questionnaire for the country as a whole in order to provide a general overview of the national scope of compliance monitoring.

Countries organise their GLP compliance monitoring in various ways - ranging from a single GLP Compliance Monitoring Programme and authority covering all groups of chemicals to several distinct Compliance Monitoring Programmes, each of which can also have several monitoring authorities as well. In some cases there is close national liaison and co-operation among several monitoring authorities in a country and they work together in a single national GLP Compliance Monitoring Programme. In other cases the various monitoring authorities each belong to a separate GLP Compliance Monitoring Programme. Questionnaires should be filled out and updated annually for each Monitoring Programme which has a Member or Observer on the Working Group.

The Working Group agreed that questionnaires should be reviewed annually by Members and Observers and updated if necessary.

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PLEASE HIGHLIGHT BY SHADING WHAT HAS CHANGED SINCE THE QUESTIONNAIRE WAS LAST SUBMITTED

NOTE: if submitting a questionnaire for only part of the GLP compliance monitoring activities in your country, please still complete sections 1 and 2, below for all activities.

COUNTRY:

1. NATIONAL GLP COMPLIANCE MONITORING PROGRAMME(S)

1.1 Name(s) of the national GLP Compliance Monitoring Programme(s) responsible for each of the chemical groups listed in 2.1. below and, if applicable, name(s) of the monitoring authority(ies). Indicate in bold the Programme(s) covered by this questionnaire.

Finnish Medicines Agency (Fimea)

1.2 Name(s) of the government bodies responsible for the establishment of the national GLP Compliance Monitoring Programme(s).

Finnish Medicines Agency (Fimea)

2. NATIONAL LEGISLATIVE REQUIREMENTS FOR GLP:

2.1 Specify legislative and regulatory documents that require the application of GLP for testing of the following chemical groups and indicate the name and address of the data receiving authority for each:

2.1.1 industrial chemicals

National legislation and receiving authority
Act on Chemicals (599/2013)

Finnish Safety and Chemicals Agency (Tukes), P.O.Box 66, Opastinsilta 12 B, FI-00521 Helsinki, Finland

EU legislation and receiving authority:
Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH')

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures ('CLP')

European Chemicals Agency (ECHA), Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland

2.1.2 pharmaceuticals

National legislation and receiving authority
Act on Medicines (395/1987)

Finnish Medicines Agency (Fimea), P.O.Box 55, FI-00034 Fimea, Finland

EU legislation and receiving authority
Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC ***(The receiving authorities for clinical trial applications is the national receiving authority)***

European Medicines Agency (EMA), 30 Churchill Place, Canary Wharf, London E14 5EU, United Kingdom

2.1.3 veterinary medical products

National legislation and receiving authority
Act on Medicines (395/1987)

Finnish Medicines Agency (Fimea), P.O.Box 55, FI-00034 Fimea, Finland

EU legislation and receiving authority
Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC.

European Medicines Agency (EMA), 30 Churchill Place, Canary Wharf, London E14 5EU, United Kingdom

2.1.4 pesticides

National legislation and receiving authority
Act on Chemicals (599/2013)

Finnish Safety and Chemicals Agency (Tukes), P.O.Box 66, Opastinsilta 12 B, FI-00521 Helsinki, Finland

EU legislation and receiving authority
Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 is the Regulation on placing plant protection products on the market. It repealed Council Directives 79/117/EEC and 91/414/EEC on 14 June 2011.

Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No

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1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

European Food Safety Authority (EFSA), Via Carlo Magno 1/A, 43126 Parma, Italy

2.1.5 food additives

National receiving authority
Finnish Food Safety Authority (Evira), Mustialankatu 3, FI-00790 Helsinki

EU legislation and receiving authority
Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings

European Food Safety Authority (EFSA), Via Carlo Magno 1/A, 43126 Parma, Italy
EU legislation: EY 1331/2008

2.1.6 feed additives

National receiving authority
Finnish Food Safety Authority (Evira), Mustialankatu 3, FI-00790 Helsinki

EU legislation and receiving authority
Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives

European Food Safety Authority (EFSA), Via Carlo Magno 1/A, 43126 Parma, Italy
EU legislation: EY 1331/2008

2.1.7 cosmetics

National receiving authority
Finnish Safety and Chemicals Agency (Tukes), P.O.Box 66, Opastinsilta 12 B, FI-00521 Helsinki, Finland

EU legislation
Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

2.1.8 biocides

National legislation and receiving authority
Act on Chemicals (599/2013)
Finnish safety and Chemicals Agency (Tukes), P.O.Box 66, Opastinsilta 12 B, FI-00521 Helsinki, Finland

EU legislation and receiving authority
Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

European Chemicals Agency (ECHA), Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland

2.1.9 other products (specify)

NA

and provide appropriate links to any documents available in English or English translation, if available.

2.2 For the submission of data for regulatory purposes, do the domestic regulators require the application of GLP principles other that the OECD Principles of GLP? If so, identify these principles and provide appropriate links to the referenced principles available in English or English translation, if available.

No

2.3 If GLP principles other than the OECD Principles of GLP were identified in 2.2, has a comparison of these principles to the OECD Principles of GLP been performed? If so, provide appropriate links to any documents reporting the comparison available I English or English translation, if available

NA

2.4. For each group of chemicals listed in 2.1 above, specify the type of testing for which GLP is mandated using the table given in Appendix A.

Requirement described in European Community legislation are followed, there are no additional requirements on national level.

3. GLP COMPLIANCE MONITORING PROGRAMMES

Provide answers for each of the questions below for each of the chemical groups specified under 2.1 above which are covered by the Monitoring Programme(s) concerned by this questionnaire.

3.1 Starting date for the monitoring programme.

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The GLP compliance monitoring programme in Finland was established in 1991. First inspection for pharmaceuticals was carried out in 1991 and for chemicals in 1998. Full responsibility of the national GLP programme was moved to Fimea from National Supervisory Authority for Welfare and Health (Valvira, previously named as Product Control Centre for Social Welfare and Health = STTV) on 1 November 2009 by the Act of the Finnish Medicines Agency (2009/593). Inspectors of Fimea (previously named National Agency for Medicines) had already before that performed inspections of pharmaceuticals in the GLP programme in Finland.

3.2 Name(s) and full address(es) (including telephone, telefax numbers and e-mail address(es)) of the GLP compliance monitoring authority(ies) and the person(s) in charge of each.

Finnish Medicines Agency (Fimea)
P.O.Box 55, FI-00034 Fimea, Finland
Street addresses: Mannerheimintie 103, Helsinki and Microkatu 1, Kuopio
Phone: +358 29 522 3341
Fax:+358 29 5223002
E-mail: registry@fimea.fi
Web: www.fimea.fi

Contact persons:

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Paula Korhola
Phone: +358 29 522 3224
E-mail: paula.korhola@fimea.fi

3.3 Name(s) and full address(es) (including telephone, telefax numbers and e-mail address(es)) of the authority(ies) and the person(s) responsible for international communication on GLP inspection and audit procedures if different from those given under 3.2. Provide appropriate links to any documents available in English or English translation, if available.

Same as above

3.4 What is the complete (national) legal basis for monitoring GLP compliance? Provide appropriate links to any documents available in English or English translation, if available.

Act on Finnish Medicines Agency (2009/593), Act on Chemicals 599/2013), Act on Medicines (395/1987)

For each of the authorities mentioned in 3.2, above, answer all of the following questions:

3.5 Identify any programme documents that describe the procedures for conducting test facility inspections and data audits. Provide appropriate links to any document available in English or English translation, if available.

GLP inspections and data audits are carried out according to internal Standard Operating Procedures of Fimea.

3.6 Describe the powers of the inspectors to access the test facilities and test data. [If GLP requirements monitored by one authority have different legal bases (see question 2), specify the powers granted under each of these cases.]

Inspectors have an access to the test facilities and test data. They also have a right to take photographs and samples. Legal basis is the Act on Medicines 395/1987.

3.7 List the number of inspectors in each compliance monitoring authority (specify full-time or part-time), the level of education, training and experience required to fill the position.

There are two qualified GLP inspectors (one full time inspector performing also GMP-, ATMP- and SOHO(= substances of human origin) –inspections, and one part time inspector performing also GMP- inspections of microbiological QClaboratories and acting as a quality manager and senior scientist in microbiology in Fimea OMCL (Official Medicines Control Laboratory) laboratory. Both inspectors have more than 10 years exprience in GLP. In addition, one GMP inspector specified in IT inspections has been trained and qualified to inspect IT-systems in GLP facilities.

3.8 What percentage of their work load do the inspectors spend on inspections and study audits and GLP related activities? How many full-time equivalents does this represent?

Inspector, who has the main responsibility in GLP, spends about 20 %, the second GLP inspector about 15 % and the IT inspector about 2 % in GLP related activities. Besides them, the director of the process, the head of the inspectorate, the chief inspector, the secretary and two preclinical assessors spend some working time on GLP. The overall time is about 50 % of a full time worker.

3.9 What is each inspector's relationship with the compliance monitoring authority (employee, external contractor, etc.)?

Inspectors are full time employees of Fimea.

3.10 Has the scope of GLP coverage of the compliance monitoring authority(ies) been extended since submission of the previous questionnaire? If so, please describe the process used to ensure adequate access to expertise. The answer could address such issues as analysis of current competencies, additional training of inspectors, access to external expertise, co-operation with domestic regulators and other compliance monitoring authorities.

Ecotoxicology (algae and Daphnea methods) and physic-chemical testing of biocides has been added to the scopes of laboratories since submission of the last questionnaire. This did not cause need of additional training However, there is a plan to gain more training in ecotoxicology (observing inspection in another

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country), if more complicated methods will be used in the ecotoxicology laboratories in the future.

Annual meetings are organised between GLP CA, the receiving authorities and the national accreditation body (Fimea, Tukes, Finas) at least once in a year to discuss about current GLP questions. Assessors from the receiving authorities may participate inspection as experts, if needed. Inspectors take part in continuous training, and their training need are evaluated annually.

4. EXPLANATION OF ORGANISATION AND MANAGEMENT OF GLP COMPLIANCE MONITORING

4.1 Describe in detail how the GLP compliance monitoring in your country is organized, including a description of the relationship between monitoring authority(ies) and the receiver of the test data (i.e. regulatory authority(ies)).

Fimea is responsible of the national GLP programme in Finland. It performs routine inspections and study audits and grants GLP licences and certificates for approved GLP test facilities. Fimea also is receiving authority for safety studies regarding medicines. For chemicals the receiving authority is Tukes. Regular meetings are arranged between Fimea and Tukes, and also training sessions in GLP has been provided to safety assessors.

Since Finland is a MS of EU, national authorities seldom act directly as receiving authorities, because safety evaluations are mostly coordinated by EU authorities like EMA, ECHA and EFSA.

4.2 i) How does the monitoring programme determine if a test facility should be inspected?

A test facility enters to the monitoring programme by applying GLP compliance status from Fimea. First inspection is always performed before a test facility is licenced. After the facility has been licenced and accepted to the programme, it will be inspected according to the risk based inspection programme (inspection frequency usually 24 months). Additional inspections may be performed performed, if major changes have taken place in the facility, or if there are any suspicions on malpractices. Inspections may also be triggered by a request of a receiving authority (national, other OECD country or EU authority).

ii) On average how many test facilities are inspected per year?

5 – 10 test facilities / year

iii) On average how many studies are audited upon request per year?

Study audits have not yet been requested. Study audits are normally performed as a part of routine inspections.

iv) What is the frequency (a range is acceptable) of inspections of each test facility?

Based on a risk assessment 1 – 3 years.

4.3 i) What are the criteria for doing the first inspection and subsequent re-inspections of a test facility?

A new test facility enters to the monitoring programme by applying GLP compliance status from Fimea. Facility has to be inspected and GLP compliance verified before GLP licence and certificate can be granted. After that, routine inspections are carried out according to annual risk-based inspection plan.

ii) What are the criteria for doing study audits?

Study audits are normally performed as a part of a routine inspection. A separate study audit could be performed upon a request by a receiving authority (national, OECD country or EU level authority).

4.4 i) Describe the actions that may be taken if non-compliances with GLP requirements are found during a test facility inspection or during a study audit.

If non-compliances are critical (could compromise reliability of studies), the facility can be ordered already at the closing meeting of an inspection to start immediately corrective actions. If findings are not critical, the facility will receive about in a week a list of findings ("draft report"), and they may respond to it already before the final report is finished, if they wish. Alternatively they may wait until they receive the final report (in 30 days after the inspection), and then provide their response (in 30 days after receiving the final report). Response should include corrective action plan and time schedule. Inspection will be closed when a acceptable response has been received by Fimea. If necessary, a follow-up inspection is performed to verify implementation of corrective actions.

ii) Summarise the main types of actions taken in the last 2-4 years.

No critical non-compliances have been identified. Facilities have been able to provide acceptable responses in time lines. Implementation of corrective actions has been verified in next routine inspections. In some cases the inspection frequency has been shortened to less than 24 months because of high number of (non-critical) findings.

iii) What are the criteria for giving a test facility the status of "not in compliance"?

If a test facility does not fulfill OECD GLP Principles requirements and is not able to provide a acceptable response to findings and correct them, it may cause a non in compliance status and removal from the GLP programme.

iv) What is the procedure used to inform other member countries about facilities or studies found to be non-compliant?

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OECD and EU GLP WG:s and national receiving authorities in Finland would be informed immediately by e-mail about non-compliance and removal from programme.

4.5 i) How are the records of and reports on inspections and study audits documented (pro forma checklists, reports, etc?)

A report format is used for writing inspection reports. Inspections are planned case by case based on preliminary information from the facility (inspection history, pre-inspection questionnaire filled by the facility and possible other requested pre-inspection documentation). No check lists are used.

ii) For how long are records of inspections and study audits retained?

Inspection and study audit reports are retained (electronic archiving) permanently.

4.6 i) How is a test facility informed about the outcome of an inspection or a study audit?

List of findings is provided in 7 – 10 days after the inspection. Test facility has a possibility to provide a response already at that point or they may choose to wait for the final report (prepared in 30 days). After receiving the final report test facility has 30 days to provide a response. If the response is not satisfactory, additional information is asked for. After the response has been accepted, test facility is informed and a new GLP certificate is granted.

ii) What is the average time between the conclusion of an inspection/audit and the notification of its result to the test facility?

1 – 2 weeks.

4.7 How does your programme respond to requests from other national GLP authorities to conduct inspections or study audits, or to release inspection reports?

Inspections and study audits would be performed, if requested by receiving authorities. Inspection reports are available by upon request.

5. DATE: 21 MARCH 2017

6. RESPONSIBLE FOR THE QUESTIONNAIRE (NAME AND TITLE):

PIRKKO PURANEN, SENIOR INSPECTOR

APPENDIX A/FINLAND

Identity of Chemicals (Categories)	Industrial Chemicals	Pharmaceuticals	Veterinary Medical Products	Pesticides	Food Additives	Feed Additives	Cosmetics	Biocides	Other Products (specify)
physical-chemical testing	-* C	+ C	+ C	+ C	+ C	+ C	+ C	+ C	
toxicity studies	+ C	+ C	+ C	+ C	+ C	+ C	-***	+ C	
mutagenicity studies	+ C	+ C	+ C	+ C	+ C	+ C	-	+ C	
environmental toxicity studies on aquatic and terrestrial organisms	+ C	+ C	+ C	+ C	+ C	+ C	-	+ C	
studies on behaviour in water, soil and air; bioaccumulation	+ C	+ C	+ C	+ C	+ C	+ C	-	+ C	
residue studies	-	-	+ C	+ C	+ C	+ C	-	+ C	
studies on effects on mesocosms and natural ecosystems	+ C	+ C	+ C	+ C	+ C	+ C	-	+ C	
analytical and clinical chemistry testing	+ C	+ C	+ C	+ C	+ C	+ C	+ C	+ C	
other studies, specify									**C:

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+ = GLP required by legislation
- = GLP not required by legislation
C = Covered by GLP Compliance Monitoring Programme
N/C = Not covered by GLP Compliance Monitoring Programme
*** = physico-chemical testing of industrial chemicals is not required to be in GLP according to REACH**
**** = safety studies of detergents, GM food & feed, medical devices, if GLP studies requested by receiving authorities**
***** = animal testing of cosmetics is not allowed in EU**