



Avaliação do Programa Brasileiro da Conformidade aos Princípios das BPL pela OCDE

Lidiane Martins de Albuquerque

11/04/2022

Contextualizando...

PROCEDURES AND PROCESSES FOR THE ON-SITE EVALUATION OF NATIONAL GLP COMPLIANCE MONITORING PROGRAMMES

(as endorsed by the 50th Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology in 2013)

Objectives

4. The objective of the initial and periodic on-site evaluation programme is to enhance confidence that data receiving authorities are provided accurate and complete assessments of the conduct of non-clinical health and environmental safety studies and of the quality and integrity of data used to support pre-marketing (pre-manufacturing) applications. The periodic on-site evaluation programme provides a mechanism for national GLP Compliance Monitoring Programmes of participating OECD member countries and non-member economies to gain increased confidence in the compliance monitoring practices of the evaluated OECD member country or non-member economy and, in the case of initial evaluations, to recommend, if applicable, the full adherence of the evaluated non-member economy. Such confidence will permit Monitoring Programmes to obtain and provide timely and accurate compliance information about foreign test facilities to their respective data receiving authorities for use in evaluating the quality of data submitted for their review and assessment.

Contextualizando...

11. Following initial evaluations, complete cycles of on-site evaluations of all GLP Monitoring Programmes in the framework of MAD will generally be carried out every ten years. The Working Group may decide, on a case by case basis and following a particular initial evaluation or periodic re-evaluation, on reduced interval (see Paragraphs 7 and 57 - 60). (The first round of on-site evaluation visits began in 2008). It is expected that four to five on-site evaluation visits will be held each year.

Summary Record⁹

56. The summary record of the Working Group meeting will report the fact that the on-site evaluation report was discussed and agreed (as amended, if appropriate) e.g. “noted the conclusion of the evaluation team and accepted their recommendation ...”. If no remedial action was agreed, it will state that a) it concluded that the evaluated Monitoring Programme had been found to be implementing the *Revised Guides for Compliance Monitoring Procedures for GLP* and the *Revised Guidance for the Conduct of Laboratory Inspections and Study Audits*, and b) for evaluations of Provisional Adherents, the Joint Meeting will be requested to endorse a recommendation to the Council for the full adherence of the concerned economy to the OECD Council Acts on MAD. If the Working Group found that the Monitoring Programme was not in compliance with the 1989 Council Decision-Recommendation (Part I and Part II, paragraph 1), therefore compromising data acceptance under the provisions of MAD, and agreed that remedial action should be taken, the summary record will state that the report was considered and agreed (as amended, if appropriate) and merely that “recommendations were made and an action plan agreed”.

Avaliação Inicial - 2009

- **1ª avaliação** do Programa Brasileiro da Conformidade aos Princípios das BPL pela OCDE - **Novembro de 2009;**
- Equipe composta por **3 avaliadores** representantes de países membros da OCDE (Nova Zelândia, Portugal e Canadá);

Maio de 2011: Formalização da adesão plena do Brasil aos Atos do Conselho da OCDE relacionados ao MAD (*Mutual Acceptance of Data*) para avaliação da segurança de produtos químicos.

Carta de Formalização da Adesão Plena do Brasil aos Atos da OCDE



Head of Division
Environment, Health and Safety Division
ENVIRONMENT DIRECTORATE

ENV/EHS/DT/jag/2011.244

Paris, 4 May 2011

To: Heads of Delegations to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology

Cc: Working Group on Good Laboratory Practice
Working Group of National Coordinators of the Test Guidelines Programme
Observer Countries
BIAC, TUAC, EEB
ENV Counsellors to OECD Permanent Delegations

Dear Sir/Madam,

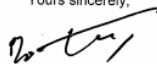
Full adherence of Brazil to MAD Council Decisions

I am pleased to inform you that on 29 March, 2011, Brazil accepted the invitation of the Council to become a full adherent to the OECD Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals and to join that part of the Chemicals Programme related to MAD, with all of the rights and obligations of member countries. This means that Brazil – like India, South Africa and Singapore – now takes part as a full Participant in that part of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology that concerns MAD, as well as in the Working Groups on Good Laboratory Practice and of National Test Guideline Co-ordinators.

At present, only non-clinical health and environmental safety test data on *pesticides* (including *biocides*) and *industrial chemicals* generated in Brazil have to be accepted in OECD countries and adhering non-Members, until such time that the scope of Brazil's Compliance Monitoring Programme is broadened to include other types of chemicals (e.g., medical products), or another Brazilian GLP Compliance Monitoring Programme for other chemical products undergoes a successful OECD on-site evaluation visit.

In order for the MAD system to continue to function smoothly, I encourage you to inform all of the receiving authorities in your country of this agreement.

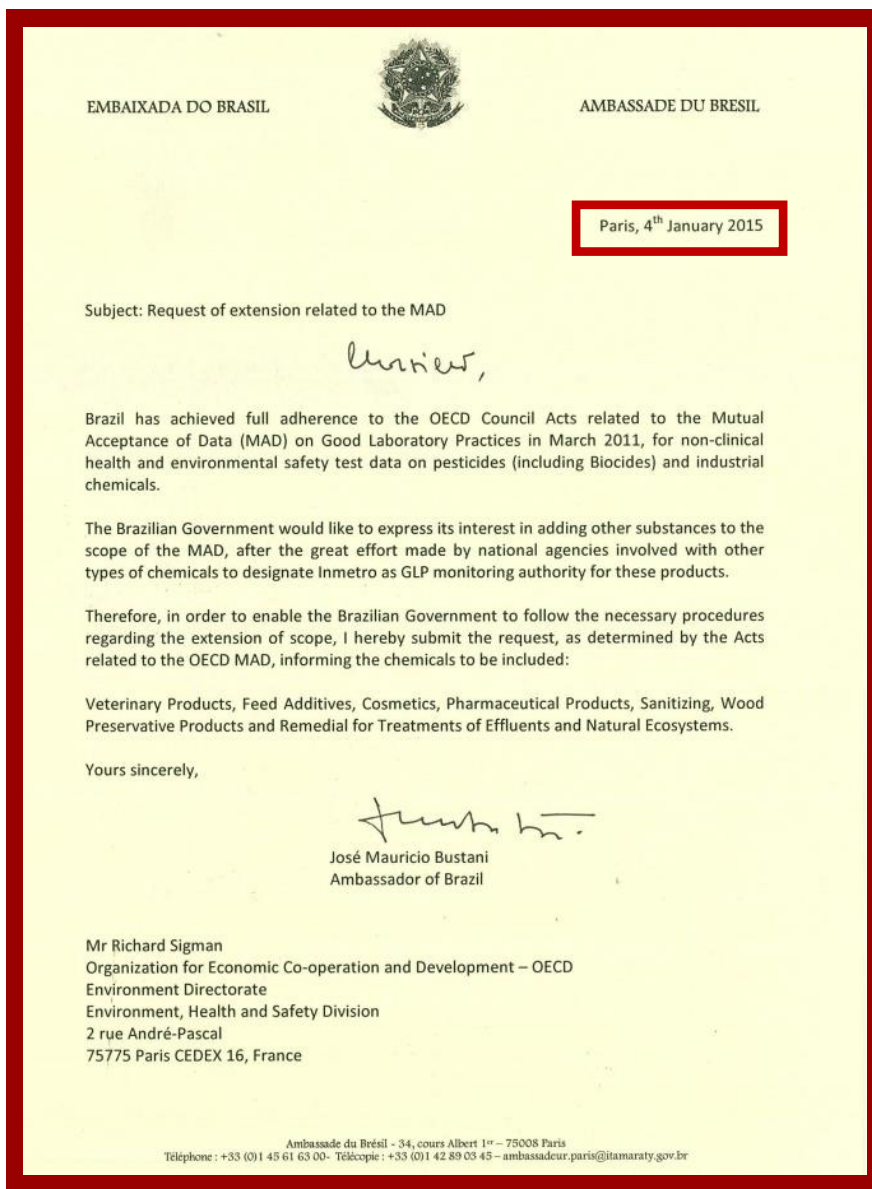
Yours sincerely,



Dian Turnheim

- Agrotóxicos, seus Componentes e Afins
- Produtos Químicos Industriais

Extensão do Escopo do MAD



- Medicamentos Veterinários
- Aditivos de Rações
- Cosméticos
- Produtos Farmacêuticos
- Saneantes
- Preservativo de Madeira
- Remediadores

Formalização da Extensão de Escopo do MAD

Message from Richard Sigman

Fevereiro de 2015

Subject: Brazil - Expansion of scope under MAD

To: Working Group on GLP

As you know, when Brazil accepted the invitation of the Council to become a full adherent to the OECD Council Acts related to the Mutual Acceptance of Data in March, 2011, only non-clinical health and environmental safety test data on pesticides (including biocides) and industrial chemicals fell within the scope of Brazilian GLP Compliance Monitoring Program (INMETRO). That is, only such test data generated in Brazil had to be accepted in OECD countries and adhering non-members.

Brazil has informed us (see attached letter) that the scope of INMETRO'S compliance monitoring programme has now been expanded to also include veterinary products, feed additives, cosmetics, pharmaceutical products, sanitizers, wood preservative products and treatments of effluents and natural ecosystems.

Best regards,

Richard

1ª Avaliação Periódica - 2019

- Período: **1 a 5 de julho de 2019;**
- Equipe composta por **2 avaliadores da OCDE:** Áustria e África do Sul.

From: Kanako.ITO@oecd.org<Kanako.ITO@oecd.org>
Sent: Friday, 07 September 2018 13:49
To: lmalbuquerque@inmetro.gov.br
Cc: ronald.bauer@ages.at; Shadrack Phophi <ShadrackP@sanas.co.za>; Richard.SIGMAN@oecd.org; Christiana.OLADINI-JAMES@oecd.org
Subject: [OECD] Schedule for the On-Site Evaluation visit to Brazil in 2019

Dear Lidian Martins,

I hope all is well with you.

I'm Kanako who has replaced Yukie in OECD.

The OSE visit to Brazil in the 2nd Round will be held in 2019.

I am writing to inform you about a standard schedule for preparation for an OSE visit.
In general, we'll start preparing for the OSE visit before 6 months of the OSE visit as below.

- Before 6 months of OSE: we, the Secretariat, inform host country to prepare and send "latest Questionnaire" and "latest Annual Overview".
- Before 3 months of OSE: host country has to complete the first part of the OSE report, section 0, 1, 2, 3, 4, 5 and 6 and the country send it to the team members.
- Before 2 months of OSE: host country sends all documents to the team members.

If you have decided on whether to hold in June or July, please let us know.

Thank you.

Best regards,
Kanako

1ª Avaliação Periódica - 2019

Ações da Dicla

**6 meses antes - Envio do
Overview e do
Questionário da OCDE
Atualizados**

**3 meses antes - Envio da
Primeira Parte do
Relatório (Seções 0 a 6)**

**2 meses antes – Envio dos Documentos do Programa
BPL/Legislações Aplicáveis (41 documentos revisados
e 31 documentos traduzidos)**

1ª Avaliação Periódica - 2019

Overview

Annual overview of test facilities inspected

Country: BRAZIL

Name of monitoring authority: Brazilian GLP Compliance Monitoring Programme (INMETRO)

Date of submission:

TEST FACILITY	DATE OF INSPECTION	STATUS	NATURE OF INSPECTION	AREA OF EXPERTISE	REMARKS
[Name and full address of test facility]	[<u>mm.yyyy</u>]	[<u>ic/nic</u> /pen/rf <u>p</u>]	[full/re-i/ <u>fac</u> /sa]	[1-8, 9:specify]	(for example: refer to <u>nic</u> notification)

1ª Avaliação Periódica - 2019

Questionário

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

(as revised in 2017)

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 ordinance. 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.

1ª Avaliação Periódica - 2019

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1ª Avaliação Periódica - 2019

Relatório

OECD GLP WORKING GROUP ON-SITE EVALUATION REPORT

Monitoring Programme: Brazilian GLP Compliance Monitoring Programme - INMETRO
(Pesticides, Biocides, Industrial Chemicals, Veterinary Products, Feed Additives, Cosmetics, Pharmaceutical Products, Sanitizers, Wood Preservative Products and Remedial for Treatments of Effluents and Natural Ecosystems)

National Institute of Metrology, Quality and Technology
(INMETRO) / General Coordination for Accreditation (CGCRE)

Address: 416 Santa Alexandrina St., 7th Floor
20261-232 Rio de Janeiro
BRAZIL

Dates of Evaluation Visit: 1st - 5 July 2019

Team Members:

Team Leader: Ronald Bauer
Affiliation: Austrian Agency for Health and Food Safety
Federal Office for Safety in Health Care
Traisengasse 5 | 1200 Wien | Austria

Team Member: Shadrack Phophi
Affiliation: South African National Accreditation System

Observers: n.a.
Affiliations: n.a.

1ª Avaliação Periódica - 2019

Ações da Dicla

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1ª Avaliação Periódica - 2019

Planejamento

**Apresentação do
Programa Brasileiro da
Conformidade aos
Princípios das BPL**

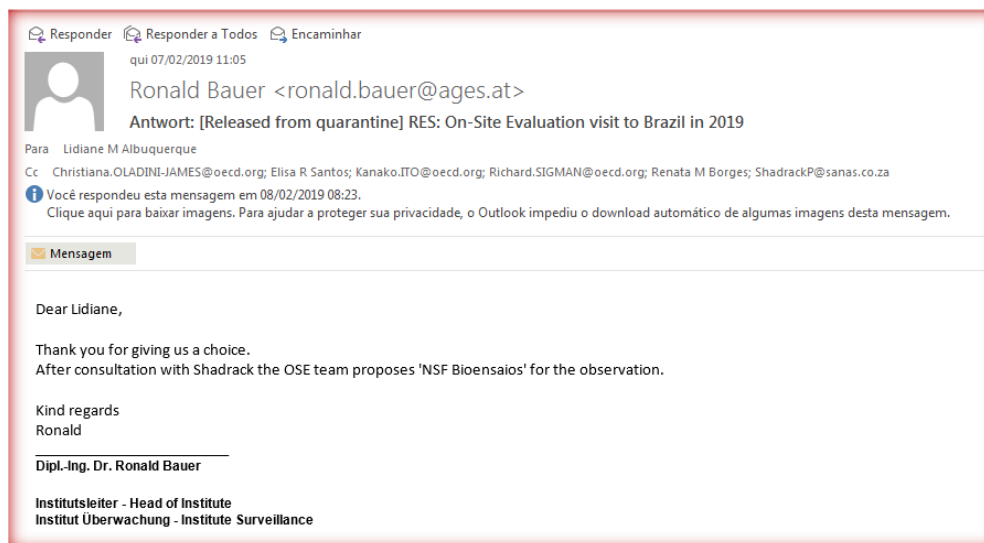


**Acompanhamento de
uma Inspeção BPL em
uma Instalação de Teste**

1ª Avaliação Periódica - 2019

Escolha da Instalação de Teste

- **Programa Anual** de Inspeções Periódicas;
- Diversas **Áreas de Especialidade** / Categorias de Itens de Teste.



1ª Avaliação Periódica - 2019

Agenda

Monday: 1 July 2019 – INMETRO's Office		
9:00 – 9:15	Opening meeting	Aldoney Freire Costa General Accreditation Coordinator Deputy
9:15 – 10:30	Compliance Monitoring Programme	Renata Martins Horta Borges Head, Laboratory Accreditation Division
10:30 – 10:45	Coffee break	
10:45 – 12:30	Procedures for Recognition of Compliance with GLP Principles	Lidiane Martins de Albuquerque Technical Officer
12:30 - 13:30	Lunch	
13:30 - 14:30	Qualification and Training of GLP Inspectors	Dicap (Accreditation Training Division)
14:30 - 17:00	Q&A Session	INMETRO
17:00	Transfer to the airport (Porto Alegre)	
Tuesday: 2 July 2019 Thursday: 4 July 2019	GLP Inspection of the Recognized Test Facility – Bioensaios	
Thursday night (4 July 2019)	Transfer to the airport (Rio de Janeiro)	
Friday: 5 July 2019 – INMETRO's Office		
9:00 – 11:00	Q&A Session	INMETRO
11:00 – 11:30	Coffee break	
11:30 – 12:30	Closed meeting of the evaluation team	
12:30 – 13:30	Closing meeting	INMETRO
13:30	Lunch	

1ª Avaliação Periódica - 2019

Equipe Inspetora

- Edson de Lara (inspetor BPL líder);
- Márcia Terezinha (inspetora BPL);
- Maria Luiza (inspetora BPL).

Tradutores

- Lidiane Albuquerque;
- Waldemar Souza.

1ª Avaliação Periódica - 2019



1ª Avaliação Periódica - 2019



1ª Avaliação Periódica - 2019

Resultados

1. *Summary of evaluation team findings, Compliance Monitoring Programme's response to the findings and team's comments on the response*

Major Deviations

none

Minor Deviations

none

Comments:

INMETRO may consider proactively prompting and soliciting information which might lead to possible conflict of interest or jeopardies independence from its external inspectors especially those that are running their own consultancy businesses

1ª Avaliação Periódica - 2019

Tratamento

Formulário

DADOS DA DEMANDA

Título da Demanda * Dicla - registro de confidencialidade inspetores BPL

Descrição da demanda * Considerando a última avaliação internacional da Cgcre pela OCDE, cabe informar que houve um comentário.
"INMETRO may consider proactively prompting and soliciting information which might lead to possible conflict of interest or jeopardies independence from its external inspectors especially those that are running their own consultancy businesses."

Justificativa da demanda * Acredito que a **Dicap poderia solicitar um novo for cgcre 069 assinado.** Assim, todos os inspetores teriam um formulário mais atualizado e seriam lembrados sobre confidencialidade e potenciais conflitos de interesse. O ponto sinalizado pela equipe da OCDE foi o tempo muito longo de assinatura dos termos (for cgcre 069) por parte dos inspetores. Assim, a Dicap já arquivaria os termos devidamente datados e assinados nas pastas dos inspetores, mantendo-os atualizados.

1ª Avaliação Periódica - 2019

Conclusão

12 Evaluation Team's Recommendation to the OECD Working Group on GLP

The OECD on site evaluation team communicates their conclusions to the Working Group and proposes to acknowledge that the INMETRO GLP compliance programme continues to be in compliance with the guidance in the annexes to the 1989 Council Act.

1ª Avaliação Periódica - 2019

34ª Reunião do Grupo de Trabalho sobre Boas Práticas de Laboratório da OCDE

- Período: **17 e 18/02/2020;**
- **Sendai** / Japão.



1ª Avaliação Periódica - 2019

34ª Reunião do Grupo de Trabalho sobre Boas Práticas de Laboratório da OCDE

Item 11. Report on the GLP Compliance Monitoring Programme of Brazil

Abril de 2020

18. The Working Group considered the report from the on-site evaluation team that had examined the GLP monitoring programme in the Brazil in July 2019. The team leader from Austria presented the report set out in Document [\[ENV/JM/GLP\(2020\)7\]](#) to the Working Group, which heard a response from the monitoring programme visited and had an opportunity to pose questions for clarification. In accordance with the “*Procedures and Processes for Periodic On-site Evaluation of National GLP Compliance Monitoring Programmes*” (endorsed by 50th Joint Meeting), the Working Group noted the report and agreed that it concluded that the evaluated Monitoring Programme had been found to be implementing the Revised Guides for Compliance Monitoring Procedures for GLP and the Revised Guidance for the Conduct of Laboratory Inspections and Study Audits. The Working Group was also informed that the appropriate cover page would be added to the report by the Secretariat, that the report should be used by members only, and that only the evaluated monitoring programme could make the report available to the public if they wish.

Manutenção da Autoridade de Monitoramento Brasileira no MAD

2ª Avaliação Periódica - 2029

KEEP CALM
AND
AGUARDE: CENAS DOS
PRÓXIMOS
CAPÍTULOS

Obrigada!!

Imalbuquerque@inmetro.gov.br

