

IMPACT: “Acquis communautaire” audits

Checklist – EU laws on chemical products
Sofia, June 2008

*Mr. Luc Van Looveren
Senior Advisor EU relations
Voka – Chamber of Commerce and Industry Antwerp - Waasland*



With the support of the European Commission



Checklist

CHEMICAL PRODUCTS

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.2. Cosmetics

I.3. Pharmaceuticals

I.4. Fertilizers

II. Obligations for all kinds of chemical products

II.1. Packaging and packaging waste requirements for all kinds of chemicals

II.2. Good laboratory practice

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.1. Classification, labelling and packaging of dangerous substances and preparations (Dir. 1967/548/EEC, Dir. 1999/45/EC and Reg. 1354/2007)

Introduction:

- *in 1960s national provisions of the six Member States on chemicals differed widely and thus hindered Community trade;*
- *a need to ensure the protection of public health, in particular the health of workers handling dangerous substances;*
- *adoption of Directive 67/548/EEC to approximate the national provisions relating to dangerous substances.*

I.1.1. Classification, labelling and packaging of dangerous substances and preparations (Dir. 1967/548/EEC, Dir. 1999/45/EC and Reg. 1907/2006)

Definitions

Substances: chemical elements and their compounds as they occur in the natural state or as produced by industry

Preparations: mixtures or solutions composed of two or more substances

EINECS: European Inventory of Existing Commercial Chemical Substances

I.1.1. Classification, labelling and packaging of dangerous substances and preparations (Dir. 1967/548/EEC, Dir. 1999/45/EC and Reg. 1907/2006)

Types of dangerous substances and preparations

explosive

extremely flammable

flammable

toxic

corrosive

sensitizing

mutagenic

dangerous for the environment

oxidizing

highly flammable

very toxic

harmful

irritant

carcinogenic

toxic for reproduction

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.1. Classification, labelling and packaging of dangerous substances and preparations (Dir. 1967/548/EEC, Dir. 1999/45/EC and Reg. 1907/2006)

Packaging:

- must prevent any loss of the contents*
- packaging and fastenings must be strong and solid*
- child-resistant fastening*

Labelling:

- name of the substance*
- origin of the substance (name and address of manufacturer, distributor or importer)*
- danger symbols + risk and safety phrases*
- ...*

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.1. Classification, labelling and packaging of dangerous substances and preparations (Dir. 1967/548/EEC, Dir. 1999/45/EC and Reg. 1907/2006)

REACH: All manufacturers and importers must identify and manage risks linked to the substances they manufacture and market .

To do:

- *establish a registration dossier for substances produced or imported in quantities of 1 tonne or more per year per company and submit it to the ECHA*
- *evaluation (e.g. verification that testing proposals do not result in unnecessary testing, especially on animals)*
- *authorisation (aim = to ensure that substances of very high concern are properly controlled, and progressively replaced by suitable alternative substances or technologies where they are economically and technically viable)*

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

- I.1.2. European Inventory of Existing Commercial Chemical Substances (EINECS)
European List of Notified Chemical Substances (ELINCS)
Chemical Abstracts Number (CAS)*

EINECS, ELINCS and CAS numbers and labelling information for specific chemical substances: see website of European Chemicals Bureau

EXAMPLE: BENZENE

Numbers and name

EC# : 200-753-7

CAS# : 71-43-2

Substance Name : Benzene

De : Benzol

Es : Benceno

Fr : Benzène

Molecular Formula : C₆H₆

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

*I.1.2. European Inventory of Existing Commercial Chemical Substances (EINECS)
European List of Notified Chemical Substances (ELINCS)
Chemical Abstracts Number (CAS)*

EXAMPLE: BENZENE

Symbols

Highly flammable



Toxic



I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

*I.1.2. European Inventory of Existing Commercial Chemical Substances (EINECS)
European List of Notified Chemical Substances (ELINCS)
Chemical Abstracts Number (CAS)*

EXAMPLE: BENZENE

Risk and safety phrases

R45: May cause cancer

R46: May cause heritable genetic damage

R11: Highly flammable

R36/38: Irritating to eyes and skin

R48/23/24/25: Toxic, danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed

R65: Harmful: may cause long damage if swallowed

S53: Avoid exposure – obtain special instructions before use

S45: in case of accident or if you feel unwell, seek medical advice immediately

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.3. Export and import of certain dangerous chemicals

(Dec. 2006/730/EC, Reg. 304/2003)

= approval of the Rotterdam Convention

Fundamental principle = PRIOR INFORMED CONSENT (PIC)

A chemical listed in the Convention may only be exported with the importing country's prior consent (notification procedure).

Detailed info on the chemicals must be provided so that decisions may be taken once data are available on the properties and the incidence of these products in particular on human health and the environment.

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.4. Restriction on the use of certain hazardous substances in electrical and electronic equipment (Dir. 2002/95/EC)

= ROHS-Directive

From 1 July 2006 lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs) in electrical and electronic equipment must be replaced by other substances

Example: lead in Printed Circuit Boards (PCBs)

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.5. Plant protection products

1) Prohibited products (Dir. 79/117/EEC)

Aim = to forbid the placing on the market and use of plant protection products containing certain active substances.

Annex includes a list of forbidden substances.

PPPs:

- protect plants against harmful organisms*
- influence the life processes of plants (e.g. plant growth regulators)*
- preserve plant products*
- destroy undesirable plants*
- destroy parts of plants, check or prevent undesired growth of plants*

Active substances = substances or micro-organisms including viruses having general or specific action against harmful organisms or on plants, parts of plants or plant products.

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.5. Plant protection products

2) Placing on the market of plant protection products (Dir. 91/414/EEC)

Uniform rules on the:

- evaluation,*
- authorisation,*
- placing on the market and*
- control*

*within the EU of plant protection products and the active
substances they contain.*

*Annex I: list with **authorized active substances***

*Annex IV and V: **Risk and Safety phrases***

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.6. Asbestos (Dir. 87/217/EEC)

*The concentration of asbestos emitted through the discharge ducts into the air during use of asbestos should not exceed a limit value of 0.1 mg/m³
(= milligrams of asbestos per m³ of air discharged).*

Exemptions possible for plants emitting less than 5000 m³/hour total gaseous discharges.

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.7. Cadmium (Dir. 83/513/EEC)

This Directive lays down:

- **Limit values** for emission standards for cadmium in discharges from industrial plants*
- **Quality objectives** for cadmium in the aquatic environment (Annex II)*

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.8. Hexachlorocyclohexane (Dir. 84/491/EEC)

This Directive lays down:

- **Limit values** for emission standards for HCH in discharges from industrial plants (Annex I)*
- **Quality objectives** for cadmium in the aquatic environment (Annex II)*

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.9. Biodegradability and labelling of detergents (Reg. 648/2004)

The Regulation permits improved protection of the aquatic environment against the surfactants in detergents and other cleaning products (e.g. fabric softeners, dishwashing products).

The legislation has been made more restrictive by including all types of surfactants and imposing stricter testing methods for detergents to determine the ultimate rather than the initial biodegradability.

Manufacturers must list on the **labelling**:

- all components in decreasing order of concentration;
- address of a website where consumers can obtain the list with ingredients;
- allergens – compulsory to indicate on the label any allergenic substance;



I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.10. Eco-label (Reg. 1980/2000)

The eco-label aims to:

- promote products with a reduced environmental impact.*
- provide consumers with accurate and scientifically based information and guidance on products*

Products must meet certain environmental requirements and specific eco-label criteria.

Applications are subject to payment of a fee + annual fee to be paid by user.



I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.10. Eco-label (Reg. 1980/2000)

Product groups for which eco-label criteria have been approved:

- Heat pumps
- Soaps, shampoos and hair conditioners
- Growing media
- Soil improvers
- Lubricants
- All-purpose cleaners and cleaners for sanitary facilities
- Hand dishwashing detergents
- Laundry detergents
- Detergents for dishwashers
- Campsite service
- Tourist accomodation services
- Portable computers
- Personal computers
- Refrigerators
- Washing machines
- Dishwashers
- Televisions
- Light bulbs
- Copying and graphic paper
- Toilet paper, kitchen rolls and other tissue-paper products
- Indoor paints and varnishes
- Bed mattresses
- Textile products
- Footwear
- Hard-floor coverings



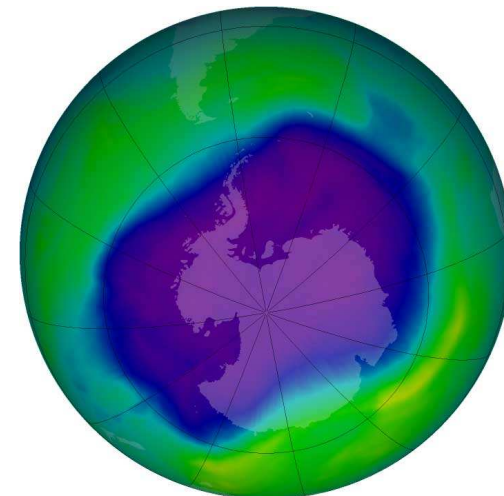
I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.1. Dangerous substances and preparations

I.1.11. Substances that deplete the ozone layer (Reg. 2037/2000)

The regulation lists in Article 3 substances which may not be produced / placed on the market:

- chlorofluorocarbons*
- other fully halogenated chlorofluorocarbons*
- halons*
- carbon tetrachloride*
- 1,1,1-trichloroethane*



I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.2. Cosmetics

I.2.1. Legal requirements (labelling, authorised ingredients, etc.)

Dir. 76/768/EEC

Ingredients/composition:

- list of forbidden substances (Annex II)*
- list of substances with restrictions (Annex III)*
- list of permitted colourings (Annex IV)*
- list of permitted preservatives (Annex VI)*
- list of permitted UV filters (Annex VII)*

Labelling:

- the name and address of manufacturer (or importer, distributor,...)*
- the nominal contents by volume or weight*
- the date of minimum durability (< or > 30 months)*
- particular precautions for use*
- the batch number*
- the product function*



I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.2. Cosmetics

I.2.2. Non-inclusion of one or more ingredients on the list used for labelling of cosmetic products (Dir. 95/17/EC)

This Directive sets out the procedure for requesting the non-inclusion of an ingredient of a cosmetic product for reasons of trade secrecy.

Period of validity: 5 years (which may be extended by 3 years)

1. Technical, labelling and packaging rules in the EU for different groups of chemical products

1.2. Cosmetics

1.2.3. Prohibition of animal tests for ingredients or combinations of ingredients of cosmetic products

The Cosmetics Directive foresees a regulatory framework with the aim of phasing out animal testing.

*= testing ban on finished cosmetic products (since 2004)
and cosmetic ingredients (from March 2009 or March 2013)*



I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.1. Pharmaceuticals for human use: marketing authorisation

Community code – medicinal products for human use (Dir. 2001/83/EC)

Authorisation is needed by the competent authorities of a Member State or by the European Medicines Agency.

Only applicants established in the EU may be granted a marketing authorisation.

In the request:

- the name and constituents of the medicinal product*
- the manufacturing method*
- therapeutic indications*
- contra-indications and side-effects*
- posology*
- method and route of administration*
- expected shelf-life*
- precautionary and safety measures during storage and administration and disposal of waste*
- the risk to the environment*
- etc.*

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.1. Pharmaceuticals for human use: marketing authorisation

Community code – medicinal products for human use (Dir. 2001/83/EC)

Labelling and packaging:

- name of the medicinal product, its dose and pharmaceutical form*
- qualitative and quantitative composition in respect of active substances*
- pharmaceutical form and contents by weight, volume or dose unit*
- method of administration*
- list of excipients, listed in the detailed indications*
- expiry date*
- special storage precautions, disposal of unused medicinal products or waste*
- authorisation number and manufacturing batch number*
- special warnings*

Advertising: strict rules ! (e.g. prohibition of advertising for products available on medical prescription only).

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.2. Good clinical practice in the conduct of clinical trials on medicinal products for human use (Dir. 2001/20/EC)

Article 3 explains under which conditions such trials can take place, especially regarding the protection of clinical trial subjects with special rules for minors and incapacitated adults.

Other topics covered:

- commencement of a clinical trial*
- conduct of a clinical trial*
- exchange of information*
- suspension of the trial or infringements*
- labelling*
- notification of adverse effects*
- notification of serious adverse reactions*
- etc.*

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.3. Guidelines of good manufacturing practice for medicinal products for human use (Dir. 2003/94/EC)

This Directive lays down principles and guidelines of GMP:

- Part I - Basic requirements for medicinal products (quality management, personnel, premises and equipment, documentation, production, quality control, contract manufacture and analysis, complaints and product recall, self inspection)*
- Part II - Basic requirements for active substances used as starting materials*
- Annexes with info regarding manufacture of:
sterile MPs; biological MPs for human use; RadioPharmaceuticals; veterinary MPs;
medicinal gases; herbal MPs; liquids, creams and ointments; investigational MPs; products derived from human blood or human plasma; etc.*

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.4. Orphan medicinal products

Aim = to introduce incentives to develop and market medicinal products for the prevention, diagnosis and cure of rare conditions.

(Ex.: MPs intended for the diagnosis, prevention or treatment of a condition affecting fewer than 5 per 10,000 persons in the EU)

Problem = high cost of pharmaceutical R&D which makes the development of orphan medicinal products uneconomic.

Incentive = exclusive marketing rights for a 10-year period

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.5. Transparency of measures regulating the price of MPs for human use and their inclusion in the scope of national health insurance systems (Dir. 89/105/EEC)

= rules to be respected by Member States when they legislate on the prices of MPs

Example:

If marketing of an MP is permitted only after a MS has approved the price, this decision must be taken within 90 days.

In case of a refusal, the grounds of the decision must be given.

Min. once per year a MS must publish the list of the MPs the price of which has been fixed + the prices which may be charged.

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.6. Pharmaceuticals for veterinary use – marketing authorisation

(Dir. 2001/82/EC – Reg. 726/2004)

Community code relating to veterinary medicinal products (Dir. 2001/82/EC):

authorisations are issued by the competent authority of the MS concerned or, where the centralised procedure established by Reg. 2309/93 applies, by the [European Medicines Agency](#).

Any request for authorisation in more than 1 MS = centralised authorisation procedure.

The marketing authorisation is valid for a renewable period of 5 years.

Labelling and packaging: name and composition of the product, “for animal treatment only”, expiry date, batch number and authorisation number, etc.

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.7. Maximum residue limits (MRLs) of veterinary medicinal products in foodstuffs of animal origin (Reg. 2377/90)

This Regulation classifies pharmacologically active substances used in veterinary medicinal products on the basis of their public health implications.

It stipulates the level which is or is not permitted in foodstuffs of animal origin.

In other words it establishes maximum limits for residues of veterinary medicinal products in such foodstuffs.

4 categories of active substances:

- substances for which MRLs have been established (Annex I);*
- substances for which an MRL is not necessary (Annex II);*
- substances for which a provisional MRL may be established (Annex III);*
- substances for which an MRL cannot be established, as they constitute a risk to human health (Annex IV)*

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.8. Medicated feedingstuffs (Dir. 90/167/EEC)

Only authorised medicated pre-mixes may be used to manufacture medicated foodstuffs for animals.

Precise instructions must be given for the utilisation of such foodstuffs.

Producers are responsible for the quality of the products placed on the market.

Packaging must be sealed + specific labelling provisions.

Medicated feedingstuffs may be supplied to stockfarmers only on presentation of a prescription from a veterinarian subject to specific conditions.

Where medicated feedingstuffs are applied to animals intended for human consumption, treated animals must not be slaughtered before the end of the legally stipulated withdrawal period.

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.9. Pharmaceuticals for human or veterinary use – colouring matters which may be added to medicinal products (Dir. 78/25/EEC)

The colouring matters which may be added to medicinal products are listed in Annex I of the Directive of 23/10/1962 about colouring matters authorized in food for human consumption.

No distinction is drawn between colouring matters which colour the mass and the surface of medicinal products and those which only colour the surface.

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.10. Patents for medicinal products (Reg. 1768/92)

Aim = to remedy the current lack of protection for pharmaceutical research offered at national level by the patents system.

*Under the current system the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the product on the market makes the **period of effective protection under the patent insufficient to cover the investment put into the research.***

*Under this Regulation, holders of both a patent and a certificate must be granted a maximum of **15 years' protection** from the time the medicinal product in question receives marketing authorization.*

*The certificate may not be granted for a period of more than **5 years**. Certificate applications may be made for products protected by a patent in a MS and which has received marketing authorization as a medicinal product. The regulation sets out the conditions for applying for a certificate.*

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.11. Using of animals for experiments and other scientific purposes (Dir. 86/609)

Aim = to harmonize disparities in national laws regarding the protection of animals used for certain experimental purposes

Application field = use of animals for following purposes:

- development, manufacture and quality, effectiveness and safety testing of drugs, foodstuffs and other substances or products in treating diseases or health problems;*
- protection of the natural environment in the interests of man or animal*

Each MS must prohibit the use of endangered species for experimental purposes.

The Directive lists measures to be taken by MS to protect animals.

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.3. Pharmaceuticals

I.3.12. Convention on the elaboration of a European Pharmacopoeia (Dec. 94/358/EC)

Aim = to harmonize national laws on the manufacture, movement and distribution of medicinal products in Europe by creating a European Pharmacopoeia

Objectives = to harmonize specifications for medicinal substances and to hasten the drawing-up of specifications for the growing number of new medicinal substances appearing on the market

Eur. Pharmac. = made up of monographs which become official standards applicable in the territories of the Contracting States

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.4. Fertilizers

I.4.1. Products which are marketed as fertilizers and designated “EC fertilizer” (Reg. 2003/2003)

This Regulation holds:

- conditions for designating “EC fertilizers”*
- conditons for their labelling and packaging*

Annex I: lists all types of fertilizers which comply with this Regulation with the minimum and maximum content of fertlizing elements (plant nutrients) for each type of fertilizer (nitrogen or phosphorous content, etc.)

A type of fertilizer is designated an “EC fertilizer” if:

- no negative effects on human, animal or plant health and the environment;*
- it is effective;*
- Appropriate sampling, analysis, and if required, test methods are available.*

I. Technical, labelling and packaging rules in the EU for different groups of chemical products

I.4. Fertilizers

I.4.2. Fertilizers containing calcium, manesium, sodium and sulphur (Dir. 89/284/EEC)

This Directive explains under which conditions (e.g. minimum quantities) a declaration may be made of the calcium, magnesium, sodium and sulphur content of “EC fertilizers”.

+ labelling requirements for “EC fertilizers” and the elements they contain.

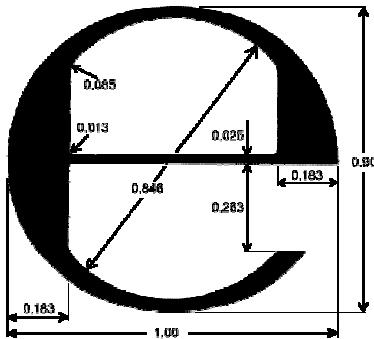
II. Obligations for all kinds of producers of chemical products

II.1. Packaging and packaging waste requirements

II.1.1. Prepackaged products in predetermined quantities (Dir. 76/211/EEC)

Prepackages (between 5 g or 5 ml and 10 kg or 10 l) must indicate on the labelling the weight or volume they contain using a harmonized format.

If products meet the metrological requirements of this Directive, they may also bear the “EEC” mark.



II. Obligations for all kinds of producers of chemical products



II.1. Packaging and packaging waste requirements

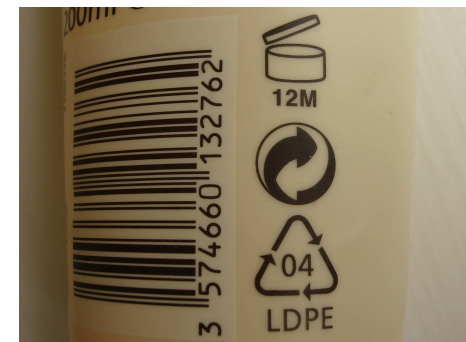
II.1.2. Packaging and packaging waste (Dir. 94/62/EC)

Member States must take measures, which may include national programmes, to prevent the formation of packaging waste and are encouraged to develop packaging reuse systems. Example: Green Dot system.

Target: by no later than 31 December 2008, at least 60 % by weight of packaging waste to be recovered or incinerated at waste incineration plants with energy recovery.

Targets for materials (by end of 2008) contained in packaging waste:

- 60 % by weight for glass, paper and board;
- 50 % by weight for metals;
- 22.5 % by weight for plastics;
- 15 % by weight for wood.



II. Obligations for all kinds of producers of chemical products

II.2. Good laboratory practice (GLP)

II.2.1. Laboratories for non-clinical testing of chemicals

1) GLP: tests on chemical substances (Dir. 2004/10/EC)

This Directive requires MS to take all measures necessary to ensure that laboratories carrying out tests on chemical products, in accordance with Dir. 67/548/EEC, comply with the principles of good laboratory practice (GLP) as laid down in Annex I.

2) GLP: inspection and verification of laboratory studies on all chemicals (Dir. 2004/2009/EC)

MS must organize inspections and checks at laboratories claiming to use GLP.