Strengthening the Administration and Help required for the practical Implementation of EU Regulation (EC) No.648/2004 on Detergents in Bulgaria

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On behalf of the Federal Environment Agency (Germany)

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Strengthening the administration and help required for the practical implementation of EU Regulation (EC) No.684/2004 on Detergents in Bulgaria

Ever since the German-Bulgarian intergovernmental agreement on the cooperation in the field of environmental protection (1993) has been signed, the Federal Republic of Germany has been supporting Bulgaria's implementation of the environmentally relevant EU legal norms and their practical application with the help of various subject-specific bi-lateral and multi-lateral consultations and projects as well as administrative partnerships (Twinning).

The Bulgarian Ministry of Environment and Water (MoEW) prepared a Twinning project for implementing the EC regulation on chemicals effectively and appropriately. Regulation (EC) No. 648/2004 on Detergents is a part of this regulation on chemicals. Unlike the classic regulation on chemicals, the EC regulation on detergents for regulating washing and cleaning agents is a combination of the regulation on chemicals and products. This requires special regulations with respect to market surveillance and enforcement.

For this special problem, two projects were implemented in collaboration with the MoEW for setting up suitable market surveillance and enforcement structures for ensuring effective and proper compliance with the statutory requirements. With a committed, constructive and reliable collaboration with the representatives of the MoEW and intensive discussions with the regional inspectors of RIEW and RIPCPH, in a short time an instrument could be created using this guideline, which facilitates transparent and uniform enforcement of Regulation (EC) 648/2004. This is a suitable example for the practical fulfilment of the market surveillance requirements, which can also be used as a sample for developing administrative regulations in other states or other projects.

An overview of the projects

As part of the first project (2008-2009), the enforcement regulations relevant for the implementation of Regulation (EC) No. 648/2004 were incorporated into an enforcement concept, for whose practical application, market surveillance structures were created as part of the second project (2010-2011).

Since two ministries – the Ministry of Environment and Water and the Ministry of Health – are responsible for monitoring Regulation (EC) No. 648/2004 in Bulgaria, a close coordination between these ministries was required in the second project, since the monitoring of the regulation according to Article 27 of the Bulgarian Chemicals Act is divided between the Regional Inspectorate for Protection and Control on Public Health and the Regional Inspectorate of Environment and Water as follows:

- Regional Inspectorate for Protection and Control on Public Health, RIPCPH: classification, labelling and packaging; specifications on the label (these must be in Bulgarian) and dosage recommendations; data sheet for the medical personnel; manufacturer information on the Internet,
- Regional Inspectorate of Environment and Water, RIEW: checking the biodegradability of the surfactants contained in detergents.

The aim of this second project "Implementation of Regulation (EC) No. 648/2004 in Bulgaria: inspections of washing and cleaning agent manufacturers" was therefore to develop a common administrative regulation by the Health and Environment ministries in the form of a guideline for carrying out inspections as well as for creating standards for analysing substances and exercising their use in practice so as to enable inspections as per a uniform procedure and thus to ensure a high level of environmental protection and human health.

The project was implemented by Dr. Astrid Rohrdanz from the Lower Saxony State Office for Consumer Protection and Food Safety (LAVES) and Dr. Burkhard Wagner (external

consultant) with the involvement of the Federal Environmental Agency and consisted of the following components:

1. Study visit of Bulgarian experts from MoEW, RIEW and RIPCPH to Germany for preparing the guideline (participation in a company inspection among other things),
2. Draft of the guideline for inspections by representatives of the MoEW with support from the German experts,
3. Inspections of two companies by MoEW, RIEW and RIPCPH in Bulgaria with the help of the guideline draft with the involvement of the German experts (pilot inspection, practical test for quality assurance of the guideline draft),
4. Training of the Bulgarian inspectors from RIEW and RIPCPH for using the guideline agreed upon between the Environment and Health ministries.

After the inspection (point 3) of the two companies by MoEW, RIEW and RIPCPH in Bulgaria with the help of the guideline draft, a detailed discussion was held about when a sampling is practical and which test parameters should be selected for an analysis. Hence, a list of the analysis parameters was also compiled, which was supposed to be an Annexe to the guideline for inspections. Furthermore, there arose a need to allocate individual surfactants to the surfactant groups according to Annexe VII a of the 648/2004/EC Regulation as well as compare the OECD degradation tests to the test methods specified in Annexe III of the 648/2004/EC Regulation. These allocations are essential for the necessary inspection of the documents to be submitted, especially point 12 of the safety data sheet.

The knowledge gained while carrying out the inspections was subsequently incorporated into the guideline draft.

Finally, the regional inspectors of the Regional Inspectorate for Protection and Control on Public Health and the Regional Inspectorate of Environment and Water in Bulgaria were trained for using the guideline. Two-day events were organised, from 13:00 hours to 13:00 hours in both the cases, so as to minimise the effort and thus the costs for the regional participants. This ensured comprehensive advanced training of all the Bulgarian regional inspectorates involved in the enforcement. Finally, a documentation containing all the information material (laws, presentations, guidelines, additional material, etc.) was provided on a CD to all inspectors.

Common document creation for supporting the enforcement

In addition to the legal definitions, the guideline created for inspections also contains information for classifying other law sectors as well as four Annexes which, according to the German experts, are helpful in practice:

1. The form of a checklist for a “detergents inspection”,
2. The sample of an English letter from the relevant authority to foreign detergent manufacturers if Regulation (EC) 648/2004 has been violated,
3. A list of the methods for determining the biodegradability according to Annexe III of Regulation (EC) 648/2004 as well as
4. Methods and parameters for the analytical inspection of detergents.

After the guideline was completed, it was officially adopted by the Environment ministry and the Health ministry and released as an administrative regulation.

With this, the project “Implementation of Regulation (EC) No. 648/2004 in Bulgaria: inspections of washing and cleaning agent manufacturers” was successfully completed as interpreted by the Bulgarian and German participants.

Implementation as a sample in other states

The following must be complied with in order to implement the project on a trial basis in other states and/or for using it on a trial basis for other legal provisions:

a) The EC law must first be put into national legislation provided this has not already been done in the relevant state.

b) The enforcement duties must be clearly defined in the national law.

c) The enforcement authorities must be clearly mentioned in the national law.

d) The enforcement duties must be clearly assigned to the respective enforcement authorities.

e) The guideline must then be adapted with respect to the enforcement duties, enforcement authorities, legal definitions, information for classifying other law sectors as well as Annexes.

Annexe: Bulgarian guideline for the implementation of surveillance measures for enforcing the 648/2004/EC Regulation on Detergents

I. GENERAL INFORMATION

Regulation (EC) 648/2004 [1] on Detergents is the basic legal provision of the EU, which introduces specific requirements for detergents. It is valid in Bulgaria since 1 January 2007. The measures for enforcing this regulation are adopted in the Law on Protection from Harmful Impact of Chemical Substances and Preparations (LPHICSP)[2] . In chapter 3 of this law, the ***responsible authority*** is determined as defined by Article 8 (1) of the regulation; a procedure for approving the exceptional requirements about the biodegradability of certain surface active substances (surfactants) (Articles 4-6 and 12 (2) of the regulation) and an administrative procedure about the information exchange between the laboratories which are accredited for testing the surfactants are adopted. In chapter 7 of this law (LPHICSP), the ***surveillance authorities*** are determined who are responsible for the adoption and enforcement of the regulation, and ***administrative and punitive measures*** are adopted, which must be taken if the regulation is not complied with.

Regulation (EC) 648/2004 adopts harmonised requirements with reference to:

complete biodegradability under aerobic conditions of the surface active substances (surfactants) in the composition of detergents;

the restrictions while using surfactants owing to their biodegradability;

the labelling of detergents, including the fragrances that can cause allergies, which include information that should be provided to the end user over the Internet;

the detergent manufacturer's duty to inform medical personnel and surveillance authorities.

Regulation (EC) 907/2006[3] modifies ***Annexe III*** (methods for monitoring the complete biodegradability of surfactants in detergents) and ***Annexe VII (***labelling and data sheet of the components) *of Regulation (EC) 648/2004*. Annexe III contains an additional test guideline for the biodegradability of poorly water soluble surfactants, and Annexe VII specifies the rules for additional labelling and information requirements, which are supposed to be provided to the end user for composition of the detergents, which must be specified on the *packaging* and *on the manufacturer's website*.

Regulation (EC) 551/2009[4] ***modifies the Annexes V and VI*** *of Regulation (EC) 648/2004* as follows – in Annexe V, the first surfactant is entered in the EU, for which an exception in requirements regarding the complete biodegradability is permitted as defined by Article 5, 6 and 12 (2) of Regulation (EC) 648/2004 and the titles of the tables in the Annexes V and VI are specified with reference to the "EC number", which also includes the so-called NLP number (No Longer Polymer) in addition to the EINECS- and ELINCS number. (This includes

[1] Regulation (EC) 648/2004 of the European Parliament and Council dated 31 March 2004 on Detergents (OJ, L 104, pg. 1 dated 8.04.2004).

[2] (*Bulgarian*) Law on Protection from Harmful Impact of Chemical Substances and Preparations, (last mod. SB 63 dated 2010, valid from 13.08.2010) releas. SB. 10 dated 4 February 2000, mod. SB 91 dated 25 September 2002, mod. SB 86 dated 30 September 2003, mod. SB 114 dated 30 December 2003, mod. SB 100 dated 13 December 2005, mod. SB 101 dated 16 December 2005, mod. SB 30 dated 11 April 2006, mod. SB 34 dated 25 April 2006, mod. SB 95 dated 24 November 2006, mod. SB. 82 dated 12 October 2007, mod. SB 110 dated 30 December 2008 (LPHICSP)

[3] Regulation (EC) 907/2006 of the Commission dated 20 June 2006 for modifying the Regulation (EC) 648/2004 of the European Parliament and Council on Detergents, with the aim to adapt it to the Annexes III and VII (OJ, L 168, pg. 5 dated 21.06.2006).

[4] Regulation (EC) No. 551/2009 of the Commission dated 25 June 2009 for modifying the Regulation (EC) No. 648/2004 of the European Parliament and Council on Detergents with the aim to adapt it to the Annexes V and VI (Derogation of surface-active substances-surfactants) (OJ, L 164, pg. 3 dated 26.06.2009).

substances which are no longer valid as polymers according to the seventh modification of the 67/548/EEC guideline from the year 1992).

II. RESPONSIBLE AUTHORITY FOR THE ENFORCEMENT AND SURVEILLANCE AUTHORITIES FOR COMPLIANCE WITH THE REQUIREMENTS OF REGULATION (EC) 648/2004

The regulation prescribes that the member states define a responsible authority that is responsible for the national enforcement of the legal provisions in this sector and maintains contact with the European Commission with reference to information on the enforcement (Articles 8 (1) of Regulation (EC) 648/2004). According to Article 8 of the LPHICSP, the Bulgarian Minister for Environment and Water is the responsible authority as defined by Art. 8 (1) of the regulation.

Article 18 obligates the member states to include requirements for determining the surveillance authorities and the administrative violations and sanctions in their national legal provisions, which are imposed if the regulations are violated. According to LPHICSP, the ***regional surveillance authority for environment and water*** is the authority responsible for monitoring the enforcement of the requirements of Regulation (EC) 648/2004 on the biodegradability of surfactants and detergents containing surfactants (Art. 27 (1) in connection with Art. 25, P. 17) and ***the regional health inspections*** – for the labelling and packaging requirements of detergents and for detergents containing specific surfactants and for provision of information on the detergent composition (Art. 27 (2) in connection with Art. 25, P. 18 and 19).

According to Art. 28 of LPHICSP, the surveillance authorities have the following rights while performing their activity depending on their functional responsibility:

- a free access to the firms and companies which produce detergents and surfactants for detergents and offer them for sale;
- requesting for information and documents;
- sampling for laboratory analyses;
- collection of information about persons who offer detergents and surfactants for detergents for sale, about produced, imported and marketed detergents and about the identity of their suppliers and the downstream users.

III. TARGET GROUP, TO BE MONITORED ACCORDING TO REGULATION (EC) 648/2004

Manufacturer: a natural or legal entity based in the EU that produces a substance within the Union and is responsible for marketing a detergent or a surface active substance (surfactant) intended for a detergent. This especially includes every ***manufacturer (formulator), importer, bottler acting on his own account,*** as well as all persons who modify the properties of a detergent or a surface active substance intended for a detergent, or design or modify the labelling intended for these products. For example, someone who receives washing and cleaning agents and subsequently pre-packages them in his scope and/or re-labels them and/or gives them a new product name is also considered to be a manufacturer. A natural or legal entity that **does not modify** the composition, labelling and/or packaging of

a detergent or a surfactant intended for a detergent**, *is not considered as a manufacturer as defined by this regulation****, unless the entity is an ***importer*** in its capacity.*

It is pointed out that there is a significant difference between the definitions of the "manufacturer" in the EC Regulation 648/2004 and the EC Regulation 1907/2006 (REACH). According to REACH, a manufacturer, as part of Regulation EC 648/2004, can be a manufacturer, importer or downstream user; [5] this affects his specific obligations according to this regulation and the level of information which he has about substances (including surfactants) that he uses while performing his activities.

Distributor: Every natural or legal entity based in the EU, including retailers**,** who stores or distributes substances individually or within a mixture for third countries. For purposes of surveillance, the distributors are a target group but do not have any obligations according to Regulation (EC) 648/2004 as regards the labelling and declaration of the detergent composition which they offer for sale.

IV. DUTIES OF THE MANUFACTURER ACCORDING TO REGULATION (EC) 648/2004

The manufacturers of detergents and surfactants intended for detergents are under obligation:

- to have information about the **results of the tests** ready for determining the biodegradability of surfactants according to a procedure specified in Annexe III of the regulation, about **the type of the procedure used** and **the degree of biodegradability of the surfactants** and provide it if requested by the surveillance authorities;
- to have ready, for purposes of surveillance, **the documentation of the results of the tests carried out** to authenticate the compatibility of surfactants in detergents with the regulation requirements and papers which confirm **the proprietary right to the test results**, which are not available publicly;
- to **immediately and voluntarily** provide a **data sheet about the substances according to Annexe VII C** of the regulation to **every member of the medical personnel** who has confirmed and requested it;
- **to pack and label** the detergents and surfactants intended for the detergents, which they **offer for sale to the consumers**, irrespective of whether they contain surfactants according to the additional requirements for the composition and dosage labelling as per Art. 11 and Annexe VII A and B of the regulation; **to label and pack** them according to the 67/548/EEC guideline *on the classification, packaging and labelling of hazardous substances* and, if applicable, according to Regulation (EC) 1272/2008 (CLP);
- to release information on detergents on the Internet, which they offer for sale to the end user according to Annexe VII D of the regulation, modified by Regulation (EC) 907/2006.

[5] Persons who modify the properties or the labelling and the packaging of a chemical substance (detergent or surface active substance intended as a part of a detergent composition) are manufacturers as defined by Regulation 648/2004 and downstream users according to Regulation EC 1907/2006 (REACH). The processing, handling, filling in containers, decanting from one container into another, etc. are defined as "using" a substance.

The manufacturers of detergents intended for industrial and commercial purposes, which are not offered for sale to the consumers, and for which there are not additional labelling requirements as regards the composition according to Annexe VII A, shall provide the required information to the commercial users via material safety data sheet (MSDS) or information data sheets.

V. DISTRIBUTION OF THE RESPONSIBILITIES OF THE SURVEILLANCE AUTHORITIES ACCORDING TO REGULATION (EC) 648/2004

The measures for enforcing Regulation (EC) 648/2004 are introduced in chapter three of the LPHICSP and the surveillance implementation is regulated in chapter 7 of the law.

According to Art. 25, Pos. 17, 18 and 19 of the LPHICSP, the compliance with the requirements with respect to the biodegradability of surfactants in detergents, the labelling and packaging of detergents and surfactants intended for detergents and the specifications regarding the composition need to be monitored.

The surveillance authorities specified in Art. 27 (1) and (2) of the LPHICSP monitor the enforcement of the requirements of Regulation (EC) 648/2004 in accordance with their authorities, as follows:

1. The Regional Inspectorates for Environment and Water (RIUG-RIEW) check the compliance with the requirements with respect to the complete biodegradability of surfactants specified in Art. 9 (1) and (2) of the EC Regulation 648/2004;

2. The Regional Health Inspectorates (RGI) check the compliance with the requirements with respect to:

- the labelling and packaging of detergents specified in Art. 11 and Annexe VII A of Regulation (EC) 648/2004; in addition to the requirements with respect to the classification, labelling and packaging according to Regulation (EC) 1272/2008 (CLP), if applicable;
- the dosage specifications of the laundry detergents intended for consumers on the label according to Art. 11 (4) and Annexe VII B of the EC Regulation 648/2004;
  - providing information to the medical personnel according to Art. 9 (3) and Annexe VII C of Regulation 648/2004;
- providing information to the consumers according to Annexe VII D of Regulation 648/2004.

VI. PRACTICING THE SURVEILLANCE ACTIVITIES

According to Art. 26 of the law, the surveillance is preventive, continuous and successive. The continuous surveillance is enforced with the execution of:

1) planned inspections on the basis of an annual plan for the surveillance activities;
2) tests, on the basis of complaints or suggestions from physical or legal entities;
3) tests in cases suspected by the relevant authority;
4) tests if requested by another relevant EU authority or a relevant authority of a member state or another country according to the EEA agreement.

The surveillance takes place by means of market checks, or document checks at the manufacturer's site, sampling and/or laboratory analyses. The surveillance is carried out by means of independent or common inspections of the authorities according to Art. 27 (1) and (2) LPHICSP on the market or at the manufacturer's site. While fulfilling their inspection functions, the surveillance authorities prepare reports about the inspection, where they fill out the form according to Annexe 1 of this guideline.

While planning the inspections with respect to fulfilment of the requirements of Regulation (EC) 648/2004, the surveillance authorities define the number of inspections and the firms to be inspected, taking into account the entire workload of the inspectors who are responsible for the surveillance and other aspects of handling chemicals, as well as for the priorities of the surveillance activities (legislation aspects, regulated substances, industry branches, etc.) for the planned period. The priorities of the inspection activities are determined by the health minister and environment minister within their competencies in accordance with the Chemicals Act. The frequency of the inspections can be determined depending on the results of the previous inspections and usually from the conformities of/violations by the companies/firms. While planning the inspection activities, one must strive for coordination with the other authority so as to avoid double inspections of one and the same responsible person and an optimisation of the inspection activities.

The inspection authority gets ready for the inspection of the corresponding company before the inspection. During this preparation, the inspector(s) study(ies) the dossier of the company to be inspected, which is prepared and stored as per the *Guidelines for implementing inspection measures within the scope of Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorisation and restriction of CHemicals (REACH)*. It is determined as to which requirements of the legal provisions shall be inspected and how – in the documents with an on site inspection of the production hall and warehouse, by sampling and subsequent analysis, or a combination of all the techniques specified for the inspection. If there is no or limited information available about the company to be inspected, the surveillance authority requests for the information available on the company inspections carried out by other surveillance authorities, which are important for enforcing the regulation. Within the scope of their inspections, the surveillance authorities combine the specialised inspection in accordance with Regulation (EC) 648/2004 with the finding of conformity with the other legal provisions on chemicals (REACH, CLP, biocide and other regulations as regards LPHICSP), if it is practical.

Depending on the distinctiveness of the company to be inspected, in line with Art. 26 (6) of the Chemicals Act, the inspections of the RIU and RGI can be carried out jointly. During the joint inspections, the individual authorities create separate logs according to their functional competency, in which they describe the facts and conditions found and provide instructions for rectifying the problems found.

For better organisation, the inspection authority/authorities can inform the company/firm about the upcoming plan inspection, except in cases when the inspection is being carried out on the basis of a signal or complaint.

VI.A Checks

While checking the **biodegradability** of surfactants, the **RIEW** experts require the technical documentation and/or the MSDS, which authenticates the degree of complete

biodegradability of surfactants in detergents. The experts can obtain information from the **database of the European Commission on the substances in detergents**, the so-called **DID list**, which contains information on particular tests, including the biodegradability of surfactants used in detergents, and methods for determining the biodegradability according to Annexe No. 4 of the instructions. The DID list is published on the website of the European Commission:
http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf ,

and on the website of the "Chemicals" ministry
http://www.chemicals.moew.government.bg/chemical/site/Pages/detergents.page.

The information in the DID list does not invalidate the manufacturer's obligation to authenticate the biodegradability of surfactants to the surveillance authority in the form of documents. At least this information should be available in the MSDS. The detergent manufacturer is under obligation to ask for this information from his surfactant suppliers in advance.

In this context, the International Association for Soaps, Detergents and Maintenance Products (AISE) and the European Committee of Organic Surfactants and their Intermediates (CESIO) have prepared practical references which they recommend the surfactant suppliers to include in section 12 (details regarding the environment) or section 15 (information according to the valid standard requirements) of the MSDS, with the following texts:

Version 1	Version 2
The surfactant/s included in this mixture fulfils/fulfil the criteria regarding the biodegradability of Regulation 648/2004/EC on detergents. The data confirming this is available to the responsible authorities of the member states and can be provided to them upon their request or that of a manufacturer.	This surfactant fulfils the conditions of biodegradability specified in Regulation 648/2004/EC on detergents. The data confirming this is available to the responsible authorities of the member states and can be provided to them upon their request or that of a manufacturer.

VI. B Analytical inspection

The inspectors of the **RGI** carry out **analytical inspections** of the detergents offered for sale, where they take samples and analyse their composition in laboratories so as to check the conformity with the **labelling** regulations as well as the concentration limit values specified on the label/packaging according to Annexe VII A of Regulation (EC) 648/2004. If a violation is observed on the manufacturer's side in the information on the label, the MSDS of the raw materials, the information data sheet for the medical personnel and the information for the end users, which should be available on the Internet, the RGI inspectors can take samples for laboratory analyses. The samples are taken on the basis of Art. 28 (2) of LPHICSP and according to *Regulation No. 25*[6] *on the conditions and procedures for taking samples and carrying out laboratory inspections, analyses and taking expert opinions, which are necessary for purposes of national health inspections* and are carried out with a method

[6] Regulation No. 25 on the conditions and procedures for taking samples and carrying out laboratory inspections, analyses and taking expert opinions, which are necessary for purposes of national health inspections (released by the health ministry, pub. SB No. 48/15. June 2007)

approved by the Ministry of Health. As a result on the inspection of the technical documentation (MSDS of the raw materials and information data sheet), the labelling and packaging of detergents, and if violation is observed as well as in case of suspected cases, the RGI inspectors can select the **priority parameters for the analytical inspection in line with the guidelines in Annexe No. 4**. Discrepancies in case a violation in the information on the labels and in the MSDS of the raw materials/in the information data sheet and/or on the Internet is observed in the detergents intended for the end user, the target products are determined for the laboratory analysis. In detergents for commercial use, it is advisable to check the MSDS of the corresponding mixture if the information about the composition according to Annexe VII A of the regulation is missing on the label. Parameters for the check are selected depending on the declared composition and the determination of the corresponding detergent.

If violations are observed among the distributors, the inspection authority traces the supply chain so as to find out the detergent manufacturer.

VI C: Procedure for taking samples

For laboratory analyses of detergents, one or two laboratory samples of every produced or imported batch are taken, where a first, an agent and a laboratory sample are taken in succession. If requested by a natural or legal entity, three laboratory samples can be taken – the first two are sent to the RGI laboratory and the third sample is stored in suitable conditions in the firm where it was taken. In cases where two samples are sent to the RGI laboratory, one is properly stored for a re-inspection if it so happens that the results are disputed. The samples are taken in the same manner and the same quantities and packagings as the individual sample and are packed and labelled such that their source remains protected. The sampling is documented in the sampling log according to the form in Annexe No. 1 of Art. 5, Para. 7 of Regulation 25 on the conditions and procedures for taking samples and carrying out laboratory inspections, analyses and taking expert opinions which are necessary for purposes of national health inspections, along with the name of the detergent, the batch number and quantity of the sample taken and is signed by the person who has taken the sample. Three copies of the log are made, from which one copy remains with the person who has offered the detergent for sale, and one each with the surveillance authority and the RGI laboratory where the inspection is carried out. One copy is sent back to the person who had taken the sample, and the other is stored in the RGI together with the sample and the logs of the laboratory inspection. The samples are processed, inspected or analysed using methods according to BDS, EN, ISO or other international standards or validated and verified methods, which are specified as methods of accredited laboratories of the RGI. A log is issued for the results of the laboratory inspections carried out and a certificate is issued for the inspection in the accredited RGI laboratory. Every inspection certificate contains an inference regarding the conformity or violation of the sample as compared to the statutory requirements. The log and the inspection certificate of the laboratory tests are handed over to the inspector who has taken the sample, the relevant person or his authorised representative against receipt. Within three working days of receiving the results of the laboratory inspection, the relevant person can appeal against it in writing to the superior of the national health inspector through the RGI Director.

The laboratory inspections of the samples taken for purposes of public health inspections are charged to the RGI. The laboratory inspections of samples requested by natural and legal

entities of the firms which produce, treat, store and distribute cleaning agents must be paid by these entities. If a violation of the instructions on labelling/packaging is ascertained as a result of the analysis, those responsible for this pay the costs for the analyses carried out according to Art. 28 (5) of the LPHICSP.

VI.D Inspection log

For every surveillance of a company/firm in the scope of application of Regulation (EC) 648/2004, the surveillance authorities create a log, which is signed by the relevant entity who has carried out the inspection, and by a representative of the company/firm. In the confirmatory part of the log, the surveillance authority enters all the facts and conditions ascertained during the inspection. If any violations are ascertained, binding instructions for their rectification are specified along with a deadline and the person responsible for their implementation is chosen.

The instructions should be written in simple language and clear unambiguous requirements for the obligated person must be formulated. Every instruction should have some requirement. The deadline for the implementation should be realistic, taking into account the time required for the technical implementation. The instructions must not contradict the requirements of the regulation and make any additional demands on the obligated person.

After the completion of the inspection activities in the firm being inspected, the experts document the results of the inspection in a checklist (checklist for inspection) according to Annexe 2 in this guideline, in which they describe the facts ascertained, the prescribed rectification measures and the actions taken and if necessary – determine the priorities for a subsequent inspection of the same firm. The checklists are sent to the Environment ministry via email, and if necessary, to the other surveillance authority. In case of violations or in suspected cases, reports of inspections carried out are sent to the Environment ministry and, if applicable, to the other surveillance authority. The information from the inspections is analysed in the Environment and Health ministry and the results are used for identifying the need for a training of the inspection authority and/or for determining priorities of the inspection activities.

If, during the inspection, a violation of *Regulation (EC) 648/2004* is ascertained or something similar is suspected, for which another authority is responsible, the relevant surveillance authority is informed for the purpose of taking over competent activities, where the facts ascertained during the inspection are listed.

The following surveillance is carried out by the inspectors by inspecting the implementation of the requirements. If any violations are ascertained, administrative penalties or administrative measures within the scope of LPHICSP must be imposed.

According to Art. 27 (4) of LPHICSP, the surveillance authorities are under obligation to not reveal any information (industrial or trade secrets) while performing their duties, which has become known to them during their surveillance activities.

VII. PENALTIES FOR VIOLATIONS OF THE REQUIREMENTS OF REGULATION (EC) 648/2004 AND ADMINISTRATIVE MEASURES

In case of violations of the regulation, the RIEW and RGI Directors are authorised to impose penalties or fines specified in Art. 35 of LPHICSP, or administrative coercive measures according to Art. 32 of LPHICSP. The law prescribes penalties amounting to 1,000 to 40,000 BGN for violation of Regulation (EC) 648/2004.

While awarding the fine/penalty, the severity of the violation, the reasons why it was caused, mitigating/aggravating circumstances and other things must be deliberated. In case of mitigating/aggravating circumstances, the lack or existence of earlier penalties for violations of LPHICSP, the degree of negative effects on the environment and/or human health to be expected, financial damage due to the offence and much more is applicable.

According to Art. 27 (6) of LPHICSP and Art. 18 of Regulation (EC) 648/2004, the Minister for Health or a person authorised by him has the right to order for a recall of the detergent batches from the market or from the end user at the cost of the person responsible for marketing them if there is a risk to the health and safety of persons and a violation of Regulation (EC) 648/2004 is ascertained. This measure is taken as a last resort if all the measures taken are not adequate to prevent or limit the risk to human health.

According to Art. 30 (2) of LPHICSP, the Health Minister and Minister for Environment and Water can, in line with their powers, temporarily ban the marketing of a detergent if there is a reason to assume that despite it fulfilling the requirements of Regulation (EC) Nr. 648/2004 it poses a risk to the safety and health of people and animals or the environment, as well as temporarily require the fulfilment of specific prerequisites.

The administrative coercive measure is imposed on the basis of a justified decision of the Director of the Regional Inspectorate, as prescribed in Art. 33 of the law, and is expressed in the form of a ban on the use, marketing and/or import of the detergent or the surfactant for the detergent, until the cause is rectified, which resulted in the imposition of the measure, where a deadline and the type of its application are defined.

ANNEXES:

Annex 1: Form of the checklist for a detergent inspection

Annex 2: Sample of a letter to the responsible authority in case of violations of Regulation (EC) 648/2004 on Detergents

Annex 3: Methods for determining the biodegradability according to Annexe III of Regulation (EC) 648/2004, modified by Regulation (EC) 907/2006

Annex 4: Parameters for the analytical inspection of detergents

ANNEX 1.

Form of the checklist for a detergent inspection

Name of the inspector:

Surveillance authority:

Date of the inspection:

Name of the inspected firm:

Address of the inspected firm:

Managed by (legal entity)

Represented by …… Tel. ……

with the headquarters of the legal entity

Statute of the inspected company in accordance with Regulation (EC) 648/2004: and name of the detergent, which is the object of the inspection: ……

Inspected duties	**Answer**	**Remarks**
1. Are MSDSs available for all raw materials, compositions and products?	☐ Yes ☐ No ☐ In some cases	
2. Have the used substances/mixtures been classified according to *Regulation (EC) 1272/2008 (CLP)*?	☐ Yes ☐ No ☐ In some cases	
3. Have the MSDSs of the substances and mixtures been prepared in the Annexe II form of *Regulation (EC) 1907/2006 (REACH)*?	☐ Yes ☐ No ☐ In some cases ☐ No	
4. Do sections 12 or 15 of the MSDS contain information about the biodegradability of the surfactant, with the specification with the specification of the biodegradability	☐ Yes ☐ No ☐ In some cases	

process *according to Art. 9 (1) Annexe III of Regulation (EC) 648/2004*?		
5. Has the limit value of the phosphate content in detergents been adhered to?	☐ Yes ☐ No ☐ In some cases	
6. Have the requirements with respect to the labelling of the products, including the requirement for labelling in Bulgarian, intended for the consumers been fulfilled according to Art. 11 and Annexe VII A of Regulation (EC) 648/2004, modified by Regulation (EC) 907/2006?	☐ Yes ☐ No ☐ In some cases	
7. Have the requirements for labelling the fragrances, which can cause an allergy, been fulfilled including the enzymes, the optical bleaching substances, the fragrances, the preservative agents, according to *Annexe VII A of Regulation (EC) 648/2004*?	☐ Yes ☐ No ☐ In some cases	
8. Does the labelling of the disinfectant (biocide) fulfil the requirements of *Regulation 528/2012/EC* and *Annexe VII A of Regulation (EC) 648/2004*?	☐ Yes ☐ No ☐ In some cases	
9. Is a dosage specification of the laundry detergents depending on the water hardness available according to Art. 11 (4) and *Annexe VII B of Regulation (EC) 648/2004*?	☐ Yes ☐ No ☐ In some cases	
10. Does the label correspond to the details in the technical documentation (MSDS/information data sheet)?	☐ Yes ☐ No ☐ In some cases	
11. Is information about the composition of the detergents intended for commercial purposes available in the form of MSDSs or technical information data sheets?	☐ Yes ☐ No	
12. Is the information data sheet which	☐ Yes	

is predetermined for medical experts available?	☐ No	
13. Does the information data sheet fulfil the requirements of Art. 9 (3) and *Annexe VII C of Regulation (EC) 648/2004*?	☐ Yes ☐ No ☐ In some cases	
14. Is a list of ingedients according to Annexe VII D *of Regulation (EC) 648/2004*)? for private consumers available on the Internet?	☐ Yes ☐ No	
15. Does the publicised list of ingredients fulfil the requirements according to Annexe VII D *of Regulation (EC) 648/2004*)*?*	☐ Yes ☐ No ☐ In some cases	
16. Were samples taken? *(If yes, specify in the "Remarks" section the requirements for which a sample was taken, followed by an analytical inspection)?*	☐ Yes ☐ No	
17. Was an analytical inspection carried out?	☐ Yes ☐ No	
18. Were violations ascertained on the basis of the inspection carried out? *(If yes, specify in the "Remarks" section as to the requirements against which violations were ascertained)*	☐ Yes ☐ No	
19. Were administrative measures imposed?	☐ Yes ☐ No	
20. If yes, which?	☐ Regulation ☐ Fine/forfeiture of assets according to Art. 35 of LPHICSP ☐ Withdrawal from the market according to Art. 27 (6) of LPHICSP ☐ Temporary ban on the marketing according to Art. 30 (2) of LPHICSP	

ANNEX 2:

Sample of a letter to the responsible authority in case of violations of Regulation (EC) 648/2004 on Detergents

To
Company
Address
Address
Country

Date:
Fax:
Clerk:
Reference number:

Violation of Regulation (EC) No 648/2004 on Detergents

Your product XXXXX

Dear Sir or Madam, in monitoring compliance with the Bulgarian Law on protection against the harmful effects of chemical substances and mixtures (LPHICSP) and Regulation (EC) No. 648/2004 a breach of relevant legal provisions was found for the following product:

Product name:	
Article 11 (2)	The information indicated on the label does not comply with the requirements.
Reasons: The following information is missing from the label: ☐ The name or trade name or trademark and full address and telephone number of the party responsible for placing the product on the market. ☐ The address, email address, where available, and telephone number from which the datasheet referred to in Article 9(3) can be obtained.	
Article 11 (3)	The information according to Annex VII A does not comply with the requirements.
Reasons: ☐ Analytical control of the product showed failure to label the following ingredients: ☐ Analytical control of the product showed errors in the weight percentage ranges indicated for the following constituents:	

<table>
<tr><td colspan="2">☐ A comparison of the label and the information specified in section D of Annex VII showed the following differences:

☐ The required information is not given in Bulgarian.
☐ The website address from which the list of ingredients mentioned in section D of Annex VII can be obtained does not appear on the packaging.</td></tr>
<tr><td>Article 11 (4)</td><td>The information according to Annex VII B for laundry detergents does not comply with the requirements.</td></tr>
<tr><td colspan="2">Reasons:
☐ The required information is not given in Bulgarian.</td></tr>
<tr><td>Annex VII D</td><td>The information according to Annex VII D does not comply with the requirements.</td></tr>
<tr><td colspan="2">Reasons:
☐ The information according to section D of Annex VII is missing on the website.
☐ Access to the website is subject to restrictions or conditions.
☐ The website address is not correct and shows only an error message.</td></tr>
<tr><td>Directive (EC) No. 1999/45 and/or Regulation (EC) No. 1272/2008</td><td>The information on the label does not comply with the requirements.</td></tr>
<tr><td colspan="2">Reasons:</td></tr>
</table>

We ask you to comment on the facts stated above by XX.XX.XXXX (Date)

Sincerely,

For the …..

ANNEX 3

Methods for determining the biodegradability according to Annexe III of Regulation (EC) 648/2004, modified by Regulation (EC) 907/2006

METHODS FOR MONITORING THE COMPLETE BIODEGRADABILITY (MINERALISATION) OF THE SURFACE ACTIVE SUBSTANCES IN DETERGENTS

OECD 310 (EN ISO 14593:1999 CO2-headspace-test) – not less than 60% biodegradability within 28 days

OECD 301 A	Annihilation of the dissolved organic carbon (GOK) – minimum 70% biodegradability within 28 days
OECD 301 B	Carbon dioxide - development test (CO2), modified Sturm test (standard method) – not less than 60% biodegradability within 28 days
OECD 301 C	MITI Test I (standard method) – not less than 60% biodegradability within 28 days
OECD 301 D	Closed bottle test (standard method) – not less than 60% biodegradability within 28 days
OECD 301 E	Modified OECD screening test, annihilation of the dissolved organic carbon – minimum 70% biodegradability within 28 days
OECD 301 F	Manometric respirometry – not less than 60% biodegradability within 28 days
BODIS	ISO 10708 Test (assessing the complete biodegradability under aerobic conditions of the organic compounds in water – Determination of biochemical oxygen demand in a two-phase closed bottle test) – not less than 60% biodegradability within 28 days

ANNEX 4

Parameters for the analytical inspection of detergents

An analytical inspection depends on the following:

product substances
risk from the product
product user

Parameters	***Remarks, preparation***
pH	Liquids: direct measurement, if necessary, (in case of concentrates) dilution of the product (10% or concentration to be used) Powdery: prepare a 10% or 1% solution (depending on the content of alkaline or acidic compounds)
Acidity/Alkalinity:	only if the pH value is < 2 or > 10
Evaporation residue:	for determining the total content of the substances
Surfactants (surface active substances)	Thin layer chromatography as screening (qualitative) Titration for determining the quantity of anionic, cationic and non-ionic surfactants/soaps *Sample preparation*: Liquids: direct measurement (or dilution with ethanol/water 50/50) Powdery: extracting with ethanol; the dilution depends on the details on the label
Preservative agents	High-performance liquid chromatography (HPLC) only for liquids *Sample preparation:* Preparing a 10% solution
Bleaching agents	on the basis of oxygen, on the basis of chlorine *Sample preparation*: Liquids: not required Powdery or tablets: grind/levigate finely Determining the quantity for both the sample types: Titration: Add KJ or H_2SO_4 at the same time
Formaldehyde	Photometry or high-performance liquid chromatography (HPLC) with post-column derivatisation
Solvent	Headspace gas chromatography e.g. alcohol, aliphatic/aromatic hydrocarbons
Fragrances/perfumes	Especially allergenic fragrances which are specified in the list of substances according to Annexe III, Part 1 of the 76/768/EEC Guideline Gas chromatography/mass spectrometry *Sample preparation*: Special process for extraction by stirring