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Enforcement project on biocides 2017-2018

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Summary

Background
In Switzerland, pursuant to the Ordinance on Biocidal Products (OBP), biocidal products may not be placed on the market for private, professional or commercial use unless they are authorised, notified or possess a mutual recognition. These authorisation procedures enable a reduction of the risks associated with the use of biocidal products in order to protect humans, animals and the environment. Currently there are about 4500 biocidal products. A general authorisation requirement has been imposed since 2005.
Routine checks and national and European enforcement projects in recent years have revealed significant shortcomings in the implementation of the requirements defined by the OBP. This is the reason why a country-wide enforcement project was created.

Enforcement project
As part of a control of the national market, 127 biocidal products were evaluated in 2017 and 2018. Compliance of the implementation of the requirements with the decisions defined by the OBP were assessed. In particular, the classification, labelling, the safety data sheet and the labelling requirements for the biocidal products were assessed. Certain product samples were analysed.

Results
The results of the checks showed deficiencies in the safety data sheets, the labelling specific to biocidal products, the labelling of the dangers and the advertised claims. The deficiencies in the safety data sheets are the missing Swiss emergency telephone number, the transposition of the H-phrases in the safety data sheet, also a labelling problem, and the name and concentration of the active substances reported incompletely in more than 20% of the cases. The labelling specific to biocidal products was also incorrect in some cases; in almost 20% of the products the authorisation number was missing or incorrect, and information on the authorisation holder was not correct in 30% of the cases. As regards the statement that must be included in all advertisements for biocidal products “Use biocidal products safely. Always read the label and product information before use”, it was missing in 46% of the investigated products. On the other hand, the product name, the hazard pictograms, the product type, the active substances used and declared were in conformity with the safety data sheet and figured on the product label in more than 80% of the cases.

Conclusions
Checks carried out in 2017 and 2018 led us to realise that the stakeholders in this sector are either not adequately informed or do not take seriously the decisions issued by the authorities which aim to define a framework for the sale and use of biocidal products. Only 12 of the 127 checked products were considered to be fully compliant on the market, and for six products a sales ban had to be issued.

Zusammenfassung

Ausgangslage
In der Schweiz dürfen Biozidprodukte nur in Verkehr gebracht und privat, beruflich oder gewerblich verwendet werden, wenn sie konform mit der Biozidprodukteverordnung (VBP) in Verkehr gebracht werden (Zulassung, Mitteilung oder Anerkennung). Die mit ihrer Verwendung verbundenen Risiken werden durch solche Zulassungsverfahren zum Schutz von Mensch, Tier und Umwelt verringert. Heute gibt es rund 4500 zugelassene Biozidprodukte in der Schweiz. Die allgemeine Zulassungspflicht gilt seit 2005.
Routinekontrollen, aber auch nationale und europäische Kampagnen haben in den letzten Jahren zahlreiche Mängel bei der Erfüllung der Anforderungen nach VBP aufgezeigt. Aus diesem Grund wurde eine landesweite Kampagne lanciert.

Kampagne
2017 und 2018 wurden im Rahmen einer nationalen Marktkontrolle 127 Biozidprodukte geprüft. Es wurde kontrolliert, ob die Anforderungen der Zulassungsverfügungen gemäss VBP rechtskonform umgesetzt wurden. Überprüft wurden die Einstufung, die Kennzeichnung gemäss Chemikalienverordnung, die Sicherheitsdatenblätter und die biozidspezifische Kennzeichnung. Auch wurden bei etlichen Mustern chemische Analysen durchgeführt.

Ergebnisse
Die Ergebnisse der Kontrollen zeigen Mängel bei den Sicherheitsdatenblättern, der biozidspezifischen Kennzeichnung, der Gefahrenkennzeichnung und der Werbung. In den Sicherheitsdatenblättern wurden die Notrufnummer, die H-Sätze - die auch ein Problem bei der Kennzeichnung darstellen - sowie die Bezeichnung und die Konzentration der Wirkstoffe zu mehr als 20 % unvollständig wiedergegeben. Die Mängel bei der biozidspezifischen Kennzeichnung waren ebenfalls erheblich: Bei fast 20 % der Produkte war die Zulassungsnummer nicht oder falsch angegeben und bei 30 % waren die Angaben zur Zulassungsinhaberin nicht korrekt. Der Hinweis, der in der Werbung für jedes Biozidprodukt enthalten sein muss («Biozide vorsichtig verwenden. Vor Gebrauch stets Etikett und Produktinformationen lesen»), fehlte bei 46 % der kontrollierten Produkte. Andererseits waren der Handelsname, die Gefahrenpiktogramme, die Produktart sowie die verwendeten und deklarierten Wirkstoffe im Sicherheitsdatenblatt und auf der Produktetikette zu mehr als 80 % konform.

Fazit
Die 2017 und 2018 durchgeführten Kontrollen haben gezeigt, dass die Akteure im Biozidbereich nicht ausreichend informiert sind oder die behördlichen Zulassungsverfügungen, die einen Rahmen für den Verkauf und die sichere Verwendung von Biozidprodukten setzen, nicht ernst nehmen. Nur 12 der 127 kontrollierten Produkte wurden sind komplett rechtskonform auf dem Markt und bei sechs Produkten musste ein Verkaufsverbot verhängt werden.

Résumé

Contexte
En Suisse, les produits biocides ne peuvent être mis sur le marché pour être utilisé à titre privé, professionnel ou commercial que s'ils sont autorisés, déclarés ou détiennent une reconnaissance mutuelle selon l'Ordonnance des produits biocides (OPBio). Ces procédures d'autorisation permettent de diminuer les risques liés à leur utilisation afin de protéger l'homme, les animaux et l'environnement. A ce jour, il y en a environ 4500. Une obligation générale d'autorisation s'applique depuis 2005.
Les contrôles de routine mais aussi les campagnes nationales et européennes de ces dernières années ont montré de nombreuses lacunes dans la mise en œuvre des exigences définies par l'OPBio. C'est pour cette raison qu'une campagne d'envergure nationale a été mise en place.

Campagne
Dans le cadre d'un contrôle de marché national, 127 produits biocides ont été évalués durant les années 2017 et 2018. La conformité de la mise en œuvre des exigences tenues dans les décisions définies par l'OPBio ont été contrôlées. La classification, l'étiquetage, la fiche de données de sécurité et les exigences d'étiquetage des produits biocides en font notamment partie. Certains échantillons de produits ont été analysés.

Résultats
Les résultats des contrôles indiquent des manquements dans les fiches de données de sécurité, l'étiquetage spécifique aux biocides, l'étiquetage des dangers et l'exécution de la publicité. Pour la fiche de données de sécurité, ce sont le numéro d'appel d'urgence, la transposition des phrases H, également un problème dans l'étiquetage, et la dénomination et la concentration des substances actives qui ont été reportés de façon lacunaire à plus de 20%. L'étiquetage spécifique aux biocides n'était pas en reste ; pour près de 20% des produits, le numéro d'autorisation manquait ou était erroné et pour 30%, les informations concernant le titulaire de l'autorisation n'étaient pas correctes. Quant à la mention que doit contenir toute publicité pour les produits biocides « Utilisez les produits biocides avec précaution. Avant toute utilisation, lisez l'étiquette et les informations concernant le produit. », elle manquait pour 46% des produits contrôlés. D'un autre côté, le nom du produit, les pictogrammes de danger, le type de produit, les substances actives utilisées et déclarées étaient conformes à plus de 80% dans la fiche de données de sécurité et sur l'étiquette des produits.

Conclusion
Les contrôles menés en 2017 et 2018 ont conduit à constater que les acteurs de ce secteur ne sont pas assez informés ou ne prennent pas aux sérieux les décisions émises par les autorités afin de définir un cadre pour la vente et l'utilisation des produits biocides. Seuls 12 des 127 produits contrôlés ont été considérés comme conformes sur le marché et six interdictions de vente ont été émises.

Sintesi

Contesto
In Svizzera i biocidi possono essere immessi sul mercato per l'impiego a titolo privato, professionale o commerciale solo se sono stati omologati, comunicati o se sono l'oggetto di un riconoscimento reciproco secondo l'ordinanza sui biocidi (OBioc). Queste procedure di omologazione permettono di ridurre i rischi legati all'impiego dei biocidi, allo scopo di proteggere l'uomo, gli animali e l'ambiente. Attualmente ve ne sono in circolazione circa 4500. Dal 2005 si applica un obbligo generale di omologazione.
I controlli di routine ma anche le campagne nazionali ed europee di questi ultimi anni hanno rilevato numerose lacune nell'adempimento dei requisiti definiti dall'OBioc. Per questa ragione è stata lanciata una campagna nazionale di vasta portata.

Campagna
Nel quadro di un controllo del mercato nazionale, 127 biocidi sono stati valutati durante il periodo 2017-2018. È stata controllata la conformità dell'adempimento dei requisiti definiti nelle omologazioni previste dall'OBioc. Ne fanno parte, segnatamente, la classificazione, l'etichettatura, la scheda di dati di sicurezza e i requisiti di etichettatura dei biocidi. Ne sono stati analizzati alcuni campioni.

Risultati
I risultati dei controlli indicano delle lacune nelle schede di dati di sicurezza, nell'etichettatura specifica ai biocidi, nell'etichettatura dei pericoli e nell'esecuzione della pubblicità. Riguardo alla scheda di dati di sicurezza, sono stati riportati in modo lacunoso in più del 20 per cento dei casi il numero di chiamata d'urgenza, le frasi H – anch'esso un problema di etichettatura – nonché la denominazione e la concentrazione dei principi attivi. L'etichettatura specifica ai biocidi non era da meno; per circa il 20 per cento dei prodotti, il numero di omologazione mancava o era errato e il 30 per cento delle informazioni concernenti il titolare dell'omologazione non era corretto. Quanto alla menzione che deve recare ogni pubblicità per i biocidi «Usare i prodotti fitosanitari con precauzione. Prima dell'uso leggere sempre l'etichetta e le informazioni sul prodotto.», essa mancava nel 46 per cento dei prodotti controllati. D'altro canto, il nome del prodotto, i pittogrammi di pericolo, il tipo di prodotto, i principi attivi utilizzati e dichiarati erano conformi per più dell'80 per cento sulla scheda di dati sicurezza e sull'etichetta dei prodotti.

Conclusione
Dai controlli effettuati nel periodo 2017-2018 è emerso che gli attori di questo settore non sono stati sufficientemente informati o non hanno preso sul serio le decisioni emesse dalle autorità per definire un quadro per la vendita e l'impiego dei biocidi. Sul mercato, solo 12 dei 127 prodotti controllati sono stati considerati conformi e, d'altra parte, sono stati emanati sei divieti di vendita.

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Overview
1 Context and Issues

In Switzerland, a general obligation to obtain an authorisation for biocidal products exists since 2005.

In recent years routine checks by the cantonal authorities as well as in national and European enforcement projects have revealed numerous problems in this domain[1]. This is the reason why an enforcement project at the national level has been set up. In order to be able to enforce in a fair and broadly based manner, guides and information sheets were distributed to upgrade knowledge and understanding of biocidal products.

On-the-spot checks were carried out at the manufacturers/importers as well as in retailers and at professional users in order to verify that the biocidal products sold or used by professionals had been authorised.

The check of the market of the authorised biocidal products included the classification, labelling, packaging, technical data sheet and the safety data sheet. For some products the identity and the contents of active substances were analysed.

The check must ensure that the products placed on the market comply with the current provisions and that the information required for the appropriate protective measures is available to the user.

2 Legislation

The Ordinance on Biocidal Products (OBP, SR 813.12), the Chemicals Ordinance (ChemO, SR 813.11) and the Chemicals Risk Ordinance (ORRChem, RS 814.81) define the conditions required for placing biocidal products on the market.

With regard to the classification, packaging design and hazard labelling of biocidal products, the OBP refers to the Chemicals Ordinance (ChemO; SR 813.11) that itself makes reference in the majority of cases to the Regulation CLP (EC) No 1272/2008.

Active substances comprised in the biocidal products must be notified[2], included in the list of active substances for a simplified procedure[3] or be approved[4]. Biocidal products may not be placed on the Swiss market for private, professional or commercial use unless they are authorised, notified or possess a mutual recognition according to OBP.

At the Swiss level:
- Ordinance on Biocidal Products (OBP, SR 813.12)

At the European level:
- Regulation on Biocidal Products (BPR, R (EU) No 528/2012)

International agreement:
- Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment (ARM; SR 0.946.526.81)

[1] e.g. Swissbiocides 2011-12, FOPH; Eurobiocides, CLEEN, 2011
[2] Delegated Regulation (EU) N°1062/2014 (review program)
[3] Annex 1, OBP (SR 813.12)
[4] Annex 2, OBP (SR 813.12)

3 Objectives, concept and conduct of the enforcement project

3.1 Objectives

The following objectives have been pursued:

- Reduce the number of unauthorised biocidal products on the Swiss market.
- Ensure that the biocidal products on the market comply with the authorisation decision.
- Ensure that the biocidal products on the market contain only compliant active substances.
- Provide up-to-date information to the enforcement services.

3.2 Concept and conduct

The enforcement project comprises 4 modules:

- Distribution of information to the relevant persons
- Routine checks at the manufacturers/importers
- Checks in retailers and at professional users
- Analytical checks.

The cantonal services have distributed information specific to this topic to the relevant companies. The brochures “Authorisation, sales and use of biocidal products” and “Information obligation in regard to articles that comprise biocidal products” are available in french, german and italian on the website www.organedenotification.admin.ch ->Thèmes-> Législation sur les produits chimiques et guides d'application -> Guides d'application et interprétation de la législation -> Matériel d’information sur les produits chimiques. This module will not be treated further in this report.

In routine checks at manufacturers/importers the cantonal services verify the authorised biocidal products and unauthorised products that claim biocidal activity or that may contain an active substance on the basis of the lists of products.

For the authorised biocidal products (transitional national authorisation, authorisation A_L[5] or recognition according to the harmonised European procedure), the checks are primarily intended to verify the transposition of the facts of the decision (labelling, safety data sheet, packaging, publicity (internet and catalogue)). For some products the active substances and their concentrations will be analysed.

In regard to commercially available biocidal products that do not have an authorisation, they will be evaluated and an authorisation procedure has to be initiated in order that they may remain on the market.

The checks in shops and at professional users principally aim to identify biocidal products placed on the market as chemical preparations.

The following cantonal services for chemical products participated in the enforcement project:
AG, AR, BS, BE, FR, GE, GR, JU, NE, SG, SO, TG, TI, URK, VD, ZH.

3.3 Analytical method

The following active substances have been analysed by ultra-performance liquid chromatography coupled with mass spectroscopy (UPLC-MS):

- carbamates: carbendazim, iodopropynyl butylcarbamate (IBPC)
- isothiazolinones: benzisothiazolinone (BIT), chloromethylisothiazolinone (CMIT), methylisothiazolinone (MIT), octylisothiazolinone (OIT)

[5] In Switzerland, 5 authorisations A_L attributed. None was checked.

- pyrethrinoids and pyrethrins: allethrin, lambda-cyhalothrin, Cypermethrin, cyphenothrin, deltamethrin, empenthrin, imiprothrin, permethrin, phenothrin, prallethrin, pyrethrin I and II, tetramethrin, transfluthrin
- others: acetamiprid, ethyl butylacetylaminopropanoate (EBAAP), piperonyl butoxide (PBO), chlorpyrifos, DEET, dichlofluanid, dichlorovos, diuron, fipronil, methoprene, propiconazole, tebuconazole, terbutryn, *cis*-9-tricosene, imidacloprid.

The active substances were extracted in an appropriate solvent that dissolved them completely (e.g. a mixture of water/methanol, methanol, propanol). After possible microfiltration or centrifugation the measurement solutions were prepared by dilution so as to obtain concentrations of active substances within the calibration range.

Titrimetric analyses were carried out for certain acids and bases used as biocidal products. Acetic acid and caustic soda were thus analysed by pH-metric titration. Hydrochloric acid was analysed by potentiometric titration of the chloride ions (silver electrode) with a solution of silver nitrate. Trichloroisocyanuric acid was analysed with hypochlorous acid (HClO), formed by dissolving the trichloroisocyanuric acid in water, and then analysed by classic iodometry (redox reaction).

4 Results

In this enforcement project 127 biocidal products were sampled and checked.

According to the verification list drawn up for the enforcement project, 91 of the 104 products holding a transitional authorisation have been checked. 7 products have been withdrawn from the market:
- 3 products as a result of the checks,
- 4 products even before the complete check could be carried out by the inspectors.

23 of the products are products authorised by the recognition procedure. These products were sampled abroad at the authorisation holder. They were checked in accordance with the verification list drawn up for the enforcement project.

In the following chapters the results of 84 products with transitional authorisation and 23 recognised biocidal products are compared. The number of biocidal products taken into account can vary for each topic, however, as the verified points are not relevant for all products.

4.1 Analyses

For both biocidal products with transitional authorisation or recognition, analyses have shown differences in concentrations or of identities of active substances from those given in the decisions (Fig. 1). Some concentrations of active substances have been found to be too high as well as lower than the indicated concentrations.

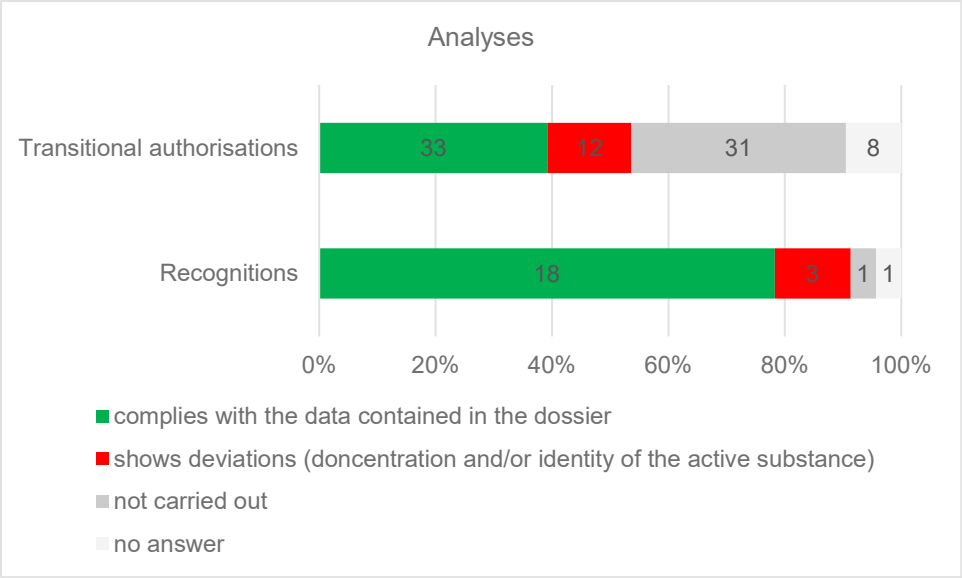

Fig. 1 Comparison of the results of the analytical check with the data of the decision. Comparison of transitional authorisations and recognitions. The results are shown in % and the actual number of products is written in the bars.

4.2 Safety data sheet

The safety data sheet (SDS) is a key element for the transmission of information concerning a dangerous product. Inter alia the SDS provides to the professional or commercial users data on the potential dangers of the product, its physico-chemical, toxicological and eco toxicological properties as well as safety measures to handle it safely (Art. 18 ChemO). For biocidal products the requirements for the safety data sheet are defined in Art. 40 OBP in which it is clearly stated that when the ChemO refers to the manufacturer, it shall be understood to mean the authorisation holder in the sense of the OBP (see Annex 2 REACH).

4.2.1 Safety data sheet: sections 1 to 3

Details of the checks of section 1 of the safety data sheet are shown in Figure 2. Results of the checks on the biocidal products having a transitional authorisation or recognition are compared therein.

Data relating to the address of the authorisation holder, the product name and product type were compared with the data of the decision. They must agree. The results of the checks of the section are similar for products with a transitional or recognised authorisation. Non-compliances with the decision mainly concerned:

- The address of the authorisation holder
- The applications for which the biocidal product is authorised.
- The type(s) of product.

Moreover, the absence of the telephone number of the Swiss poisons information centre is one of the commonest reported deficiencies.

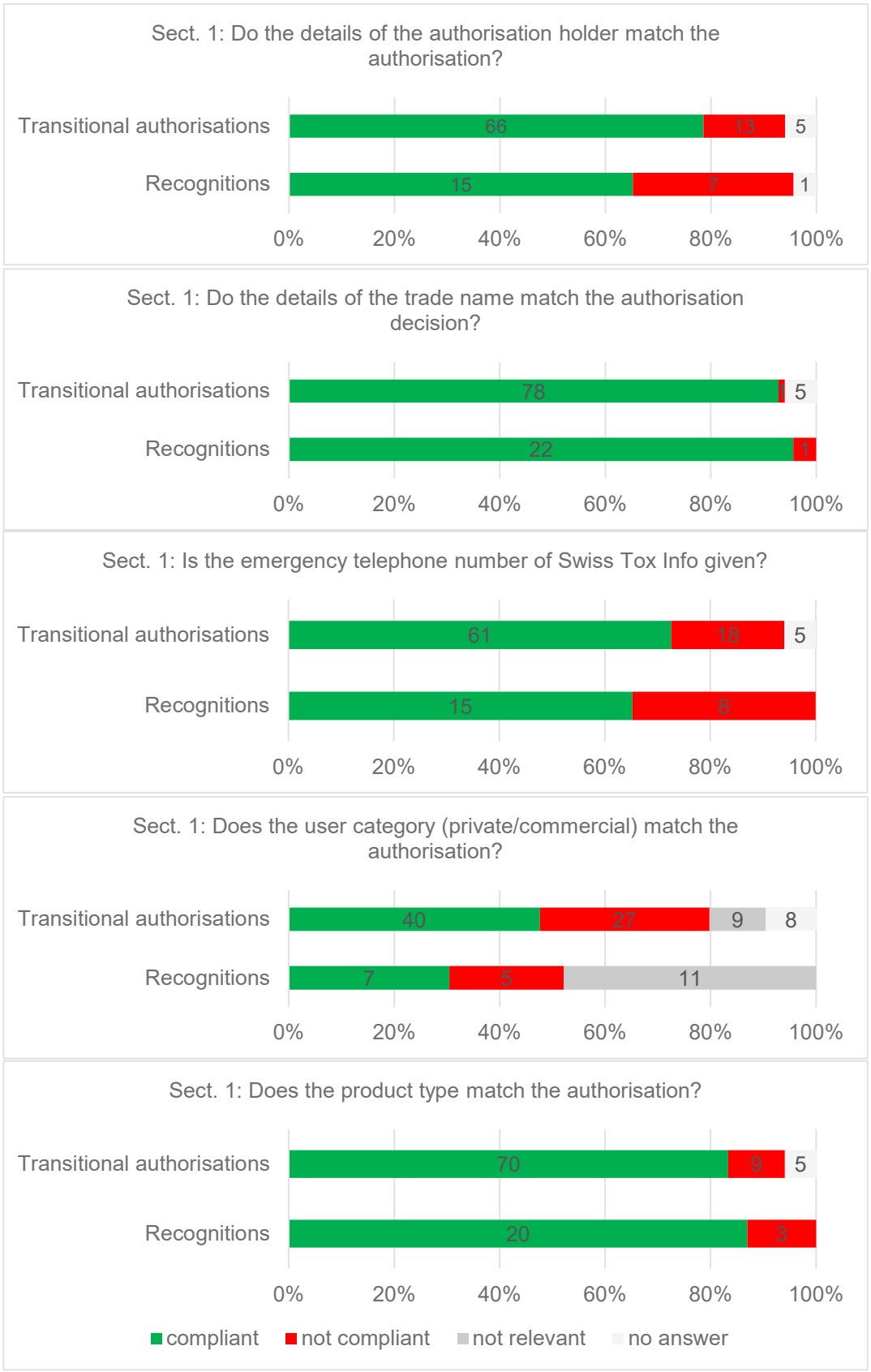

Fig. 2 Verification of section 1 of the safety data sheet. Comparison of transitional authorisations and recognitions. The results are shown in % and the actual number of products is written in the bars.

Detailed results of the checks of section 2 of the safety data sheet are shown in Figure 3. They concern the identification of the hazards.

Labelling elements such as hazard pictograms, the signal word and the hazard statement (H-phrases) are part of the decision. In addition, for the recognitions, the P-phrases are given in the decision; they are the responsibility of the authorisation holders for biocidal products with a transitional authorisation. The information shown in section 2 must be in agreement. For the products with a transitional authorisation the greatest observed difference related to the transposition of the H-phrases. They did not agree with the data of the decisions in more than 25% of the safety data sheets of the checked biocidal products, whereas all were transposed correctly for the recognised products.

The plausibility of the P-phrases was checked. The results showed that the P-phrases were judged to be non-compliant in 20% of the SDS of the products with transitional authorisation. For products with recognition these phrases in section 2 were found to be non-compliant in more than 50% of the cases.

The classification of the biocidal products appeared in section 2 for more than 80% of the checked products, whether biocidal products with transitional authorisation or with recognition.

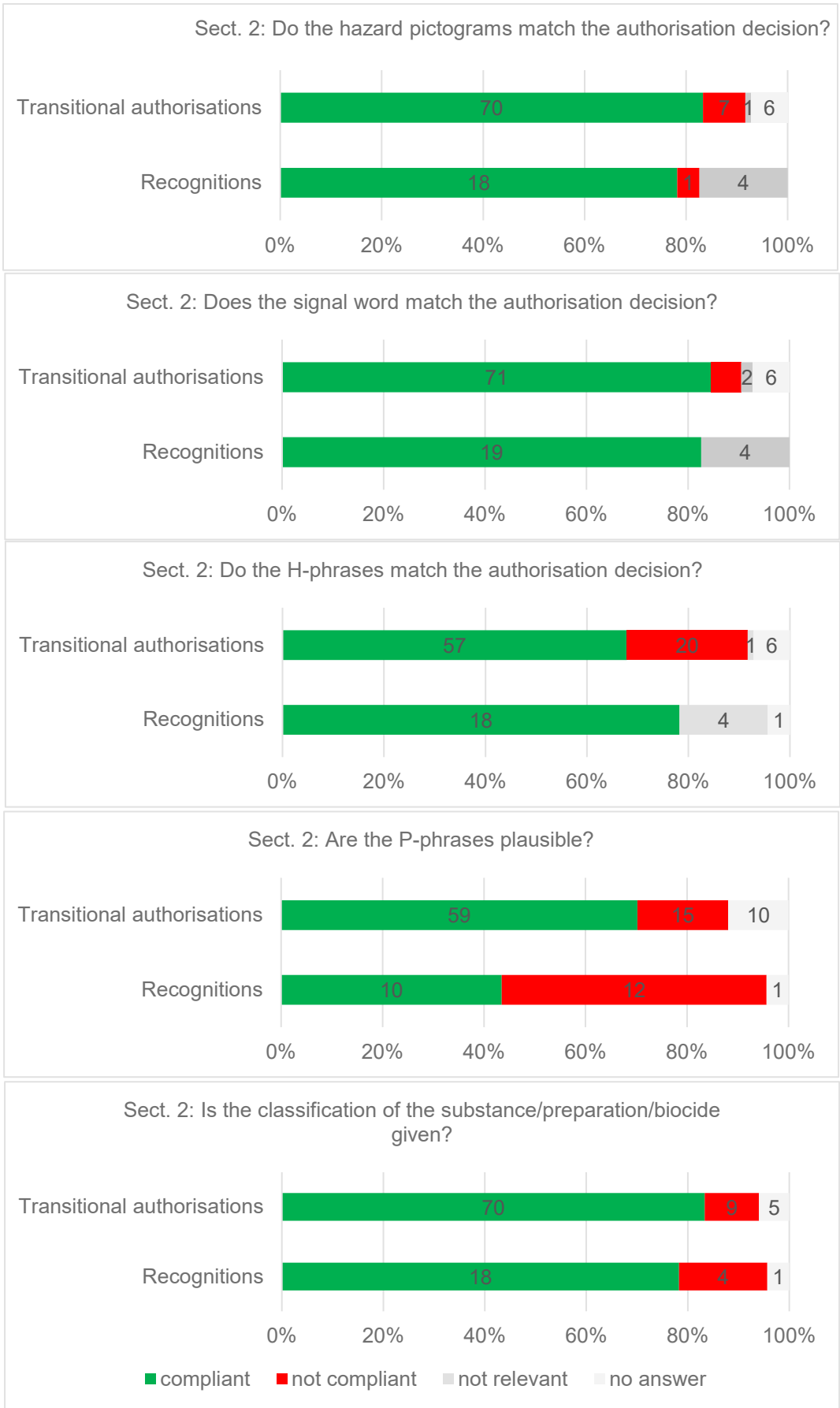

Fig. 3 Verification of section 2 of the safety data sheet. Comparison of transitional authorisations and recognitions. The results are shown in per cent (%) and the actual number of products is written in the bars.

The transposition of the data for the active substances of the decision was also verified (Fig. 4).

The charts show that for 3 biocidal products with a transitional authorisation these data were not correctly transposed. For all the biocidal products with recognition the data corresponded with the decisions.

In regard to the classification and the concentration of the substances given in section 3, they were compliant in approximately 85% of the biocidal products with transitional authorisations. These data were non-compliant in only one biocidal product with recognition.

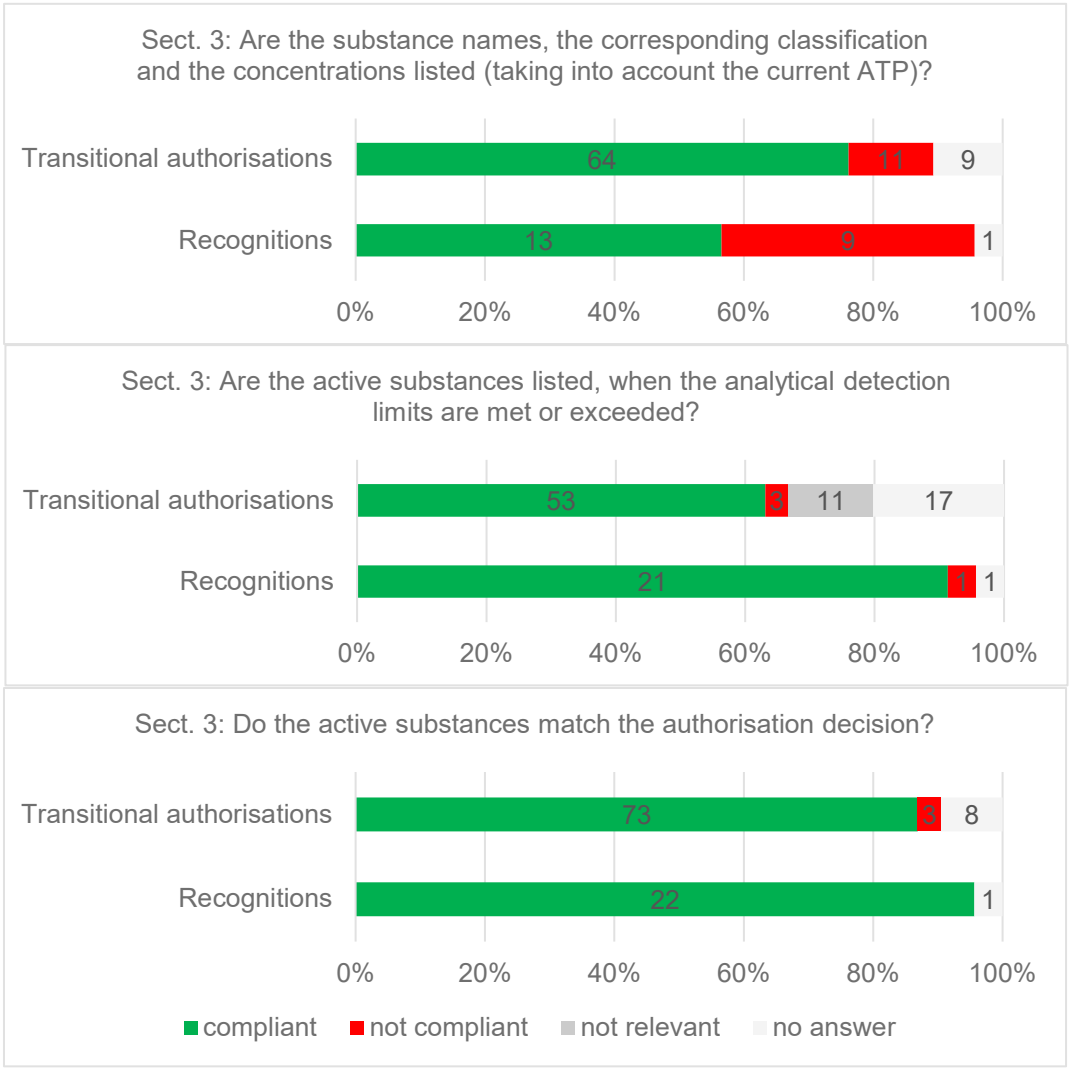

Fig. 4 Requirements relating to section 3 of the safety data sheet. Comparison of transitional authorisations and recognitions. The results are shown in per cent (%) and the actual number of products is written in the bars.

4.2.2 Safety data sheet: Section 13

Results of the checks of section 13 of the safety data sheet relating to waste disposal are shown in Figure 5. The considerations on waste disposal were assessed as non-compliant for 27% of the safety data sheets of the biocidal products with transitional authorisations; for the biocidal products with recognition, in almost the double (52%) of cases the information in this section was incorrect. For example, the indications were solely of a general nature and did not correspond to the specific disposal rules for these products.

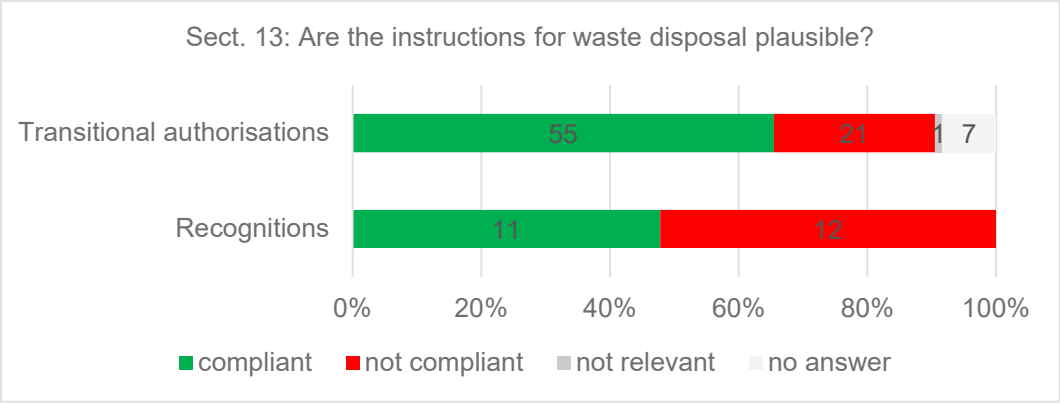

Fig. 5 Requirements relating to section 13 of the safety data sheet. Comparison of transitional authorisations and recognitions. The results are expressed in per cent (%).

4.3 Labelling specific to biocidal products

Checks were carried out in regard to the specific labelling required for biocidal products (Art. 38 OBP; Art. 69 para. 2 RBP); the results are presented in Figures 6 and 7.

The federal authorisation number, the authorisation holder, as well as the identity of the active substances and their concentration are the most frequently reported deficiencies for the transitional or recognised authorisations. Deficiencies were found in all of the labelling requirements specific to biocidal products (Fig. 6).

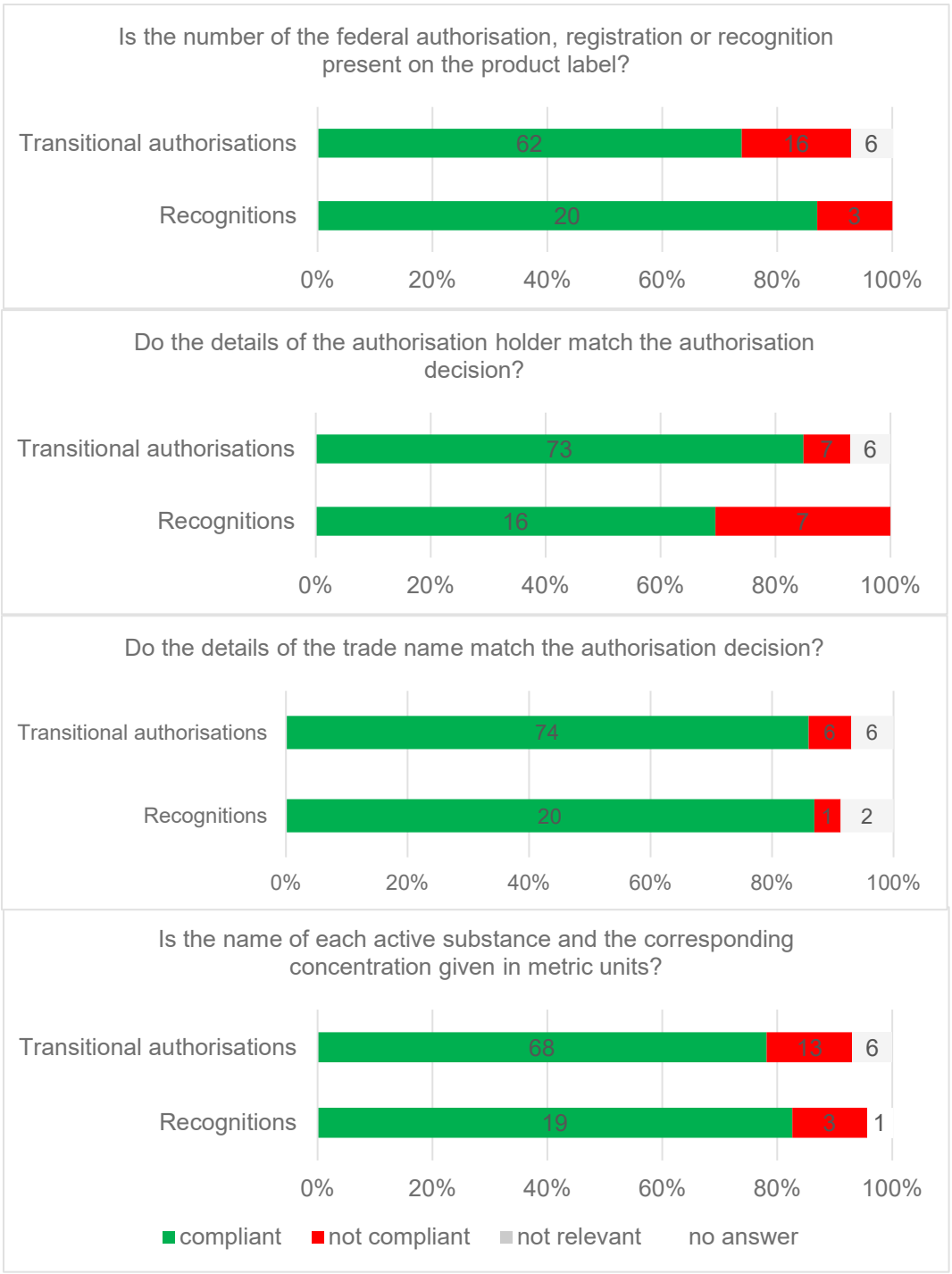

Fig. 6 Characteristics of the labelling according to the OBP. Comparison of transitional authorisations and recognitions. In the Figure the results are shown in per cent (%) and the actual number of products is written in the bars.

The results of the checks of the labelling characteristics presented in Figure 7 show that the applications for which the biocidal product is authorised, and the types of products that are in compliance account for more than 90% of the products with transitional authorisations and recognitions. In contrast, the indications concerning the categories of users are missing or are incomplete in more than 20% of the biocidal products.

The presence on the label of the category of users was judged to be irrelevant in more than 50% of the biocidal products with recognition. In fact, when the product is destined for the general public, it is not obligatory to specify the category of users on the label.

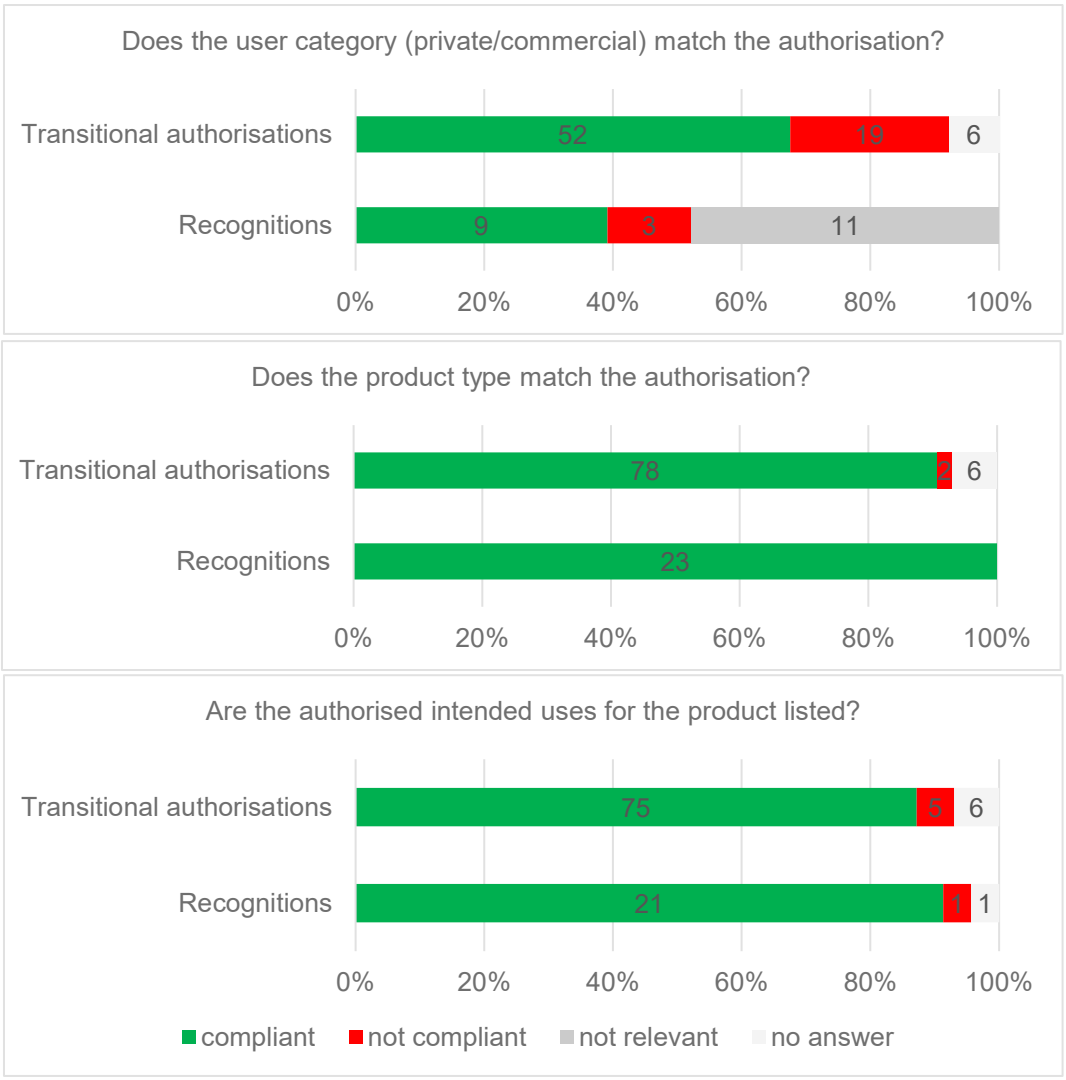

Fig. 7 Characteristics of the labelling according to the OBP. Comparison of transitional authorisations and recognitions. In the Figure the results are shown in per cent (%) and the actual number of products is written in the bars.

4.4 Labelling according to the Chemicals Ordinance

The OBP (RBP) refers to the ChemO (CLP) for the application of certain provisions on labelling.

4.4.1 Language of the labelling

The labelling of the biocidal products shall be written at least in two official languages (Art. 10 al. 3 let. b ChemO; Art. 17 para. 2 CLP). For either the biocidal products with transitional authorisation or with recognition products were not labelled in the two official languages (Fig. 8). The percentage of non-compliance was greater for the biocidal products with recognition (26% versus 15%).

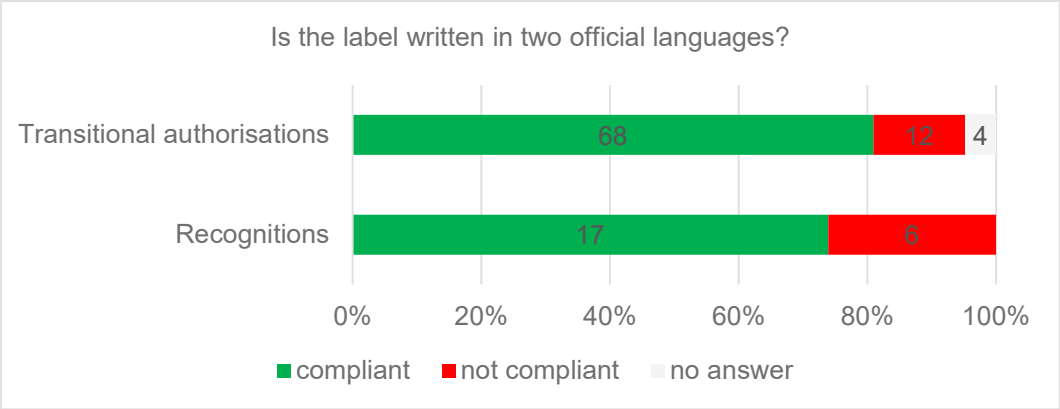

Fig. 8 Languages used for the labelling of the checked products. Comparison of transitional authorisations and recognitions. The results are shown in per cent (%) and the actual number of products is written in the bars.

4.4.2 Labelling of dangers

The dangerous nature of a product depends on the substances comprised therein and their concentration. Hazard pictograms indicate the principal dangers of the product; the hazard statements (H-phrases) describe in detail the inherent hazards of the product (Art. 10 ChemO; Art 17 para. 1 (d-g) CLP). This information, except for the precautionary statements (P-phrases) for transitional authorisations, forms part of the decision and shall be correctly transposed on the label (Art. 20 al. 2, let b, ch. 9 OBP; Art. 22 al. 2, let. i BPR).

The required H-phrases, for example, were missing on 23 of the 79 checked products. With regard to pictograms, precautionary statements and active substances, nearly 90% of the checked products were compliant (Fig. 9).

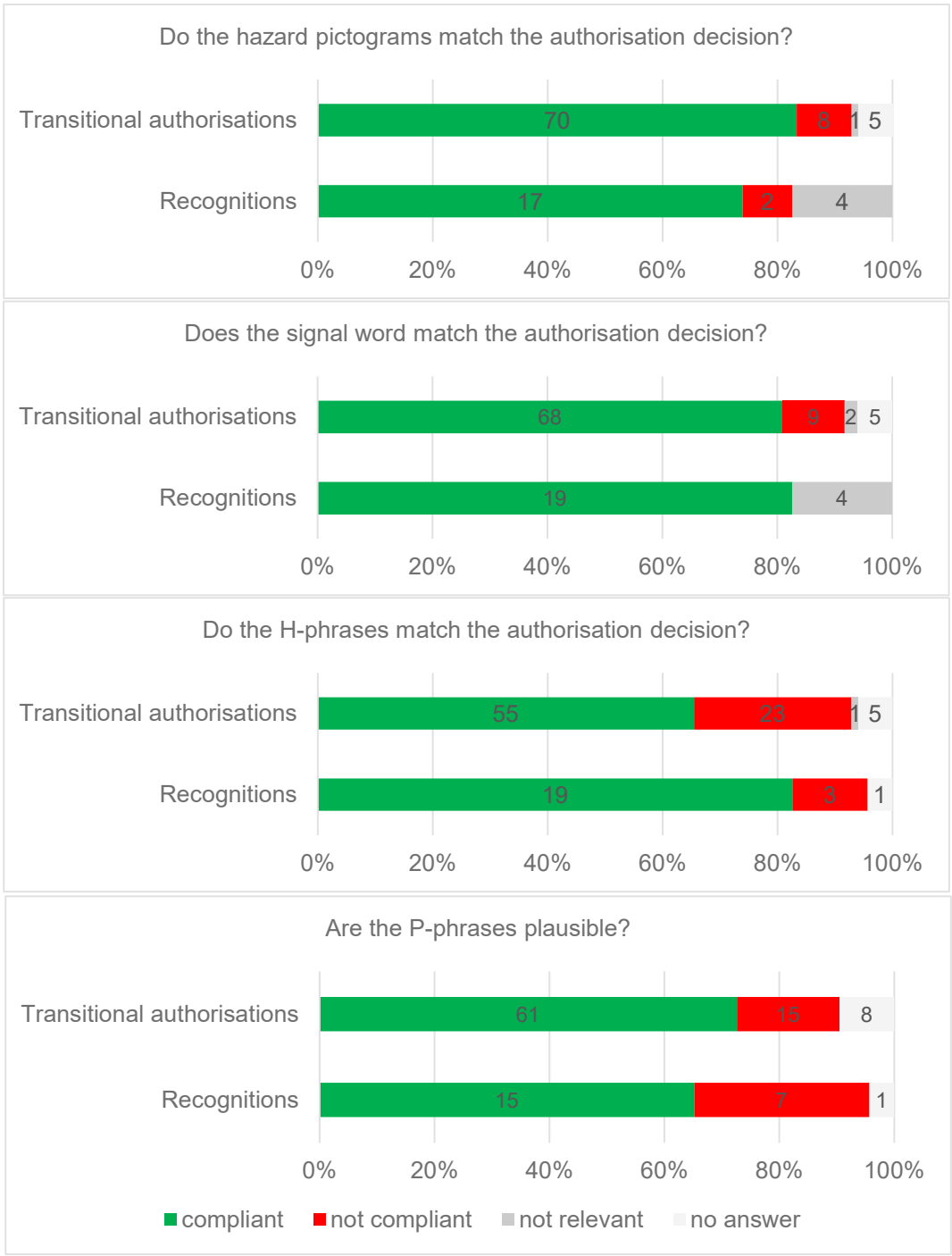

Fig. 9 Labelling provisions for hazards in accordance with the requirements of ChemO. Comparison of transitional authorisations and recognitions. In the Figure the results are shown in per cent (%) and the actual number of products is written in the bars.

4.4.3 Size of the pictograms

The results for the control of the size of the pictograms (Art. 10 al. 1 let. a ChemO; Art 31. Para. 4 CLP) are presented in Figure 10.

The hazard pictograms provide initial information on the dangerous nature of the products. It is important that the pictograms stand out clearly from the background and be of such size and spacing as to be easily read. This requirement could not be verified for all the products. In those products that were checked, 8% of the biocidal products with a transitional authorisation and 17% with recognition were not in compliance.

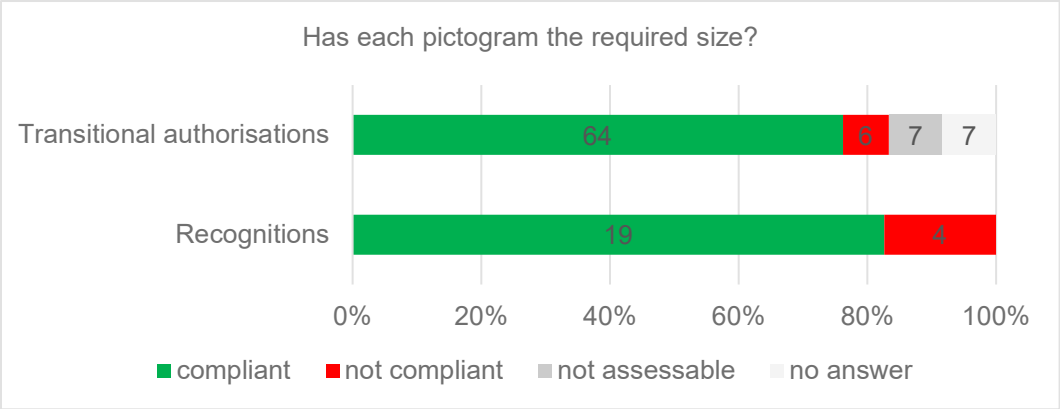

Fig. 10 Provision concerning pictogram size (ChemO). Comparison of transitional authorisations and recognitions. In the Figure the results are shown in per cent (%) and the actual number of products is written in the bars.

4.4.4 Legibility and durability of the label

The label shall be clearly visible, easily read and sufficiently durable (Art. 10 al. 1 let. A ChemO; Art. 34 para. 3 CLP). In general, the labelling was legible and durable (Fig. 11).

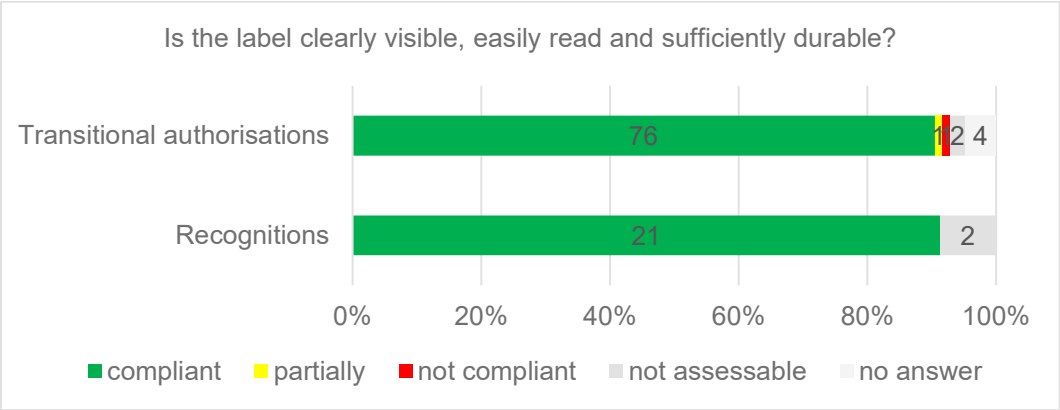

Fig. 11 Legibility and durability of the labelling according to ChemO. Comparison of transitional authorisations and recognitions. In the Figure the results are shown in per cent (%) and the actual number of products is written in the bars.

4.5 Packaging

Packaging containing hazardous mixtures such as biocidal products shall meet requirements to avoid accidents with e.g. children, but also to avoid any confusion with cosmetics, foodstuffs or other types of products (Art. 8 ChemO; Art. 35 CLP).

On the whole, the packaging for the biocidal products complied with the checked requirements. A tactile warning of danger was missing on only four products with a transitional authorisation (5%), and one product could have been confused with foodstuffs (Fig. 12).

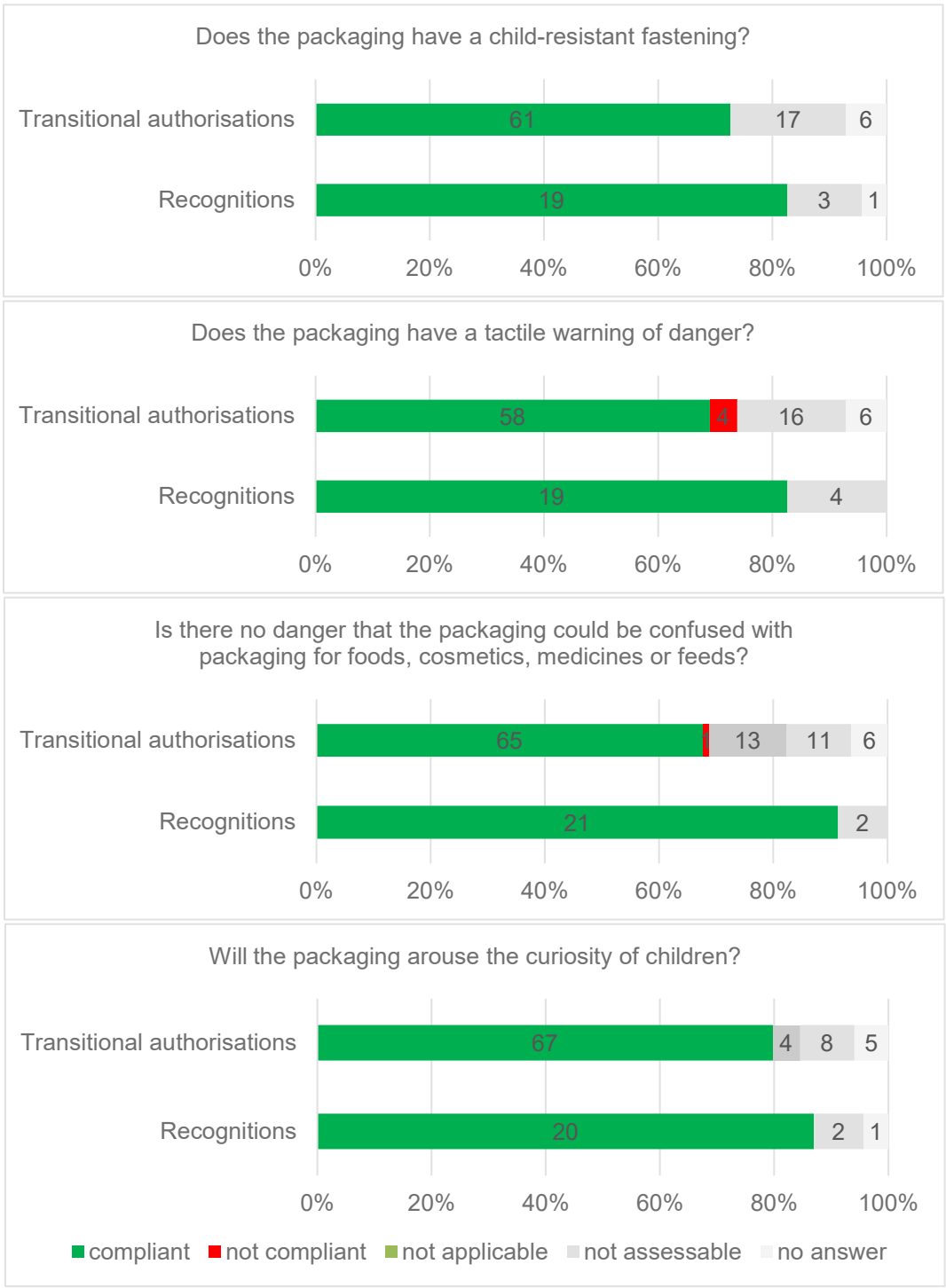

Fig. 12 Characteristics of the packaging according to ChemO. Comparison of transitional authorisations and recognitions. In the Figure the results are shown in per cent (%) and the actual number of products is written in the bars.

4.6 Advertising

Any advertisement for biocidal products shall include the sentences ‘Use biocides safely. Always read the label and product information before use.’ The sentences shall be clearly distinguishable and legible in relation to the whole advertisement (Art. 50 al. 3 let. a and b OBP; Art. 72 RBP). The results of the checks are presented in Figure 13.

The sentences to be indicated on advertisements were not present for 60% of products with a transitional authorisation and for more than 30% of products with recognition. This is one of the most frequent deficiencies.

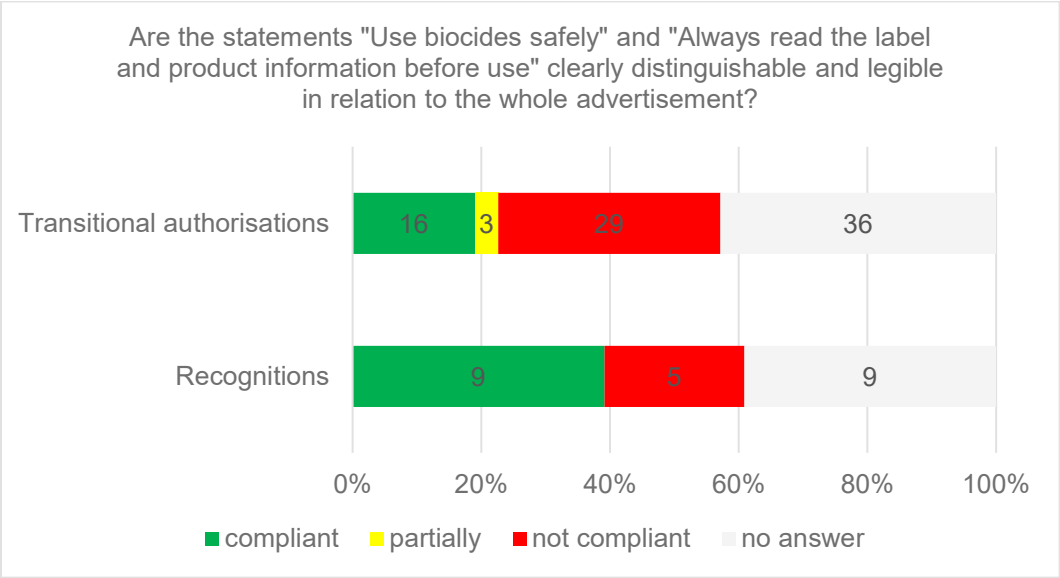

Fig. 13 Verification of advertisements concerning the sentence "Use biocides safely. Always read the label and product information before use". Comparison of transitional authorisations and recognitions. In the Figure the results are shown in per cent (%) and the actual number of products is written in the bars.

In addition, advertisements for the checked products were verified for the presence of the user category, product type and the applications for which the biocidal product was authorised. These data were compared with the data from the decision of the products.

Figure 14 shows that the data corresponded with the data from the decision for most of the checked biocidal products; in only 3 products the user category differed from that given in the decision, and in 2 products the applications authorised for the biocidal products did not agree with those of the decision. The types of products corresponded for all products. For a great number of products these checked points were irrelevant because no advertisement was found.

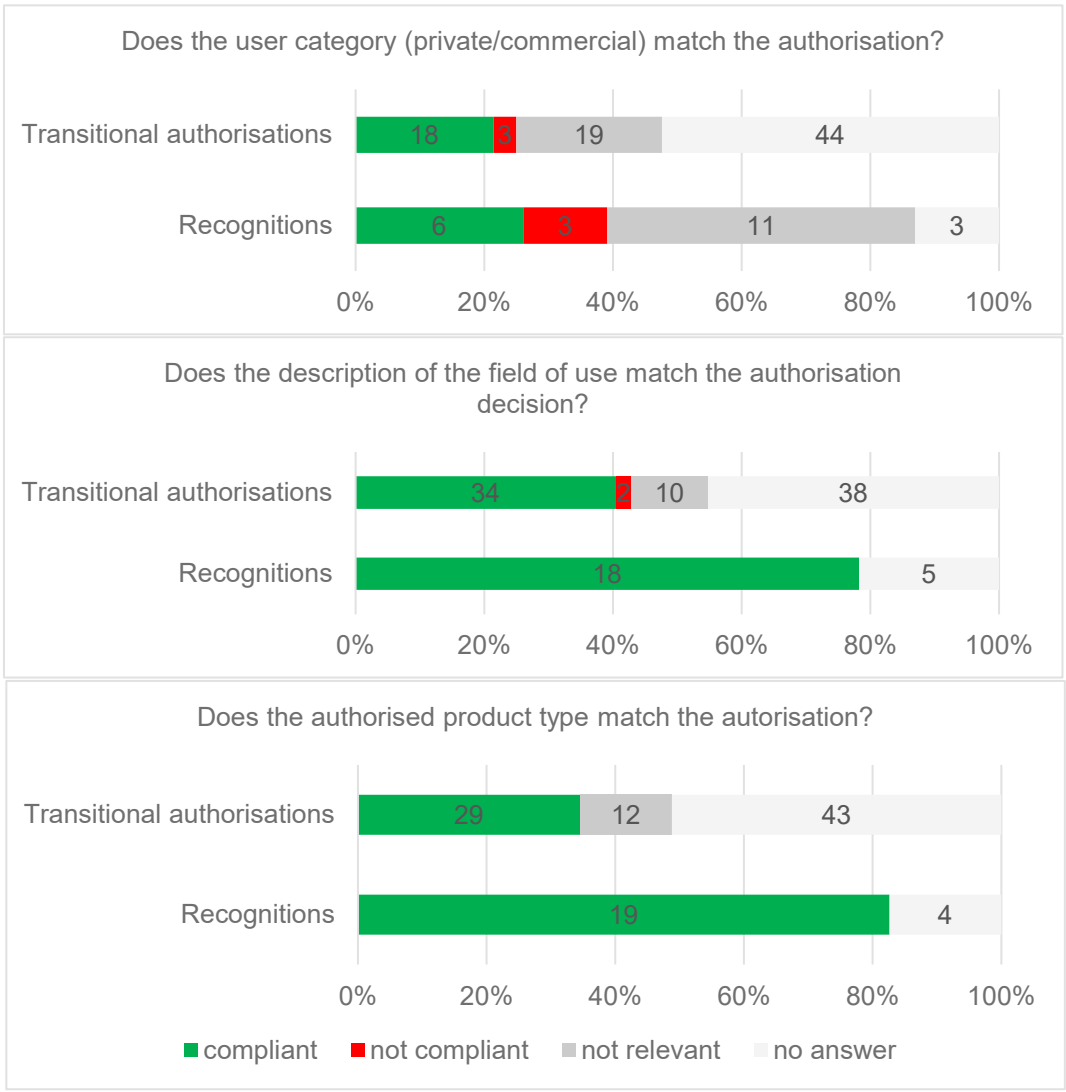

Fig. 14 Verification of the presence of product type, field of application and user category in the advertisement. Comparison of transitional authorisations and recognitions. In the Figure the results are shown in per cent (%) and the actual number of products is written in the bars.

5 Transposition of the conditions

The decision for a transitional authorisation contains, when appropriate:

- additional indications or details in the safety data sheet (Art. 20 al. 3 let. I OBP; Art. 22 BPR).
- additional data (Art. 20 al. 3 let. I OBP; Art. 22 BPR).

This additional information must be transposed on certain product materials (label, SDS, etc.) just like the other points of the decision. The same applies for recognitions (Art. 22 BPR)

The results show that this information, although mandatory, was not included in the label and the SDS for more than 30% of the products with a transitional authorisation. For the SDS of the products with recognition, the conditions were not transposed in 75% of the products (Fig. 15).

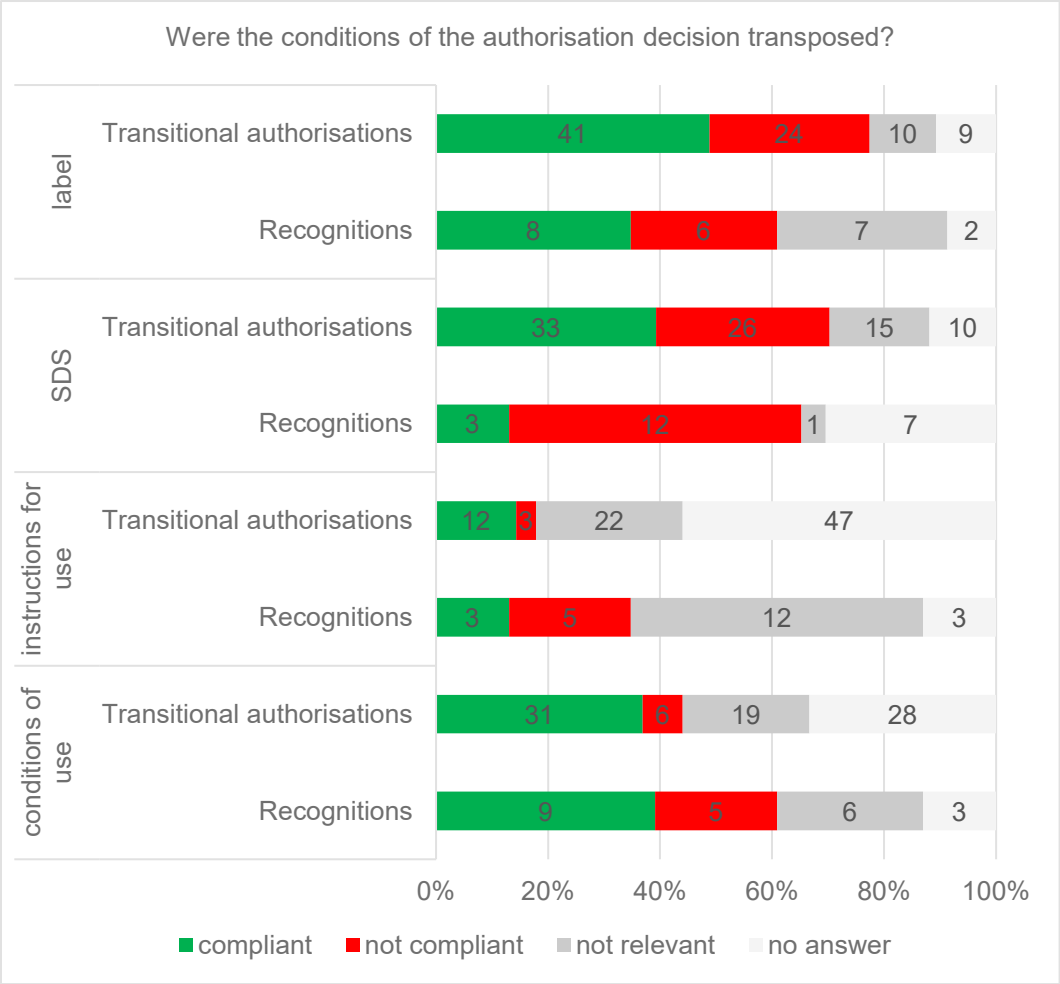

Fig. 15 Verification of the transposition of the conditions. Comparison of transitional authorisations and recognitions. In the Figure the results are shown in per cent (%) and the actual number of products is written in the bars.

6 Banned or restricted substances (ORRChem)

No substance banned in accordance with ORRChem was reported in either biocidal products with a transitional authorisation or with recognition.

7 On-site inspections

7.1 Routine checks at the manufacturers/importers

Based on a list, inspectors evaluated products suspected to be biocidal products (e.g. products containing an active substance, products with a name implying a biocide, products for which the transitional authorisation had been withdrawn, …) in the course of routine checks at manufacturers.

Figure 16 shows that no measure needed to be taken for one third of the products that had been suspected to be biocidal products. The products had already been withdrawn from the market by the manufacturers, the function of the active substance was not biocidal or the product was a treated article. For 1% of the products the biocidal claims had been withdrawn and the products were able to be sold

as preparations. On the other hand, as a consequence of the inspection, one third of the products have been withdrawn from sale. There are a variety of reasons for this, e.g. the products were indeed biocidal products but sold as preparations, or the biocidal products were no longer authorised for sale (transitional authorisation no longer valid) and the manufacturer continued to sell them.

In 7% of the cases the products were evaluated as biocidal products, and to remain on the market an application for authorisation must be made. At the time of editing this report 28% of the products on the list have not yet been checked.

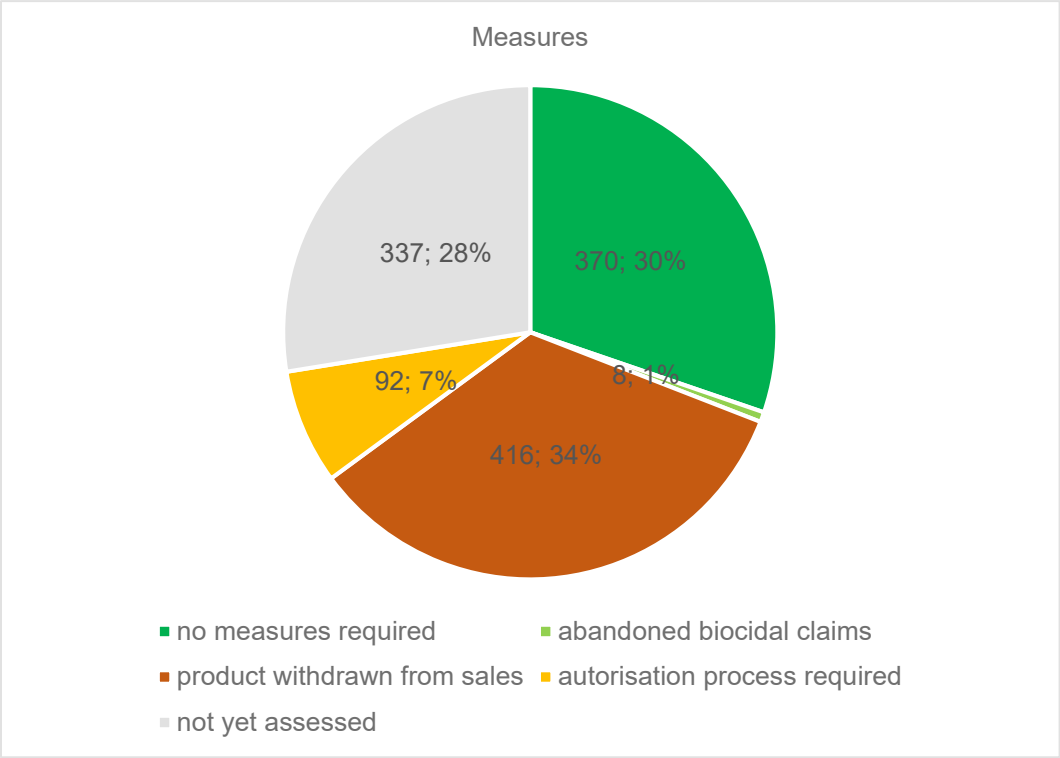

Fig. 16 Measures taken during the checks of the products contained in the list of products suspected to be biocidal products (n=1223).

7.2 Checks in commercial establishments and at professional users

In the inspections of the commercial establishments and at professional users the inspectors checked a total of 1285 products, of which 941 were authorised biocidal products (Table 1).

Of the 941 biocidal products, 263 were found to have flagrant deficiencies. This corresponds to about one fifth of the biocidal products checked in commercial establishments and at professional users.

In regard to the 344 products that were not authorised as biocidal products it was necessary to clarify whether they were biocides or if they fell under another legislation. An application for authorisation will have to be submitted for approximately 60% of the products sold as a preparation.

Table 1 Summary of the checks in commercial establishments and at professional users.

	authorised biocide correct	authorised biocide incorrect (manifest errors)	mixtures, cosmetics, etc. correct as not biocide	mixtures etc. for which an application for authorization must be made	Borderline case to be clarified	Total no. of checked products
Store						
Pharmacy, Druggist	97	14	51	6	6	174
Retail	91	30	21	44	4	190
Building market, DIY, etc.	141	48	0	23	24	236
Other	71	65	8	64	31	239
Trade						
trade without special licences	243	98	0	56	6	403
trade with special licences	35	8	0	0	0	43
Total	*678*	*263*	*80*	*193*	*71*	*1285*

8 Discussion

Biocidal products are a great help in numerous fields: disinfectants for hands and for floors, insecticides, products for rodent control, wood preservatives, anti-fouling paints for boats. However, by definition, they are manufactured with the intention to destroy, repel or render harmless any harmful organisms. This is why their placing on the market is strictly regulated.

Reducing the risks associated with the use of biocidal products.
The authorisation process for these products was put in place in order to reduce the risks associated with their use. It begins with an evaluation of the active substances as part of the EU “Review Program” that decides whether they may be used for a defined application. If required, conditions are laid down in view of the planned use of the substance in a product (labelling, use, users,…). The evaluation of the active substances is followed by the evaluation of the products. In this step the following points are evaluated and defined:

- the product is sufficiently effective (concentrations of active substances),
- the contents of the safety data sheet,
- the intended use,
- the category of user,
- labelling of dangers
- labelling specific to biocidal products,
- a child-resistant fastening and a tactile warning of danger,
- as well as, if necessary, conditions specific to the products.

It may occur that the conditions specific to the products or corrections of the authorisation holders’ proposals in regard to the safety data sheet be specified in what we call the “conditions”. These conditions are communicated to the authorisation holders by way of a decision. They are important, because if respected, they allow a use of the biocidal products under controlled risk conditions.

The aim of the checks is to verify the application by the authorisation holders under the conditions defined by the authorities for a placing on the market and a use of the biocidal products under controlled risk conditions. The checks carried out involve analyses, advertising as well as labelling and the safety data sheet. In addition, two types of authorisation processes were compared. However, the differences in conformity between products with a transitional authorisation or with recognition were not found to be significant. For this reason the discussion will address the products as a whole. Whenever a difference was found it is discussed.

Analyses
The identity of the active substances and their concentration were verified. Overall, the active substances identified by analyses corresponded to those declared in the authorisation process. In 3 products, non-declared active substances were detected. For example, PBO (piperonyl butoxide) was detected in a product instead of permethrin. PBO was in the former composition of the product. The authorisation holder informed us that he had forgotten to inform the production department. The other cases of non-compliance involved significant differences between the declared concentrations of active substances and those analysed.

Safety data sheet
Sections 1, 2, 3 and 13 were checked. In section 1 that contains general information on the product and the authorisation holder, the category of user (professional or private) was assessed as non-compliant in more than one third of the products. A closer look at the data intimated that the checks were carried out strictly. That is to say, in the case of transitional authorisations, the products for private use which did not have this information, were assessed as non-compliant. However, the Ordinance states that the category of user shall be given “when applicable” (Art. 38 al. 4 let. a OBP). The present interpretation of this Article is that the category of user does not need to be stated if the products are for private use, because their use does not require specific knowledge. In this case the percentage of non-compliance is exaggerated.

A recurring issue, both for biocidal products and preparations, is the absence of the number of the Swiss poisons information centre. This enforcement project again confirms this deficiency. A Swiss number is indispensable; in the case of an accident the users can be advised on how to react correctly and rapidly to an intoxication.

In section 2, and solely for biocidal products with a transitional authorisation, the H-phrases had not been transposed in accordance with the decision in more than 20% of the products. The H-phrase, like the signal word and the pictograms, are elements that are part of the decision, and must be applied both in the safety data sheet and on the labelling. Moreover, this deficiency also exists in the labelling. There are also problems in regard to the name of the substances, their concentration and the existing classification in section 3. Proportionally, more cases of non-compliance were found in the products with recognition (22% versus 11% for the products with a transitional authorisation). This is perhaps a bias that could be attributable to the difference in the number of products checked.

Section 13 stipulates the requirements for waste disposal. The requirements at the national level must be specified.

Conditions of the decision
The conditions are requirements specific to a product as determined by the assessment authorities. They concern the labelling, the safety data sheet or other characteristics such as the use. They form part of the decision and must be included in order that a biocidal product may be placed on the market in a compliant manner. Checks showed that corrections relating to the safety data sheets were not included for almost 50% of the biocidal products. The conditions of the decision were not respected by the authorisation holders. It is true that the labels and safety data sheets existed before the product was authorised, but it appears that these supporting materials were not updated after the decision had been received.

Labelling specific to biocidal products

Elements of the labelling specific to biocidal products are stipulated in Art. 38 of the Ordinance on Biocidal Products (Art 69 para. 2 RBP). The product name, product types and the authorised applications of the biocidal product were in conformity for more than 90% of products. In contrast, the authorisation number was missing or incorrect for a non-negligible part of the checked biocidal products (20% transitional authorisations and 13% recognitions respectively). This is also the case for the declaration of the active substances, the authorisation holder and the categories of user. In fact, 30% of the data of the authorisation holders were incorrect for the biocidal products with recognition. For example:

- the name of the authorisation holder was missing, i.e. there was no contact data,
- the name of the importer was on the label instead of the name of the authorisation holder,
- the name of the authorisation holder was present but it was stated that another person was the authorisation holder.

In regard to the categories of user, there was the same issue as that discussed for the safety data sheet.

Labelling of dangers

The labelling of dangers, which comprises pictograms, the signal word and the H-phrases, are part of the decision and must also be transposed on the label. None of these elements is totally compliant for the transitional authorisations. Furthermore, in nearly 30% of the cases, the H-phrases do not agree with those of the decision. When the dossier is submitted for an authorisation the companies submit a draft label. On comparing the draft label of the products evaluated as non-compliant with the decisions, it appears that even then the draft labels did not correspond with the requirements of the decision for labelling the dangers. This observation tends to support the idea that the documents, like the labels and the safety data sheets, were not modified after the decision had been received.

Packaging

In order to avoid accidents or any confusion, the packaging of dangerous products is also subject to requirements (Art. 8 ChemO; Art. 35 CLP). These were conscientiously carried out. Child-proof fastenings were found on all products that required them. Only the tactile warning of danger was missing on four products and one product could have been confused with foodstuffs.

Advertising

All advertisements for biocidal products must include the statement “Use biocidal products safely. Always read the label and product information before use”. (Art. 50 al. 3 let. a and b OBP). These statements were not added to the product adverts in 60% of the products with a transitional authorisation. The percentage of non-compliance was 30% for the products placed on the market with recognition. However, the number of checked product is not comparable (n=14 and n=48 respectively). This requirement seems to have been neglected or unrecognised by the persons making the advertisements for biocidal products.

9 Conclusions

The aim of the requirements enacted by the ordinances is to contribute to the reduction of risks when biocidal products are used, i.e. to protect the users, their surroundings and the environment.

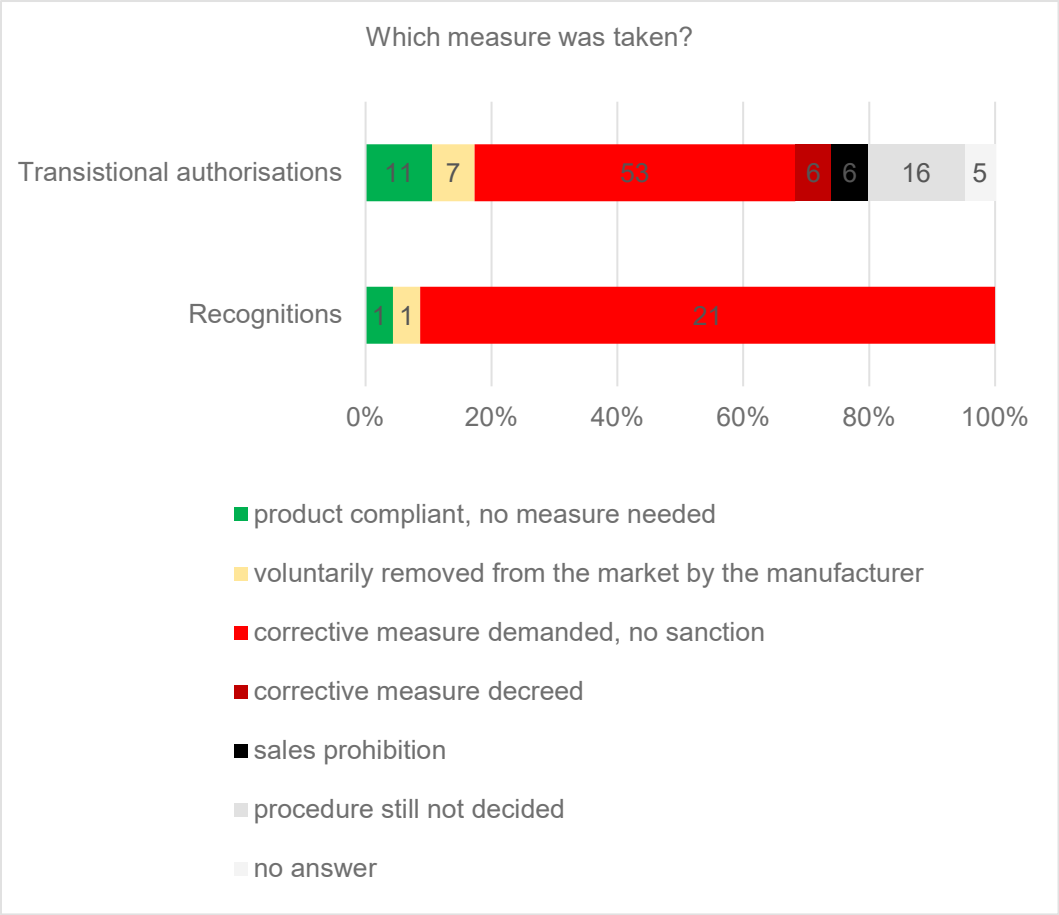

Fig. 17 Measures undertaken after having checked the biocidal products. Comparison of transitional authorisations and recognitions. In the Figure the results are shown in per cent (%) and the actual number of products is written in the bars.

The results of this enforcement project show that the efforts invested in the evaluation of the biocidal products which defines the basis for their sales and their use, are not always taken seriously by the stakeholders of this sector. At the time of editing this report, 11 biocidal products with a transitional authorisation out of 83 for which measures were taken, were considered to be in compliance on the Swiss market. Of the biocidal products with recognition only one product out of 23 was compliant (Fig. 17). Moreover, six prohibitions of sale have been issued because the products were not authorised in Switzerland. Besides the deficiencies in the points that may be qualified as "administrative" - such as the number of the Swiss poisons information centre, the language of the label or the information on the authorisation holder - the checks revealed major deficiencies in the biocidal products on the Swiss market. Deficiencies in the H-phrases and the requirements for waste disposal, claims that do not correspond to the authorised product types and the products for which the category of users was missing have been reported. These requirements must be respected so as to ensure an appropriate level of safety when using biocidal products.

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www.echa.europa.eu/regulations

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