

BPRS second harmonised enforcement project - BEF-2

Workshop with ECHA Accredited Stakeholders
25 March 2024

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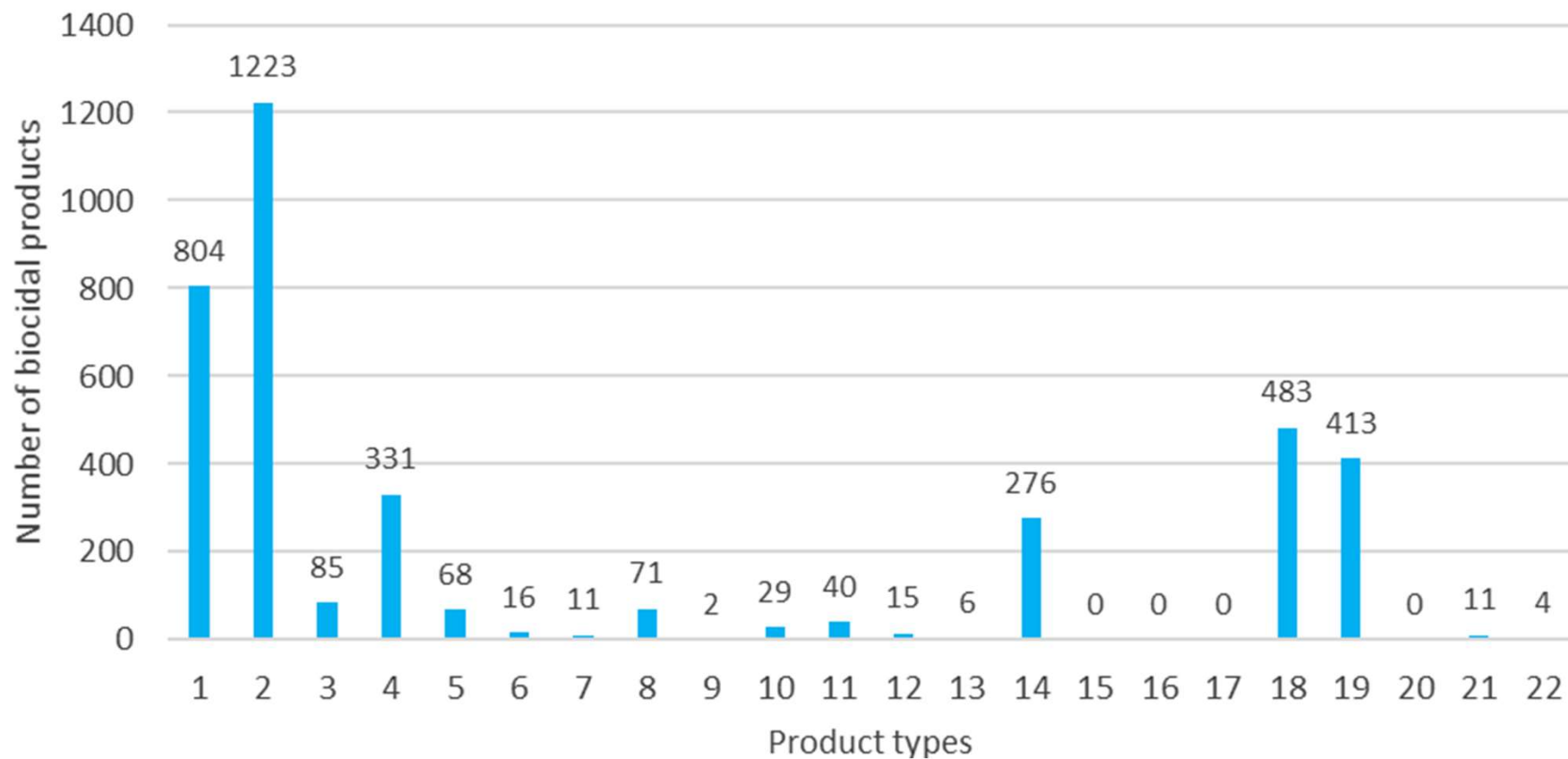
BEF-2 scope and objectives

- Focus on **biocidal products, allowed/non-allowed active substances** and **disinfectants (PT 1, 2, and 4)**
- Wide ranging of inspections – all product types for biocidal products under the **BPR** and **national transitional measures**
- All actors **placing and making available** biocidal products
- **Raising awareness** on legal provisions for biocides and improving industry knowledge
- Ensuring **safer market** for biocidal products, and a better **level playing field** among EU companies

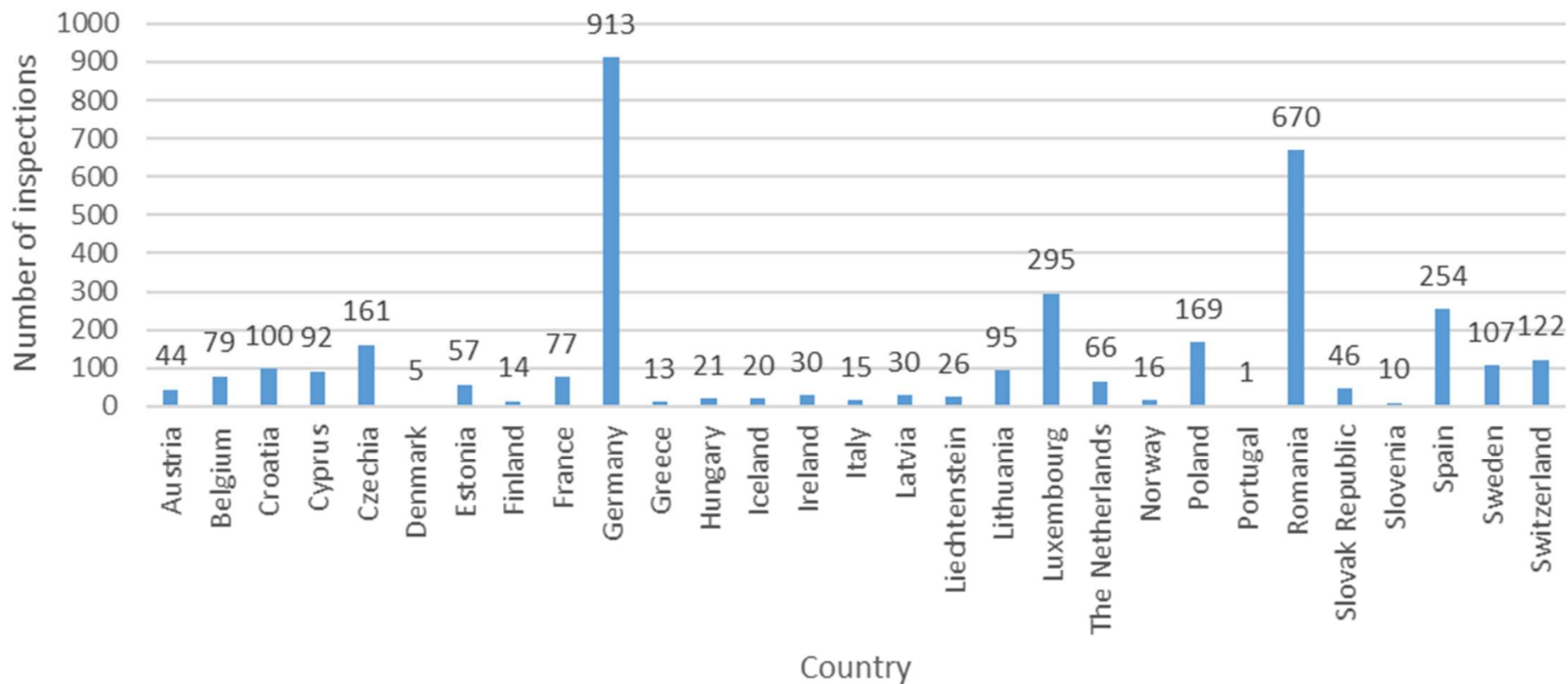
BEF-2 results

- **29** countries participated to the project
- **3548** biocidal products inspected in EEA and Swiss market
 - 22 % EU biocidal products (authorised under Article 17 of the BPR)
 - 78 % transitional biocidal products (available under national transitional measures as per Article 89 of the BPR)
 - 52 % were disinfectants in PT 1, 2 or 4

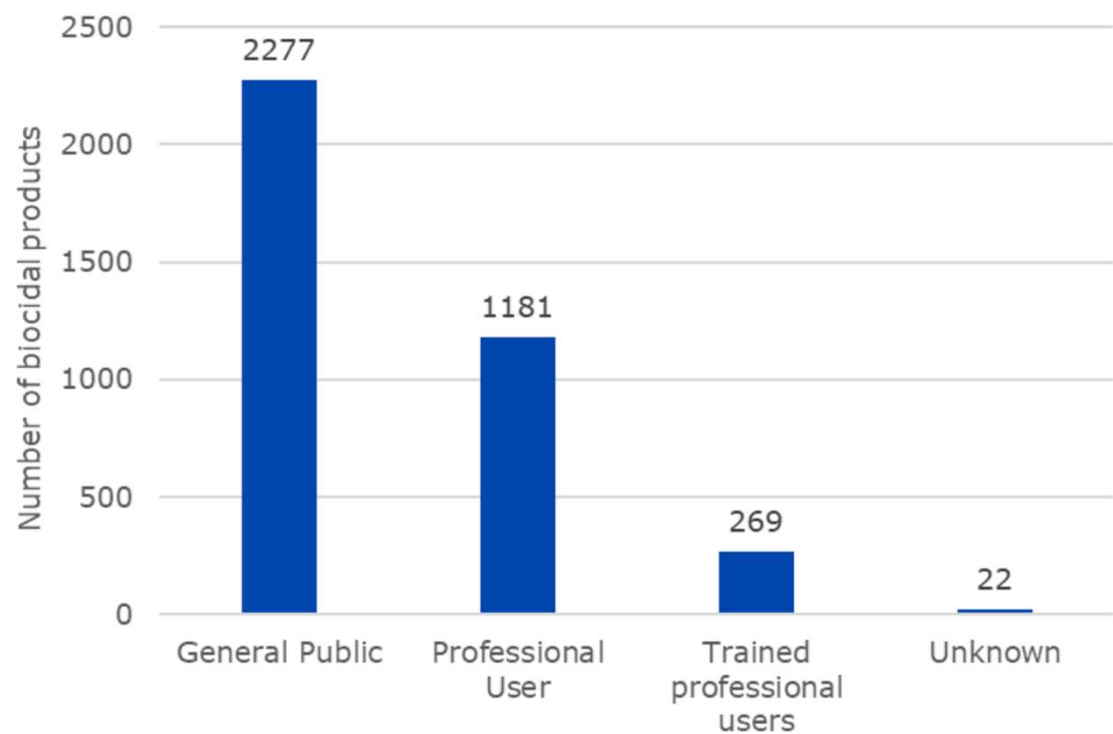
BEF-2 product types inspected



Participating country and number of inspections



User category for inspected biocidal products



BEF-2 active substances

- 220 different active substances were controlled
- 35 substances could not be identified e.g. CAS number and name didn't match

Active substance	CAS	Number biocidal products
Ethanol	64-17-5	848
Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))	68424-85-1	407
Propan-2-ol	67-63-0	325
Didecyldimethylammonium chloride (DDAC)	7173-51-5	269
Active chlorine released from sodium hypochlorite	7681-52-9	214
Permethrin	52645-53-1	119
2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (Piperonyl butoxide/PBO)	51-03-6	97
Geraniol	106-24-1	96
Eucalyptus citriodora oil, hydrated, cyclized	1245629-80-4	94
D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine(2:1) (CHDG)	18472-51-0	91
Hydrogen peroxide	7722-84-1	89

BEF-2 non-allowed active substances

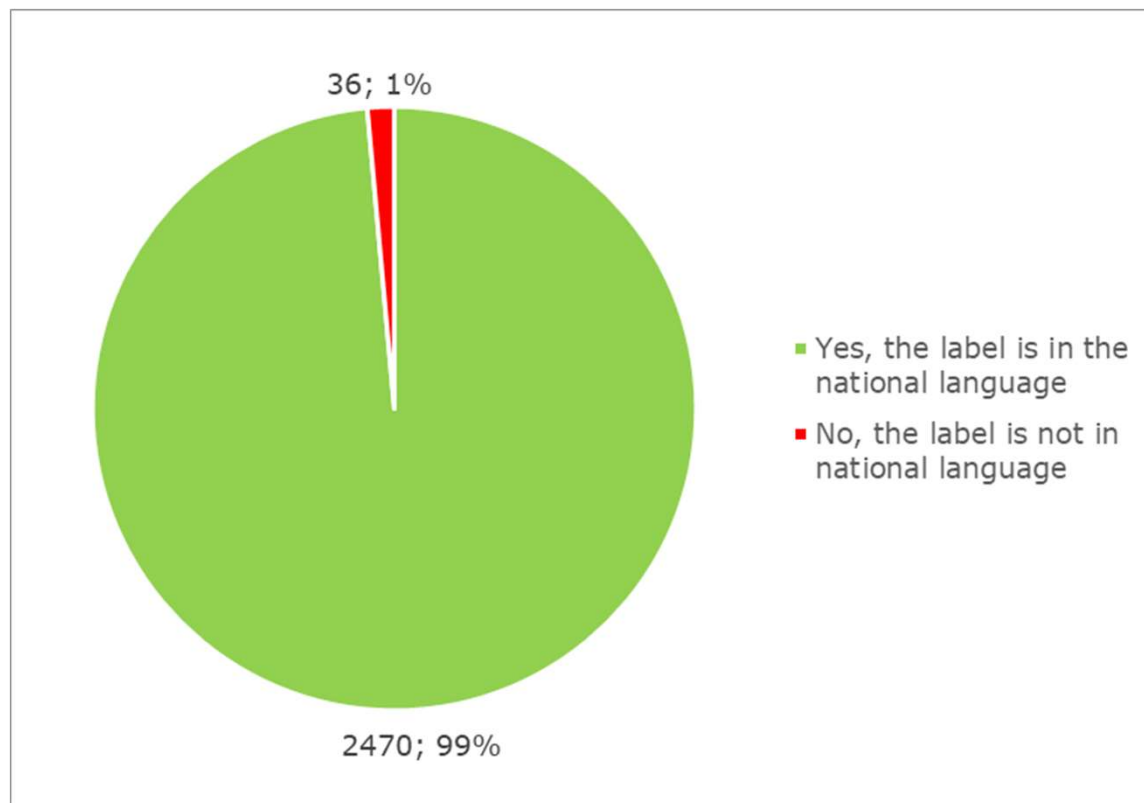
- About 60 different substances were identified as non-allowed active substances
- Non-allowed: No longer supported in the review programme, used in the wrong PT, not an identified active substance, non-approval decision

Active substance	Number of biocidal products	Non-compliances
Citronella oil	17	Not allowed in biocidal products as active substance
Esbiothrin	12	Not approved for product type 18
d-allethrin	7	Not approved for product type 18
Cymbopogon nardus oil	4	Not allowed in biocidal products as active substance
Rosemary essential oil	3	Not allowed in biocidal products as active substance
Butanone	2	Not allowed in biocidal products as active substance
4-chloro-3,5-xyleneol	2	Not allowed in biocidal products as active substance

BEF-2 labelling obligations - national languages

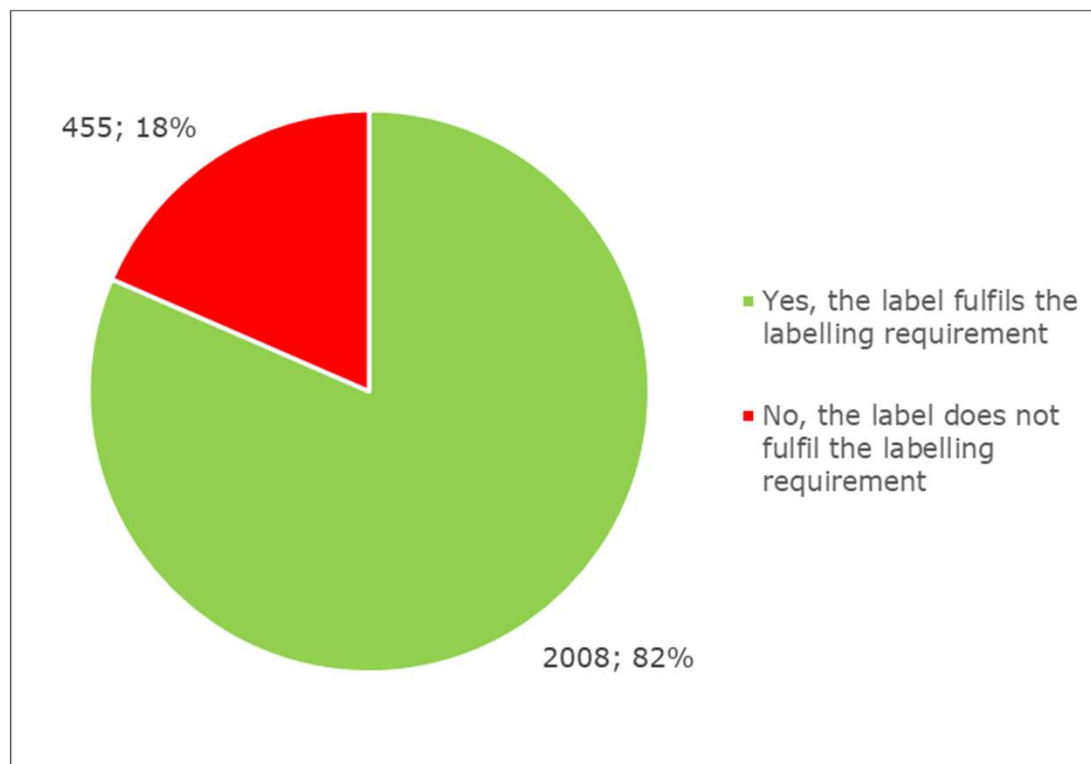
501 EU biocidal products + **2005** transitional products inspected \implies

Only **36** products did not have national language



BEF-2 Article 69(2)/national labelling obligations

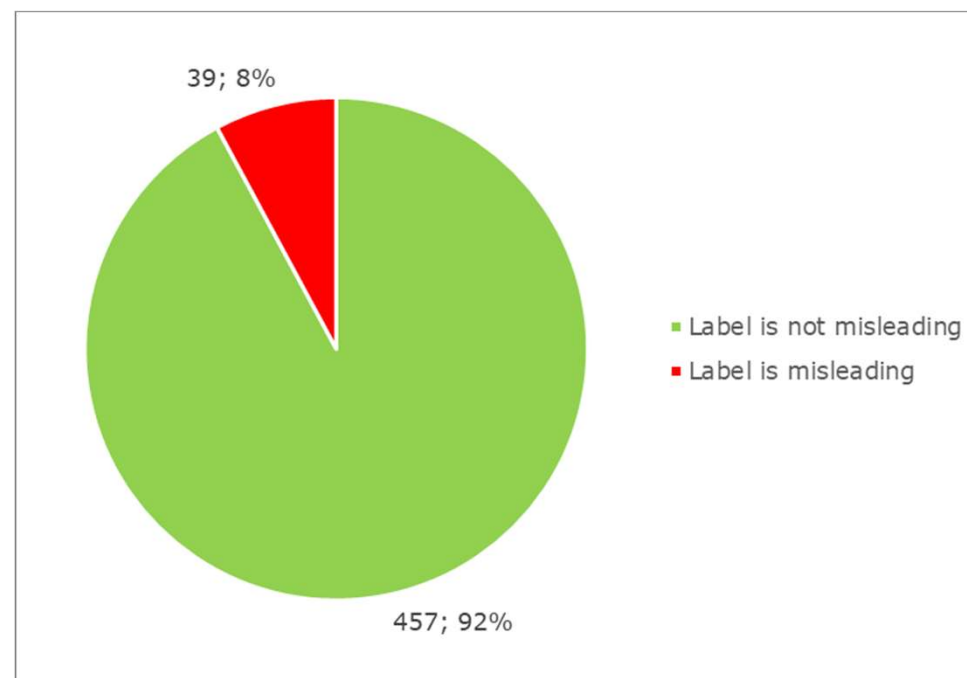
464 EU biocidal products + **1999** transitional products inspected
⇒ **455** products did not fully cover labelling requirements - non-compliances do not differ much between EU and transitional products



BEF-2 Article 69(2)/misleading labels

496 EU biocidal products inspected

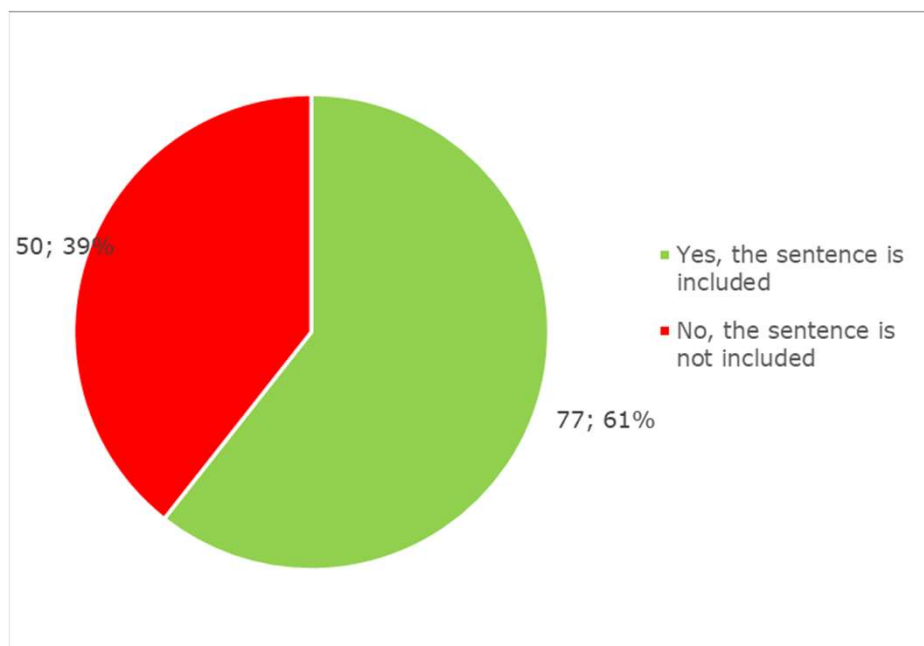
A label should not be misleading in respect to human health, animal health or the environment. And should not include terms such as non-toxic, natural, environmentally friendly etc.



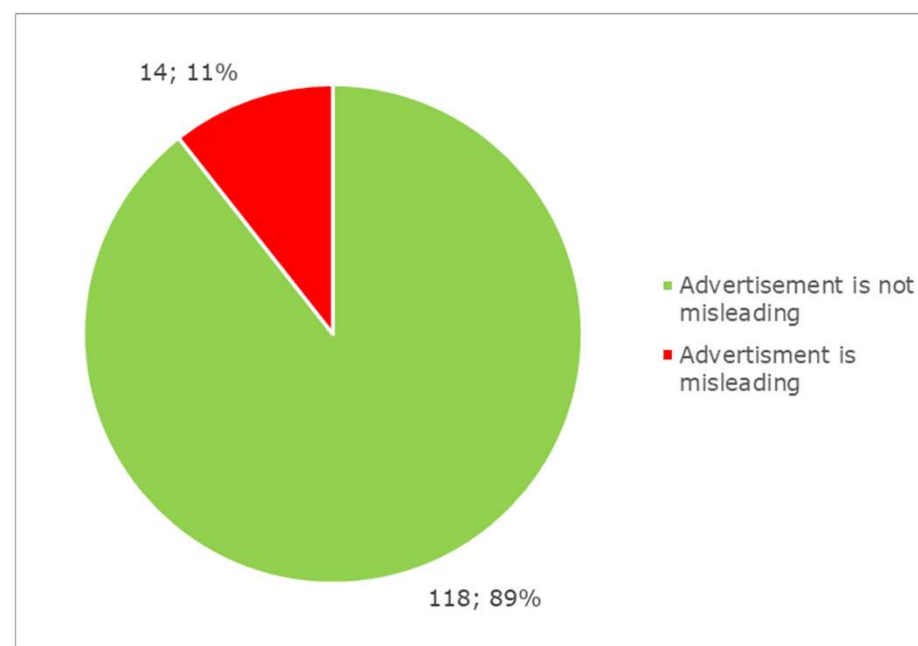
BEF-2 Advertisement – Article 72 of the BPR

Around 130 EU biocidal products inspected

Article 72(1)

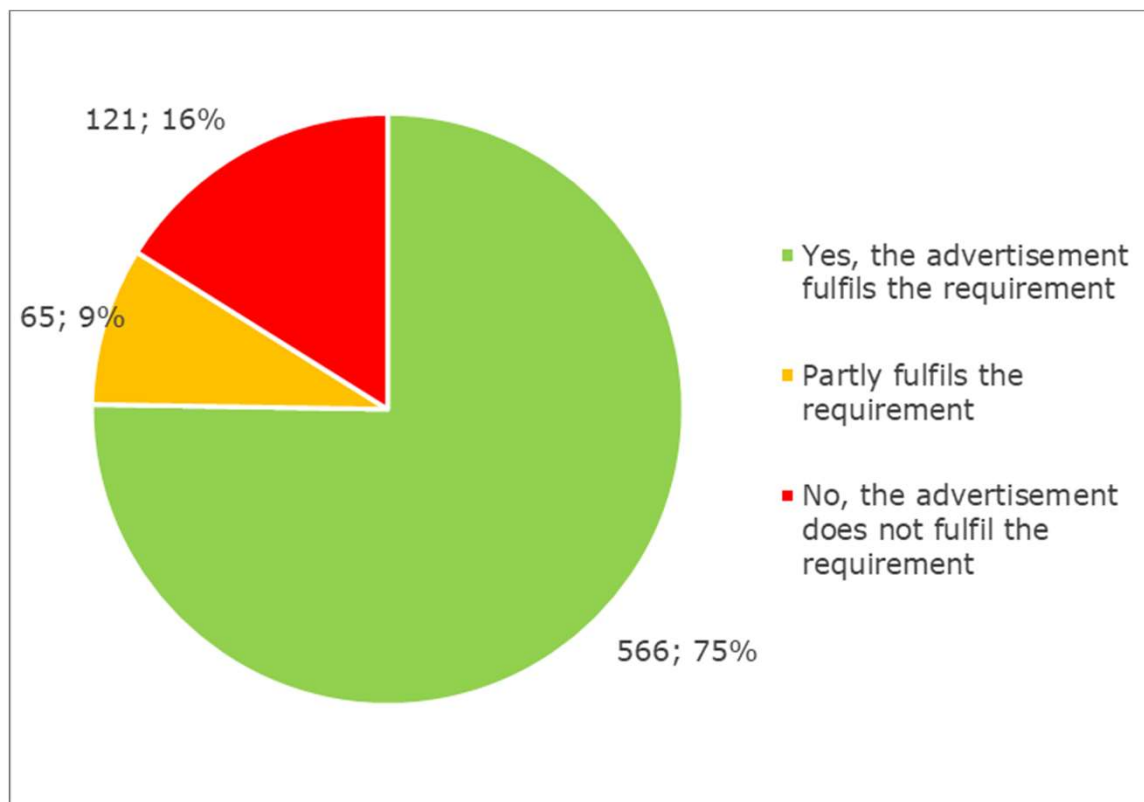


Article 72(3)



BEF-2 Advertisement – national legislations

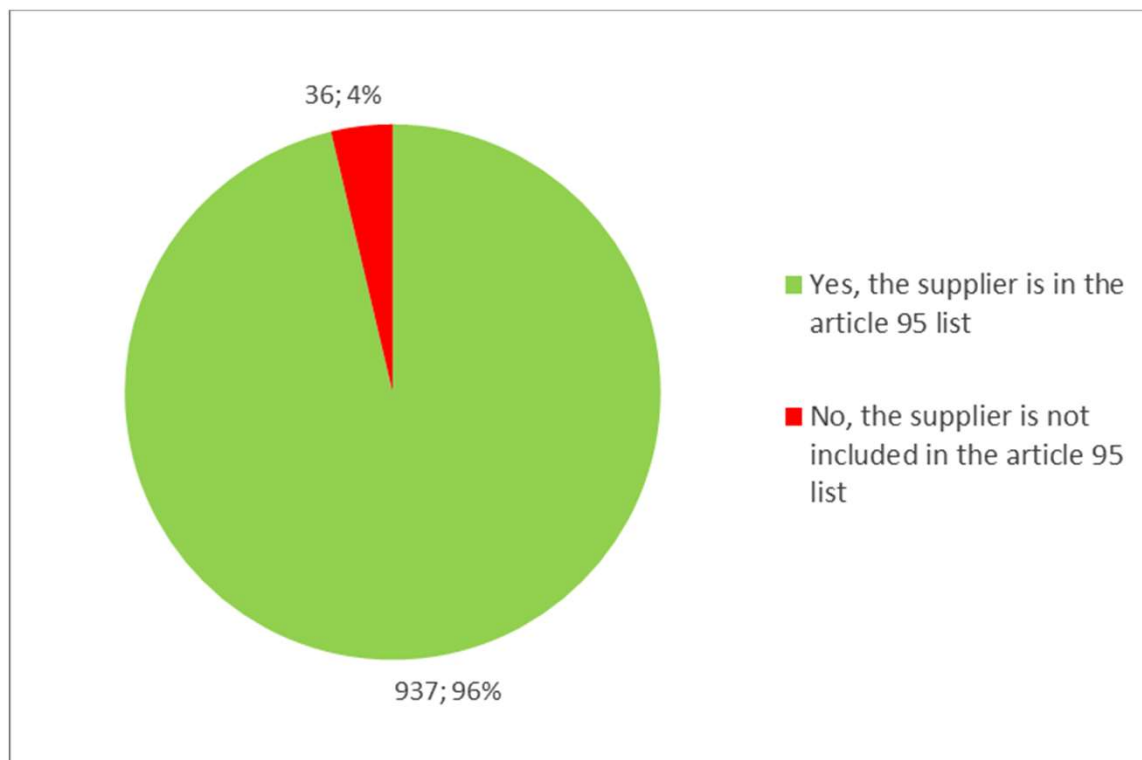
752 transitional biocidal products inspected



BEF-2 Article 95 legal obligations

973 products inspected concerning Article 95

⇒ **36** non-compliant products

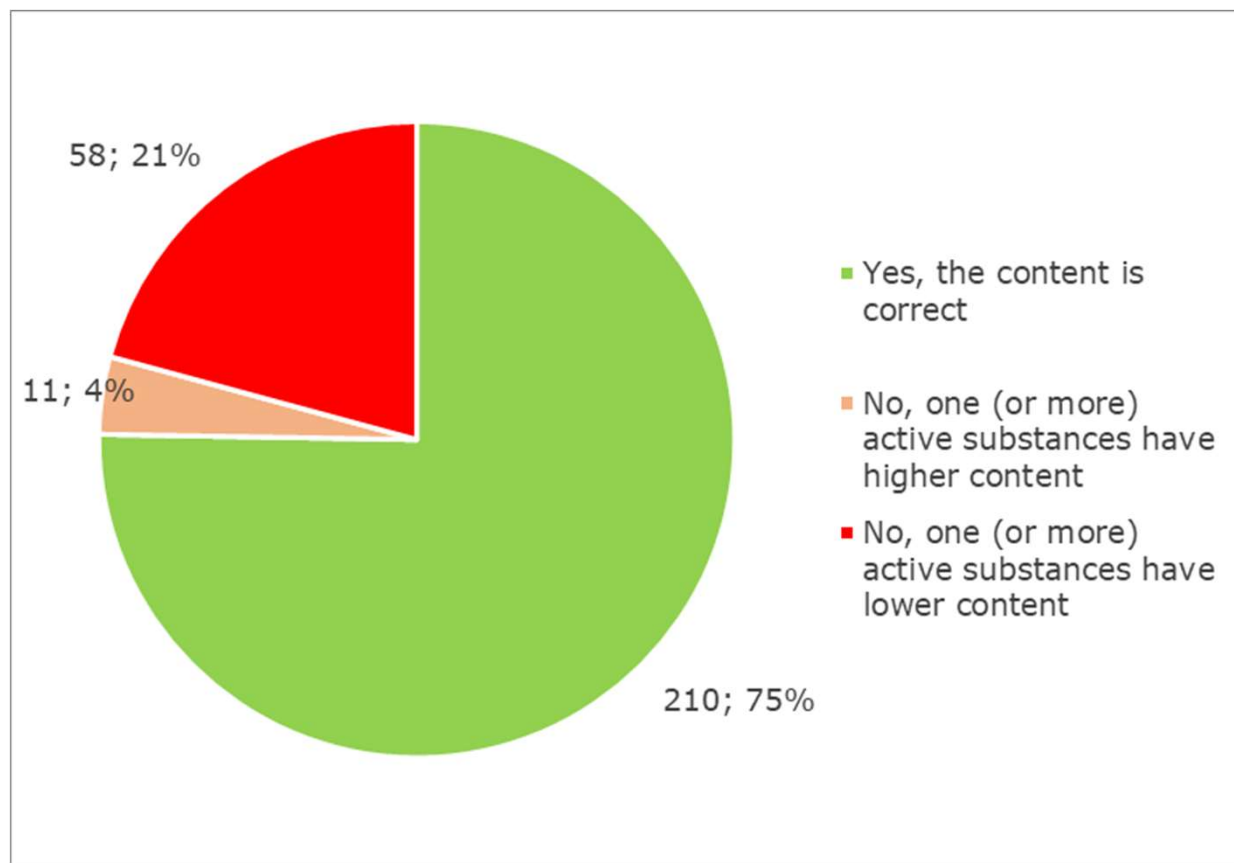


BEF-2 Chemical analysis

285 biocidal products analysed (mostly PT 1, 2)

25% did not contain the active substance in the concentration stated in the documentation

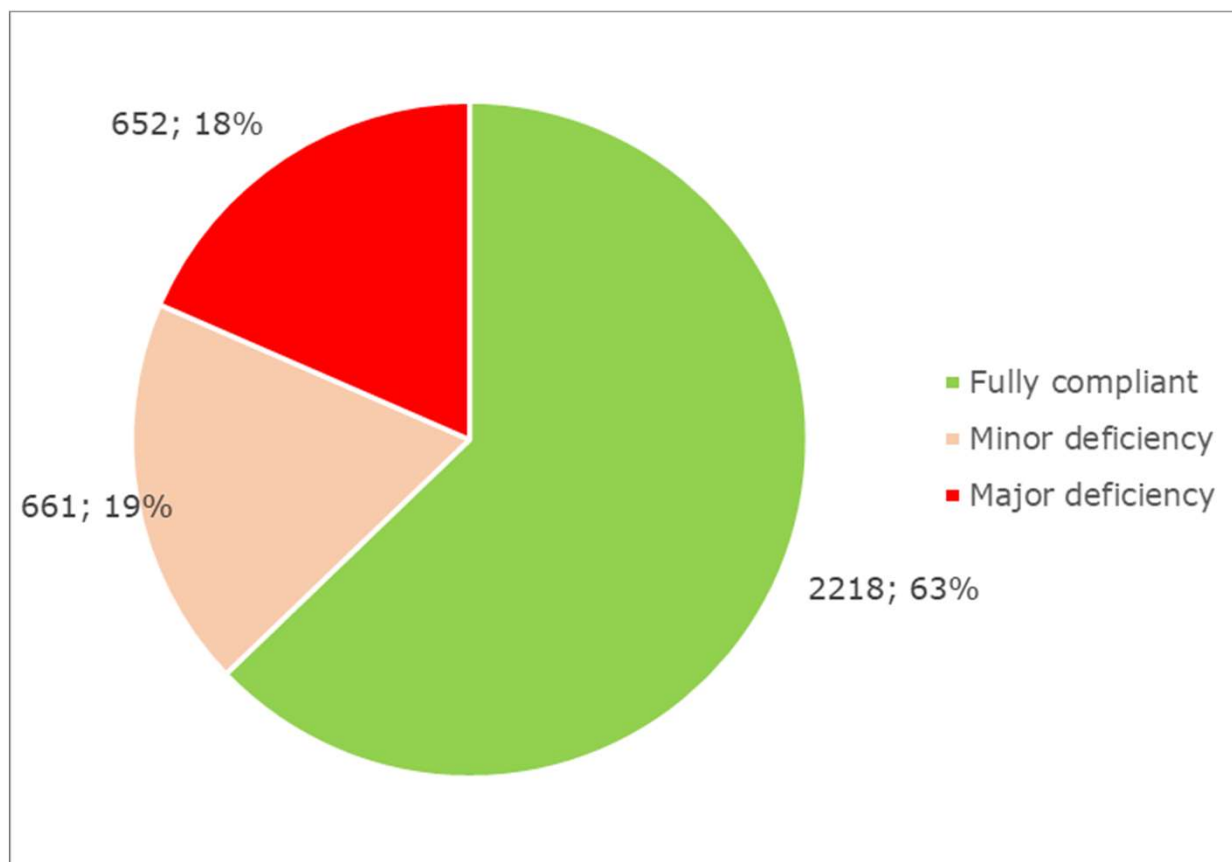
Are the concentrations of the a.s. correct?



BEF-2 non-compliant biocidal products on the EU market

Major deficiencies: lack of authorisation, presence of non-allowed active substances, severe non-compliances related to labelling and advertisement

⇒ Would have an impact on the making available - based on national inspectors' judgement



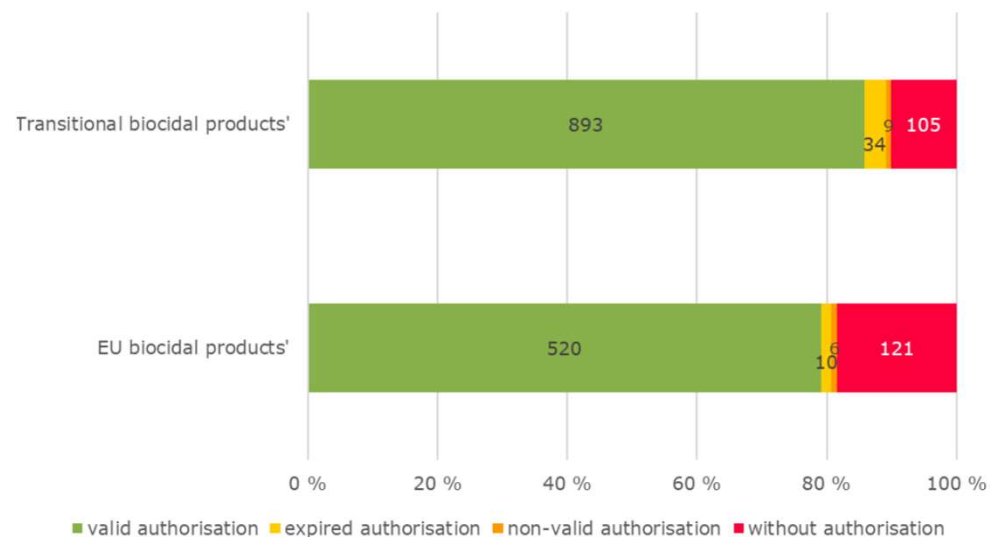
Non-compliances concerning authorisations (disinfectants excluded)

1041 'transitional biocidal products'

⇒ 105 missing authorisations

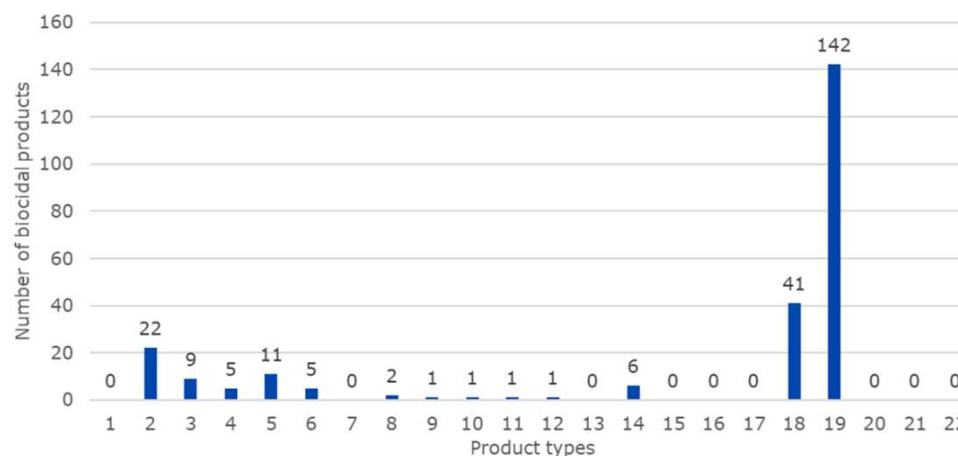
657 'EU biocidal products'

⇒ 121 missing authorisations



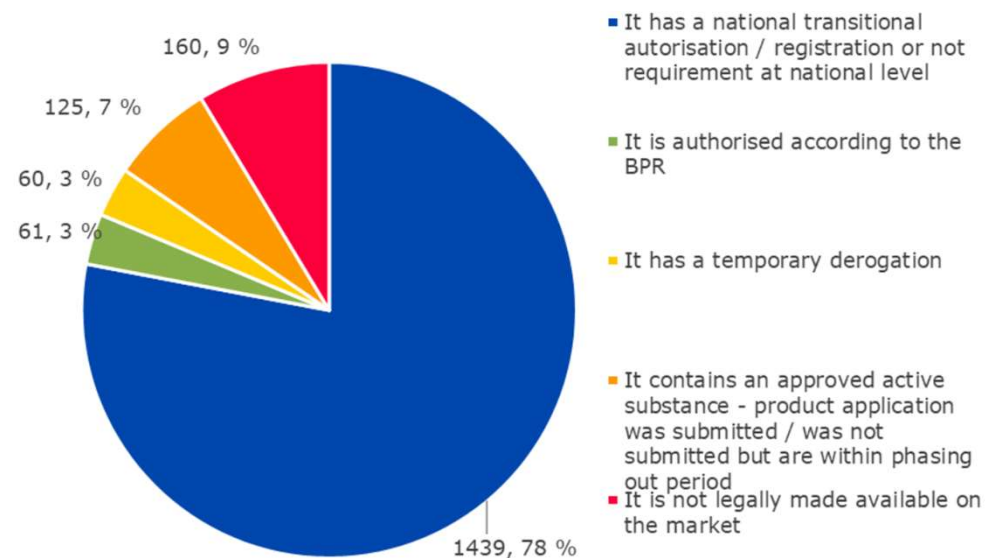
Non-compliant BPs lacking authorisation

- The majority of the biocidal products lacking authorisations belonged to product types 2 (algicides), 18 and 19.
- Those biocidal products were frequently intended for use by the general public.



Disinfectants – non-compliances

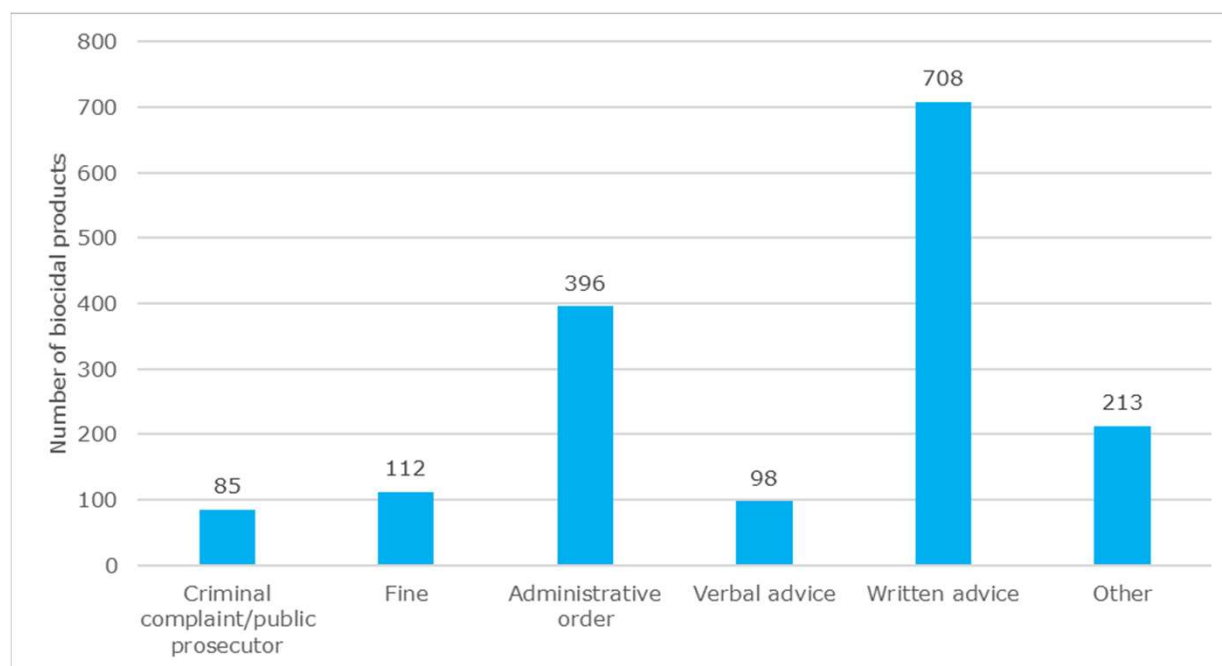
- 91% of inspected disinfectants were compliant with the BPR or national transitional measures.
- 60 disinfectants had been granted temporary permits
- 160 disinfectants (i.e. 35 'EU biocidal products' and 125 'transitional biocidal products') were non-compliant mainly due to the lack of authorisations



Labelling and advertisement are not considered in this figure (number of BPs: =1845)

BEF-2 Actions taken after inspections

- **2218** biocidal products considered fully compliant
- Written advice most common measure



BEF-2 conclusions

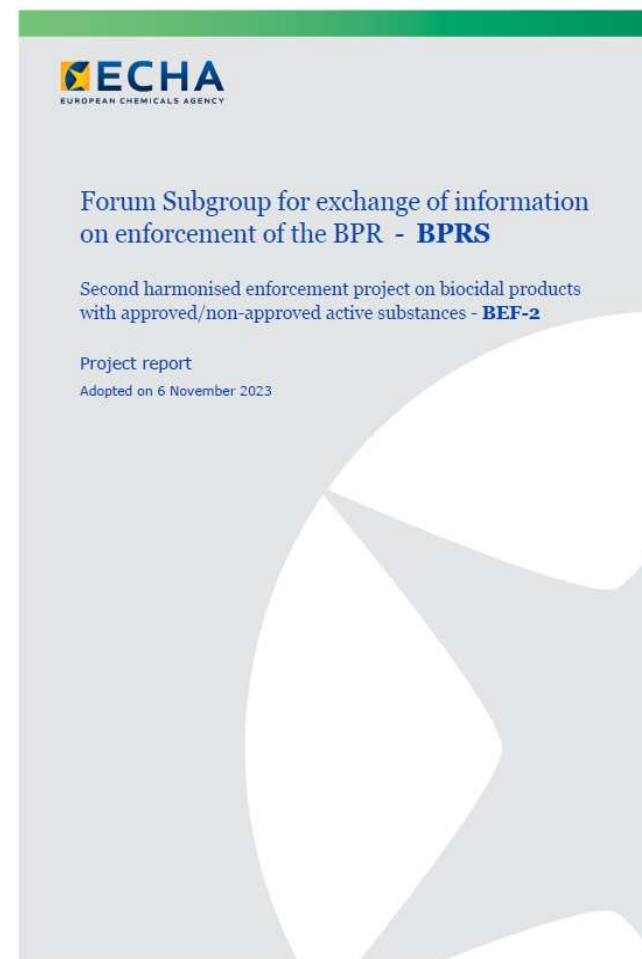
Topic	Good	Medium	Poor
Non-compliant biocidal products lacking authorisations			
Presence of allowed active substances in biocidal products			
Chemical analysis and correctness of active substance concentrations			
Labels in national languages			
Labelling requirement in line with Article 69(2) points a) to o) of the BPR			
Misleading labelling			
Advertisement requirements indicating the obligatory phrase 'use biocides correctly [..]'			
Misleading advertisement			
Compliance with Article 95			

BEF-2 recommendations

- **Member states** should continue providing training and information campaigns to both NEAs and industry, aiming at improving knowledge on BPR requirements
- **Industry** should increase their level of knowledge and awareness about the legal responsibilities in making available biocidal products on the EU market. Only when relevant hazard and risk assessments are duly performed, consumers can use safe biocidal products.
- Misleading labelling and advertisement showed an inadequate situation in terms of information for consumers. Targeting actions from **industry's** side highly recommended.
- **Industry** need to ensure correctness of active substance concentrations before the making available on the market of biocidal products.
- There is the need to bring to an end the review programme for active substance. The current coexistence of the BPR and transitional authorisations creates unclarity, and difficulties in harmonising enforcement actions in EU.

BEF-2 report

- Available on ECHA website at:
<https://www.echa.europa.eu/sv/web/guest/about-us/who-we-are/enforcement-forum/forum-enforcement-projects>



Thank you for your attention

A large, abstract graphic on the right side of the slide consists of several overlapping, curved yellow shapes that resemble segments of a circle or a stylized sunburst. The background is a solid blue color.