A·I·S·E

International Association for Soaps, Detergents and Maintenance Products

cefic sector group

European Biocidal Products Forum

A.I.S.E. & EBPF SURVEY
BPR IMPACT ON BIOCIDAL PRODUCTS AND INNOVATION

Report
December 2015

List of acronyms used in this report

AS: Active Substance
BP: Biocidal Product
BPR: Biocidal Products Regulation
BPF: Biocidal Product Family
MR: Mutual Recognition
MS: Member State
NA: National Authorisation
No.: Number
PT: Product Type
PTM: Multi-PT Product (applies to biocidal products reported to be supplied for different Product Types)
SBP: Same Biocidal Product (regulation)
SME: Small and Medium Enterprise
UA: Union Authorisation

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0. Executive Summary

A.I.S.E. and Cefic EBPF conducted a survey amongst their members in order to get an insight on the impact of the Biocidal Products Regulation (BPR) on companies' portfolio and innovation, and more specifically about companies' intention to use the Union Authorisation (UA) and Biocidal Product Family (BPF) approaches. A similar survey had been run in 2011 in order to enquire about the number of UA dossiers expected to be submitted under the forthcoming BPR.

The current findings are based on the input from 47 companies producing biocidal products, about half of which are SME's. Whilst the 2011 industry survey was estimated to cover a fair portion of the biocidal products market (about 40%), this new survey covers around 2300 products, i.e. about 11% of the current market[1]. Even with almost all biocidal product types covered in this new survey[2], it is important to note that the response rate has been very low for some product types, as compared to the related known number of products currently subject to authorisation. About 50% of the products from this survey are disinfectants (main group 2). Therefore, findings from this survey may not be fully representative of the current market.

It is also noteworthy that most of the companies indicated to have based their answers on tentative expectations rather than firm plans, which shows that there are still a lot of uncertainties linked to the BPR process.

Quantitative part:

Despite the low response rate, some interesting trends can be drawn from the replies received:

- Overall, about **26% of the products currently on the market (covered by this survey) are expected to be withdrawn in the future**. The same withdrawal rate is observed across the different biocidal products main groups. This trend equally affects SME's and large companies.
- **Professional use (including industrial use) products represent about 70% of the products** covered by the survey.
- From this survey, **74% of biocidal products expected to be supported in the future would be grouped into families**. This matches the same finding of the 2011 survey, and reconfirms the high interest of industry for the BPF concept, as it enables a considerable reduction of the total number of dossiers to be evaluated in the future, and as such the forthcoming workload for both industry and authorities.
- From this survey, less than 10% of the products currently on the EU market are sold at local level, i.e. in one or two Member States. Around half of the products are sold in more than 10 countries, i.e. 30% in 11 to 15 Member states, and another 25% in more than 15 Member States. This trend is expected to be maintained in the future.
- The intention to use UA seems to have decreased slightly since the last survey, as **in this survey around 44% of the future dossiers** (58% individual products and 42% families) **would be submitted to UA**, versus 56% in 2011[3].

[1] Based on a previous EU Commission estimation of 20000 individual biocidal products on the EU market
[2] The survey covers all PT's except PT15, PT16, PT17 and PT20
[3] It is to be noted that in both cases the ratio is considered to be over-estimated

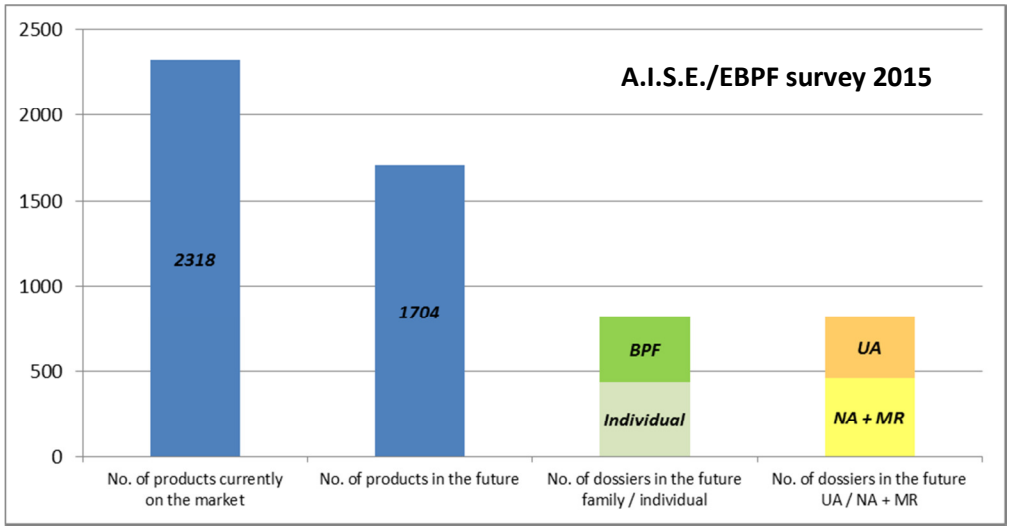
Qualitative part:

The majority of the companies who participated to this survey, whether SME or larger company, indicated that the BPR has a direct impact on their portfolio, leading to a considerable decrease of the number of biocidal products, mainly due to high BPR costs (costs for dossier preparation, registration, resources for dossier management, etc…), demanding technical and regulatory requirements, and decreasing number of available active substances.
As a result, modification of companies' product portfolio has reduced to the minimum, i.e. mainly modification of existing formulations (e.g. to allow grouping of products into families). The launch of new products has been very limited over the last 3 years and this is not expected to change in the future.
The BPR is seen by most of the companies as a major obstacle to innovation due to high resources involved in BPR activities (both human and financial), long timelines and decreasing availability of active substances.

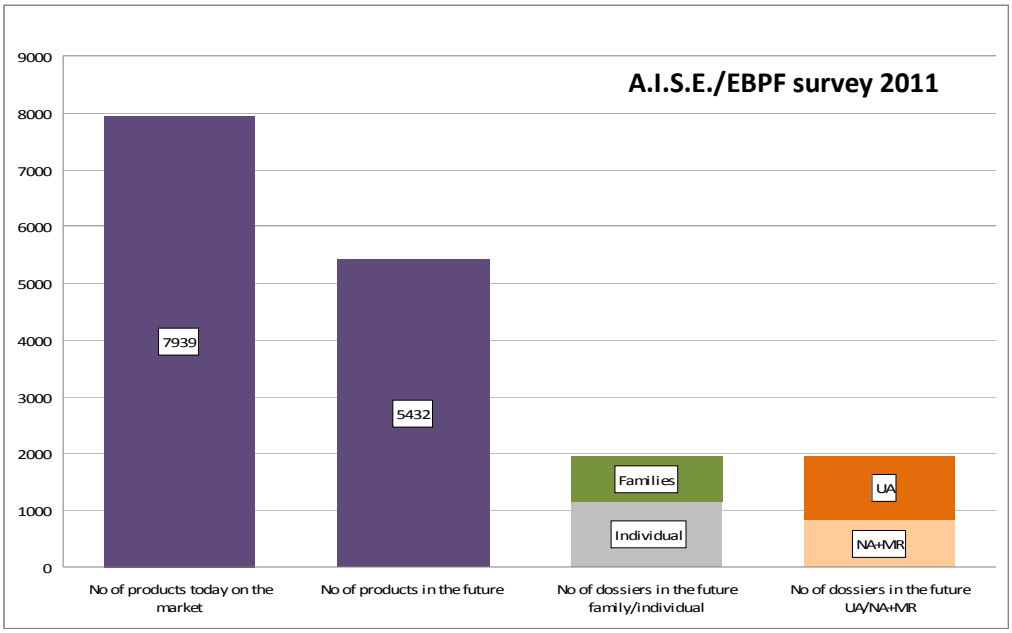
> ⇨ **As a consequence, it is anticipated that certain biocidal products used for very specific applications may disappear, which may negatively affect public health in the future.**

Nevertheless, most of the companies who replied to this survey see some opportunities for simplification and reduced administrative burden, when applying the UA and BPF approaches.
Using the UA pathway instead of National Authorisation + Mutual Recognition (NA + MR) presents for many companies advantages such as reduced administrative burden, harmonisation across EU and ease of access to the EU market. However, UA costs are seen as definitely too high by a majority of companies, regardless of their size. **Companies reported that lower ECHA fees and a guarantee that no double annual fees would apply would make UA much more attractive.** As such, cost is the main driver to choose between UA and NA+MR, depending on the number of countries where the products will be placed on the market. In addition, several companies expressed concerns that, with UA being a new process, all parties involved still lack experience, and therefore they see uncertainty about the adherence to timelines and outcome of the authorisation process.
The UA phasing approach per PT and current exclusion of some PT's from UA have also been reported by several companies as an issue and a missed opportunity to use UA.

Main findings of the survey and comparison with the 2011 survey:



BPF: Biocidal Product Family / UA: Union Authorisation / NA+MR: National Authorisation + Mutual Recognition



1. Introduction

In 2011, A.I.S.E. and Cefic/EBPF ran an enquiry amongst their members about the number of biocidal product dossiers foreseen to be submitted via Union Authorisation (UA) under the forthcoming Biocidal Products Regulation (BPR). Since then, the BPR has come into force, bringing a number of changes to the way biocidal products are authorised and the associated costs.
A.I.S.E. and EBPF decided last year to run a new survey amongst their members, in order to understand possible changes in trends caused by the entering into force of the BPR, publication of the Fees Regulation and other developments. As such, the enquiry covers aspects such as impact on companies' product portfolio, intention to use the UA and Biocidal Product Family (BPF) approaches, impact of BPR on innovation.

The survey was run in the form of a questionnaire distributed amongst A.I.S.E. and EBPF membership; it was composed of two parts, the first part asking for quantitative information, the second being of qualitative nature. Data collection took place between December 2014 and May 2015.

It is important to note that the majority of companies indicated to have based their answers on tentative expectations rather than firm definitive plans, and are aware that these predictions can evolve in the coming years.

2. Results

✓ Response rate

In total **56 replies** were received. Amongst those replies:

- 9 companies indicated that they will not participate to the survey; the main reasons for non-participation were the lack of time and too many uncertainties/ open questions due to BPR.
- 6 companies provided data for the quantitative part only.
- 1 company provided data for the qualitative part only.

Therefore **the entire analysis that follows is based on 47 responses** (i.e. completed questionnaires), split as below:

Total number of responses	**47**
Total for quantitative part	46
Total for qualitative part	41

✓ SME's participation

About half of the questionnaires received were sent in by SME's[4] (see detailed figures below):

SME's	23	48,9%
NON SME's	23	48,9%
Not specified	1	2,1%

2.1 Quantitative Part

This first part of the survey enquired about companies' current and future portfolio in the EU market, including questions related to BPF, UA, professional versus consumer uses, expected number of products requiring comparative assessment.

✓ Number of products covered by the survey

The survey covers a total of **2318 individual products reported to be currently on the market** (i.e. number of formulations - not of brand names - on the market today, subject to primary authorisation). 25% of these products are coming from SME's.

[4] In the meaning of Recommendation 2003/361/EC

✓ Product Types covered by the survey

Main group 1: Disinfectants

No.	Product Type	Comment
PT1	Human hygiene	-
PT2	Disinfectants and algaecides not intended for direct application to humans or animals	-
PT3	Veterinary hygiene	-
PT4	Food and feed area	-
PT5	Drinking water	-

Main group 2: Preservatives

PT6	Preservatives for products during storage	-
PT7	Film preservatives	Less than 5 companies reported data for this PT
PT8	Wood preservatives	Less than 5 companies reported data for this PT
PT9	Fibre, leather, rubber and polymerised materials preservatives	Less than 5 companies reported data for this PT
PT10	Construction material preservatives	Less than 5 companies reported data for this PT
PT11	Preservatives for liquid-cooling and processing systems	-
PT12	Slimicides	-
PT13	Working or cutting fluid preservatives	Less than 5 companies reported data for this PT

Main group 3: Pest control

PT14	Rodenticides	Less than 5 companies reported data for this PT
PT18	Insecticides, acaricides and products to control other arthropods	-
PT19	Repellents and attractants	Less than 5 companies reported data for this PT

Main group 4: Other biocidal products

PT21	Antifouling products	Less than 5 companies reported data for this PT
PT22	Embalming and taxidermist fluids	Less than 5 companies reported data for this PT

Multi-PT products

PTM	Applies to biocidal products reported to be supplied for different PT's	PT2/4 represents more than half (56%) of the multi-PT products

① ***Important notes:***

- In this section of the report, data are reported by main group and, where possible, by PT. For several PT's, namely **PT7, PT8, PT9, PT10, PT13, PT14, PT19, PT21 and PT22, the response rate was very low i.e. data were provided by less than 5 companies. As such the basis was too small to aggregate and report the data for those PT's.** In addition, it has not been possible to include the data for main group 4 as the number of responses in this group was below 5.
- It is worth mentioning that PT2/4 represents more than half (56%) of the multi-PT products, therefore in the quantitative analysis, data have also been extracted for this specific category.

Graph 1 shows the distribution of products reported in the survey into the different main groups:

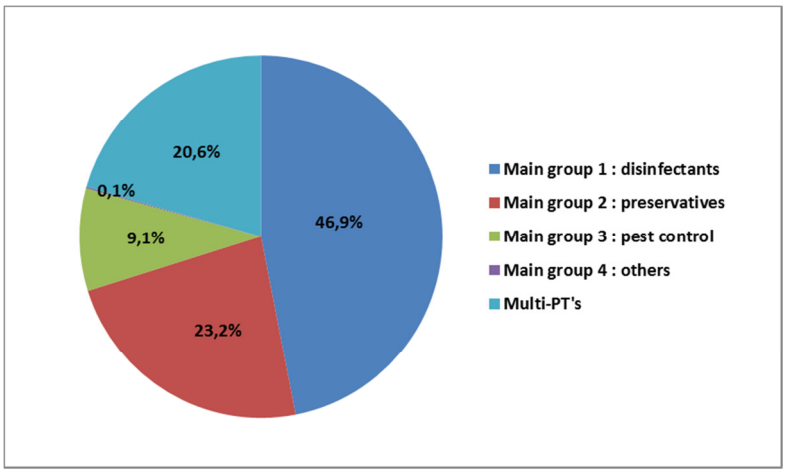
- About 47% of the products covered by the survey belongs to the main group 1 disinfectants; taking into account that in addition more than half of the multi-PT products are PT2/4 products (about 10% of the total number of products), it means that **more than 50% of the products covered by the survey are disinfectants.**

- Main group 2 preservatives represent a bit less than 25% of the total number of products reported in the survey
- Less than 10% of the products covered by the survey belong to main group 3 pest control
- Less than 1% of the products belong to main group 4 (other biocidal products).

① *Important note:*

Given that for some PT's the response rate was very low as compared to the known number of products currently subject to authorisation under BPR (e.g. for PT14, c.a. 2800 products are currently subject to authorisation, whilst for main group 3 pest control, about 200 products have been reported in this survey), **it has be kept in mind that figures from the present report may not be fully representative of the current market, especially for some PT's**.

Graph 1: Percentage of products covered by the survey in each main group



✓ Expected product drop rate in the future

Out of the 2318 individual products covered by this survey, a total of **1704** products are expected to remain on the market (once active substance(s) is(are) approved) and be submitted for authorisation (24% of them come from SME's) - Table 1 provides a comparison of the current and future situation.

Table 1: Products currently placed on the market and expected to remain on the market

	Products currently placed on the market	Products expected to be placed on the market in the future
Total number	**2318**	**1704**
SME's	25%	24%
Non SME's	75%	76%

⇨ **From this survey, about 26% of the products currently on the market are expected to be withdrawn in the future.**

Table 2 shows the number of products present today on the market and the expected drop rate in the future per PT. The expected drop rate is further illustrated in Graph 2, by PT (normalised to 100% of products in each PT).

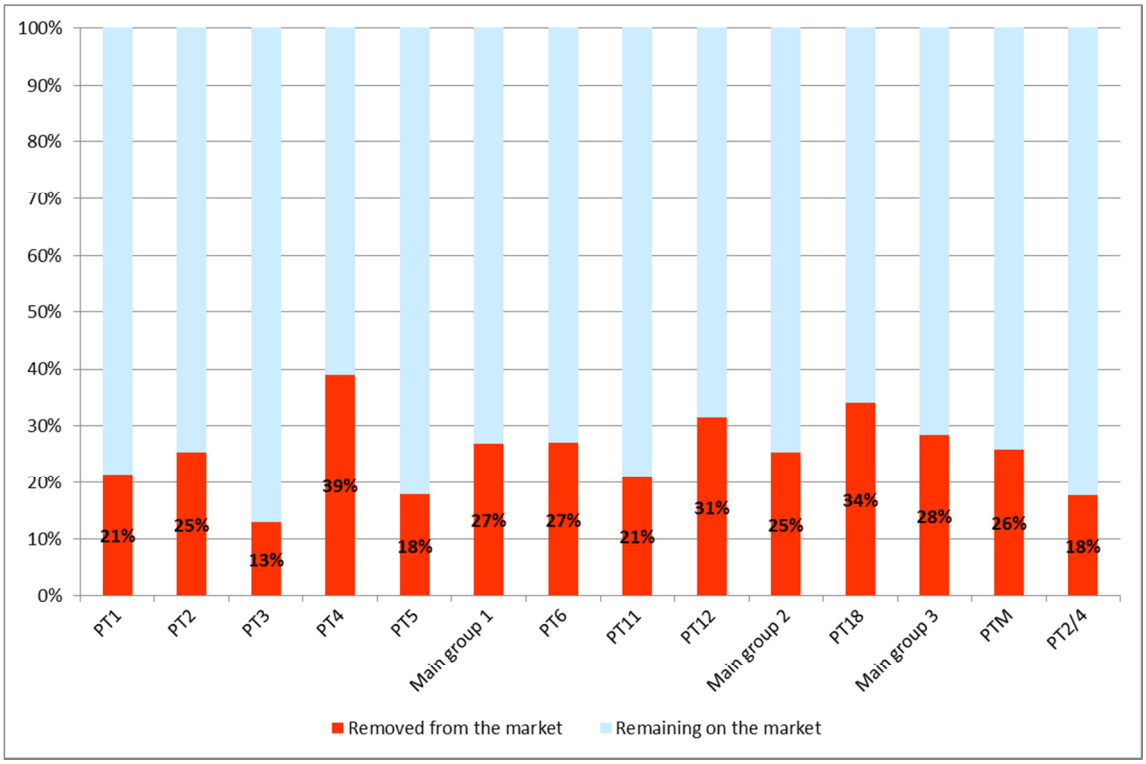
For most of the PT's reported in the table, the expected drop rate is around 20-30%. Looking at the main groups 1, 2 and 3, the expected drop rate is in the same range (respectively 27%, 25% and 28%). The PT's for which the highest drop rate is observed are PT4 (39%) and PT18 (34%).

While the overall trend indicates a reduction in number of products, a few companies (7) reported that their portfolio will likely increase in the future.

Table 2: number of products on the market today and in the future per PT

	No. of products today	Average by company	No. of products in future	Average by company	No. of products expected to be droped in future	Expected % of removal from the market
PT1	98	5	77	4	21	21%
PT2	516	17	385	13	131	25%
PT3	138	14	120	12	18	13%
PT4	297	17	181	10	116	39%
PT5	39	5	32	4	7	18%
Main group 1	**1088**	**13**	**795**	**10**	**293**	**27%**
PT6	189	19	138	14	51	27%
PT11	109	14	86	11	23	21%
PT12	54	11	37	7	17	31%
Main group 2	**538**	**14**	**402**	**11**	**136**	**25%**
PT18	147	25	97	16	50	34%
Main group 3	**212**	**19**	**152**	**14**	**60**	**28%**
PTM	477	10	354	7	123	26%
PT2/4	266	12	219	10	47	18%
Total	**2318**		**1704**		**614**	**26%**

Graph 2: Percentage of products expected to be removed from the market



✓ Professional versus consumer use products

Current situation

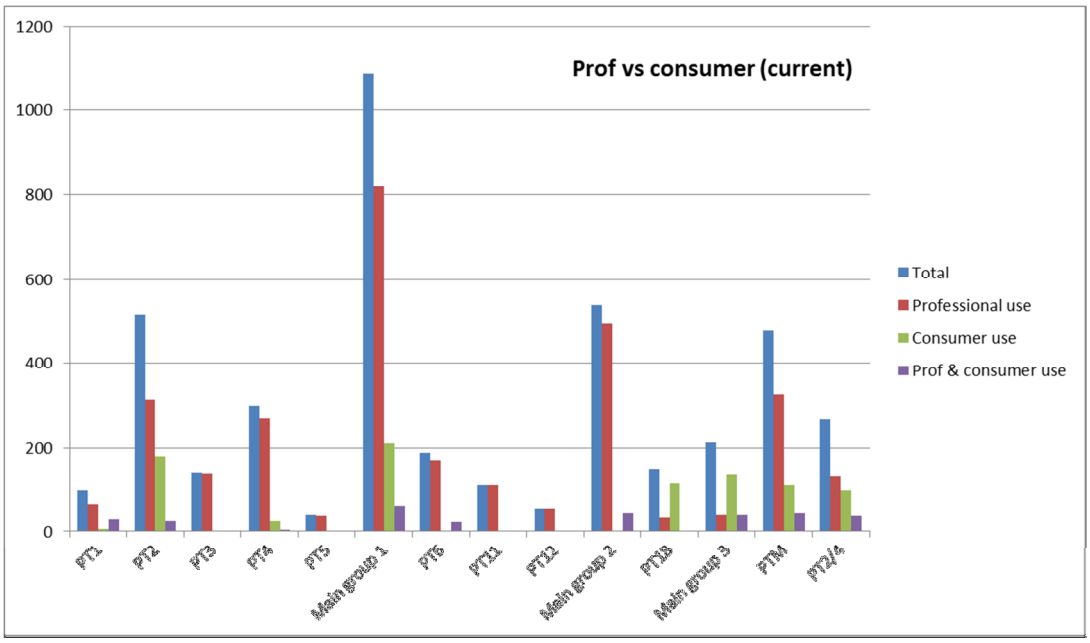
Out of the 2318 individual products covered by this survey, **professional use products** (including industrial use) **account for 72%**, whilst **consumer use products account for 20%**; 8% of the products were reported to be for both professional and consumer use.

Table 3 and Graph 3 provide a detailed overview of the distribution between professional and consumer uses per PT.

Table 3: Professional versus consumer use products (current situation)

	No. of products today	No. of professional use only products	No. of consumer use only products	No. of professional & consumer use products
PT1	98	63	7	28
PT2	516	312	179	25
PT3	138	137	0	1
PT4	297	269	24	4
PT5	39	38	0	1
Main group 1	1088	819	210	59
PT6	189	167	0	22
PT11	109	109	0	0
PT12	54	54	0	0
Main group 2	538	494	1	43
PT18	147	32	113	2
Main group 3	212	39	134	39
PTM	477	324	110	43
PT2/4	266	130	98	38
Total	**2318**	**1679**	**455**	**184**

Graph 3: Professional versus consumer use products (current situation)



Situation expected in the future

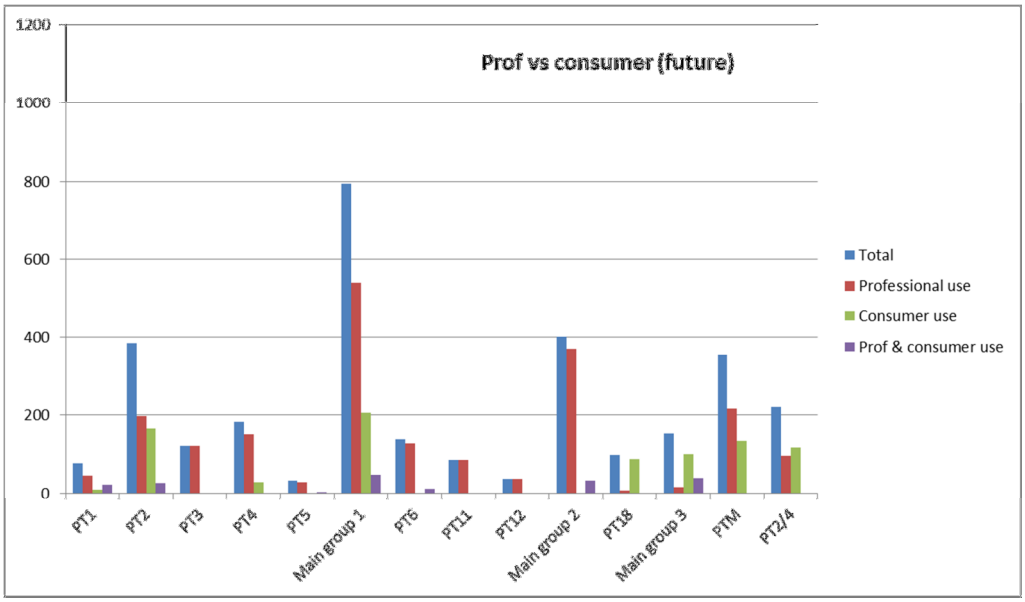
In the future, the distribution of professional versus consumer use is expected to stay in the same range as currently, i.e. **professional use products** would **represent 67% of the total number of products on the market**, **consumer use products would account for 26%, and dual use products 7%**.

Table 4 and Graph 4 provide a detailed overview of the expected distribution between professional and consumer uses per PT in the future.

Table 4: Professional versus consumer use products (future situation)

	No. of products in future	No. of profesional use only products	No. of consumer use only products	No. of professional & consumer use products
PT1	77	45	9	23
PT2	385	195	164	26
PT3	120	120	0	0
PT4	181	149	28	0
PT5	32	29	0	3
Main group 1	795	542	205	48
PT6	138	127	0	11
PT11	86	86	0	0
PT12	37	37	0	0
Main group 2	402	369	1	32
PT18	97	8	88	1
Main group 3	152	15	99	38
PTM	354	214	133	0
PT2/4	219	95	116	0
Total	**1704**	**1148**	**445**	**111**

Graph 4: Professional versus consumer use products (future situation)



✓ Biocidal Product Families

Out of the 1704 products covered by this survey that are expected to remain on the market, a total of **1265 individual products would be grouped into families, i.e. almost 75% of the products. Those products would be grouped into 389 families in total, which means an average of 3,25 products by family.**

Table 5 shows the breakdown of foreseen number of families per PT.

The highest number of families was reported for PT2 (89 BPF's).

The PT's with the highest rate of products grouped into families (above 80%) are: PT1, PT2, PT2/4 and PT3.

The table also provides an overview of the total number of dossiers expected to be submitted (BPF + individual products not fitting within a BPF). PT2 is the PT where the highest number of dossiers is expected (excluding PTM), representing 16% of the future dossiers. PT2 and PT2/4 represent about 1/4 of the dossiers expected to be submitted.

The average number of biocidal product families per company is for almost all PT's below 4.

The average number of products fitting into biocidal product family(ies) per company is for most PT's below 10, except for PT2, PT3, and PT18.

Table 5: No. of BPF and product dossiers expected in the future

	No. of BPF's	% of products fitting within BPF's	No. of products not fitting into BPF's	Total no. of dossiers	Average no. of BPF / company	Average no. of individual products covered by BPF / company
PT1	22	90%	8	30	1	4
PT2	89	88%	43	132	3	12
PT3	20	83%	21	41	2	10
PT4	44	76%	43	87	2	8
PT5	8	56%	14	22	1	2
Main group 1	183	83%	129	312	2	8
PT6	24	54%	64	88	2	7
PT11	13	36%	55	68	2	4
PT12	5	32%	25	30	1	2
Main group 2	81	54%	184	265	2	6
PT18	17	70%	29	46	3	11
Main group 3	38	72%	42	80	3	10
PTM	86	77%	78	164	2	6
PT2/4	59	90%	22	81	3	9
Total	**389**	74%	**433**	**822**		

NB: 2 companies did not provide accurate figures in relation to the number of products fitting/ not fitting within families (corresponds only to 6 products over PT2 and PTM, for which it is not known whether they fit within a family or not).

✓ Number of Member States in which products are placed on the market

Current situation

Table 6 shows the number of Member States (MS) in which the products covered by this survey are typically placed on the market, per PT. Since companies reported ranges (e.g. from 2 to 6 MS), the lowest, highest and average numbers of MS markets are shown.

Products present on the markets in more than 10 MS (in average) fall within the following product types: PT3, PT11, and PT12, and the main group 2 overall.

Looking at the highest number of MS markets declared, for all PT's reported in the table, products are placed in more or equal to 10 MS markets, whilst only products belonging to PT12 are placed in more than 15 MS markets.

It is noteworthy that the difference between the average and median values are explained by the rather small sample size of this survey.

Table 6: Number of Member States in which products are currently placed on the market

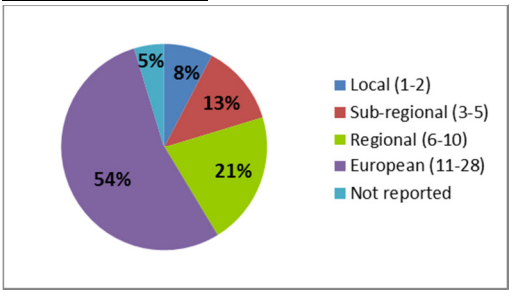
	Lowest no. of MS declared		Highest no. of MS declared		Average no. of MS	
	Average / company	Median	Average / company	Median	Average / company	Median
PT1	5	3	11	10	8	7
PT2	5	2	11	8	8	5
PT3	8	5	13	12	11	8
PT4	6	2	12	10	9	8
PT5	9	4	11	9	10	6
Main group 1	6	2	12	10	9	8
PT6	7	5	14	14	10	11
PT11	9	5	15	15	12	10
PT12	11	10	17	15	14	15
Main group 2	8	5	14	15	11	11
PT18	5	5	12	10	9	8
Main group 3	4	2	11	10	8	8
PTM	7	1	11	7	9	4
PT2/4	3	1	10	7	7	4

For the purpose of the 2011 A.I.S.E./EBPF survey report, a grouping of products in MS bands had been devised as described in Table 7. Graph 5 provides a representation of the distribution of products in different MS bands using that scale. It shows that around half of the products fit within the "European" band *i.e.* are sold in more than 10 countries, whilst less than 10% of the products are sold at local level i.e. 1 or 2 countries only.

Table 7: Scale used in the 2011 survey to assess the number of MS where products are placed on the market

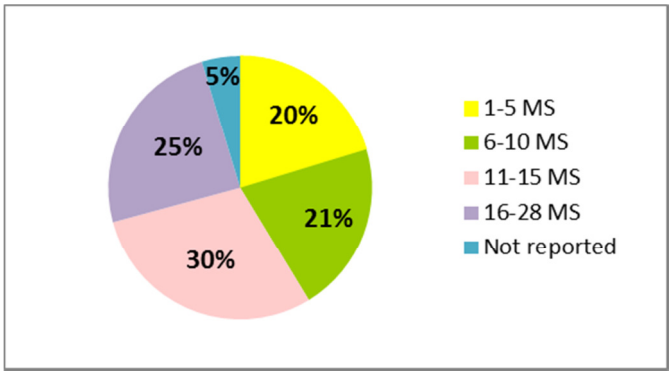
Scale	No. of MS where products are placed on the market
Local	**1-2**
Sub-Regional	**3-5**
Regional	**6-10**
European	**11-28**

Graph 5: Distribution of products in different MS bands using the 2011 scale (current situation)



Looking at the data of the present survey, another interesting pattern can also be devised, namely grouping the local and sub-regional band (i.e. 1-5 MS) and splitting the European band (i.e. 11-15 MS and 16-28 MS) – see Graph 6 below:

Graph 6: Distribution of products in different MS bands (current situation)



Situation expected in the future

Table 8 shows the number of MS in which the products are expected to be placed on the market, per PT.
Products expected to be present on the markets in more than 10 MS (on average) fall within the following product types: PT3, PT4, and PTM. Looking at main groups, only main group 2 preservatives present this profile.

Looking at the highest number of MS markets declared, for all PT's reported in the table except PT5, products would be placed in more than 10 MS markets (but none above 15 MS).

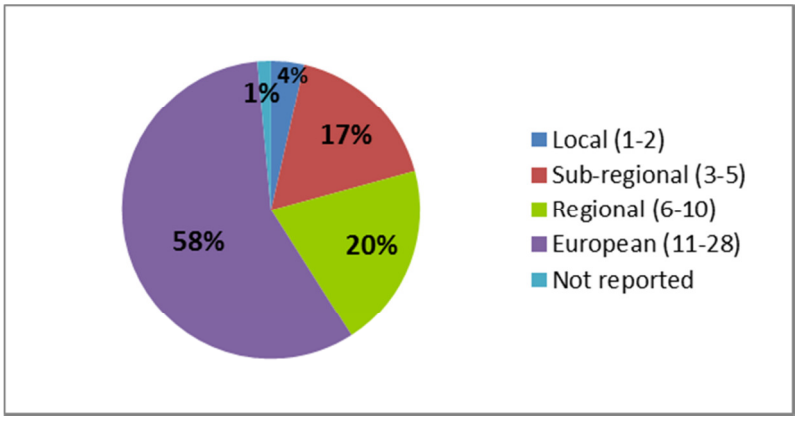
Again, it is noteworthy that the difference between the average and median values are explained by the rather small sample size of this survey.

Table 8: Number of Member States in which products are expected to be placed on the market

	Lowest no. of MS declared		Highest no. of MS declared		Average no. of MS	
	Average / company	Median	Average / company	Median	Average / company	Median
PT1	6	3	15	10	10	8
PT2	6	3	14	15	10	9
PT3	10	5	14	10	12	8
PT4	8	5	14	13	11	9
PT5	10	5	10	5	10	5
Main group 1	7	5	14	10	10	8
PT6	6	5	14	15	10	12
PT11	8	6	13	14	10	10
PT12	8	6	12	15	10	10
Main group 2	7	5	15	15	11	10
PT18	5	4	15	15	10	10
Main group 3	4	2	15	15	10	8
PTM	8	5	15	15	12	10
PT2/4	5	1	13	10	9	6

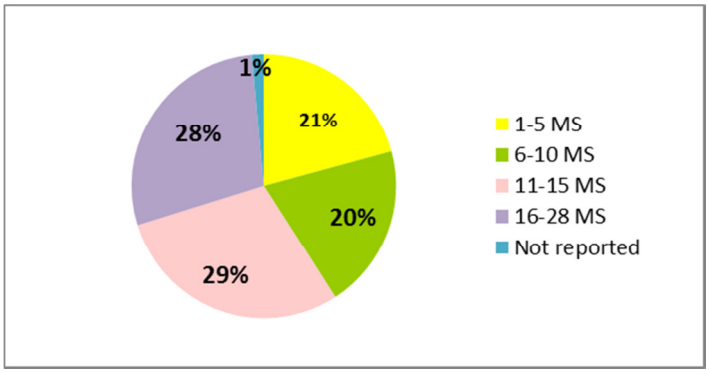
Graph 7 shows that the expected distribution of products per MS band is very similar to the current situation: again just over half of the products fit within the “European” band, and a similar spread over the other bands is observed.

Graph 7: Distribution of products in different MS bands using the 2011 scale (future situation)



Splitting the MS using the second scale described in the section above (1-5 MS/ 6-10 MS/ 11-15 MS/ 16-28 MS), the expected distribution of products per MS band (Graph 8) is also very similar as the current situation (Graph 6).

Graph 8: Distribution of products in different MS bands (future situation)



✓ Union Authorisation

From this survey, **360 dossiers** are planned to be submitted for UA, which corresponds to **44% of the total number of foreseen dossiers**. Out of these 360 UA dossiers, **42% are expected to be BPF** dossiers.

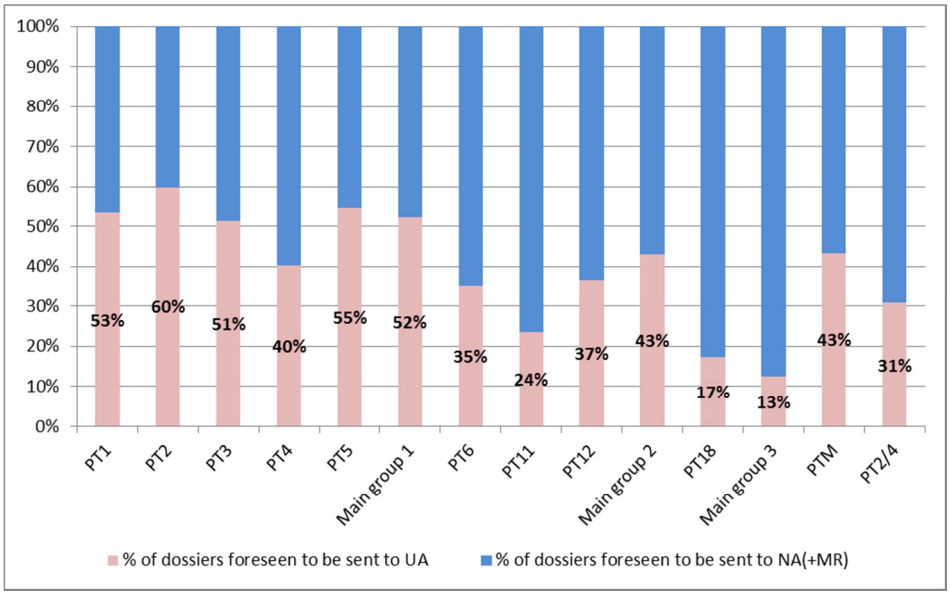
Table 9 presents per PT the total number of dossiers foreseen to be submitted for UA (including the breakdown of BPF dossiers versus individual product dossiers) and the related percentage of UA dossiers versus the total number of dossiers (see also Graph 9).
The highest numbers of UA dossiers foreseen to be submitted are for PT2 (79 UA dossiers, i.e. 22% of all UA dossiers). Jointly PT2 and PT2/4 represent a total of 104 UA dossiers, i.e. almost 30% of all UA dossiers across PT's.
Overall the main group 1 disinfectants present the highest rate of UA intention (52% of the dossiers from this group would be UA dossiers); looking in details at the PT's from this main group, PT1, PT2, and PT5 present the highest rate of UA intention (respectively 53%, 60% and 55%).

NB: for some PT's, namely PT1, PT2, PT3, PT4, PT5, PT9, PT22, PTM (including PT2/4), a few companies reported a number of UA dossiers (sum individual product dossiers + BPF dossiers) higher than the total number of dossiers foreseen (obtained by summing the number of BPF and the number of individual products not fitting within a BPF). **Therefore there is a certain over-estimation of the number of UA dossiers**.

Table 9: Number of dossiers foreseen to be sent to UA

	No. of individual BP to be sent to UA	No. of BPF to be sent to UA	Total no. of dossiers to be sent to UA (individual BP + BPF)	Total no. of dossiers (UA + NA/MR)	UA dossiers versus all dossiers (%)
PT1	6	10	16	30	53%
PT2	30	49	79	132	60%
PT3	13	8	21	41	51%
PT4	15	20	35	87	40%
PT5	10	2	12	22	55%
Main group 1	74	89	163	312	52%
PT6	27	4	31	88	35%
PT11	12	4	16	68	24%
PT12	7	4	11	30	37%
Main group 2	91	23	114	265	43%
PT18	3	5	8	46	17%
Main group 3	3	7	10	80	13%
PTM	40	31	71	164	43%
PT2/4	10	15	25	81	31%
Total	**209**	**151**	**360**	**822**	**44%**

Graph 9: Percentage of dossiers foreseen to be submitted to UA



Remarks:

- It was investigated whether there is a correlation between the number of MS in which the products are expected to be placed on the market and the percentage of dossiers foreseen to be submitted via UA (per PT). The outcome of the analysis was that no correlation can be drawn. This may indicate that the number of MS in which the products are placed is not the main driver for companies to decide whether to choose the UA route (see also section 2.2 qualitative part).
- It was not possible to compare the percentage of dossiers that would be submitted to UA from SME's versus non-SME's. Reason is that as mentioned previously, for some PT's a few companies reported a number of UA dossiers higher than their total number of dossiers foreseen (see detailed explanation above), leading to an over-estimation of the number of UA dossiers. It appears that this is the case mainly for SME's as compared to non-SME's, so comparison of the UA intentions rate is not relevant.

✓ Comparative assessment

Table 10: Number of products that (would) require comparative assessment

	No. of products requiring comparative assessment	% from current portfolio	Average by company	Median
PT1	0	0%	0,0	0
PT2	9	2%	0,3	0
PT3	8	6%	0,9	0
PT4	6	2%	0,4	0
PT5	1	3%	0,2	0
Main group 1	24	2%	0,3	0
PT6	22	12%	2,4	0
PT11	15	14%	2,1	0
PT12	15	28%	3,8	3
Main group 2	71	13%	2,0	0
PT18	10	7%	2,0	1
Main group 3	54	25%	5,4	3
PTM	8	2%	0,2	0
PT2/4	4	2%	0,2	0
Total	**157**	**7%**		

As per Table 10, overall 7% of products reported in this survey that are currently on the market are expected to require comparative assessment. **This figure is not considered to be representative of the current market**, since as explained earlier, the response rate was very low for some PT's as compared to the known number of products currently subject to authorisation under BPR. For some of those PT's it is known that most of the products require comparative assessment, for instance:

- For PT14, c.a. 2800 products are currently subject to authorisation, whilst for main group 3 pest control, only about 200 products have been reported in this survey. For PT14 100% of the products will require comparative assessment;
- Similarly for PT8, the response rate in this survey was extremely low, whilst about 1300 products are currently authorised under BPR, many of them requiring comparative assessment.

2.2 Qualitative Part

The following questions were asked as part of the qualitative questionnaire:

1. Has or will the BPR influence the number of biocidal products in your portfolio? If yes, how (increase/ decrease)? Please explain why (e.g. cost, change in market requirements, expect product will not be authorised…)

2. Which features of the UA system do you see as significant differences (positive or negative) to the process of NA(+MR)?

3. On which grounds or main criteria will your company decide to apply for UA vs NA(+MR)?

4. What would make UA more attractive to your company (please give reasons)?

5. What are the main reasons for you to consider the Biocidal Product Family concept?

6. What are your main criteria when you will select the evaluating Competent Authority (e.g. Fees, opinion, good experiences from the past, adherence to timelines, interaction, reputation)?

7. Do you intend to apply the Same Products Regulation (for yourself or in conjunction with your clients)? If yes, which percentage of your portfolio is distributed via this path?

8. Does your products' portfolio include products which require comparative assessment? If yes, will you continue supporting these products?

9. Which opportunities for innovation do you see in the area of biocides?

10. Could you indicate the number of new biocidal products (per PT) your company has introduced over the last 3 years (please indicate if the active substance(s) are approved under the BPR and their approval has or will have an influence)? Do you predict change in these trends in the coming years?

11. What are the most common changes in your product portfolio (per PT) (e.g. introducing new products, modifying existing formulations)?

12. Are your answers based on firm plans, an overall strategy or tentative expectations?

A total of 41 companies replied to this qualitative part. A summary of the replies is provided below.

It is important to note that the majority of the companies have based their answers on tentative expectations, and are aware that these predictions can evolve in the coming years, which shows that there are still a lot of uncertainties linked to the BPR process. Many companies are still in the process of defining their internal strategy.

✓ BPR impact on product portfolio and innovation

The majority of companies expect that the BPR will have a significant impact on their biocidal product portfolio, by decreasing considerably the number of products (some companies reported a reduction of around 50% of their portfolio); this equally affects SME's and large companies. Some companies have already started reducing and reorganising their product portfolio. Cost has been indicated by almost all companies as the main reason for such reduction, including cost of dossiers preparation, authorisation fees, and resources for dossier management. As such, companies have to rationalize their portfolio, maintaining products that guarantee return on investment and withdrawing products with low turnover; this may result in lower availability of niche products for very specific applications. Besides cost, the increase of technical and regulatory requirements is also a driver for product portfolio reduction. Finally, it is expected that some products will have to be phased-out due to reduced number of active substances available in the future (exclusion/ substitution criteria).

Few companies either foresee no influence from the BPR on their product range and intend to maintain their current portfolio, or expect to increase the number of biocidal products in their portfolio in the future.

Beyond the important withdrawal of biocidal products that has been reported above, the most common change in companies' portfolio is the modification of existing formulations. A few companies provided reasons for such change, mainly harmonizing products' composition to allow

grouping into BPF (products not fitting into BPF may be removed from portfolio); also optimising formulas to enhance efficacy in order to meet new standards was given as a reason for change.

Introducing new biocidal products is not a common change in companies' portfolio; it has been very limited over the last 3 years: typically, companies who reported launch of new products had introduced less than 4 biocidal products per PT over the last 3 years, mostly containing active substance(s) not approved yet under the BPR. This trend may even decrease in the future as the BPR active substance review program and subsequent product authorisation process progress. Some companies reported that they are not planning any new product launch in the coming years.

Comparative assessment

About half of the companies reported having products in their portfolio that require/ may require comparative assessment. Whilst some companies have not decided yet whether they would support such products in the future, since they still see uncertainties regarding procedure and cost for comparative assessment, a majority will try to maintain those products in their portfolio.
Again it has to be reminded that this outcome may not be representative of the market, since the response rate in this survey was very low for some PT's for which it is known that most biocidal products would require comparative assessment.

Innovation

It is clear from the replies that most companies, being SME's or large companies, see none to very limited opportunity for innovation in the area of biocides; the main obstacles to innovation that have been reported are:

- Cost: product authorisation costs are too high to justify R&D efforts needed for innovation
- Human resources: regulatory compliance is taking a lot of companies' resources, therefore there are no resources left for innovation
- BPR timelines : long regulatory timelines and uncertainty
- Availability of active substances: the number of active substances available is decreasing, and very few new active substances are introduced, which directly impacts innovation in the field of biocidal products.

The only reported areas for potential innovation are dosing and dispensing system (to control the product dose) and product (re)formulation to a limited extent (e.g. minor changes to an existing formulation).

A few companies expressed their concern about this very limited opportunity for innovation. Due to significant reduction in the number of available active substances and high BPR costs, some niche products used for very specific biocidal applications may disappear, which may affect public health in the future (e.g. hospital patients). With that, the fear for possible resistance development due to a greater use of a reduced number of biocides was expressed. Some companies do believe there is a need for innovation in the biocides area (e.g. development of new 'safer' chemistries), but that the barriers may be too high to allow the innovation that is needed.

✓ **Union Authorisation versus National Authorisation + Mutual Recognition**

It is important to note that there was overall great consistency between the replies from SME's and non-SME's with regard to UA.
For the majority of companies, regardless of their size, cost is the main criteria to choose the authorisation route. The UA or NA+MR path will be chosen based on a cost/benefit analysis depending on the number of MS where the products will be placed on the market. Costs

associated to UA are seen by most of the companies as definitely too high: lower UA ECHA fees and a guarantee that no double local annual fees would apply would make UA more attractive. In addition, a lot of companies are still concerned about the UA process given the lack of experience from all parties involved (lack of certainty about timelines, about process outcome, etc…). On the other hand, for many companies UA presents advantages over NA+MR such as harmonisation across EU, ease of access to the EU market, reduced administrative burden.

A more detailed analysis is provided below:

Cost

Cost was the comparison element between UA and NA+MR the most frequently reported by companies, regardless of their size:

- The ECHA UA fee is seen as too high and, as such, prohibitive for some companies; it was suggested that the ECHA fee should be proportional to the work required and to the added value to the process, since the initial dossier evaluation is performed anyway by an eCA.
- Double annual fees is a big concern for a lot of companies, since there is still a lack of clarity whether national annual fees will apply on top of the ECHA annual fee.

As such, a reduction of the ECHA fees and a guarantee that no local annual fee would be charged by MS's on top of ECHA fees would make UA much more attractive to a larger number of companies.

Cost is therefore the main driver for choosing between UA and NA+MR. To do so, companies are looking at the number of MS in which products in current/ future portfolio are/ are expected to be placed on the market, and then run a cost/benefit analysis (products sales, profitability and market potential in EU versus authorisation fees and dossier costs). The common opinion is that UA is too expensive if the products are sold in only a few MS. A few companies provided an indication of the threshold MS value above which UA would be more interesting to them; this value varies from 5 MS to 15-20 MS[5].

Process

The process appears to be the second matter of concern related to UA for many companies. UA is a new process, for which parties involved lack experience, and as such it is unclear whether the process will run smoothly, both from a timelines and outcome point of view. There is concern that with the UA approach, each MS has the opportunity to object to/ refuse the product authorisation request, leading to uncertainty and delays. Some companies even see a high risk with UA not to get authorisation at all as compared to the NA+MR process.

More certainty on the UA process would therefore make UA more attractive to many companies; this includes certainty that the procedure will 'work', that harmonised criteria will be applied for all products, guarantee about the quality of the evaluation and that ECHA's opinion will be respected and accepted by MS, guarantee that expected authorisation dates will be met. In this respect, it has been reported that receiving positive feedback from parties who have experienced the UA process would make UA more appealing.

[5] NB: From the quantitative part of the survey, no correlation could be drawn between the number of MS in which the products are expected to be placed on the market and intention to submit the dossiers to UA.

Simplification, ease of access to EU market and harmonisation

Many companies see the administrative simplification and ease of access to the EU market as the biggest advantage of UA over NA+MR. They see that UA offers:

- less administrative burden: one dossier for all EU countries, also avoiding unnecessary testing due to optimized data requirements
- a simplified process and harmonised approval: process driven by ECHA with clear deadlines; reduction of the uncertainty related to the interpretation of the regulations and administrative delays at national level; getting approval for all MS by one registration process means less effort compared to NA+MR; smaller number of contact points (ECHA + eCA) compared to individual communication with each MS within NA+MR
- one authorisation valid across all EU countries means a streamlined access to the EU market ("one stop shop" for an authorisation covering 28 MS).

Product Types

The UA phasing approach per PT and current exclusion of some PT's from UA have been reported by several companies as an issue. The UA phase-in periods per PT (according to BPR Article 42(1)) and current AS Review Program time limits per PT (Annex III of the Review Program Regulation) are forcing companies to go to NA+MR in some cases (PT2 and PT13 have been cited).

Selection of the eCA

When selecting the eCA, companies often look at a combination of several criteria:

- **Fees level** is by far the main criteria reported by companies, regardless of their size. Only a very few companies clearly mentioned that the fee is a secondary criteria or even not a criteria at all.
- **Communication and interaction with the eCA** also plays an important role: good experience from past interactions and good connection with the eCA are critical. For some companies, the local CA will be the preferred one because of the common language that facilitates communication. In case communication is not possible in their mother tongue, companies' experts will prefer an English speaking MS.
- **The experience and competence of the eCA** has also been cited by many companies, covering: scientific/ regulatory knowledge, technical competence and working methods, experience with the biocidal product being evaluated and related active substance(s), pragmatism, flexibility on data requirements. In relation to this, the eCA's reputation plays a key role, for instance its reputation to apply scientific rather than political criteria.
- **Adherence to timelines and eCA's internal resources** are also relevant criteria taken into account by companies.

✓ **Biocidal Product Families and Same Biocidal Product regulation**

Biocidal Product Families

Companies often reported a combination of several reasons for considering the BPF concept:

- **Product portfolio**: the most obvious reason to consider product grouping into a BPF is the composition of the companies' product portfolio. Companies having many similar formulations with similar uses in their portfolio will very likely apply the BPF concept. Some companies reported that having core formulations / technologies as a basis for their product range (for instance few variants of concentrations of active substances and a few physical forms, but a lot of variants of perfumes and colours) is part of their formulation strategy.

Only a few companies indicated that they will not use the BPF approach because it is not relevant for their product portfolio.

- **Cost saving** was the most frequently reported driver for considering applying the BPF concept, as it is seen as a cost effective approach that allows reduction of the administrative cost per product.
- **Reduced administrative burden** was the second benefit pointed out by companies: grouping several products under one common dossier instead of several dossiers allows reducing the workload and complexity in dossier management. Companies trust it will simplify and optimize the application and authorisation process, and allow time saving.
- **Flexibility** was also cited as a benefit by several companies: the BPF concept facilitates the placing on the market of new products when eligible as a new member of an authorised family, and gives the possibility to optimize the formulations or the production process within an authorised BPF.
- **Helping management of customers' portfolio** is also seen by a few companies as a benefit; a few examples have been reported such as companies manufacturing private label products for their customers, use of the BPF concept in combination with UA and Same Biocidal Product (SBP) regulation, i.e. to establish one product family and give access to single members of the family to different customers.

It is to be noted that, as for other topics, there was overall consistency between the replies from SME's and non-SME's.

SBP

Around half of the companies, both SME's and non-SME's, indicated an intention to make use of the SBP Regulation, for themselves or for their clients. The possibility to use the BPF approach in combination with UA and the SBP regulation has been mentioned as a driver for using the SBP regulation. In most of the cases the SBP would apply to more than one third of companies' portfolio - some companies have even reported above 70% of their portfolio distributed via this route.

3. Comparison with the findings of the A.I.S.E./EBPF 2011 survey

Table 11 below provides an overview of the main findings of the 2011 survey and the present one.

Table 11: comparison between the 2011 & 2015 surveys

	2011	2015
Response rate		
Number of companies who provided input	89	47 (amongst which 22 had participated in 2011)
SME's contribution	38,2% SME's	48,9% SME's
Products covered by the survey		
Number of products	7939 (1)	2318
PT's covered	Main group 1: PT1, PT2, PT3, PT4, PT5 Main group 2: PT6, PT7, PT8, PT9, PT10, PT11, PT12, PT13 Main group 3: PT14, PT18, PT19, PT20 Main group 4: PT21, PT22, PT23 PTM	Main group 1: PT1, PT2, PT3, PT4, PT5 Main group 2: PT6, PT7, PT8, PT9, PT10, PT11, PT12, PT13 Main group 3: PT14, PT18, PT19 Main group 4: PT21, PT22 PTM
Distribution of products in each main group	Main group 1: 59% Main group 2: 21% Main group 3: 13% Main group 4: 5% PTM: 3%	Main group 1: 47% Main group 2: 23% Main group 3: 9% Main group 4: 0,1% PTM: 21% (half of them PT2/4)
Expected product drop rate in the future	32%	26%
Biocidal Product Families		
% of products that would be grouped into BPF	71%	74%
MS in which products are placed on the market		
Distribution of products in "MS bands" Local: 1-2 MS Sub-regional: 3-5 MS Regional: 6-10 MS European: 11-28 MS	 Local: 16% Sub-regional: 19% Regional: 33% European: 32%	 Local: 8% Sub-regional: 13% Regional: 21% European: 54% (2)
Union Authorisation		
% of dossiers (individual products and BPF) that would be submitted for UA	56%	44% (3)

(1): in 2011 one company had indicated extremely high number of products in the PT2 and PT18 categories
(2): for 5% of the products the number of MS in which products are placed on the market was not reported by companies
(3): considered to be over-estimated since a few companies reported a number of UA dossiers higher than their total number of dossiers foreseen.

The response rate in the present survey was much lower than in 2011 (almost 2 times less). **The number of products covered is also much lower than in 2011, respectively 2318 versus 7939 in 2011**. Both surveys cover a large number of product types; however as previously reported, in the present survey the response rate was extremely low for some PT's, namely PT7,

PT8, PT9, PT10, PT13, PT14, PT19, PT21 and PT22. The main group 1 disinfectants is the most represented product category for both surveys, representing 59% of the total products in 2011 and 47% in 2015.

The current prediction regarding the product withdrawal rate (once the active substance is approved) remains in the same range as compared to 2011 (i.e. around 30%). The proportion of products expected to be grouped into BPF has remained quite similar as well, i.e. around 70% of the products in both surveys.

With regard to the number of MS in which products are placed on the market, figures indicate a trend towards European scale: in 2011 the survey indicated 32% of products sold in 11 to 28 countries, versus 54% in the present survey.

On the other hand, this trend does not seem to correlate with the intentions to get products authorised via UA, since in 2011 companies indicated that 56% of the dossiers would be submitted to UA, versus 44% in 2015.

4. Conclusions

Despite the relatively low response rate as compared to the 2011 survey, the present survey allows drawing interesting conclusions with regard to the impact of BPR on companies' portfolios, on the impact on innovation, and on UA and BPF - two main new features introduced by the BPR.

The majority of companies who participated to this survey, whether SME or larger company, indicated that the BPR has a direct impact on their portfolio, leading to a considerable decrease of the number of biocidal products, mainly due to the heavy compliance costs and heavy technical and regulatory requirements. Overall, about one fourth of the products currently on the market covered by this survey are expected to be withdrawn in the future.
The BPR is seen as a major obstacle to innovation due to the high resource requirements involved in BPR activities (both human and financial), long BPR timelines and decreasing availability of active substances. As a consequence of these high costs linked to the implementation of BPR, the very limited innovation possibilities and the reduced availability of active substances, it is anticipated that some niche biocidal products used for very specific applications may disappear, which may negatively affect public health in the future.

On the other hand, the survey shows that most of the companies who replied see some opportunities for simplification and reduced administrative burden when applying the BPF and UA concepts.
The 2011 survey had shown that many companies were interested into the BPF concept; 4 years later, and about 2 years after the entry into force of the BPR, this new survey shows that the BPF concept is still appealing to industry. Indeed, about 75% of products expected to remain on the market in the future (from this survey) are intended to be grouped into BPF, with cost saving and reduced administrative burden being the main drivers reported by most of the companies.
Similarly, UA still remains attractive to industry, even if the intentions to go to UA seem to have decreased since the last survey: 44% of the future dossiers (individual products and families) from the present survey would be submitted to UA versus 56% in the 2011 survey. Whilst many companies see advantages in using the UA pathway instead of NA+MR - such as reduced administrative burden, harmonisation across EU and ease of access to the EU market - UA costs are seen as definitely too high by a majority of companies, regardless of their size. Companies reported that lower ECHA fees and a guarantee that no double annual fees would apply, would make UA much more attractive.

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