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Basic Substances in Organic Agriculture: Current Status

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Abstract

Basic substances are one of the new categories of active substances created under the "new" plant protection products (PPP) Regulation EC 1107/2009. They are approved for use in the European Union and are mostly biorationals, medicinal plant extracts, products used in human medicine, food compounds or additive and common substances sold as biocide, fertiliser or cosmetic but now triggered to be used as plant protection means. A list of 24 basic substances approved is available through the EU Pesticides database. However, numerous applications of biorationals as basic substances were rejected, from inadmissibility or ineligibility, through abandonment or withdrawal, to non-approval, with the explanation for these decisions, their excessive risk for the operators, applicators or consumers by the substance itself or its possible residues. Nevertheless, these substances are still sold for their original purpose, without any modification which would have been expected due to this risk evaluation conclusions. In sum, it is too dangerous to use them in crop protection.

1. Introduction

For the purpose of sustainable and qualitative organic food production, biocontrol has grown tremendously through the last few years. European regulation followed and carried this development with the introduction of new classes of phytosanitary products, in particular Basic Substances (Katouzian-Safadi et al., 2020; Marchand 2015, 2016, 2017a, b, c, Marchand et al., 2021), but also new laws and simplification theoretically accompanied by the ease of registration processes for low-risk substances.

Basic substances may be of major importance in biocontrol (Robin and Marchand, 2019), representing 11% of the biocontrol agents (BCA). Basic substances are approved for an unlimited period, EU wide, with no Maximum Residue Limit (MRL) (Charon et al., 2019) and allowed in the organic sector itself (Marchand, 2017b, c).

The standard-folder to deposit a Basic Substance, called 'Basic Substance Application (BSA)' in the "EU PPP basic substance" context, is based on IUCLID 6 software from EFSA (European Food Safety Agency) for active substances which can be used for different purposes.

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2. Materials and Methods

Basic Substance criteria are defined by article 23 of PPP regulation (EC) N° 1107/2009. SANCO 10363 rev.10 is the Guideline involved in this process. Organic basic substances are dependent on Article 24 of organic regulation and listed in Annex I of Regulation (EU) 2021/1165 (Romanazzi et al., 2022).

3. Results

In 11 years, only 37 % (24 basics) of BSA submitted have been approved and 63 % refused (Figures 1&3). Among approved basics, 19 were realised by the ITAB, placing our institute as the leader concerning basics and probably having the largest experience concerning those files.

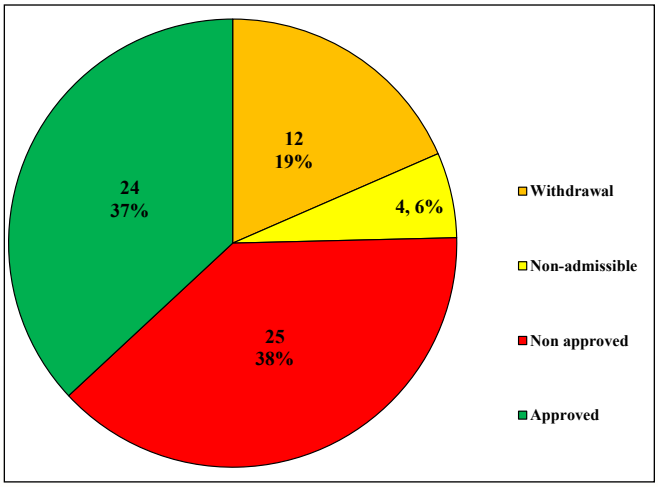

Figure 1: Repartition of basic substances applications with official admissibility check

These statistics are available on visible BSA, those which have given rise to EFSA opinions. Behind the official amount (51), the results exhibited in Figure 1 of this publication are still largely higher (65) including cases not voted. Added to these calculations are the BSA competing for admissibility and under evaluation treatment.

3.1. Approved basic substances

Considering this important hidden part, the amount of approved basics (24) is surprising low whereas dozens of applications were launched (Figures 1 & 3 and Table 1). The evolution of approved basic, including organic production inclusion, is detailed in Figure 2 and Table 1.

Observation can be made on the curve in Figure 2 that after 4 years of a real implementation (2014-18), a stagnation is manifest (2018-22).

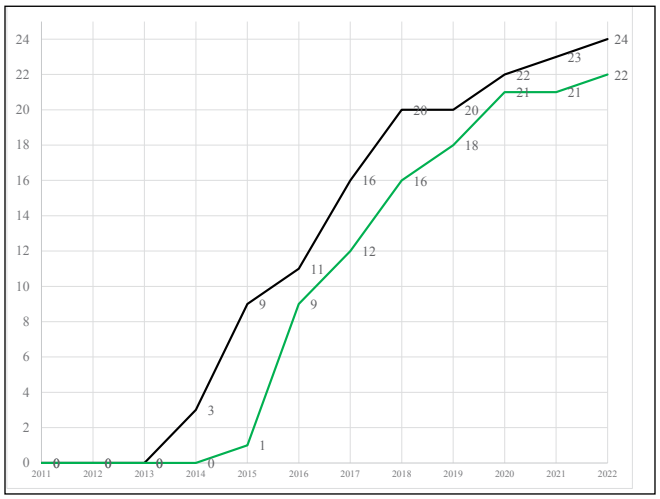

Figure 2: Evolution of basic substances including allowance in organic production (green)

Table 1: Approved basic substances

Substance	Year	Origin	Status	Organic
Equisetum arvense L.	2014	Plant	Food	☑
Chitosan hydrochloride	2014	Animal	Food	☑
Sucrose	2015	Plant	Food	☑
Lecithins	2015	Plant	Food	☑
Calcium hydroxide $CaOH_2$	2015	Mineral	Medicinal	☑
Vinegar	2015	Plant	Food	☑
Salix spp. cortex	2015	Plant	Food	☑
Fructose	2015	Plant	Food	☑
Sodium hydrogen carbonate	2015	Mineral	Food	☑
Diammonium phosphate	2016	Mineral	Oenological	☑
Whey	2016	Animal	Food/Feed	☑
Sunflower oil	2016	Plant	Food	☑
Hydrogen peroxide	2017	Chemical	Medicinal	☑
Beer	2017	Plant	Food	☑
Urtica spp.	2017	Plant	Food	☑
Clayed charcoal	2017	Mineral/ Plant	Feed	£

Substance	Year	Origin	Status	Organic
Sodium chloride NaCl	2017	Mineral	Food	☑
Mustard seeds powder	2017	Plant	Feed	☑
Talc E553B	2018	Mineral	Medicinal	*
Onion oil	2018	Plant	Food	☑
L-cysteine	2020	Animal	Food	☑
Cow Milk	2020	Animal	Food	☑
Allium cepa L. bulb extract	2021	Plant	Food	☑
Chitosan	2022	Microbial	Oenological	£

*: Validated by EGTOP, ongoing vote at EU RCOP Committee; £: Ongoing application

After approval, a basic substance can be subject to an extension of usages corresponding to one or more line addition in the GAP Table (Good Agricultural Practices). In fact, many of these basic substances were initially approved with a weakly constituted GAP Table due to the absence of field data/trials.

These voted extensions of uses have therefore been materialized by simple updates in the Review Reports in the pesticide database, with or without Implementing Regulations. In any case, all these extensions had to provide during application the results of field trials and letters of support from users and/or sectors concerned by these usages, at least to obtain admissibility.

3.2. Rejected basic substances

From all applications since 2012, 38% were non-approved (Figure 1&3) corresponding to 25 BSA in Table 2.

The reasons to such a number of refuses are mainly due to a lack of data or an eventual toxicity concerning a component, active or not, of the substance. They are detailed in our last review (Romanazzi et al., 2022), however, these substances are still qualified for diverse uses: oenological, medicinal, food or feed, cosmetic… Moreover, some non-approved basic substances were approved by Member States for these other usages although considered as toxic/ecotoxic for crop protection purposes by EFSA and led to the rejection.

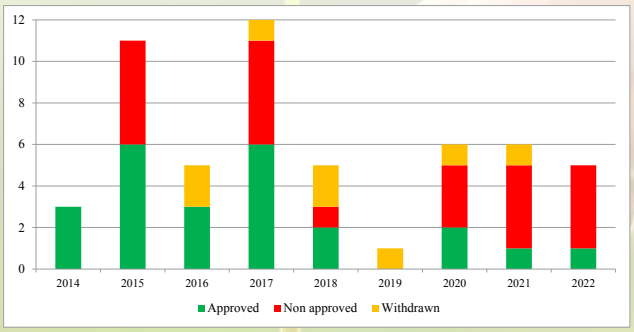

Figure 3: Evolution of basic substances application issues

Despite everything, food additives should not be considered intrinsically as all innocuous, because certain chemical pesticides such as thiabendazole, a fungicidal active substance, are also (E 233). More recently *Achillea millefolium* L. rejected as basic was allowed as herbal traditional substances while the EFSA opinion as basic qualified the extract as "contains chemicals of possible concern to human health when used in food and food supplements".

This may suggest that horizontal information exchange does not exist and that separate regulations are managed in stovepipe by the same Authority/Agency. Then, many substances (in red in Figures 1 & 3) were the subject of a very negative EFSA opinion and therefore a non-approval. This is currently the case for numerous basics (Table 2).

It is also painful to see that largely more half of BSAs is failing and that in the last 4 years, only 14 BSA evaluations have been finalized when there is 16 pending (Table 3) when only 9 are available in EU pesticide database and 6 of them already proposed for non-approval (Table 2).

Similar situation is observed for extension of uses and 8 extensions or more are pending (Table 4).

3.3. Application pathway time frame

Timeframe is also controversial since, as an example, talc and onion oil have been approved in 2018 though first was deposited in 2017 and talc in 2013. Last approved chitosan, in 39 months was initially deposited as an extension of use and requalified later by Commission as a separate basic.

Legal delay, about 18 months maximum considering all phases (Figure 4) does not appear as abnormal, the average delay is over the legal timing.

Unfortunately, all other stages are extremely close to maximum delays or above and it is not possible to compensate slow one step by another faster step, these stages being linked and successive. These facts clearly highlight an important issue: European authorities do not comply with their own written laws and rules, and finally

Table 2: Not approved basic substances

Substance	Year	Origin	Status
Achillea millefolium L.	2017	Plant	Food/Pharmacopeia
Arctium lappa L. (aerial parts)	2015	Plant	Medicinal
Artemisia absinthium L.	2015	Plant	Food/Pharmacopeia
Artemisia vulgaris L.	2015	Plant	Food/Pharmacopeia
Capsicum annuum L. var. annuum, longum group, cayenne, extract (Oleoresins capsicum)	2021	Plant	Food/Feed/Pharmacopeia
Carbon dioxide (basic substance)	2021	Chemical	in air/a.s.
Comfrey steeping	2021	Plant	Food
Dimethyl Sulfide	2021	Chemical	-
Grape (*Vitis vinifera*) cane tannins	2020	Plant	Oenological
Landes pine tar	2018	Plant	Medicinal
Origanum vulgare L. essential oil	2017	Plant	Food/Feed/Pharmacopeia
Paprika extract (capsanthin, capsorubin E 160 c)	2017	Plant	Food
Potassium sorbate E 202	2017	Mineral	Food
Propolis (Water soluble extract)	2020	Plant	Food/Medicinal
Rheum officinale root extract (rhubarb)	2015	Plant	Food/Pharmacopeia
Saponaria officinalis L. roots	2020	Plant	Food/Pharmacopeia
Satureja montana L. essential oil	2017	Plant	Food/Pharmacopeia
Tanacetum vulgare L.	2015	Plant	Food/Pharmacopeia
Calcium propionate E 282	2022	Mineral	Food
Black Soap E 470a	2022	Plant	Food/Cosmetic
Lemon essential oil £	2022	Plant	Food
Willow bark and stem extract £	2022	Plant	-
Hydrogen peroxide silver-stabilised £	2022	Chemical	Biocide
Yucca schidigera extract £	2022	Plant	Fertilizer

£: Proposed vote at EU Plants, Animals, Food and Feed (PAFF) Committee

that's the organic sector, majority in the applicants, which suffer because of this lack of consideration. No statistics are published about basic substances, so, to assess precisely at which step of basic substances approval problems were met, all accessible data concerning this subject had been collected and analysed. Those results show that most of stages in charge of EU (DGSante, Member States, PAFF), are mainly exceeding legal delays fixed as goal (Figures 5&7).

And more worrying, it seems that those stages are lasting longer as the years go by, except for Figure 5&7.

The average between EFSA outcomes and vote in Figure 7 is 7.6 months and there is still an important number of basics not placed to the vote with published EFSA opinions above 6 months.

4. Discussion and Perspectives

4.1. Effective needs

There is, a lack of BCAs and basics might be a good solution, for a part. But, authorities in charge of this regulatory process, except for nice announcements, aren't going fast enough and the problem becomes harder to solve every year. If we are not able to solve such an important need environmentally and healthy solutions, with solutions such as basics, how could we find a way to preserve our planet while holding agricultural production?

Basics, probably less efficient and practical to use than other active substances authorized as PPP, are known

Table 3: Pending Basic Substances Applications (BSA)

Pending (EFSA outcome published)	Ongoing applications
Ozone	Hop (*Humulus lupulus*) extract
Caffeine	Organic polyphenolic botanical compost
$CaOH_2$	Sainfoin (*Onobrychis viciifolia* var. Perly) dried pellets
Sodium hypochlorite	*Allium fistulosum* extract
	Quassia amara
	Eggshell
	Moringa oleifera
	Psidium guajava L. leaf extract
	Pepper dust
	Ocimum gratissimum extract
	Water
	Grape seed extract
	Magnesium hydroxide
	Natamycin
	Hexane
	Ginger extr.
	Capsicum f. oleoresin

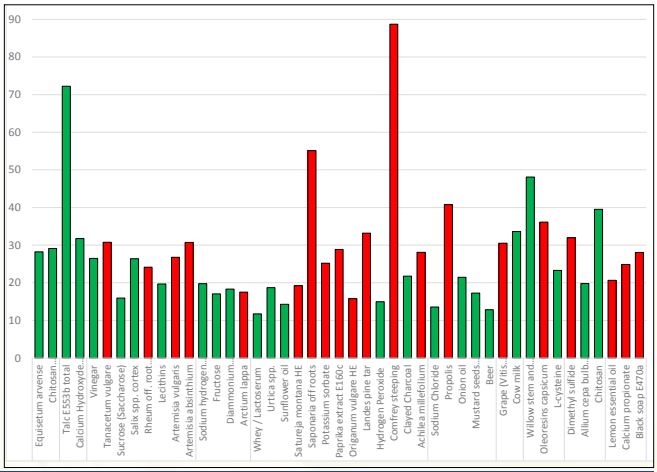

Figure 4: Total timing from deposit to vote by deposit year (in months)

and used by producers since decades (Katouzian-Safadi et al., 2020) sometimes as substitution mean and still demonstrated their efficacy. When such biorationals demonstrate a minimum efficiency to a crop protection purpose, in this context, it is a terrible waste to see that 2/3 of BSA failed. A waste for EU authorities,

Table 4: Extensions applications for approved basic substances

Pending (EFSA outcome published)	Ongoing applications
Sunflower oil	$CaOH_2$
Urtica sp.	*Urtica* sp.
Equisetum arvense	*Salix* cortex
Sodium chloride (NaCl)	Lecithins

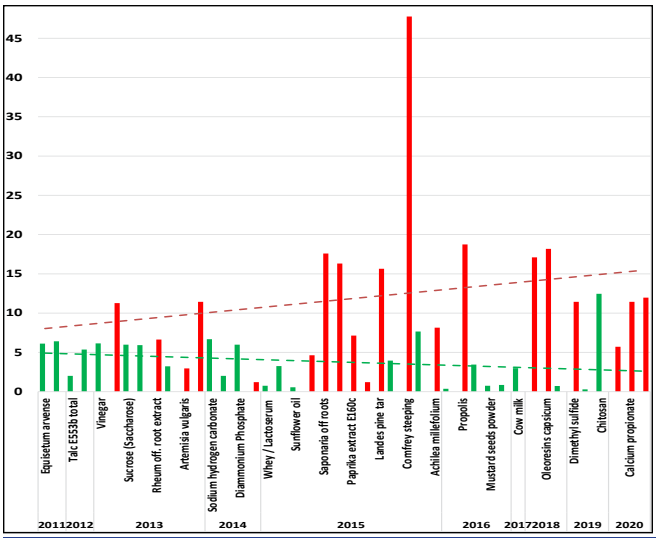

Figure 5: Delays required for admissibility by deposit year (in months)

which are handicapping themselves by going against European projects on basics, regulations and directives, but especially for producers that are directly suffering from this increasing lack of solutions. Another problem is that a lot of chemical PPPs aren't renewed and leaves a gap for some uses, called "orphan uses". As the recent derogations for neonicotinoids shows, EU rather temporary authorised withdrawn PPPs rather than allowing better environmentally friendly substances for these usages. Indeed, EU shall legalize some lighter PPP, because farmers can't stand without solutions for these gaps.

But these basics seem to be evaluated more and more strictly over time, completely erasing the specificity and the initial criteria of these substances: "already authorized and sold in Europe for other purposes **and** useful for the protection of plants". Although the situation seems to be effective and positive regarding implementation of basics with 24 approved, some systemic problems are still unsolved. It is currently not possible to predict the outcome of an application even for food substances (i.e., *Capsicum* pepper, Grape (*Vitis vinifera*) cane tannins, potassium

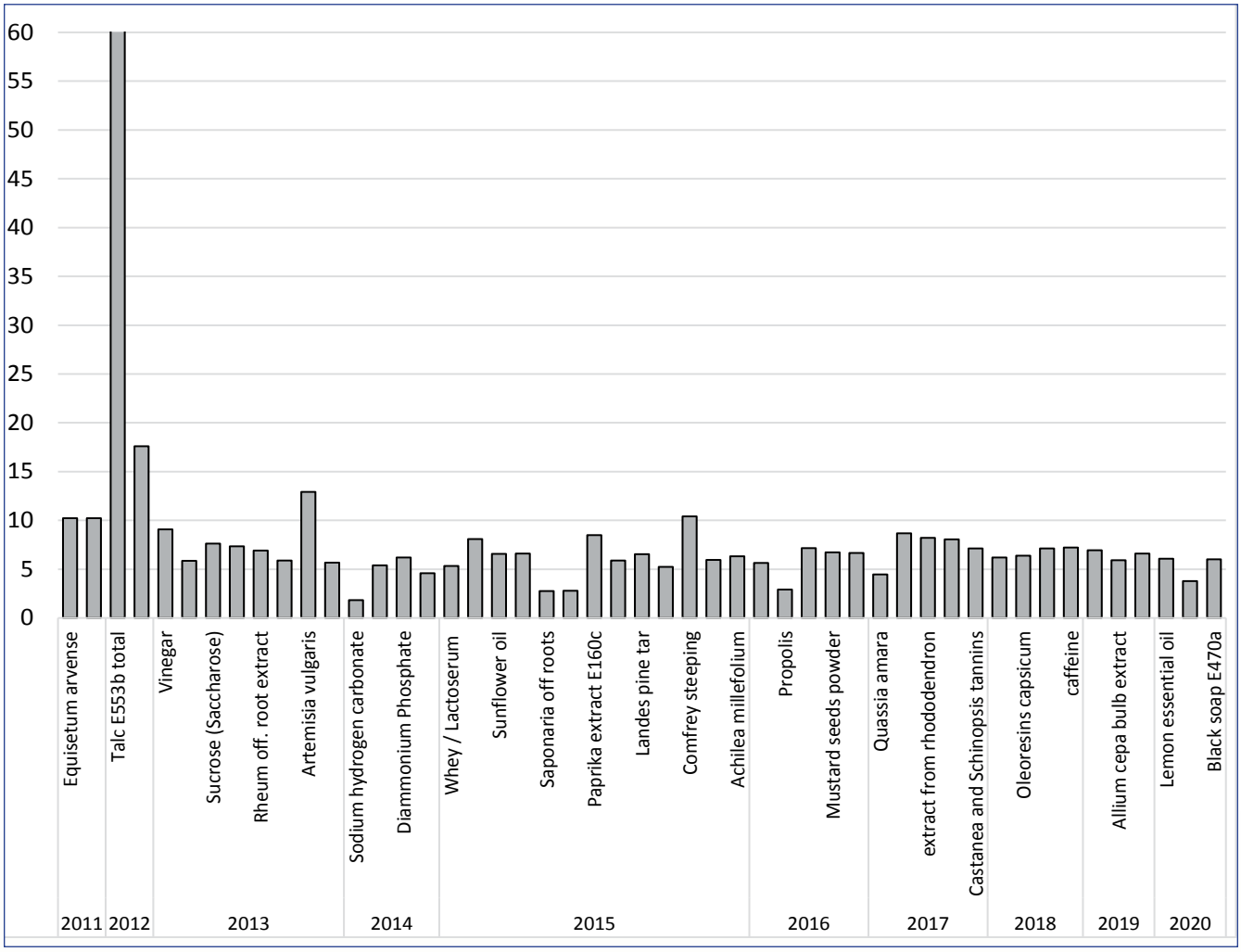

Figure 6: Delays required from admissibility to EFSA outcome by deposit year (in months)

sorbate E 202, propolis, potassium metabisulfite E 224), medicinal on skin (i.e., *Actium lappa*), or even with very limited uses (i.e., dimethyl sulphide). Furthermore, when non-approvals are decided based on toxicological statement, basics are still authorized for their others main uses and no retro action regarding horizontal health security is engaged. In fact, harmonisation, horizontal verification, management nor retroaction loop is never engaged at EU level. Finally, if producers' security and welfare are mentioned during evaluation/votes, refusing healthier used solutions because they're not perfect, place users in illegality even using foodstuff.

Another reason is the complexity of BSA. Extremely strict criteria are required for an approval, concerning toxicity, environmental impact, economic aspect…

Most of the time, all points can't be totally completed because of the availability of scientific data, especially when traditional feed, foodstuff are involved, globally leading to a refusal. For example, it is frequently asked for *totum* plant extract to details the whole composition and to define active ingredient(s) overall to set doses based on chemical molecules standards.

Moreover, some abandoned substances should be transformed in basic (i.e., pepper dust) without excessive delay.

Finally, a few eligible applications were withdrawn (Figures 1&3), with or without an EFSA outcome. The withdrawal was made mainly due to the inability to answer the questions during the evaluation. Moreover, non-approved basics may be applied later, but in fact, refused basics are almost impossible to bring it back to the EU review nor gaining approval (capsicum spice case).

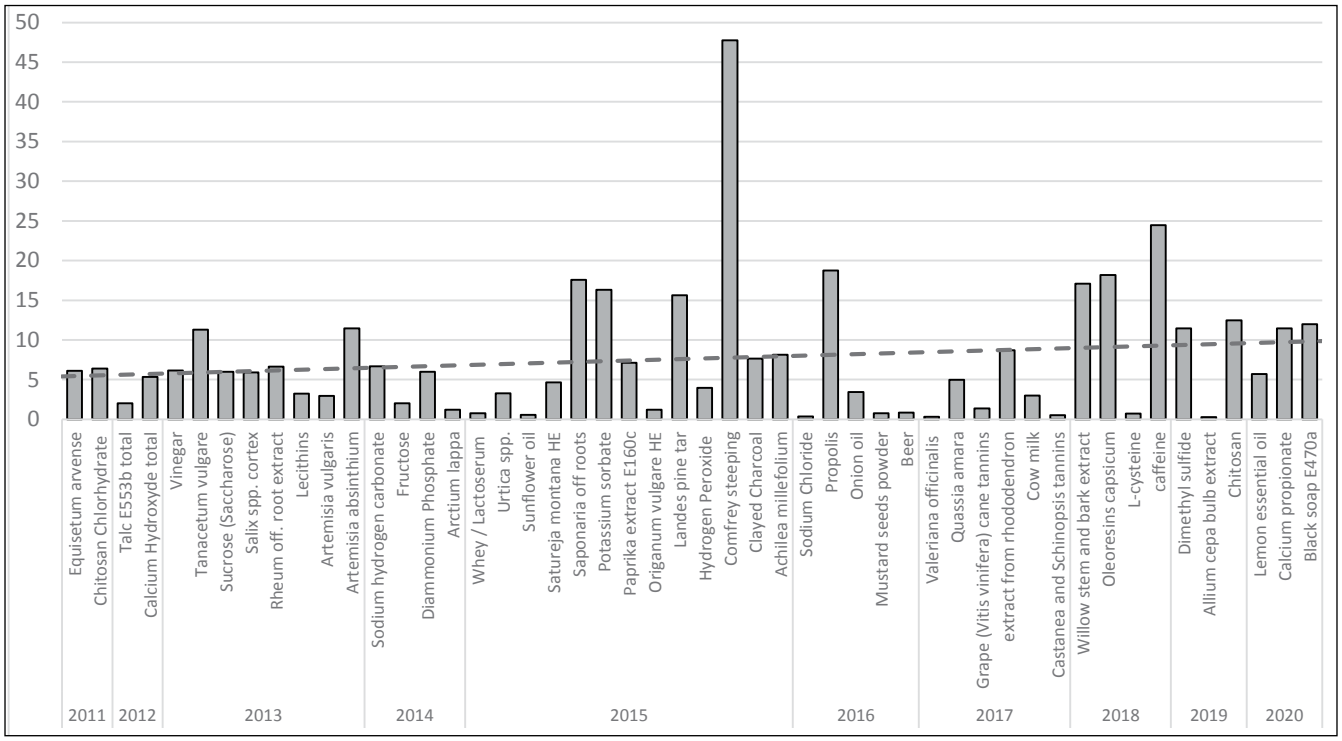

Figure 7: Delays required from EFSA outcome to vote by deposit year (in months)

4.2. Basic substances: crop protection substances, but not completely

Basics are considered as any other PPP category, even getting stricter effective criteria.

Lastly, a special case of applications resulting in a regulatory progress without EFSA outcome nor admissibility appeared in 2020, that of carbon dioxide (CO_2) already approved as an active substance, for which the candidacy as basic resulted in a non-approval, demonstrating that an active substance cannot be a basic.

Apart, the approval of sodium bicarbonate as basic has generated numerous and recurring disputes. Contested after basics approval, its withdrawal is regularly requested before and after the parallel low-risk approval, even going to EU Court for trials, and later after corresponding market authorisations. This removal possibility, initially just a fear, is now very real, resulting in the withdrawal of certain BSA and the questioning of certain possible applicants.

New BSA deposits via IUCLID6 software were launched. However, our first deposits were tougher and messy, despite promises issued.

5. Conclusion

Basics are still a very promising PPP category following the massive ongoing reduction of the chemical PPPs. However, European authorities always demand more from these BSAs, despite being food/feed products. Instead, actual massive basics non-approvals generate fear and withdrawals from applicants, however, future projects concerning new basic substances are still on the way.

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