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Evolution of Regulation (EU) No 540/2011 since its entry into force

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Abstract

Regulation (EC) No 1107/2009 concerning the placing of plant protection products (agrochemicals) entered into force in 2011. Implementing Regulation (EU) No 540/2011, in turn, manages the list of approved active substances in the European Union. This implementing regulation is divided into five parts: Part A (initial active substances dating from 2011), Part B (renewed and newly approved active substances), Part C (basic substances), Part D (low-risk active substances), and Part E (candidates for substitution) that have emerged over the years. These parts have evolved over time, with an unavoidable decline of Part A and a logical increase of the other parts. Less harmful substances for the environment have been favored by this regulation (Parts C and D); however, some candidates for substitution (Part E) will remain allowed in the coming years, despite their problematic status. This study has also examined the postponement of the final date of approval, which has resulted in one half of the active substances being affected by an extension of their approval periods.

Keywords: agrochemicals, Regulation (EU) No 540/2011, Regulation (EC) No 1107/2009, active substances, basic substances, low-risk substances, candidates for substitution

1. Introduction

The term "pesticides" is generally related to crop or plant protection products (PPP) and post-harvest products. PPP brings together the active substances and the formulation components. To be allowed for this purpose, the active substance of pesticides need to be authorized (approved in regulating terms).

The European pesticides management rules are triggered by Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, which entered into force in June 2011 [18], and revoked previous Directives 79/117/CEE [7] and 91/414/CEE [8]. Directive 79/117/CEE prohibited the placing on the market and use of plant protection products containing certain active substances, whereas Directive 91/414/CEE concerned the placing of plant protection products in the market during previous 20 years.

Implementing Regulation (EU) No 540/2011 (IR540) [2] managed the development of Regulation (EC) No 1107/2009, and contains indexes of all authorized active substances. When IR540 came into force, it was composed of 398 distinct active substances only in part A. These active substances were further classified into two parts, A and B, by the IR540; Part B expanded slowly due to the approval of new substances and renewal of the existing substances, while Part A is supposed to decrease inexorably since there is no new admissions into the initial list [2, 3].

The aim of this study was to examine the evolution of the different parts of Implementing Regulation (EU) No 540/2011 since its entry into force and over the last 8 years.

2. Materials and Methods

Raw data were taken from the website EUR-Lex [10] for Implementing Regulation (EU) No 540/2011, and the regulations for each substance or block of substances were used to index all the approvals, renewals, withdrawals, and extensions of the approval periods (prolongations) or changes of category. They were also used to determine which and when other parts of the IR540 were added since 2011.

It has to be noted that one substance can only be in one part at the same time with its own classification number. Each time a substance is moved from one part to another, a new, independent number is assigned to it in the corresponding part.

3. Results

Implementing Regulation (EU) No 540/2011 is currently composed of five parts, among which active substances often move or appear. Figure 1 describes the possible changes of active substances between different parts and the corresponding

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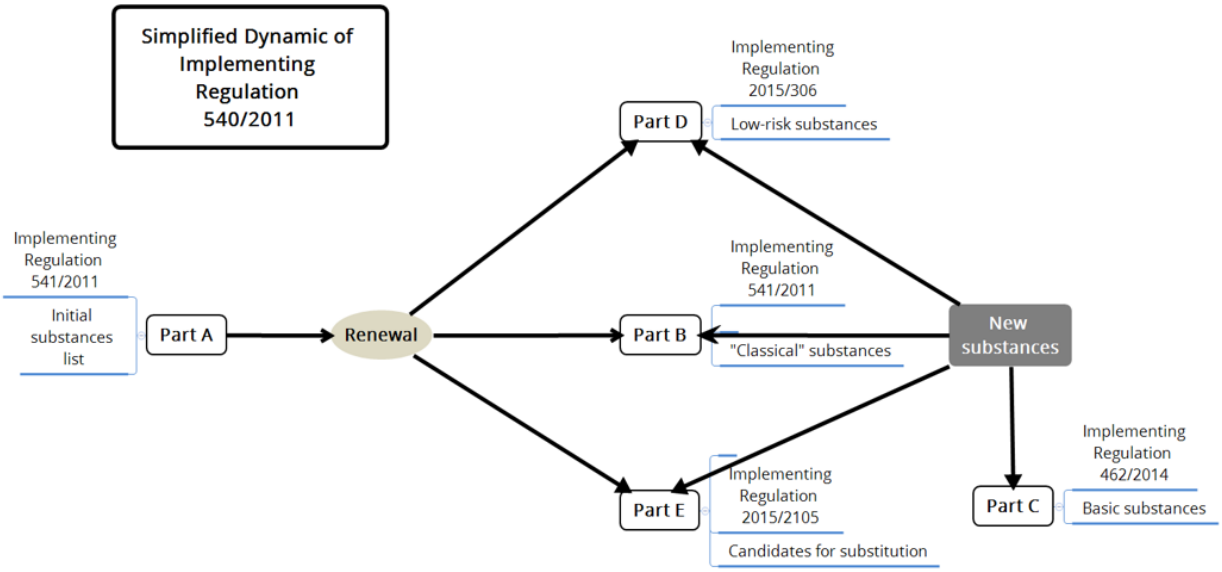

Figure 1: Simplified Dynamic of Implementing Regulation 540/2011.

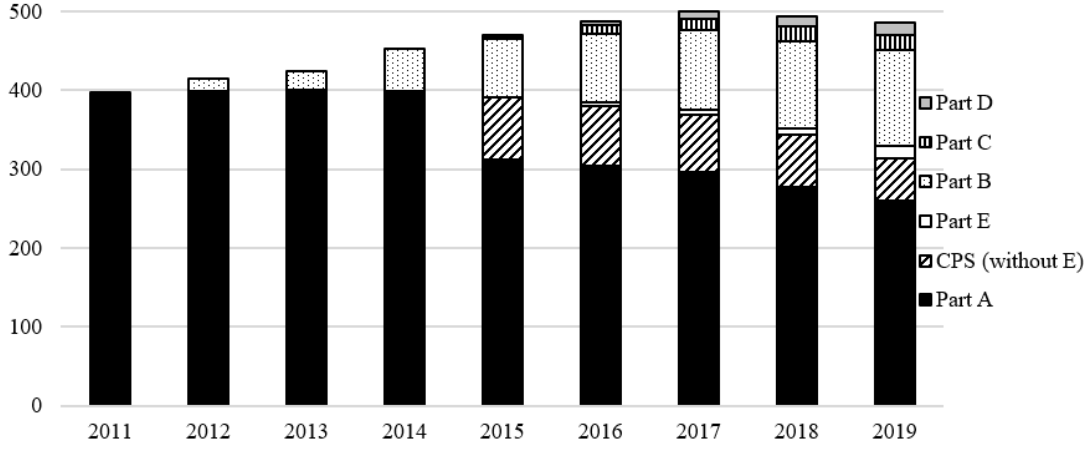

Figure 2: Evolution of Parts of Regulation 540/2011 since its entry into force.

initial implementing regulations, whereas Figure 2 depicts the developments in the different parts since 2011 in terms of number of substances.

Part A is the list of initial active substances authorized at the entry into force of the IR540. Renewed, non-renewed or withdrawn active substances left Part A, which led to a decrease in the total count of substances listed therein (down from 398 substances to 304). Part B is shown alongside Part A in the Implementing Regulation (EU) No 541/2011 [3], and was initially composed of all new and renewed active substances. At the present time, 129 substances are included in Part B. Later, Parts C, D and E were created by the first substance entries in these parts.

Therefore, 531 distinct active substances - not all authorized simultaneously - have been used in fields since 2011. From these, 234 active substances have been processed (46 were not renewed, 58 were renewed, and 130 newly approved were included in parts B, C, D or E).

Three parts, C, D and E, include specific types of active substances; basic substances, low-risk substances, and candidates for substitution (CfS), respectively. The Commission Implementing Regulation (EU) No 462/2014 opened and implemented Part C, with the approval of *Equisetum arvense L.* as a basic substance defined by Article 23 of Regulation (EC) No 1107/2009 [14, 15, 18]; Part C currently includes 20 substances. Low-risk substances defined by Article 22 of Regulation (EC) No 1107/2009 [17, 18] are classified since 2015 by the Commission Implementing Regulation (EU) No 2015/306 in Part D, which currently includes 15 substances. It also needs to be mentioned that the numbering of EU legal acts changed in January 2015 [12].

Part E is the last part generated by Implementing Regulation (EU) No 540/2011. The list of candidates for substitution (CfS) defined by Article 24 of Regulation (EC) No 1107/2009 [18] was published in January 2015. Candidates for substitution are complying with the criteria provided for in Article 4

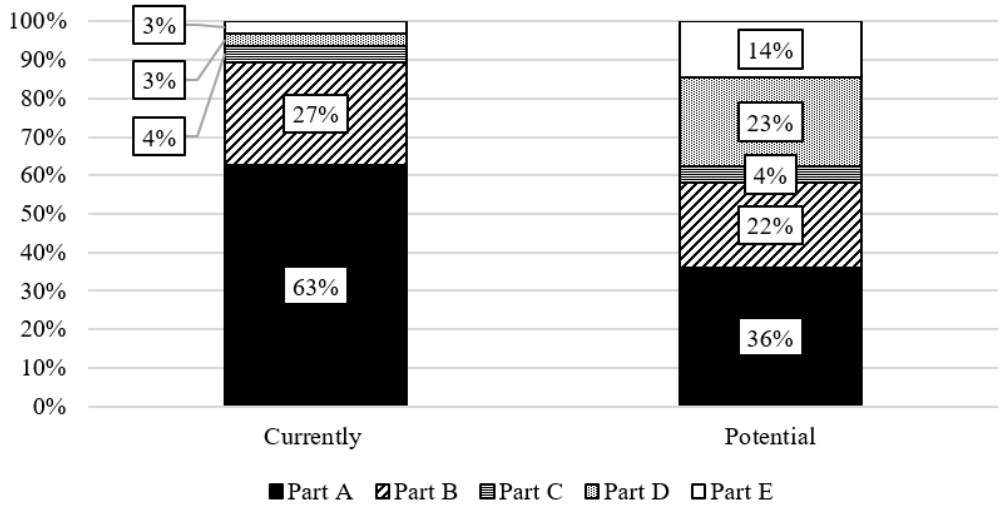

Table of results:

Number of Active Substances	Currently	Potential
Part A	303	174
Part B	129	107
Part C	20	20
Part D	15	112
Part E	16	70
Total	**483**	**483**

Figure 3: Potential % of substances in the different parts.

and additional criteria laid down in point 4 of Annex II of Regulation (EC) No 1107/2009. Initially, 77 CfS were listed [9]. CfS substances newly approved or renewed (from Part A) since the entry into force of Commission Implementing Regulation (EU) No 2015/2105 are classified in Part E. Thus, not all the CfS (71 in total) are listed in Part E, which is currently composed of 16 active substances (including the last two approved substances: flumetralin and benzovindiflupyr).

A hypothetical scenario has been made for the future development of these Parts, with two hypotheses: 1) All the CPS will enter in Part E, and 2) all the potential low-risk substances referenced by the Commission Notice (2018/C 265/02) [6] will be entered in Part D. The outcome is shown in Figure 3 and displays a significant decrease of Part A (63% to 36%), together with Part B (27% to 22%), which means that most of the CfS substances (potentially directed towards Part E) or potential low-risk substances (theoretically targeted to Part D) will need to undergo a renewal procedure.

Another result obtained by examination of the IR540 regulation is a finding that the number of substances with approval prolongation increased constantly since its entry into force, as shown in Figure 4. Normally, the fate of phytosanitary substances is stated at the end of the allowed period. However, for many reasons, an important number of substances have undergone an extension of their approval periods. Since the entry into force of Regulation (EC) No 1107/2009, 531 prolongations have been voted and approved, and the last two years have seen the largest number of approval period extensions, as shown in Figure 5 (the 2019 period is not over). Since 2011, 322 active substances out of 532 have been extended at least once. Moreover, nine substances have been extended four times (diquat, pymetrozine, famoxadone, melaxyl-M, flumioxazine, ziram, *Pseudomonas chlororaphis* strain MA342, thiacloprid and milbemectin), which is currently the highest number of approval duration prolongations.

4. Discussion

One of the major purposes of Regulation (EC) No 1107/2009 is "to ensure a high level of protection of both human and animal health and the environment" [18]. Therefore, this goal influences the renewal and the approval of active substances, which would lead to a safer pool of allowed substances over time. The evolution and development of the different Parts of the IR540 reflects this objective.

Moving forward, all active substances in Part A will automatically disappear, either by renewal of the approval and assignment into another Part of the IR540 (B, D, E or hypothetically C) or by the non-renewal or withdrawal of its approval. Theoretically, with no further prolongations, the renewal of Part A substances (initial active substances of IR540) would have to end by 2021, with the end of the initial approval periods.

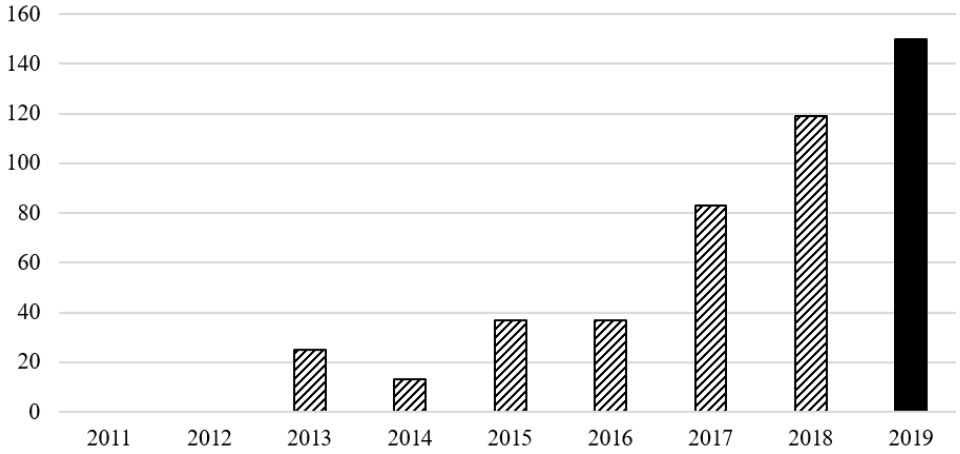

Figure 4: Number of substances with prolonged approval periods by year since the entry of Regulation (EC) No 1107/2009 in 2011.

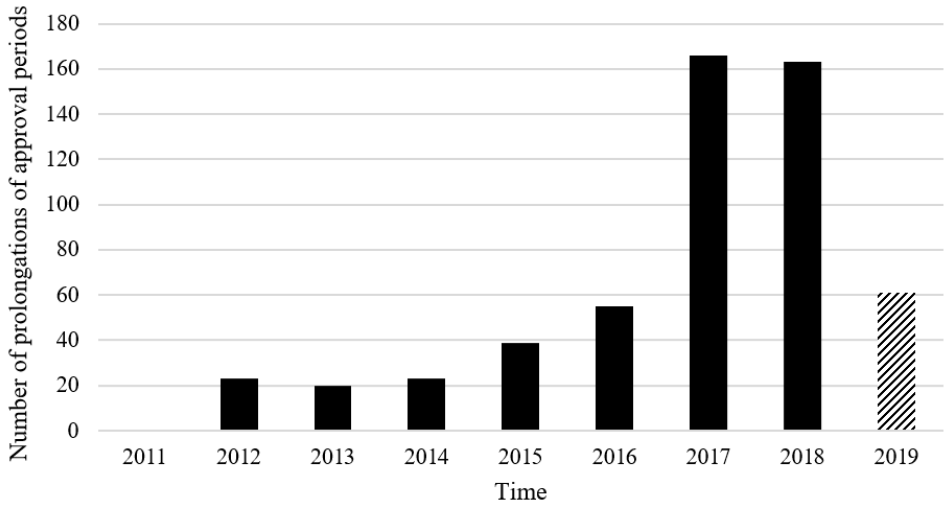

Figure 5: Number of prolongations of approval periods since the entry of Regulation (EC) No 1107/2009 in 2011.

However, at the current rate of prolongations, this dead-line has already been exceeded, and the disappearance of Part A is now not expected until 2024. A delay between five and ten years relative to 2021 seems to be more realistic, based on the speed of substances being processed by the Commission and the increasing timelines due to prolongations. For example, 42 substances [1] were again delayed in July 2018 alone.

In 2011, all active substances transferred from Directive 91/414/EEEC had a date for expiration of approval, scheduled over the years, with only a few left to handle in 2011. However, delays accumulated within a few years and prolongations were a necessity. One cannot compare the processing time of active substances before and after 2011 with the impact of Regulation (EC) No 1107/2009, because this process was at national and not at European level, before its entry into force.

Since active substances are approved for a certain period (10 years for active substances, 15 years for low-risk substances), an organized renewal process is necessary. Global renewal programs were launched previously under Directive No 91/414/EEC; the AIR-1 program (7 substances), initiated under Regulation EC No 737/2007 [19]; and the AIR-2 program (31 substances) initiated under Regulation EU No 1141/2010 [20]. The third renewal of the AIR-3 programme under Regulation EU No 686/2012 [21] can explain in part the number of prolongations generated by Regulation EU No 844/2012 [22]. This third program comprised over 150 substances whose approval expires between January 1st, 2013 and December 31, 2018. The extension of the approval periods is considered necessary to allow the applicants to prepare their application following the rules of the Commission Implementing Regulation (EU) No 844/2012 of September 18, 2012 [22]. A subsequent AIR-4 program will comprise the 214 active substance whose approval expires between January 1, 2019 and December 31, 2021 under Regulation (EU) No 2016/183 [23]. Low-risk substances and possibly non-renewed actives substances will be prioritized. A fifth renewal of the AIR-5 program under Regulation EU No 2018/155 [24] deals with active substances with approval expiring between January 1, 2022 and December 31,

2024 and will prioritize Candidates for Substitution [11].

The intention is that all "classical" substances will ultimately be listed in Part B. This part will increase, at least in the comingyears, with the renewals of active substances from Part A. However, the tightening of the regulation in recent years, especially with environmental, toxicological [27], and human health criteria, will decrease the number of renewed and newly allowed active substances, which may lead to a decrease of Part B.

Part C is composed of Basic Substances, which meet the following definition: "an active substance which (a) is not a substance of concern; and (b) does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and (c) is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and (d) is not placed on the market as a plant protection product" [18]. Many indications suggest that further increase of this part is likely, in view of the actual number of cases deposited. One is that basic substances are approved for an unlimited period; therefore, there are no concerns about renewal procedure as with other approved active substances, and secondly, basic substances have simplified dossiers in compared to regular active substances, which can facilitate the procedure of approval [16, 18].

Part D is composed of low-risk substances [25] that fulfil a number of criteria, as mentioned in Annex 2, point 5 of Regulation (EC) No 1107/2009 [18, 13], modified lately [5], and are considered as less harmful to human and environmental health. The main advantage is that they are allowed for 15 years instead of 10 for "classical" substances [27]. A list of active substances expected to meet the requirements of article 22 of the regulation has been communicated by the European Commission on July 27, 2018 [6]. The corresponding substances, which are those in the "potential" column in Figure 3, could foreseeably be placed in Part D quite soon. This Part D will undoubtedly increase in the coming years, and will probably undergo a significant growth from 3 to 23%.

Candidates for substitutions will be included in Part E over time [4]. They respond to the strict criteria referenced in Annex 2, point 4.5 of Regulation (EC) No 1107/2009 [18], and are destined to be replaced by active substances less hazardous for human and environmental health. Contrary to other substances, they are approved for a maximum of seven years [18]. Over the longer term, CfS will disappear, but Part E is currently being used to help the transition; seven CfS have been renewed and two have been newly approved since 2011. If all the CfS were placed in Part E (as in our hypothesis), they would correspond to 14% of the total substances, as shown in Figure 3. It has to be noted that for some CfS the applicants does not renew the approval, and substances are no longer allowed after the expiration of their approval (e.g. oxadiazon and glufozinate).

It has to be noted that biocontrol agents (BCA) or their allowance in organic production have no link to the IR540, although they represent the near totality of Parts C and D. All these parts have only a general agrochemical regulation purpose, and do not consider the "biorational", "biosourced" or "organic" identity of the substances.

5. Conclusions

The evolution of the different Parts of the Implementing Regulation (EU) No 540/2011 has deeply affected its global footprint since 2011.

The number of approved active substances has increased since the Regulation (EC) No 1107/2009 came into force and they have moved between different Parts of the IR540 as shown in Figure 6. This primarily [18] encourages active substances less harmful for human health and the environment (i.e. biocontrol agents) [26], as shown by the size growth of Part C and D (basic and low-risk substances, respectively). However, as evidenced by the existence, renewal, and approval of CfS substances, some controversial substances show persistence but will likely disappear in the long run.

Examination of the data shows a general increase in the total number of approved substances since 2011. This total number reached a maximum of 501, but a slow and potentially irreversible decline is being observed. Currently, the number of approved substances has already fallen to 483 (Figure 7). These finding are corroborated with previous refined analyses of the global substances footprint [26].

5.1. Highlights

- Implementing Regulation (EU) No 540/2011 (IR540) was initiated in 2011 with 398 active substances in Part A;
- IR540 was impacted with the successive inclusion of four new Parts (B, C, D and E); and
- IR540 currently managed 483 active substances in all Parts (A-E).

6. Declaration of Conflicting Interest

The authors declare no conflict of interest.

7. Disclaimer

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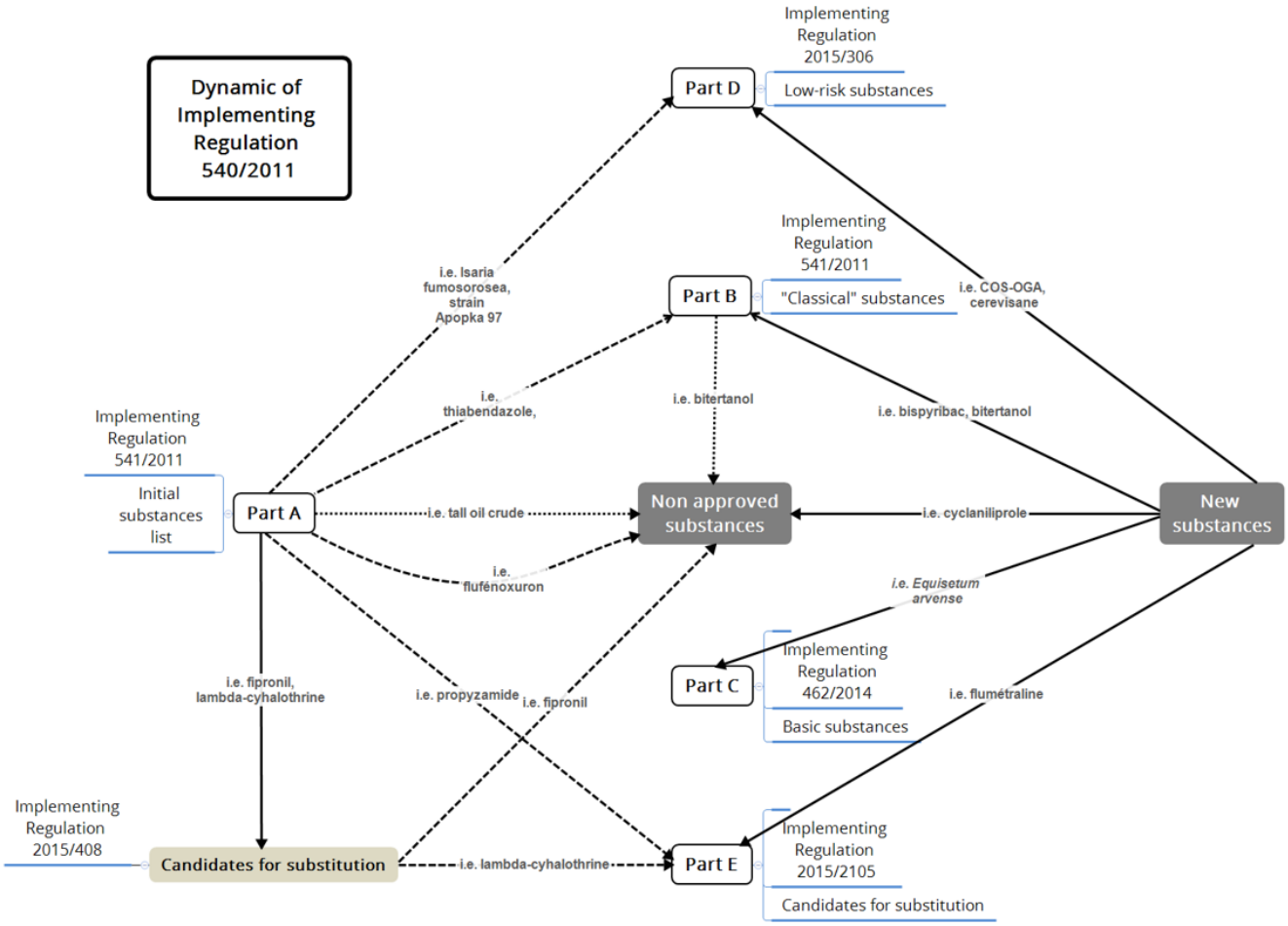

Figure 6: Dynamic of Implementing Regulation 540/2011.

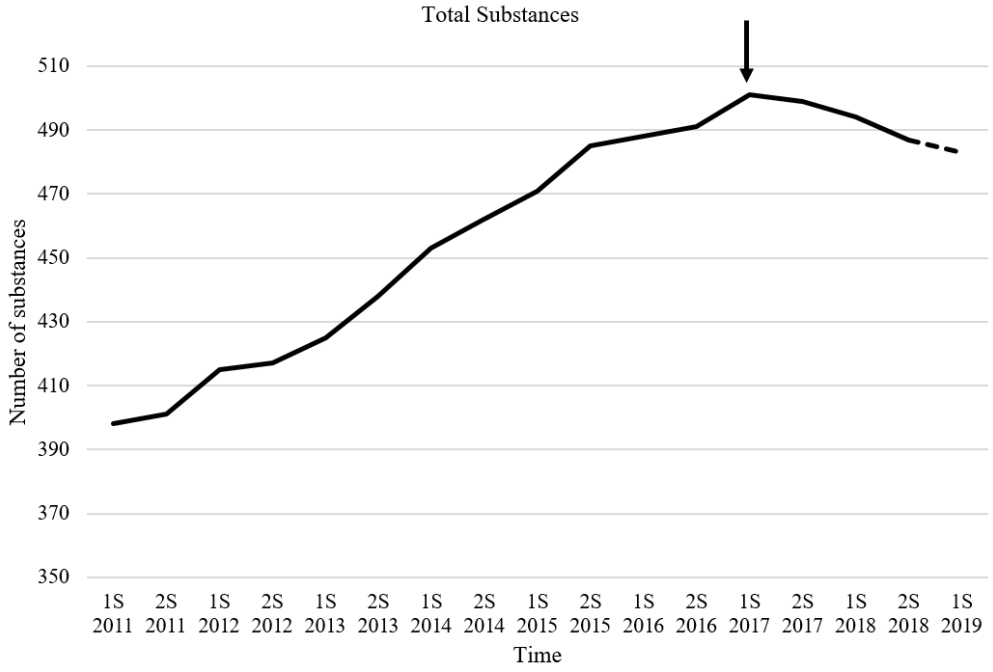

Figure 7: Evolution of total approved active substance at IR540 since 2011 with peak substance.

9. Article Information

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