

Consultation on a proposal to update fees for pest control products

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Background

Health Canada is responsible for helping people in Canada maintain and improve their health. One of the roles we play in carrying out this mandate is that of a regulator of pesticides, also known as pest control products, which we accomplish through various activities including the following:

- Evaluation of products before they are authorized for sale
- Re-evaluation of these products every fifteen (15) years
- Overseeing compliance with the *Pest Control Products Act* and its regulations

Regulatory services for pest control products are funded through a mix of fees charged to applicants of new products and registrants of existing products (mainly pesticide companies) and public funding (taxpayers). Health Canada has been charging fees for pest control products since the 1990s. The current *Pest Control Products Fees and Charges Regulations* (fee regulations) were implemented in 2017.

The landscape around cost recovery has changed since then. In 2017, the Government of Canada introduced the *Service Fees Act*, which established requirements for an <u>annual report on fees</u> to be tabled in Parliament. It also mandated that departments establish service standards and policies to remit fees when these standards are not met. The act also increased transparency, accountability and predictability for the fees that the federal government charges.

Under the Treasury Board's <u>directive on charging and special financial authorities</u>, federal departments must review their fees from time to time. Periodic reviews help determine whether existing fees and performance standards are still relevant.

Furthermore, in response to the commitments announced in <u>August 2021</u> to strengthen the capacity and transparency of the review process for pesticides, Health Canada's Pest Management Regulatory Agency (PMRA) has developed and is implementing a broad <u>Transformation Agenda</u>. While significant progress has been made and various initiatives are already underway, the modernization of pesticide review processes will be gradual, starting in April 2024.

Given the above, the modernization of fees for pest control products will occur in two phases:

- Phase 1 (current proposal): update the annual charge payable for each registered pest control product
- Phase 2 (planned for 2028): align fees to reflect ongoing transformation of the pesticide program, in particular modernized business processes. This will include updating application fees to register new pest control products and amend existing registrations

Health Canada is seeking comments on its Phase 1 proposal from:

- the public
- industry stakeholders
- grower and other user groups
- other interested organizations
- provincial and territorial governments

Feedback received will inform a formal regulatory proposal anticipated in 2024, which will also be subject to consultation.

Why we are updating the annual charge

To inform this proposal, Health Canada undertook an analysis of its current post-market fees for pest control products and found that:

- they do not reflect the current regulatory costs for post-market regulatory activities, and taxpayers are assuming an increasing economic burden
- they are not aligned with fees charged by other international regulatory bodies, like the United States Environmental Protection Agency (USEPA)

Health Canada's post-market fees are outdated

The proportion of post-market regulatory costs that are recovered from registrants is low compared to the regulatory costs assumed by Health Canada. Health Canada recovers about 18% of the costs when compliance and enforcement activities are included. Compliance and enforcement costs are currently being funded entirely from public funds.

When the new fee regulations came into effect in 2017, Health Canada increased the annual charge by 30%. This reflected some of the increase in inflation over the twenty years since implementation of the previous fee regulations. The current annual charge increases each year to reflect changes in the consumer price index.

Health Canada is faced with an increased volume of work, particularly in its post-market reevaluation program, as well as added complexity from scientific and technological advancement, and globalization. These factors are placing added pressures on Health Canada to deliver regulatory services with existing resources.

The low proportion of post-market regulatory costs that Health Canada recovers has hampered its ability to identify and address pesticide-related risks by making timely post-market re-evaluation decisions.

Both people in Canada and registrants benefit from robust regulatory oversight of pest control products used in food production and other sectors. Registrants of these products gain commercial benefits from post-market regulatory activities. For example, a re-evaluation decision that authorizes continued registration of a pesticide active ingredient and related products means the registrant may distribute these products legally in Canada.

Registrants also benefit from compliance and enforcement activities, as they:

- deter unauthorized or unregistered products from entering the market
- increase security
- increase public confidence in the market
- promote economic growth
- improve commercial reputation

International considerations

The annual charge differs from post-market fees of other pesticide regulators internationally, including the USEPA.

The 2017 pesticide fee regulations established the maximum annual charge at an amount slightly under the USEPA's maintenance fee. However, the USEPA has since increased this fee.

The structure of the annual charge also varies to the USEPA's maintenance fee. Over threequarters of pest control products pay a minimum or reduced annual charge due to low or no reported sales. In contrast, the USEPA limits mitigation on its maintenance fee to small businesses and agricultural pesticides used primarily on specialty crops and pesticides used in public health programs.

Refer to Table 2 for a comparison.

What we are proposing

This section presents the guiding principles and main elements of this fee proposal.

Guiding principles

Health Canada is proposing to restructure the annual charge that is payable for each registered pest control product. The proposal reflects Health Canada's <u>guiding principles</u> for cost recovery and regulatory fees:

- accountability and transparency
 - \circ includes transparent fee setting and costing methodology
- predictability and sustainability
 - \circ $\,$ includes established processes for regularly reviewing and updating fees
- stewardship and fairness
 - includes consideration of fee mitigation measures, where appropriate

The revised fee-setting ratio for the annual charge is primarily set on an assessment of the public and private benefits of post-market regulatory activities.

Fee-setting ratio for annual charge

Consistent with the Government of Canada's <u>guide to costing</u>, this proposal sets the annual charge at an amount that allows Health Canada to recover an appropriate portion of the corresponding regulatory costs. The portion of costs recovered by fees (the fee-setting ratio) is determined by analyzing several factors, including public-private benefit. The goal is to determine the degree to which an activity or service provides private benefit to industry versus the benefit received by the public. Multiple factors are considered, such as:

- financial or competitive advantage
- potential disincentives for regulatory compliance
- market access and innovation development in Canada

Health Canada assessed the private benefits of post-market pesticide review and pesticide-related compliance and enforcement activities to be both at 75%. This assessment recognizes the significant benefits to registrants from:

- post-market review decisions that authorize continued registration of pesticides
- post-market compliance and enforcement activities
 - includes deterring unauthorized or unregistered products from entering the Canadian marketplace, and increasing public confidence

Since compliance and enforcement activities will be included under the annual charge structure for the first time, the fee setting ratio for these activities is proposed to be at 40%. This reduces the annual charge amount that would be payable and thus reduces the burden on industry.

Overall, the weighted average fee setting ratio for all cost-recovery activities included under the annual amount will be 64%, or \$6130 per registration.

Health Canada is proposing to apply this \$6130 annual charge to each pest control product registration. The exception will be products subject to mitigation (refer to the following section).

Mitigation measures

Health Canada is proposing three categories of reduced fees under the annual charge structure: for qualifying small businesses, biopesticides and certain niche products.

Currently, the annual charge payable is reduced for products with low sales (Table 1). Over three-quarters of products qualify for mitigation, including many products owned by large businesses

Under the proposal, the lowest annual charge would apply for a registrant that qualifies for multiple types of fee mitigations.

Reduced fee for small businesses

A reduced annual charge of \$2000 per pest control product would apply to qualifying small businesses.

An eligible small business is a person (both individuals and organizations), including its affiliates, that has:

- fewer than 100 employees, and
- less than \$5 million (CAD) in annual gross revenues

The employee total and annual gross revenue must be from the entire business. This includes all employees and revenue regardless of geographic location (domestic and international) or product line (pesticides and other products).

This approach reflects Health Canada's revised small business definition for cost recovery.

Reduced fee for biopesticides

A reduced annual charge of \$1000 would apply to registered biopesticides. These include microbials, semiochemicals and non-conventional pest control products.

This reduced fee reflects public interest in supporting the availability of biopesticides, given the favourable risk profile of many of these products. It is also in line with the ancillary objective under the *Pest Control Products Act* of "facilitating access to pest control products that pose lower risks."

Reduced fee for certain niche products

A reduced annual charge of \$1000 would apply to certain pest control products where there is limited economic incentive to maintain registration but have high value uses, specifically:

- low-acreage crops
- products that support public health programs
- products that support environmental protection
 - for example, to control invasive non-native species and protect species at risk

Annual adjustment

In accordance with the *Service Fees Act*, the proposed annual charge would be adjusted in April every year to reflect the previous year's consumer price index for all items. This practice is similar to the minimum and maximum annual charge amounts that are adjusted for pest control products every year.

Fee name	Current approach	Proposed approach
Fee-setting ratio	No fee-setting ratio specified during the 2016 fee proposal, which led to the current fee regulations	Re-evaluation and special review costs: 75% Compliance and
		enforcement: 40% Weighted average for both activities: 64%
Annual charge	\$4,135.95 for pest control products with actual gross revenue above \$103,398.75 for the preceding fiscal year	\$6130 per registration
Fee mitigation	Amount payable for pest control products with actual gross revenue under \$103,398.75 for the preceding fiscal year:	\$2000 per registration for qualifying small businesses\$1000 per registration for
	 4% of actual gross revenue during the preceding fiscal year but not less than \$114.88 	biopesticides \$1000 per registration for certain niche products

 Table 1
 Current and proposed approach for the annual charge structure

Performance standard

For the purposes of meeting the *Service Fees Act*, our performance standard for the annual charge is to issue invoices:

- by April 30 of the current fiscal year or
- within 30 days of submitting a completed form (if after April 30)

This fee proposal maintains this standard.

Health Canada also has separate <u>performance targets in place for post-market re-evaluation</u> <u>activities</u>, which are unrelated to the *Service Fees Act*.

International comparisons

How post-market regulatory fees are structured and the types of activities that they support vary widely among international regulators. For example, pesticide regulators in the European Union (EU), Australia and the United Kingdom (UK) charge application review fees for post-market reviews.

Australia, the UK and several EU member states also apply variable post-market fees based on a percentage of pest control product sales. Variable fee revenue:

- subsidizes pre-market application review costs in Australia
- supports pesticide-related external monitoring activities in the UK and France

USEPA pesticide regulatory fees represent an important comparator for Health Canada's pesticide regulatory fees. Growers and other users are sensitive to the possibility that higher pesticide fees in Canada may:

- erode registrant incentives to register pest control products in Canada; and
- reduce competitiveness of Canadian growers and other producers compared to their counterparts in the United States

Canadian grower groups have raised these concerns in past consultations. This led to the development of the current fee regulations.

In 2022, the United States Congress authorized increases to most fees. Congress also extended the USEPA's authority to collect pesticide maintenance fees and application fees through to 2027 and 2029, respectively. These fee increases took effect in 2023.

Our proposed changes to the annual charge structure are in line with the main elements of the USEPA's maintenance fee (Table 2).

	Proposed annual charge	USEPA maintenance fee
Regular amount (without mitigation)	\$6130 CAD	\$6,338 CAD (\$4,875 USD)
		Per registrant cap on maintenance fee payable: \$360,720 CAD (\$277,200 USD)
Small business	\$2000 CAD per registration	25% discount on first product for registrants that hold no more than 5 pesticide registrationsPer small business registrant cap on
		maintenance fee payable: \$240,240 CAD (\$184,800 USD)
Biopesticides	\$1000 CAD per registration	n/a

Table 2 Comparison of proposed annual charge and current USEPA maintenance fee

for: for: products used mainly on low-acreage crops products that support public health programs products that support products that support public health programs products that support		Proposed annual charge	USEPA maintenance fee	
 products used mainly on low-acreage crops products that support public health programs products that support 	Niche products	1 0	Fee waiver for products used on	
 low-acreage crops products that support public health programs products that support 		for:	low-acreage crops and products that support federal and state public	
(e.g., control of invasive alien species and species at risk)		 low-acreage crops products that support public health programs products that support environmental protection (e.g., control of invasive alien species and species 		

Consultation process and next steps

Health Canada is committed to meaningful engagement and consultation.

The current consultation on this fee proposal will cover a period of 60 calendar days, starting on 31 January 2024 and ending on 31 March 2024.

If you would like to comment, see the <u>Pest Management Regulatory Agency Publications</u> <u>Section</u> page for contact information. Please be sure to include the title of the consultation document on which you are commenting.

Once the consultation period ends, Health Canada will:

- collect and review the comments before identifying any required revisions to the fee structure
- conduct a cost-benefit analysis

Health Canada will consider the comments received as it develops its regulatory proposal, which will also be subject to consultation through the Canada Gazette process (Part I).

We hope to finalize the proposed changes to the annual charge through regulatory amendments to the *Pest Control Products Fees and Charges Regulations* in 2025. This target date is subject to the government approval process.

Appendix I Context

This annex provides information on Health Canada's role in pesticide regulation and current pesticide fees.

Pest control products and Health Canada's responsibilities

Pesticides are substances used to repel or control certain organisms, such as weeds, insects and diseases, which are considered pests.

Pesticides are critical in food production and other industrial settings. They're also used in common consumer products, such as insect repellents, pool and spa chemicals, rodent control products and wood preservatives.

Pesticides also:

- keep processing facilities and shipping containers free of pests
- protect human health by controlling pests that carry diseases, such as Lyme disease

Under the authority of the *Pest Control Products Act*, Health Canada undertakes a range of activities:

- before a pesticide may be registered for distribution, sale and use in Canada
- after initial registration

As part of pre-market regulatory activities, we:

- conduct a thorough review of the submission and comprehensive data on the pesticide's active ingredients, formulations and proposed uses
 - we consider factors such as toxicology, environmental fate, value and potential exposure to humans and non-target organisms
- register a pesticide after a science-based evaluation of the product's human health and environmental safety to ensure that any risks are acceptable

As part of post-market regulatory activities, we:

- re-evaluate pesticides that are on the market every 15 years to ensure they meet current scientific standards
- conduct special reviews any time we believe that a registered pesticide poses unacceptable risks
- undertake other activities to identify new or emerging risks associated with the use of pesticides
 - these include monitoring adverse incident reports, pesticide use and sales information, and the scientific literature

We also provide post-market compliance and enforcement oversight of all parties regulated under the *Pest Control Products Act* and its regulations, including registrants, manufacturers, importers, distributors and users. We do this through the following 4 key activities:

- Compliance promotion
 - conduct outreach and provide important information to regulated parties to foster regulatory compliance
- Compliance verification
 - monitor ongoing compliance with the act and its regulations through inspections, surveillance, sampling and related activities
 - to ensure that regulated parties and products entering the Canadian marketplace meet regulatory requirements
 - to verify that users follow label directions when using pest control products
 - verify label claims and complaints that we receive about pest control products that may not be compliant with the act
 - includes advertising claims that are contrary to the legislation
- Enforcement
 - conduct timely interventions in keeping with the risk level when we identify non-compliance
 - we use various enforcement measures and options to stop, sanction and address the non-compliance
- Border activities
 - implement monitoring processes with the Canada Border Services Agency to reduce risks posed by imported pesticides
 - we verify whether a pesticide suspected of contravening the act and its regulations may be admitted into Canada
 - unauthorized or unregistered pest control products are refused entry

There are currently 698 registered pesticide active ingredients in Canada. These chemicals act to control the pest. They are contained in over 8,000 products used in agriculture and other sectors. Over 120 million kilograms of pesticide active ingredients are sold in Canada every year.

Canadian pesticide sales across all sectors totaled \$4.4 billion in 2020 (based on regulatory filings by registrants and third-party information purchased by Health Canada). There are also signs that the pesticide industry continues to grow. According to S&P Global, Canadian agricultural pesticides sales grew by 27% between 2018 and 2022, compared to sales growth of 14% in the United States, 13% in Europe and 17% worldwide. Canadian agricultural pesticide sales represent 3.7% of the world market.

Cost recovery for Health Canada pesticide regulatory activities

Our costs related to pesticide regulatory activities are recovered through:

- application fees to register or amend the registration of a pest control product
- since application fees would not change under this proposal, these fees are not discussed
- an annual charge payable on each pest control product

The revenue from the annual charge currently supports some of the costs associated with postmarket re-evaluation and special review activities. Currently, pesticide-related post-market compliance and enforcement activities rely fully on public funding.

Under the 2017 fee regulations, the annual charge increased by 30% to account for some of the inflation over the 20 years since the previous fees came into effect. This increase meant the maximum annual charge amount was slightly under the USEPA's comparable maintenance fee, which the USEPA applies annually to each registered pest control product.

The current annual charge is based on the sales of each pest control product. Consistent with the *Service Fees Act*, the minimum and maximum annual charge are adjusted every April to reflect the change in the previous year's consumer price index for all items. Current annual charge amounts (as of 1 April 2023) for pest control products are as follows:

- \$4135.95 for products with actual gross revenue above \$103,398.75
- 4% of the actual gross revenue for the preceding fiscal year for products with gross revenue between \$2872.00 and \$103,398.75 (reduced annual charge)
- \$114.88 for products with actual gross revenue under \$2872.00 (minimum annual charge)

Appendix II Costing details for post-market regulatory activities

This appendix provides information on how we developed the fee proposal.

Fee-setting authority

Health Canada has the authority to set fees by regulation under section 63 of the <u>Pest Control</u> <u>Products Act</u>.

The current annual charge is under section 9(1) to 9(6) of the <u>Pest Control Products Fees and</u> <u>Charges Regulations</u>.

Costing methodology

In conducting this regulatory activity-based costing exercise, the standard and generally accepted principles and concepts to arrive at the post-market regulatory costs, outlined in the following reference documents, were applied:

- <u>Guide to costing</u> (Government of Canada)
- <u>Guide to establishing the level of a cost-based user fee or regulatory charge</u> (Government of Canada)

We based the cost estimates on existing costs and estimated prospective costs, using several information sources, including the department's financial system (SAP).

Existing costs

The cost of existing post-market activities is based on actual 2022-23 fiscal year expenditures. These were validated by activity tracking. (Note that 2022-2023 represents the "back-to-normal" registration processes following 2 years of skewed data due to COVID measures.)

Health Canada was able to identify costs for each regulatory activity as follows:

- We used a program-wide time tracking system to assign direct and indirect program salary costs to specific activities, where possible. In some cases, costs from SAP were utilized and validated with available tracking information.
- Allocated operations and maintenance costs from SAP.
- Allocated capital costs as appropriate.
- Allocated branch overhead and corporate costs evenly to all regulatory activities.

We determined the existing costs (Table 3) by totalling all applicable costs, which include:

- program costs
- capital costs
- corporate costs

Type of cost	Description				
Program costs*	Direct salary: Costs for staff that work directly on regulatory oversight activities. This system is used to collect level of effort by activity, including tracking time spent conducting pesticide re-evaluations and special reviews.				
	Non-salary (operating and maintenance): Includes professional services, travel and training.				
	h overhead: Costs for indirect salary and non-salary expenses related to narket regulatory activities. For example, executive management support as those staff working in the Assistant Deputy Minister's office is allocated s service areas. Costs allocated to each area based on a ratio of total am costs incurred by each activity.				
Capital costs	Includes maintenance, upgrade and investment costs for laboratory equipment, information systems and fleet costs for inspectors.				
Corporate costs	 Related to services provided by Health Canada's corporate branches. Includes: 27% of salary costs for the Employees Benefits Program 22% of total program costs for internal services, such as: management and oversight for access to information requests audits and evaluations communications human resources financial management information management and technology 13% of salary costs for Shared Services Canada 				

Table 3Existing costs by type

*Costs are identified through our financial system and reconciled with detailed activity tracking using a programwide time tracking system. They're attributed to each service area.

Prospective costs

Prospective costs relate to the additional funding required to respond to increased workload related to post-market reviews projected to be initiated in the future.

The costs of pesticide post-market activities are mainly driven by statutory requirements to initiate re-evaluations on a 15-year cycle. Current resource allocations are insufficient to initiate and appropriately process the number of re-evaluations that we anticipate in coming years.

To determine prospective costs, we apply the current fully loaded costs (including program, capital and corporate costs) to the number of re-evaluations we anticipate every year (Table 4). These costs total \$4.37 million.

\$ million	Program costs (direct and indirect)	Corporate costs	Capital costs	Total costs	
Post-market rev	iew activities	-	-	-	
Current	\$19.79	\$13.31	\$0	\$33.10	
Prospective	\$2.56	\$1.80	\$0	\$4.37	
Post-market compliance and enforcement activities					
Current	\$9.90	\$6.48	\$0.019	\$16.38	
Total costs	\$32.25	\$21.59	\$0	\$53.85	

Table 4Current and prospective costs

Current annual charge revenue

The 2017 fee regulations updated the annual charge to account for inflation over the 20-year period since the previous fees came into effect. In other words, we increased the annual fees by 30%. Unlike application fees, no fee setting ratio or target was identified.

Annual charge revenue covers some of the costs associated with activities such as post-market re-evaluations and special reviews (Table 5). Pesticide-related post-market compliance and enforcement activities are currently exclusively funded by appropriations.

Table 5 Current fee revenue (previous fiscal years)

Fee line	Current fee amount (2023-24)	Number of transactions in the last fiscal year	2019-20 fee revenue	2020-21 fee revenue	2021-22 fee revenue
Annual charge for a registered pest control product	The lesser of \$4135.95 and 4% of the actual gross revenue during the registrant's preceding fiscal year, but not less than \$114.88	7562	\$8.7 million	\$8.0 million	\$9.1 million

Appendix III Proposed fees

Health Canada is proposing to replace the current annual fee structure (the fee that's payable is based on the sales of each pest control product). We want to:

- amend the fees based on recent program costs
- eliminate the revenue-based fee
- introduce 3 new categories of fees: 1) based on company size, and 2) based on the characteristics of the pest control product

We're proposing annual charges as follows:

- regular charge for each pest control product (unless a reduced charge applies) of \$6130 (amended fee)
- reduced charge for qualifying small businesses of \$2000 (new mitigation)
- reduced charge for biopesticides of \$1000 (new mitigation)
- reduced charge for certain niche products of \$1000 (where there is limited economic incentive to maintain registration but have high value uses) (new mitigation)

Fee setting: Public-private benefits analysis

We used the Government of Canada's Public-Private Benefit Assessment Tool to assess the private benefits of these activities at 75%. This implies that the private sector gains a significant advantage from post-market regulatory activities.

This ranking stems from 2 main factors:

1. Excludability (medium):

- These activities offer the following benefits, which are not limited to fee payers:
 - increased safety
 - preservation of the environment
 - o increased public confidence and trust in government decisions
- However, fee payers enjoy a significant and unique benefit, especially for re-evaluations, in that an authorized pest control product gains access to the Canadian market.
- Through compliance and enforcement regulatory oversight, unregistered products or products whose registration is cancelled are removed from the market. This gives better market access for registered products.

2. Rivalry (medium):

- The average cost to perform individual re-evaluations, special reviews and inspections is high.
- For every 1 re-evaluation, special review or inspection, Health Canada is unable to conduct other post-market activities. This affects our ability to carry out these activities efficiently.

This fee update will be the first time that compliance and enforcement activities are included in the annual charge structure (Table 6).

The fee-setting ratios are as follows:

- for post-market compliance and enforcement: 40%
- for post-market review: 75%

This gives us a weighted fee-setting ratio of 64%.

Table 6	Post-market regulatory	activities annual	costs and	proposed fee

Activity	Program costs	Annual volume*	Unit cost	Fee- setting ratio	Calculated fee	Proposed combined fee adjusted for 2025-26**
Post-market review	\$37.5 million	6019	\$6225	75%	\$4669	n/a
Post-market	\$16.4	6019	\$2721	40%	\$1089	n/a
Compliance and	million	0017	<i><i><i><i><i><i><i>ϕ ϕ <i>ϕ <i>ϕ ϕ <i>ϕ <i>ϕ ϕ ϕ <i>ϕ <i>ϕ ϕ <i>ϕ <i>ϕ <i>ϕ ϕ <i>ϕ <i>ϕ <i>ϕ <i>ϕ <i>ϕ <i>ϕ <i>ϕ <i>ϕ <i>ϕ ϕ <i>ϕ ϕ <i>ϕ ϕ</i> </i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i></i>	1070	<i>4</i> 1007	
enforcement						
Total pesticide	\$53.85	6019	\$8946	~64%	\$5758	\$6130
program	million					

*Assumed a 20% drop-out rate in annual product registration

**Proposed annual charge account for annual adjustments (4.4% for 2023 and 2% for 2024)