

Sustainable Drug Manufacturing Planning Under Different Regulatory Scenarios

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Abstract

Current environmental regulations typically follow a *command-and-control* approach mandating the installation of state-of-the-art abatement technology and hard emission thresholds. However, this type of regulation does not encourage process improvement and technological research to cut down emissions below compliance levels. On the other hand, *market-based* models stimulate continued improvement of cleaner manufacturing practices by creating economic incentives for sustained emission reduction. This paper aims at furnishing regulators and manufacturers with a tool to assess the impact of future regulatory scenarios. Two problems still not solved in a systematic fashion are how plant managers should optimally plan under different regulatory scenarios and how regulators should optimally design the regulations. In order to assess the impact of different regulations, this paper proposes a holistic model for commodity chemicals, pharmaceutical and specialties manufacturing operations including standard recycle and treatment options. This proposed work employs realistic chemical engineering models of pollution abatement operations in order to assess the feasibility of a treatment option, estimate its cost and expected emissions. Furthermore, this work introduces rigorous mathematical optimization techniques for designing regional emission reduction efforts at reasonable cost to manufacturers. This approach will offer plant managers a systematic tool to ascertain expected compliance cost of new environmental regulations and regulators a systematic methodology to design regulations considering manufacturers' budgets.

Methodology

Systematic selection of pollution prevention technology

There are many different ways of converting a hazardous waste into environmentally benign material through a series of chemical and physical transformations known as unit operations. The *Combinatorial Process Synthesis* automatically produces a set of recycle treatment options for converting a given effluent stream into one or more benign residuals. A complete description of the CPS is available elsewhere (Chakraborty et al., 2002, 2003ab, 2004). This work uses a modified CPS considering a group of plants to analyze the impact of different regulatory scenarios on a whole region. In order to obtain the optimal plant strategies, we need to supply to the CPS the business forecast that includes the plant inventory, the business plan and the waste forecast. Then we model different regulatory strategies to reduce the CO₂ emission and finally analyze in detail the impact of each model to the region. We have selected CO₂ as the pollutant to analyze because the current lack of

regulation on it and the global interest in reducing greenhouse gases. The methodology is general enough that can be applied to other pollutants or many of them together.

Superstructure Generation

This paper evaluates the impact of applying different regulatory scenarios on a region. For the case study, we assume that only four plants are present in the region. Although more plants could participate in a region, we use four for illustrative reasons. We consider four distinct sites with unique waste type, production forecast and plant infrastructure.

The superstructure (SS) for all plants in the region delineates what is technologically possible in terms of waste reduction and pollution prevention, without changing the manufacturing process. The details of the obtained superstructure are summarized in the appendix. Each SS contains different number of treatment policies. However, it should be noticed that the SS, assuming that no novel treatment technology has been recently developed, includes all the feasible technological options to treat each distinctive waste mixture. Each policy gives rise to different treatment cost and emissions. Some of the recycle options using different separation produce very little emissions but are also expensive. Some of the SS operations that are technologically feasible are not realizable at the plants since the equipment may not be available. In the next section, we show how an optimal investment-planning model can produce strategies for upgrading the plants treatment options. These upgrades may be motivated by sound cost optimization or because newer and more stringent environmental regulations are enforced. In any event, it would be desirable to know, when to invest and how big the plant should be, such that a given regulatory change can be implemented without unacceptable costs to each manufacturer. Alternately we conjecture that new regulations could be designed using the concepts in this paper to achieve desirable emission reduction with lowest cost to the industry. We call this, *optimal regulations*.

Significance

This work proposes a systematic framework that uses precise unit operations models to accurately predict the optimal investments policies of a region under different regulatory scenarios. It is shown that it is possible to combine chemical engineering knowledge with simplified market models to predict the impact of regulatory changes. Therefore, this work could assist regulators in designing the policies that satisfy environmental objectives, while considering their impact on the manufacturers' operation.

This paper has considered a simplified market model; in future, we would like to improve this model by considering a more accurate market behavior by including price flexibility using a game theory approach. Another interesting feature to be included in future work is the consideration of uncertainty in the market and price forecasts.

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